The Chronicle Of Discovery Of The Causation Of AIDS

A Thesis by
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1.
PREFACE

It was in our blood and no one knew it. Hiding until it could invisibly jump from one person to another. When its first victim fell, no one sounded the alarm. Even when others followed, doctors the world over failed to see the signs of something new. A killing disease was within our very bodies; and fast becoming nothing less than the single worst epidemic in the history of mankind. This microscopic monster has been called GRID, HIV, LAV, but today the whole world knows it as AIDS.

In a time when science was under attack by U.S. Government officials, this little known infection crept onward to become a worldwide threat. Few researchers during that period dared to tackle the menace as no one knew who, why, or how this disease picked its victims.

In this book we will step back in time to those early years of discovery. We will also bear witness to the complacent attitude as the world left the homosexual community to fend for themselves; and the horror when it became undeniable that this burgeoning, opportunistic virus had crossed into the general population. Men, women, Caucasian, Asian, Hispanic, young, old – all were at risk.

The whole planet turned to science. Yet science had no answers. Until one medical researcher proved what others could not; that retroviruses do exist in man. This single discovery gave birth to the field of Human Retrovirology; and to the hypothesis that perhaps this killing epidemic was in fact caused by a retrovirus. Dr. Robert C. Gallo's laboratory eventually proved this theory correct. At last an understanding of how this disease infected us, and the havoc it did to our bodies, came to light. So when the world turned to science, science turned to him.

However, when Gallo's laboratory catapulted itself straight into the arena of AIDS research, they triggered an unparalleled controversy. One so enormous it actually held up the unfettered process of AIDS advancement. Reputations and relationships were forever affected as shocking probes hit the mainstream press. Did Dr. Gallo, America's preeminent medical researcher, steal the first isolated AIDS virus from French researchers at the Institut Pasteur? Was that virus used to develop a blood test used to screen the world's blood supply against the disease? Did he claim their work as his own and take all the credit for himself? Meanwhile, on the international stage, the French and U.S. Governments clashed over the hundreds of millions of dollars in royalty payments generated annually from a single patent. Just the first year projections alone predicted revenue from the AIDS blood test to exceed the 300 million dollar mark.

In this probe we will follow the story and prove what allegations are false, and which are true. These will be supported by the many documents, notes, letters, and confidential memos that have been acquired. As a retired police officer, the author knows how to disseminate information; separate fact from fiction; to analyze by adhering to the root of all police work: means, motive, and opportunity.

This story is unique in that it appears that others, who have written about it, have seemingly aligned themselves with a strictly one-sided interpretation of the events; never really being fair to the accounts from both sides. It was time someone applied investigative skills to sort through all the events and comments, and really uncover all the unbiased facts. It's taken more than three years and a mountain of papers, but I have read through all the records, published papers, news articles, personal accounts, and have personally sat down to ask questions of those involved. And to think this controversy all began with just one reporter on a personal crusade, which lasted well over a decade.

Although this story has been chronicled before, and many articles have been published, books have been written, even a movie was made; not one writer of these major works ever once asked Dr. Gallo -or the members of his team- for an interview! Dr. Gallo adds, *"With the rare exception of an openly hostile reporter who had already written his biased opening,"* no one has calmly asked what their side of the story was. No one went through the steps, from start to finish with Gallo or his team until now.

Additionally, this work offers something vital no other ever has before; full access to all the American scientists directly involved in this story; plus in-depth interviews and documents from the French side as well. New revelations have come to light, now that some original, protective relationships have fractured within the French camp. This is a valuable step towards halting some of the fabrications associated with this story from ever becoming historical fact. Most important of all, I was given unrestricted, unsupervised access to files from many sources; including all personal files belonging to Dr. Gallo himself! He has never before shared any of these files ever. It was a once in lifetime opportunity. Plus, I had complete freedom to use or reproduce anything at all. Dr. Gallo's files by themselves were stored in 17 separate, large boxes and in about 15 massive other piles, all over a foot and a half high each. The sheer total of cumulative pages was truly daunting as you might imagine. It took months of reading to get through it all. My gratitude to all the many interviewees who allowed me such total access, which helped shape this book.

My qualifications as an experienced investigator brings a fair, true account of the most ruthless scandal ever to hit research medicine, regarding the worst disease to ever hit our present-day world. Unless otherwise noted, the reader can assume all *"italicized"* quotes herein are from interviews specifically conducted for this book. Keep in mind that not all AIDS researchers are from the United States, and their quotes also reflect their individual ability to communicate in English.

This story is heavily researched and one that finally focuses light on the true evidence of this very tangled tale. Written for both scientists and the general population, it is an engaging story with an easy to follow narrative. It also charts when the disease came to light, how it spread, how many became infected, as well as landmark people and events that shaped the history of AIDS in the United States. With a month by month chronology of discoveries, disputes, decisions, and verdicts that has never been done before, anywhere else. Included with the narrative are documents important to proving

how key events transpired. Even the issue of blood banks and their unwillingness to heed the caution of scientists is discussed. Consequences of many actions by many people and entities are thoroughly examined, and contamination trails are followed back to their source.

In the United States, the progress of scientific research in almost all fields of discipline was forever hindered by some very shameful difficulties and persistent obstacles; much the result of malfunctioning bureaucratic procedures and failures in communication among political figures and the media. This is a shake-your-head-in disbelief read, to serve as an honest record of many scientific facts, detailing events in those early years of discovery when the coming blight of an AIDS epidemic was not quite known to the world. And the steps notable people took in defining a disease that more than twenty years later has become the most widespread, the most lethal epidemic in the entire recorded history of man. Truly, our blackest plague.

Not all the people I spoke to were anxious to revisit those days. Gallo: *"Most people that are my colleagues or friends, they want to forget those days. It's past, it's over. They forget the history (of scientific record which) has been massively distorted by a man and it sits there. And a movie, sits there. They say, "Bob, let's just forget all this and get away from it." But you can't, because it's out there."*

What follows is the beginnings of AIDS research and the many battles this virus caused; shared with you, and for history.

2.
THE RAID OF POLITICS ON SCIENCE

A dark shadow had swept over American Science during the latter part of the 20th century. This blemish on science and medical research was primarily created by Representative John Dingell (D-Michigan); Chairman of the Energy and Commerce Committee and, Chairman of the Oversight and Investigations Subcommittee. Representative Dingell began his career by building a reputation as Congress' watchdog over the use of billions in federal funds given away by the Executive Branch. He prowled the nation's federal agencies, weeding out corruption and monetary misuses, wherever he would find evidence of wrongdoing, and he was justly hailed as a hero for his successes in protecting the taxpayers' money. He uncovered and prosecuted many cases of truthfully unjustified cost overruns, illegal kickbacks, and/or unwarranted expenditures. Then he publicly and shamefully exposed those federal bureaucrats who had wasted or stolen public funds; ever on the lookout for new instances of financial abuse.

Soon he turned his sights toward seeking and punishing presumed corruption in medical and scientific research establishments by probing into lab records. To this end, he started hearings on allegations of scientific fraud by the NIH (National Institutes of Health) grantees and NIH researchers; making sure to always garner for himself national media coverage on these cases. NIH responded to the challenge by creating the Office of Scientific Integrity (OSI) to investigate and decide cases of alleged scientific misconduct. Later, the OSI was moved to the Department of Health and Human Services (DHHS) at the recommendation of NIH officials, and was renamed the Office of Research Integrity (ORI). This recommendation was made for the simple fact that the NIH did not want to be a part of the machinery that investigated itself, thwarting any opportunistic accusations of cover-ups.

In time, Dingell decided to concentrate his efforts on a series of sensational, hence highly publicized cases, against U.S. scientists, all of whom were famous in their respective fields. This decision apparently sent him on a power trip which he fed by questioning the image of science, then, by tarnishing the reputation of specific scientists in the eyes of the public and their peers. Apparently, his intention was to reestablish political authority on scientific personalities and institutions. "The private research university is arguably the most successful institution in the country, the formidable engine of its economic growth, and the protector of its most humane values. The fact that

these institutions are largely isolated from the political process is surely a key to understanding their success[1]."

Regrettably, Dingell developed a long arm of the law mentality and exposed the country to another wave of "McCarthy-esque" hearings in a deplorable abuse of power. This time, the hearings were on "un-American research activities" rather than on simple "un-American activities;" as was the case in the 1950s. Under the pretence of having proven scientific misconduct and a prior assumption of guilt, Dingell's staff ruthlessly went after the heads of acclaimed scientists with thuggish tactics, fabrications of evidence, distortions of truth, and media smears. Routinely threatening and pressuring witnesses beyond the breaking point became standard practice in their arsenal of fear tactics. Moreover, these political accusers engaged in clandestine activities and invoked special protective clauses in the law (so as to escape accountability) whenever dubious activities came to light. Their practices, unrestrained by the Judicial Rules of Evidence, came to threaten the very foundations of the entire U.S. Medical Research establishment. The damage caused to American prestige in basic science was very nearly irreparable.

By 1992, however, escalating criticism over these investigative methods was ultimately instrumental in creating an Appeals Board at the Department of Health and Human Services; which consisted of lawyers. For the first time ever, the accused could finally, and rightfully, confront their accusers, question the evidence, and challenge all accusations. By late 1993, the downfall of that entire misconduct handling system came crashing down after several embarrassing defeats, all highly publicized in the media. The Appeals Board no longer allowed scientific misconduct charges without prior proof of: a) the misconduct itself and, b) additional proof of intentional and deliberate intent to deceive.

In retrospect, no Congressional Inquisition, prompted by whistle-blowers (intended, in many instances, to hurt other scientists/labs which were competitors), were needed to keep research on track. Scientific competition for peer recognition through peer review publishing was/is a much more natural, unobtrusive, and effective mechanism of accomplishing this same goal. More precisely, the goal in science is to seek independent peer verification of findings, which then establishes the work as valid and true. This does not deny the incidents of true scientific misconduct, or the usefulness of an official misconduct handling system. It is only meant to identify that honest errors in experimentation, interpretation, and reporting are expected and excused in research. What is not excused, however, is intent to deceive. But the accused must always be protected against 1) breaches of confidentiality, at least during the course of the investigative phase and, 2) the abuse of due process during which fraud must be proven beyond a reasonable doubt in a formal courtroom trial.

These cases, prosecuted at enormous taxpayer expense, followed extensively by the media, and which resulted in crushing defeats for the ORI, are summarized below. It would be a mistake to see each of these defeats as isolated cases. Taken together, they show how people with uncontrollable power and self-serving ambition can undermine due process. Even after victimizing innocent people by damaging their reputations, forcing them to commit vast amounts of their own time, money, and effort, in defense of wrongful allegations. Here are some of the more important cases:

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[1] Rep. John Dingell: Who Will Watch This Watchman?, by David Warsh, The Boston Globe, March 31, 1991, Sunday City Edition, p. A1.

The Seife Case - Marvin Seife, a divisional head who was Chief of Generic Drugs at the FDA, was accused of fraud along with his department. Although many companies were convicted and fined, and other people went to jail, in Seife's case no incriminating evidence was ever produced to prove the charge against him following a very thorough government investigation. Nevertheless, he was later convicted of one count of perjury for denying, under oath, to having been treated to lunch by a pharmaceutical representative many years prior. Seife, who in 1980, had been officially reprimanded for lunching with generic drug company officials, had promised to stop. As his case was being prepared, Seife signed an affidavit for investigators on October 25, 1989. In it, he stated it was his policy "never" to have lunch with industry officials. During his trial in October 1990, the prosecution asked him a plethora of questions, and in the middle of it all, they threw in a question about…lunch. Two weeks later, his accusers produced a restaurant receipt for $59.20 (for a meal at the James III Restaurant in Rockville, Maryland, on Dec. 11, 1987) and that's what convicted him. The signed affidavit became then a second count against him. His conviction cost him his retirement pension as well. Still, Seife maintained that he simply could not recall the luncheon at all.

He was later ordered to turn himself in and serve out his sentence at the prison in Big Sands, Texas. But they had no paperwork and after a bit, he was told to report to the Three Rivers Prison. Again, there was no paperwork there either. Three Rivers took him in, and even though he was 67, even though he was voluntarily turning himself in, Warden John Oury, did not know what the charge or the conviction against Seife was. So, as a precautionary measure, Seife (inmate #27472-037) was put into solitary confinement, while prison officials would wait for his paperwork to reach them. That was February 10, 1992. He was released from solitary on February 21, 1992. In that paperwork that took its time getting to the prison, was a letter from Seife's physician warning that he suffered from Aseptic Necrosis, which causes severe pain in his joints and makes him especially susceptible to infection. But by the time he was finally removed from solitary confinement, it was too late.

His body weakened terribly. So they had to walk him in the yard for exercise. Seife wore a size 13 shoe and the prison didn't have that size jail-house issue, so they gave him something smaller. Not right away to be sure. Seife had been in solitary barefoot and got his jailhouse boots only when he was released from there; 11 days later. But as he was issued the wrong sized shoes in jail, those walks he'd been given eventually injured his foot. Because of his condition, his foot could not heal and had to be amputated. From the progression of the gangrene, Seife lost his left leg below the knee, and a toe on his right foot. Only after becoming an invalid, did a judge release him, citing that he had endured enough suffering. Seife's bitter comment following his release was one; that he had served the government all his life and all he had to show for it was a stump.

Commenting on the Seife case, Dr. Gallo says: *"When a tourist wants to see Washington, I say go to the porch of Marvin Seife – it should be required as part of the Washington tour."*

With this case, Dingell gets into science and pursues his attacks in this new arena. Eventually taking on and mauling the FDA.

The Imanishi-Kari (Baltimore) Case[2] - In 1986, Thereza Imanishi-Kari, an immunologist at Tufts, published a paper in collaboration with Nobel Prize Laureate David Baltimore and others, claiming an unexpected immune response following the rearrangement of a particular mouse gene. When other independent scientists failed to reproduce the results, the self-correcting mechanisms of research shelved the paper. Nevertheless, a biologist working in Imanishi-Kari's lab complained that her boss was doing sloppy work, but her complaints were discredited after two university investigations concluded that, in this instance, Imanishi-Kari had made an honest mistake.

Unsatisfied with the outcome, the accuser found her way to Congressman Dingell, who prompted his own investigation. Imanishi-Kari was accused of fabricating data to support her published results. As a result, for the next ten years she was barred from getting any federal grants, while Dingell's staff relentlessly fought the case in the media for four years. They even went so far as to enlist the aid of the Secret Service to prove the alleged falsification of data in her lab records. Dr. Baltimore, one of the co-authors, who had already retracted the paper in writing, stood up to the Congressman, in defense of Imanishi-Kari, decrying Dingell's incompetent intrusion into the affairs of science. Dingell, who all along was after bigger fish (namely Baltimore himself) threatened to have Baltimore and Imanishi-Kari indicted on criminal chargers of perjury by a Grand Jury. The final report on Imanishi-Kari, which found her guilty, was leaked to the press in draft form before she herself ever had a chance to review or rebut it.

In October 1994, she received the official copy of her guilt, eight whole years after the beginning of her investigation. In June 1996, after waiting another two years, the Appeal Board of the Department of Health and Human Services reversed the verdict against Dr. Imanishi-Kari and completely exonerated her. This decision vindicated Dr. Baltimore too, who in 1991 because of the controversy, was forced to resign as President of Rockefeller University. Today he is President of Cal-Tech University.

The Hammosh Case - In 1989, Margit Hammosh, a medical immunology researcher at Georgetown University, was accused of alleged scientific misconduct by a co-worker. The allegation (making a false statement on a grant application) was investigated in depth and focused on a particular reference to an animal model system in her grant application to the NIH four years earlier. After a cross check of her lab records, she was accused of not having the system up and running at the time she submitted the application. Yet, this particular system, as referenced in her application, was such a triviality that the reviewers did not even bother to consider it. Nonetheless she was found guilty of fraud and, for the next four years, Hammosh fought the charge. When she finally asked for an appeal, the ORI just dropped the charges prior to the hearing. Later, her husband would say, "My wife was accused of jay-walking, and they demanded capitol punishment. Now I learn she did not even jay-walk."

The Sharma Case - In 1989, Rameshwar Sharma, a molecular biologist at the Cleveland Clinic, submitted a grant application to the NIH, which was never even funded. A year later, influenced heavily by both pressure from Congress and media coverage, his application was investigated, and he was found guilty of scientific

[2] The Baltimore Case – A Trial of Politics, Sciences and Character, by D.J. Kevles, W.W. Norton & Co., 2000.

misconduct. His "crime" was a typo[3] referencing one specific coded biological entity, in a 50 page grant proposal, which the ORI attributed to anticipatory writing; or the inclusion of data which he did not yet posses. Sharma fought desperately for his own defense while his research activities were suspended for nearly three years. Sharma appealed and was cleared of all charges in August 1993. According to the Appeal Board, the typo was of such trivial significance that it did not matter to the essence of the entire application. Besides that, no motive was found to support alleged falsification. In contrast, there was one motive which may have driven Dingell to extra lengths. The NIH Director at the time, Dr. Bernadine Healy, stood up more than once to Dingell…and did so openly. Healy was a leading figure at the Cleveland Clinic during the Sharma investigation before becoming the NIH Director. Her husband too, also remained a key figure at the Clinic.

The Kennedy Case - Stanford University was charged by the ORI for billing part of the University's operating expense to federally reimbursable overhead costs for grants. Congressman Dingell held a hearing on the matter on March 31, 1991. Called as a principal witness was D. Kennedy, a distinguished biologist and the President of the University. Dingell confronted Kennedy with a list of charges to which Kennedy responded that, while some expenses were billed erroneously or inappropriately, all were legal under federal rules. Nevertheless, Stanford was accused of excess billing and Kennedy (as the University's top executive) took full responsibility for those acts. In July of that same year he resigned as President of Stanford University. Today, Kennedy is the Editor of Science.

The Popovic Case - Mika Popovic (a co-worker of Dr. Robert Gallo), from Czechoslovakia, was indirectly accused by John Crewdson, an investigative reporter with the Chicago Tribune Newspaper, for conspiring to steal the AIDS virus from the French. In December 1989, he became the subject of a lengthy government investigation and was finally accused of three charges of data falsification regarding a paper he had published in 1984. The most serious of these charges involved eight entries in various charts with the notation, "ND." According to the accusers, the notation ND meant that the experiments were "Not Done," while the lab records showed that they in fact were. Popovic insisted that the notation ND meant "Not Determinable," but to no avail. No matter its meaning, "ND" had absolutely nothing to do with the validity or outcome of Popovic's experiments and still, he was found guilty. Popovic appealed the verdict and won his case on November 3, 1993, after also losing four productive years of his professional life. The Appeals Board judged that the investigative body, "had used biased witnesses, misunderstood the research it was investigating, had instrumental flaws in its investigative methods, and drew unreasonable inferences from testimony and data[4]." Moreover, one of his main accusers was a scientist, Dr. Berns[5], who was later shown to have exactly the same notations in his own publication. Just as Dr. Popovic had been accused of intentional misrepresentation with his use of "ND" (to mean Not Done), Dr. Berns, Chairman of the Microbiology Department at Cornell University, had also been using "ND" in his paper to mean "Not Determinable." Dr. Berns called his usage of that

[3] Specifically, he used an incorrect subscript in a single instance of identifying a certain protein.
[4] The Fraud Fraud, by Malcom Gladwell, The Washington Post, Sunday, November 14, 1993, p. C2.
[5] Page 47, Department of Health and Human Services, Department Appeal Board, Research Integrity Adjudications Panel, Docket No A-93-100, Decision No 1446, November 3, 1993, Case: Mikulas Popovic.

term an, “honest mistake.” So Berns was not investigated for its use, whereas Popovic was.

The Gallo Case - Gallo, a chief investigator at the National Cancer Institute (NCI), was accused by the same John Crewdson, to have stolen the credit for discovering the AIDS virus from the French, not to mention the theft of the French virus itself. After almost 5 years of multiple, ruthless, government investigations (starting in November 1989), the charges against Gallo came down to the precise meaning of a clause, in one single sentence, at the conclusion of a scientific paper he had published back in 1984. Taken one way, the disputed clause seemed to contradict the factual record (which was the ORI's interpretation), but taken another, it did not. Gallo's interpretation was in fact, the unanimous interpretation of his entire group. Following Popovic's exoneration by the Appeals Board, all charges against Gallo were likewise dropped on November 12, 1993.

The Fischer Case - Bernie Fischer, one of the top clinical cancer specialists/oncologists in the U.S., was charged of scientific misconduct as Principal Investigator in a three nation (U.S., Canada, and Mexico) collaborative clinical study. He was accused of delaying his report to NIH of a serious protocol violation committed unknowingly by one of the participating physicians in Canada. The University of Pittsburg, where Fischer worked, was in fact threatened by Dingell’s staff, that “other” misconduct cases would be opened and investigated if Fischer was found innocent. Fischer was harassed unmercifully, but battled his accusers for years with the aid of expert legal advice. He finally sued the federal government for unjustified harassment and won; collecting a few million dollars in damages. But, as a result, he lost years of research and his patients lost the benefits of his care.

These certainly are all key cases. However this book will thoroughly examine the case against Gallo in particular. Because his case was of such political, personal, and international proportions, it stands alone as something completely unprecedented in the annals of science.

You will also see chronicled the collaborations and discoveries of many other scientists, and their contributions to medical research in those crucial years when AIDS was still becoming what it is today…a world-wide pandemic. Dr. Robert C. Gallo's multiple pioneering contributions have indeed made a lasting impact on medical science, clinical practice, even on public health care. No matter what else has been said about him, one fact remains; Dr. Gallo dominated the biomedical research scene during the last quarter of the 20th century.

3.
THE RIGHT STEPS

In his early years at NIH, Gallo focused his experiments on the comparative biochemistry between active molecular components outside the nucleus of both normal and leukemic human blood cells. His aim was to unravel key differences between the two cell systems which might shed some light on the mechanisms of leukemia induction. Later, he became convinced that nothing exciting would come out of all the comparative biochemistry, in so far that there was no way to distinguish between culpable biochemical changes inducing cancer, and secondary changes playing absolutely no role in cancer induction. He thus started looking elsewhere for fresh ideas and new leads.

In the early 1970s, Howard Temin hypothesized that all RNA tumor viruses transcribe their RNA genome into DNA (proviral DNA) which they insert into the genome of the cells they infect. Within a year, Temin and David Baltimore discovered an enzyme, named Reverse Transcriptase (RT), which mediates the transcription of viral RNA into proviral DNA[6]. Expectedly then, their achievements during this time period, proved catalytic in shaping Gallo's thinking and in redirecting his work since the tools of molecular biology had been refined. Just as the induction of cancer by viruses[7] in various animal species having been firmly established too by several investigators: from poultry to mammals and, on to primates in the wild. But not in man. Additionally, the genetic core of the first known cancer virus in animals, the Chicken Rous Sarcoma Virus, was successfully isolated intact. The activation of oncogenes (cancer causing genes of unknown origin at the time) from an inert state by radiation, chemicals, chance mutations, and other viruses, was theorized by some, as a hypothesis explaining the origin of all

[6] In 1975, the two received the Nobel Prize in Medicine for this discovery.

[7] Viruses are of two kinds: DNA and RNA. DNA viruses are those whose genetic information is encoded in DNA format; while RNA viruses are those whose genetic information is encoded in RNA format. Special RNA viruses, called Retroviruses, can convert their RNA into DNA upon infection. This DNA (the provirus) then integrates into the DNA of the host cell. Viruses can take over the metabolic machinery of cells to serve their own purpose. Once in control of cells, viruses seek to replicate themselves (e.g. the flu viruses), change the functional character of their host cells (e.g. some tumor viruses) or do both (e.g. infectious tumor viruses). Rare forms of DNA viruses can integrate their genetic material directly into the DNA genome of cells. Among RNA viruses, only retroviruses have this potential and only after they transcribe their genetic RNA material into the intermediate DNA form (the provirus). This transcription process occurs inside the cell following viral invasion and is mediated by a particular enzyme, called reverse transcriptase, which the retrovirus carries along. Once integrated, into the genome of a target cell, the provirus becomes a permanent component of that cell and its progeny.

tumors in all species. We now know that retroviruses sometimes captured some of these genes and made them part of their own genetic information. It was the discovery of the mechanism of reverse transcription by Howard Temin and independently by David Baltimore, that opened wide the field of Molecular Retrovirology; though still limited to animal retroviruses. These investigators succeeded in demonstrating and explaining the conversion of RNA viruses into a DNA form. This DNA form was named Provirus by Howard Temin. Moreover, the discovery of reverse transcriptase, confirmed an earlier hypotheses by Temin: that the life-cycle of a retrovirus includes an intermediate DNA form. Soon, that integration of infectious, proviral DNA into the genome of target cells and the subsequent role of the same as retroviral oncogenes, was confirmed by many groups. More important, infectious retroviruses were being found in many animal species where they often cause cancers; especially leukemia and other disorders of blood cells.

Humans were assumed to be protected since it had been demonstrated by other scientists that human sera could lyse[8] most animal retroviruses. A second reason was that in animal models, disease causing retroviruses, when present, reproduced high levels that were easy to find. It was assumed that the same would be true in humans. Gallo countered these arguments by noting that human sera had only been tested against a few animal retroviruses. So it was an open issue whether they lysed all of them. Moreover, the efficiency of the process might not preclude some cells from being infected. As to the animal models with high levels of virus, Gallo noticed that most of those animal models were selected as lab tools because of their high rate of disease, and associated high levels of virus; all irrelevant to the possibility of human retroviruses.

In the midst of all these important developments, Gallo's logic led him to redirect his research thrusts in more fruitful directions and entered the field of Retrovirology; with the ultimate long term goal of unraveling the connection between RNA viruses and cancer induction in humans. This decision was influenced partly by the push of the achievements in the field, and partly by two other scientists: the late Sol Spiegelman, and Bob Ting. Spiegelman (a molecular biologist and friend) persuaded Gallo to drop his comparative biochemistry studies and redirect attention to the level of gene activation inside the cell nucleus where all the real action was occurring. Bob Ting (a virologist and friend), on the other hand, introduced Gallo to the study of viral infectivity of animal cells in tissue culture, as the control system best suited to reveal biomolecular changes directly attributable to the cancer process.

The Development of New Biomolecular Assay Tools

Gallo first studied animal retroviruses as model systems that might teach him various fundamentals of how cancer occurs; how cancer occurs in humans; even if human cancers were never caused by retrovirus (according to the conventional wisdom of the time). However, soon after beginning his studies with animal retroviruses, Gallo became very suspicious that humans were also likely targets of retroviruses and went after this lonely task with the tenacity to prove himself right against an unconvinced scientific community. In doing so, he took an immense chance and placed his mounting reputation on the line. Gallo then undertook the venture of seeking, characterizing, and comparing reverse transcriptase enzymes of many different retroviruses, in many different infected animal species as his reference systems. His intermediate goal was to develop sensitive

[8] Certain cells contain enzymes that can "lyse" (or digest) many types of cells, including a diversity of tumor cells.

and specific assays (tests) for detecting reverse transcriptases in any mammalian system; and for differentiating reverse transcriptases from DNA polymerases[9] which mimic reverse transcriptases. Then, use those same assays to search for the presence of reverse transcriptases in human cancer cells. Such a finding would support the claim that at least some retroviruses could be infecting and possibly causing cancer in humans.

Between 1970 and 1972, Gallo's team systematically and painstakingly developed the most sensitive and specific assays ever for detecting all kinds of species-specific reverse transcriptase enzymes, under a well organized plan, and liberally made them available to the scientific community around the globe. These assays were never patented, although at the time, discoveries in molecular biology were already translating into patentable innovations. More importantly; they also advanced the state of the art for human retrovirus detection.

In 1972, armed with these assays, M. Sarngadharan (affectionately called Sarang by everybody in the lab) and Marvin Reitz, both on Gallo's team, detected the presence of reverse transcriptase in human blood cells from a patient with lymphocytic leukemia. This was an electrifying finding. The footprint of a retrovirus was finally detected in a human cancer sample. Because of this and several other simultaneous observations, suddenly, Gallo's work deservedly got the enthusiastic attention of top administrators at the National Cancer Institute. The word soon spread that whatever Gallo wants, Gallo gets.

The publication of Gallo's finding, suggesting the presence of a reverse transcriptase molecule in human leukemic cells, attracted little attention. By itself, the finding was exciting. But it was insufficient to clinch the case of a cancer-causing human retrovirus. Three important questions were still begging for answers: 1) What was the nature and origin of this reverse transcriptase? 2) What kind of retrovirus could produce such a particular reverse transcriptase? and, 3) What was the role of the alleged retrovirus in human cancer causation? Finding the answers obviously required isolation and characterization of the retrovirus to which the reverse transcriptase belonged.

However, before one could start isolating and characterizing the first human retrovirus, one had to have significant amounts of live virus on hand. This meant first solving the problem of keeping the retrovirus replicating in cells. It also meant discovering how to grow any retrovirus inside human cells within a cell culture laboratory system; a knowledge not available at the time. To accomplish that task, Gallo had to seek, identify, and use growth factors that could keep leukemic white blood cells growing in a continuous culture. Or at least long enough to allow the presumed human retrovirus to replicate in sufficient quantities. This was necessary in order to be able to prove the presence of the retrovirus, to be able to identify its features, and to be able to transmit it to other permanently growing cells[10]. Leukemia was still Gallo's primary target disease for his research during this time.

The Development of an Immortalized Leukemic Cell Line

Gallo assigned the search for a growth factor to scientists Robert Gallagher and Zaki Salahuddin. From the very start, Gallagher suggested that the best chance of finding such a factor would be to work with human embryo tissues, whose normal development

[9] DNA polymerases are enzymes found in cells that catalyse synthesis of DNA. Reverse transcriptase is a special kind of DNA polymerase carried by all retroviruses.

[10] Such cells are called a "Cell Line."

appeared to depend both upon the release -and uptake- of growth factors. This suggestion made good sense, so a corresponding approach was implemented, and the search began. One day in 1973, Gallagher and Salahuddin finally met with success when they managed to extract a potent growth factor from a culture fluid in which one of their embryo tissues was growing. It was through regular infusions of this growth factor that they could keep a population of human myeloid leukemic cells in continuous growth[11]. Success!

One of these leukemic cell populations, proved promising in that it did test positive for reverse transcriptase, signaling the presence of a retrovirus. This particular cell population, named the HL-23 cell line, remained strictly dependent upon regular infusions of the extracted growth factor for continuous growth. Surprisingly, however, another myeloid leukemic cell population, the HL-60 cell line, became spontaneously immortalized, forcing cells to replicate uncontrollably. In other words, it kept on growing and reproducing itself without the need of regular growth factor infusions; only ever requiring periodic additions of nutrient fluid. This second cell line, however, never tested positive for reverse transcriptase. Obviously, the HL-60 cell line was transformed by an unknown mechanism while the HL-23 cell line was reproducing the virus, but without becoming immortalized.

That immortalized HL-60 cell line was immediately made available to other scientist throughout the globe; and to this day remains a tool for many kinds of biochemical and biomolecular studies against this particular leukemic cell species. Indeed, it was the first time that this kind of cell (known as myeloid or granulocytic) was ever grown in the laboratory, in a continuous culture[12].

Disaster Strikes

It happened without warning one Monday morning. The freezer, where both the stock of fetal cells producing the growth factor and, the stock of the extracted growth factor itself were stored, was left unplugged over an entire weekend. Feelings of dismay, anger, and despair swept the lab. Everything was lost. Gone! Without growth factor, the HL-23 leukemic cell line could not be kept alive. Without growth factor, the virus contained in the HL-23 leukemic cell line could not be kept replicating. Meaning that without that growth factor, the HL-23 leukemic cell line, and its virus could not be made available to other scientists for independent verification studies. It was a staggering blow.

Once the initial shock from the loss was over, the search for the same, or a similar growth factor, started all over again. By this time, however, embryonic research had become a hot political issue and fetal specimens were difficult, if not impossible to get anymore. Yet, despite those difficulties, dozens of specimens were obtained and tested in the hope of recovering the badly needed growth factor from a new fetal source. These efforts continued for almost a year; unfortunately to no avail. Leaving Gallo to accept the painful reality that the original growth factor was now irretrievably lost and that the prospects of finding a substitute from another fetal source were practically nil.

Disaster Strikes Again

Simultaneous to the ongoing search for a growth factor from a new fetal source, Gallo organized a parallel search for human or animal cell lines that would continuously

[11] Leukemia occurs in different lineage of blood cells. Myeloid or Granulocytic leukemias are those which occur in bone marrow cells, which are progenitors of our blood cells called granulocytes.

[12] At that time, there were some known growth factors for these kinds of cells, but their activity was limited to the growth of these cells in small numbers and/or, for short periods of time on a solid surface.

grow in culture, and could become infected by the virus of the HL-23 leukemic cell line. Almost any cultivable cell line was tried, but the virus stubbornly refused to grow in any of them; evidenced by the discouraging negative reverse transcriptase assays performed time and time again.

Then, two independent pairs in Gallo's lab were given the same goal, hoping that they would bring an end to the problem. One pair was Robin Weiss with Natalie Teich, who came from England as experts for culturing animal viruses. The other pair was Robert Gallagher with Zaki Salahuddin, already experienced in using a variety of animal cell lines. Together, they achieved the unexpected. Their assays tested positive for reverse transcriptase activity, sample after sample. Firm evidence that the retrovirus, had transferred from the HL-23 line and had, in fact, infected the animal cell lines. Samples were immediately sent to scientists in other labs for independent examination and confirmation. Electron microscopy confirmed the presence of a retrovirus with the same structure known to cause leukemia in many animal species.

Preparations were being made to present these findings at the upcoming annual meeting of the Virus Cancer Program. The presentation went bad. In fact, it was a downright disaster. Scientists, who had received and examined the samples sent to them for independent confirmation, reported back that Gallo's findings were nothing but a case of mistaken identity (see photo, p. 15). Their study had revealed a contamination of the samples by a cocktail of three primate retroviruses, the gibbon ape virus, the woolly monkey virus, and the baboon virus. This composite contamination was most puzzling as Gallo's lab never even possessed those three primate viruses to experiment with. The suspicion at the time -and still- is that it was sabotage[13]. Regardless, the other scientists were particularly hostile and scornful in their remarks, ridiculing the very idea of a human retrovirus. "Gallo's human tumor virus is Gallo's human rumor virus" was the slogan invented; and very soon became the joke of the meeting. In fact, Gallo and his co-workers were already coming to the same conclusion, yet they believed it needed to all come out; that the facts which they had thus far had to be publicly presented.

With his scientific reputation tarnished, and his staff depressed, Gallo came to grips with the events of that meeting. That ordeal made Gallo scientifically tougher; both with himself and with others. It also became a foundational source of his perceived aggressiveness.

Also about this same time (the mid 1970s), Max Essex, from Harvard University, undertook the study of cat leukemia as an infectious disease, transmitted by a virus, which was spread through sexual contact and saliva. The virus was shown to suppress the feline immune system.

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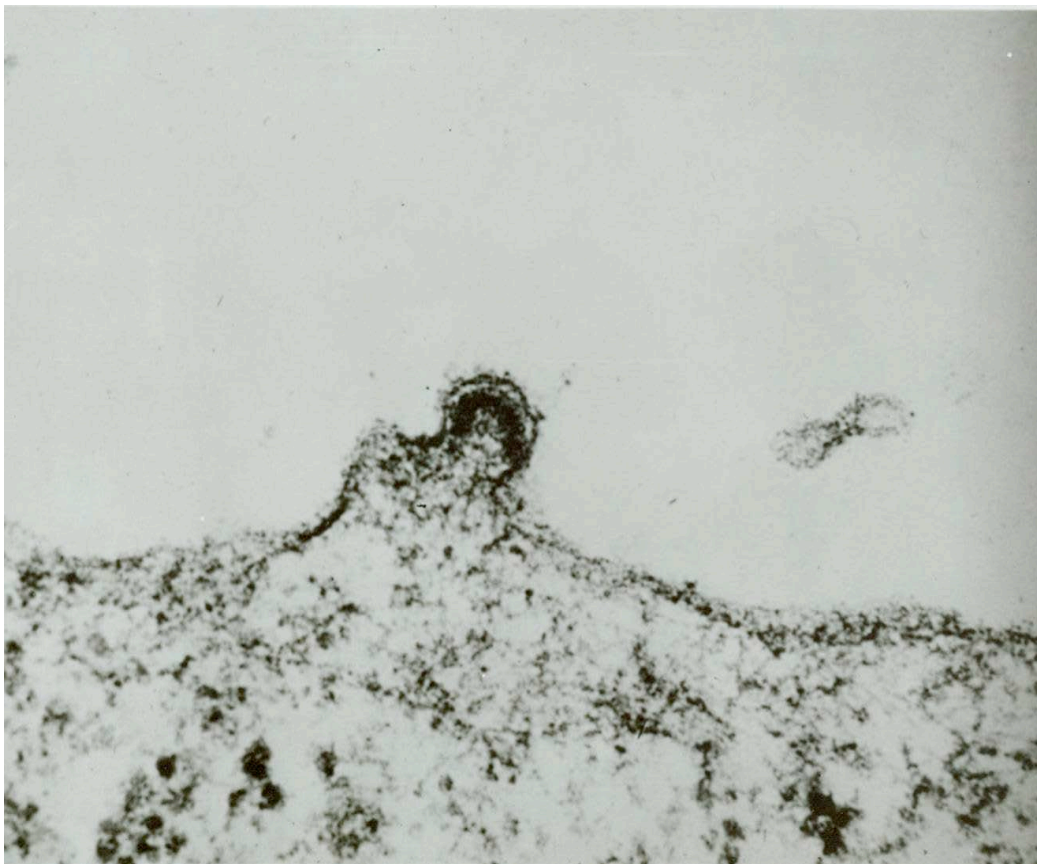
[13] "Nobody who worked with viruses, including Weiss (a collaborating British scientist) believed Gallo's lab had been the victim of an accidental contamination. What else could have been but deliberate?" Weiss continues, "If it was three viruses instead of one? Or at least two? If it was a rival group at NIH looking for human retroviruses, one could certainly make an enormous fool of Gallo." (Science Fictions: A Scientific Mystery, a Massive Cover-up and the Dark Legacy of Dr. Gallo, John Crewdson, Little Brown & Co., 2002, p. 19 - 20).



FIRST ELECTRONMICROSCOPY OF HUMAN LEUKEMIA VIRUS
JANUARY 17, 1975
…or is it?
Mistaken identity: this is actually a primate leukemia virus reported as a human leukemia virus by Gallo and associates.

4.
HUNTING A HUMAN RETROVIRUS

The Discovery of Interleukin-2

When the search for the recovery of a growth factor from new human fetal sources failed, Gallo turned his attention elsewhere. PHA is a plant extract with the strange ability to agglutinate (group/cluster together) red blood cells and to stimulate normal white blood cells (specifically lymphocytes[14]) so as to replicate once or twice in culture. Gallo wondered whether PHA stimulated T-lymphocytes released any growth factors and found that, in fact, they did. He soon realized, however, that one of these factors, known by the name GM-CSF, had already been discovered by other investigators, but whose work did not show they were derived from T-lymphocytes.

Gallo pushed on and during a very frightening 1974[15] he and his co-workers, Alan Wu and Joan Prival, pinpointed T-lymphocytes[16] as the main source of CM-CSF. This was one of the main demonstrations that cells of one lineage (lymphocytes) could regulate locally the cells of another lineage (CM-CSF has its effects on promoting maturation of cells of the myeloid lineage). Although the phenomenon of one cell type regulating another was known for hormones[17], it was not known for locally produced cellular regulators. These locally produced cellular regulators are today generically called cytokines. And if made by lymphocytes, are sometimes called lymphokines.

Doris Morgan, a post-doctoral fellow at Gallo's lab, had a PHA stimulated blood cell culture growing for long periods against all conventional wisdom, as T-cells were at the time not known to grow in culture past a few cells divisions. It was quickly discovered that T-lymphocytes in culture made, and actually released, several growth factors, one of which would keep the T-lymphocytes growing for long periods. But up

[14] Lymphocyte is the collective name given to a mixture of specialized white blood cell subspecies that are the main source of immune response. One type of lymphocyte – the B cell – makes antibodies. Another type – the T cell – is involved in a wide variety of cellular mechanisms.

[15] September 8, 1974, Gallo was booked on the ill-fated TWA Flight #707 from Tel-Aviv, via Athens to New York, which had just crashed in the Ionian Sea due to a terrorist bomb. Although he was supposed to fly on that particular flight, he fortunately never actually boarded the plane, having changed his reservation at the very last minute to attend a dinner party in Tel Aviv. Had Gallo been on that TWA flight to New York, the world would have undoubtedly suffered; for most of his major scientific contributions to public health care were yet to come.

[16] T-lymphocytes are a lymphocyte subspecies of the immune system.

[17] Molecules made in specialized glands which enter the blood stream and have their effects at a distant site.

until that time there was no known growth factor for T-lymphocytes; and no such factor was suspected to even exist. This, then, was truly a major discovery. At last! A new growth factor had been found from which T-lymphocytes could grow more T-lymphocytes in long term culture. They reported their findings in Science in 1976. Basically what D. Morgan, F. Ruscetti, and R. Gallo had discovered, was a T-cell growth factor, which allows long-term in-vitro cultivation of human T-cells and ultimately from which human retroviral infection can be detected using an RT assay. That revolutionized the technology for human retrovirus cultivation.

By 1977, this new growth factor, which came to be known as Interleukin-2, was more fully characterized in Gallo's lab by Francis Ruscetti, who slowly but surely pushed Doris Morgan entirely out the of project. According to Marjorie Guroff, a co-worker in Gallo's lab, Ruscetti, realizing, the importance of the finding, wanted the credit *"alone."* By 1980, the growth factor was purified (again, in Gallo's lab) by James Mier. In fact, Interleukin-2 was such an important tool, that it quickly attracted the attention of other scientists. Soon it found its way into most immunology and clinical oncology labs where ironically it was not only a laboratory tool; it was also used in the therapy of both cancer and AIDS.

In the case of cancer therapy for example, T-lymphocytes attack cancer cells and, therefore, can be extracted from a patient; grown in culture; then be given back in large amounts to that same host patient to help him fight the disease. Steven Rosenberg and his colleagues pioneered this approach at the National Cancer Institute of NIH, after Gallo had supplied him with Interleukin-2. With AIDS, Interleukin-2 has been used to help restore T-cells, thereby helping restore immune function in patients; work chiefly carried on by Clifford Lane working with Anthony Fauci at NIH.

No one knew it, but another important discovery was also waiting in the wings. A number of leukemic T-lymphocytes were found by Bernard Poiesz in Gallo's lab, to respond directly to Interleukin-2, and grow in long term culture, without prior stimulation from PHA. It would be from these very leukemic T-lymphocytes, stimulated with Interleukin-2 in culture, that Gallo's group would soon at last discover what other scientists scoffed at for so long...the first human retrovirus.

The Discovery of the First Human Retrovirus (the first leukemia virus)

The first cancer-causing RNA viruses were found in chickens around 1910 by Peyton Rous and proved to be infectious. Fortunately, however, cancer-causing retroviruses are less commonly infectious in mammals. It is not surprising, therefore, that when other scientists tried to verify Rous' experiments using mammals, they never did succeed. Based on such negative evidence, clinicians, rejected the notion of cancer as a communicable human disease and, in turn, rejected the idea of cancer-causing retroviruses in mammals.

Ludwik Gross was one among a handful of scientists left in the 1950s, who persisted and finally proved that retroviruses are transmissible, albeit rarely, in mice. He accomplished this by inducing leukemia and lymphomas in the laboratory; and showed that retroviruses could be transmitted especially when newborn mice were infected. Following Gross' findings, a whole variety of cancer-causing retroviruses in mammals were later discovered by other investigators.

The next breakthrough came a decade later when William Jarrett showed that transmissibility of cancers by retroviruses was not limited to laboratory animals, but

could be observed in feline species under natural conditions. Spurred by all these findings, a Virus Cancer Program was organized in the late 1960s under the National Cancer Institute, to hunt for cancer-causing retroviruses in humans. Efforts were renewed and soon they were able to prove the existence of cancer-causing retroviruses in cows and primates. More importantly, they showed that these viruses were capable of intra -and inter- species infection in those animals as well. Despite that and other advances in animal retroviruses, the Virus Cancer Program was unfortunately canceled in the late 1970s, after failing in its goal to substantiate the existence of cancer-causing retroviruses in humans.

Only Gallo stubbornly refused to let go and pressed on; even as others halted this line of investigation entirely. Moreover, by this time there were at least a dozen false starts by investigators all over the world who had earlier thought they had discovered human retroviruses, only to later realize that an experimental flaw had invalidated their work.

With sensitive biomolecular assays to detect any one kind of reverse transcriptase activity; and Interleukin-2 to keep the leukemic T-lymphocytes growing in long term culture (which -if infected with a retrovirus- might continually produce viruses); and the fact that T-lymphocytes were now known to be a major target of retroviruses in a variety of animal models; Gallo set out to prove he was right about the existence of a human retrovirus.

First, leukemic T-lymphocytes were stimulated with Interleukin-2 and grown in culture (expecting to release reverse transcriptases). Reverse transcriptases were then detected by Bernard Poiesz in the fluid of the culture. Specific antibodies both to normal human polymerases (alpha, beta, and gamma) and to different animal reverse transcriptases, were also used by Poiesz. This then proved that the reverse transcriptase detected was neither a normal human cellular enzyme, nor a contaminant from a common laboratory animal retrovirus. Rather, it was a novel molecular species. This novel reverse transcriptase species was, in turn, purified and shown to possess all the properties of a viral enzyme.

The presence of viral structures in the fluid of the culture was next demonstrated by electron microscopy. The absence of animal retroviruses in the nutrient broth, feeding the cultured cells was confirmed as well; by means of specific molecular assays so as to exclude contamination by animal retroviruses. Viral particles were identified in, and extracted from, the fluid of the culture. The major protein core component of the viral particles was isolated, purified, and tested with various antibodies, and the sequence of its amino acid components recorded; proving that the virus was novel by both criteria.

Additionally, the presence of reverse transcriptase was sought, and found, in fresh blood from leukemic patients. It was then shown to be identical to that released by the cultured leukemic T-lymphocytes. Viral genes were also sought by the technique of molecular hybridization[18], using nucleic acid probes, and found integrated in the genome of T-lymphocytes (which were drawn from leukemic patients). These results, obtained by Marv Reitz, showed that the virus was not an animal virus contaminant. Specific antibodies against specific viral components (reverse transcriptase and core protein) were then sought and found by Marjorie Robert-Guroff in the fresh blood of leukemic blood

[18] Molecular hybridization is a technique allowing direct identification of homologous genetic segments (corresponding in basic type of structure) through molecular stranding (i.e. molecular coupling).

patients, an indication of infectivity. Finally, the same new virus was independently isolated from other leukemic patients too. But…mere detection and isolation of a new virus means little by itself. Understandably then, when Poiesz first reported the detection of the retrovirus, Gallo's response was, "that this is just the beginning of the beginning of the beginning." They needed still to prove that the virus…

- was a novel RNA species,
- was infectious,
- was integrating into the DNA of human cells,
- was present not just in one patient, but to some extent in the human population,
- was the cause of the disease (a particular leukemia),
- could grow in culture from where it could be re-isolated, and even
- could be re-isolated from another sample from the same patient.

Only when all of these tasks were completed, would Gallo allow publication of the discovery. After an all out team effort[19], after over a year of hard work, and after utilizing the involvement of many of Gallo's investigators, they had discovered and characterized the first human retrovirus ever!

The discovery of this first human retrovirus by Gallo, named HTLV-1 (Human T-cell Leukemia Virus), was accomplished in late 1979 and was presented to peers at scientific meetings in 1979. The first paper was submitted in mid-1980 to the Proceedings of the U.S. Academy of Science and was published in December 1980, under the title, Detection And Isolation Of Type C Retrovirus Particles From The Cultured Lymphocytes Of A Patient With Cutaneous T-Cell Lymphoma. Other papers were also submitted to important specialty journals at about the same time. All were accepted for publication except one key article, which unexpectedly drew harsh criticism from the Journal editor; and the paper's reviewers (see page 21). Yet, after its rejection, that same paper was in fact accepted within six months – by that very same journal.

Despite the inevitable initial skepticism given over numerous scientific failures in the past, including Gallo's own, all critics were at last convinced human retroviruses did indeed exist. Soon the existence of HTLV-1 became irrefutable in view of all the overwhelming experimental evidence published. Dr. Phil Markham: *"Obviously IL-2 (Interluekin-2) was a key player in all the other isolations of HTLV-1 and all the characterizations; that was a key ingredient."*

It is of interest to note, however, that when leukemia caused by the virus finally develops in the patient, usually neither the HTLV virus nor the HTLV proteins can be detected, meaning that the virus, rarely replicates in the actual human subject (in vivo). Viral detection is only possible when the T-lymphocytes are properly cultured in vitro. This is one reason why the detection of a human retrovirus proved a most difficult task indeed.

Later in 1979, Dr. Luc Montagnier of the Institut Pasteur in Paris, France, shared with Gallo his experimental findings on mice treated with anti-interferon serum[20], which

[19] Heavy contributors to this effort were Marjorie Robert-Guroff, Bernard Poiesz, H. Rho, NIH clinical scientist John Minna, Michiyuki Maeda, V. Kalyaranaman (known to all in the lab as Kaly), M. Sarngadharan, Larry Posner, Carl Saxinger, Marvin Reitz, Flossie Wong-Stall, Mikulas Popovic, Phillip Markham and Zaki Salahuddin.

[20] Anti-interferon serum is a solution containing antibodies – in this case antibodies specifically raised against human interferon – that could boost the production of the AIDS virus and facilitate its isolation. In

did not prove helpful in better isolating viruses. But this first scientific exchange is the beginning of a fruitful collaboration between the two researchers[21]. Unknown to either men, their futures would soon collide.

In 1981, a Japanese group led by the late Yohei Ito reported the isolation of HTLV-1, about a year after the initial Gallo publication on the first human retrovirus, and provided the first independent confirmation of Gallo's discovery. The first independent isolation in the U.S. was achieved by Dani Bolognesi at Duke University. By 1982, no serious scientist would doubt the existence of human retroviruses. It should also be said that years later, those same specific antibody tests developed by Gallo's group to detect the presence of HTLV-1 proteins, would be used in American and Japanese blood banks, to screen them against the leukemia virus; protecting transfusion recipients against contaminated blood.

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theory, the production of viruses is inhibited by endogenous interferon produced by human cells, so the use of a specific anti-interferon serum could perhaps allow the virus to emerge.

[21] According to Montagnier, he and Gallo first met as early as 1973, when they shared room accommodations during one of the scientific meetings held that year.

JOURNAL OF VIROLOGY

A publication of the American Society for Microbiology

September 15, 1980

Dr. Robert C. Gallo
Laboratory of Tumor Cell Biology
National Cancer Institute
Building 37, Room 6B04
Bethesda, Maryland 20205

RE: JVI 417

Dear Bob:

I regret that your paper on the T cell retrovirus is not acceptable for publication in the JOURNAL OF VIROLOGY.

Enclosed are the comments of two reviewers, both of whom expressed grave doubts about the evidence that your protein is really analogous to a retroviral structural protein. I completely agree with reviewer #1 that there is little point in perpetuating this controversy about "the presumed viral nature of this material".

I hope you can understand that we can only accept definitive data to resolve this question. Therefore, I have no alternative but to reject this paper outright and must advise you that we cannot consider the present manuscript in any form.

Sincerely yours,

Bob

Robert R. Wagner

RRW/mc
enc.

The Rejection Letter

Unveiling the Epidemiology of the Leukemia Viruses

On the basis of reports describing clustering of T- lymphocytic leukemia or ATL (Adult T-cell Leukemia) in various parts of the world, Gallo collaborated with two international teams of scientists. The first team consisted of Yohei Ito and H. Takatsuki from Japan. Their goal was to study the epidemiology of the disease in that country. The second team of epidemiologist Bill Blattner from the U.S., and clinician Daniel Catovsky from England, were to study the spread of the disease in the Caribbean. The goal of both teams was to look for a connection between the causation and spread of this particular disease, and the infectivity of the HTLV-1 retrovirus. By that time, Gallo already had four papers published on HTLV-1, verifying the presence of human antibodies to the virus, and revealing the modes in which the virus was transmitted. Takatsuki was the first to define the disease and to describe a clustering of leukemia in southern Japan, noting that this neoplasm involved T-lymphocytes; thereby leading to opportunistic infections.

Gallo first heard of ATL clusters in Southern Japan from Ito so he already knew that the disease was endemic in Japan. Ito, however, wanted to bring more Japanese into collaboration with Gallo. So a meeting was held in Kyoto in March 1981 (four months after the Gallo group had published the discovery of HTLV-1) to discuss participation and future research thrusts. Dr. Max Essex: *"Bob (Gallo) asked if I would agree to go, and sort of mediate, be the General Chair. And he thought it was good that I wasn't working exactly in the area, but was supportive of the concept of would-be retroviruses. I remember the Japanese presented much more data than he thought they'd had, or would have. And he was really shocked by how much they had done in the last year or so and said to me, late one night, how concerned he was that he couldn't even convince the majority of people in his own lab that these viruses were real. And, would I get into the business and collaborate with him and start working with HTLVs? Because a lot of people in his own lab didn't want to work with him (on that project). He became very impressed with the data from the Japanese, and very depressed; even though I'm sure he was still considerably ahead of the Japanese. They had mobilized huge groups, and he was having trouble mobilizing even his own lab."*

An important point to keep in mind is that the disease, not the virus, was what the Japanese had first as it was prevalent in Japan. Gallo: *"Because of that, Takatsuki described an endemic leukemia which he didn't know the cause of. But he described that leukemia as a very specific disease, and he was right."*

Hinuma, one of the Japanese scientists attending the meeting, disclosed that he had already found the causative virus, then announced that he would do the serology by immuno-fluorescence, and tried to block the collaboration[22]; stunning Gallo. Hinuma then presented unpublished pictures of a virus he called ATLV; which he believed was the cause of the disease. No data was ever shown characterizing the virus, that linked the virus to the disease, or which excluded it from an animal retrovirus contaminant. Obviously, unpublished electron micrographs of an unidentified virus mean absolutely nothing; they are just curiosities. Still, Hinuma first published his findings in mid-1981, claiming that he had found the first human leukemia virus. But he was about one year and

[22] Hinuma tried to break the collaboration by saying that Gallo could never get blood from Japan because it was against their culture. Gallo argued that he already had samples sent to them by Ito. When the other Japanese scientists saw this, that Hinuma was being so unfair, they told Gallo not to argue with him; that they would take care of it in their own way.

three Gallo papers late. In fact, Gallo had already published six papers by the end of 1981, and three of those were before any subsequent confirmations coming out of Japan. Before departing, Gallo left cell lines of HTLV-1, as well as antibodies to purified viral proteins with Ito and Tadao Aoki (another collaborator). Conversely, it was years later before Gallo would receive any virus samples from Japan.

Studies conducted by the Gallo and the Japanese groups, using that sera provided by Ito, revealed that HTLV-1 was the cause of ATL, that the ATL disease clusters observed in Japan were in fact caused by HTLV-1, and that HTLV-1 was indeed infectious. It was also revealed that HTLV-1 spreads via blood and sexual contact; that it is transmissible from mother to offspring, and that, besides causing just T-cell lymphocytic leukemia, it can also cause other disorders. They further revealed that the disease has a variable latency from a few years to decades. That being said, there can be no doubt that both U.S. and Japanese scientists contributed to the etiology, and epidemiology, of ATL.

As mentioned, the disease was endemic in southern Japan. Especially in the islands of Kyushu, Shikoku, and Okinawa - where 3 to 10% of their population were carriers of the virus (HLTV-1, we now know clusters in Southern Japan). It was also found to be endemic in several of the Caribbean islands, yet not in others; and in sub-Saharan Africa with regional variations among tribes. However uncommon in the United States, it was present opportunistically just here and there, but predominantly concentrated in the southeast. As was the case in Africa and the Caribbean, it was mainly, but not solely, prevalent among blacks. Conversely, in Europe it was hardly present at all. Later, other investigators found a very high rate of infection in Hokkaido (the major northern island in Japan), a pocket of infection in southeast Italy, other pockets of infection among American Indians, among some native people of southeast Asia, and only sporadically elsewhere.

In time, the leading Japanese scientists acknowledged and agreed that ATLV and HTLV-1 were the same, and published together with Gallo's group, an article to that effect in Nature. Notably missing from the list of authors was Hinuma.

The Discovery of the Second Human Retrovirus

In the spring of 1981, Gallo attended a meeting on leukemia in Venice. There cell biologist David Golde of UCLA presented his work on a very unusual, permanently growing T-lymphocyte line, from the spleen tissue of a patient with a rare leukemia called, hairy-cell leukemia. This particular line was making lymphokines which Golde had patented and later sold those rights to Genetic Institute. Gallo was quick to realize the significance of Golde's cell line, given that animal -and by now human T-lymphocytes of the type Golde described- generally grow in culture, become immortalized, and make various lymphokines usually when they are transformed by a retrovirus. Armed with his experience on HTLV-1, Gallo suggested at the meeting that another retrovirus could be transforming T-lymphocytes into the hairy-cell leukemia species, allowing them to grow permanently in culture. In fact, the manifest differences between lymphocytic leukemia and hairy-cell leukemia were suggestive that a NEW retrovirus, not HTLV-1, but most likely a variant, might be causing the latter disease. Gallo further suggested to Golde that it might be most interesting to start looking for another retrovirus at work; so he requested access to the cell line. Because of the patient issues involved, this last suggestion was not greeted with particular enthusiasm and Gallo was refused access and

collaboration at that time.

Presumably, Golde then, equipped with Gallo's suggestion, went back to his lab to work on proving that suggestion single-handedly. Six months later, however, Golde changed his mind after unsuccessfully trying to isolate the virus on his own and he asked Gallo for collaboration, offering Gallo the media in which those cells were being grown. Although it is extremely difficult to isolate these human retroviruses from media, Gallo's team was successful in doing just that. They succeeded in isolating and characterizing another, new retrovirus, which they named HTLV-2. They also showed that the genetic homology between HTLV-2 and HTLV-1 was limited to about 50%. Golde co-authored the publication of the discovery. Kalyanaraman, a young post-doctoral fellow collaborating with Gallo, conducted the immune assays which discriminated HTLV-2 from other retroviruses, and got first authorship for this effort.

The discovery of HTLV-2 was soon confirmed independently by others.

Contrary to its predecessor (HTLV-1), HTLV-2 infections were discovered to be prevalent among drug addicts in the United States and Europe. Other studies indicated that similar retroviruses were frequent in old world monkeys and apes; and that the origin of the HTLVs in humans was likely the result of a very ancient spread (thousands of years ago) from these primates to mankind.

Gallo later collaborated with Harvard Professor Max Essex to investigate the role of the HTLV retroviruses in causing immune suppression in humans. The evidence did show that these viruses weaken the immune system of human patients and, almost overnight, Essex's studies on cat leukemia inevitably become mainstream human cancer research. If cats were severely immuno-suppressed by animal retroviruses, then why couldn't humans become severely immuno-suppressed by human retroviruses? Takatsuki's prior observations in Japan, had already shown a positive indication of human immuno-suppression, caused by both the leukemia-inducing HTLV-1 virus, and through its effects on T-cells.

Dr. Essex: *"The first time I remember having serious discussions with Bob (Gallo), was in 1971-1972. That was just about the time all the evidence came in showing that cat retroviruses were clearly linked to naturally occurring leukemias*[23]*. And that sort of kept alive the idea that such retroviruses might be in people for naturally occurring diseases. About that time we (Essex's group) published the first papers that such viruses could cause immune suppression. And Gallo was really, really excited about that."*

Meantime, outside the realm of science, during the second half of the twentieth century, people were erroneously led to believe that infectious diseases were being brought under control and would no longer pose a threat to mankind. Certainly not to the industrialized world. This misplaced faith in the powers of medical science was shattered almost overnight in the early 1980s by the AIDS outbreak in the United States. The outbreak was first detected among young homosexual men in the New York, Los Angeles, and San Francisco areas. Yet, in a sense, there was both a prelude (namely, rising venereal disease infections), and a post-script (the re-emergence of tuberculosis).

Few scientists were willing to take chances and many kept their distance from AIDS with its unconventional epidemic profile, its long latency period, its unforgiving nature (no recoveries), its aggressive spread, and its theoretical danger to those handling patients and samples; choosing instead less urgent and less risky medical projects to work

[23] First evidence of this was published by Dr. Bill Jarrett; renowned virologist from Glasgow, Scotland.

on. Scientists also foresaw the wave of high public despair coming; due to the wild spread of the disease. The extreme public demands and expectations for quick scientific progress, put rather high pressure on the entire health care establishment for assertive action.

Gallo himself had to make a personal decision too. With a number of important discoveries already to his credit, it would have been safe to do nothing, watch the events unfold, and just give informed advice to all those seeking it. Dr. Phil Markham, *"But he saw it as a wonderful opportunity."* Many believed that a well deserved Nobel Prize was already in store for the discovery of the first human retrovirus. So at that critical point in his career he had much to lose and very little to gain by entering the uncharted AIDS research arena of that time. Motivated by the challenges in the discoveries that lie ahead, his colleagues were not surprised that he jumped almost immediately into the very heart of AIDS research. On March 18, 1983, Gallo sent a memo to the NCI Director and announced his willingness to get involved in AIDS research at a time when his lab was being inundated with volumes of requests for help, reagents, and advice, stemming from his work in Human Retrovirology. The mail and the phone calls were unending. Still, he wrote he was, "tempted to add to my problems by my own competitive spirit to find out what is going on in AIDS." This was a courageous decision that, in the end, hurt him badly, and in certain respects continues to hurt him to this day. Even so, it hasn't prevented him from receiving the highest scientific prizes from many different countries and universities.

He never suspected how that one decision would fling him into the biggest scientific and political controversy ever to sweep the discipline of scientific research. One so big, the Nobel Prize Committee itself refused to get near the controversy (even though he had been awarded the Karolinska Award and made a member of their Institute). As a result, his chances of getting that prize slipped right through his hands. Many scientists I spoke to agree, it is likely (if not certain) that had Gallo delayed going into AIDS research, the Nobel Prize would have been his.

On the other hand, by getting into AIDS research from almost the very start of the outbreak, Gallo brought much to the table. Such as his previous knowledge on human retroviruses which proved critical. Without it…progress on AIDS research would have stayed years behind where it is now. Dr. Farley Cleghorn[24]: *"When you look at the scientific record, the scientific record clearly shows the body of work that led Bob to the discovery of HIV includes the discovery of HTLV, includes T-cell growth factor (IL-2); without it he would never have found HIV. None of that could have happened. We would still be back in 1985 now if all we had was the discovery of (the French isolate) LAV. The discovery of the first human retrovirus (HTLV-1) was a door that opened that allowed a truck to get through."* In fact, never was so much accomplished so quickly, over a problem this difficult. Especially if one considers the following:

- that from 1960-1981 there was the silent spread of the disease
- that the disease was identified in 1981
- the epidemiology clarified in 1982
- that a suspected agent was isolated in 1983 and verified as its cause in1984
- that a blood test for its detection was developed in 1984 and made available world-wide by 1985

[24] Began his career in Gallo's lab as a Research Fellow in Viral Epidemiology.

- that its causal virus was thoroughly characterized by 1985
- that in 1986 there was the globalization of educational programs
- that also in 1986, we saw the first treatment with AZT
- that an inhibitor for delaying the natural cause of the disease was introduced to medical practice in 1987
- that 1995 brought with it, the triple drug treatment (or cocktail).

The late Jonathan Mann called the time between 1983-1985, a "period of intense discovery and arguably the fastest movement of medical science from the first detection of a new disease – ever!"

But what does Gallo himself say on the coincidence of timing; the AIDS epidemic beginning just when the field of Human Retrovirology was created, opening a new avenue of exploration? *"Like a fairytale. It's like a fairytale. It's hard to believe. What I mean is, yeah, it's like an enormous coincidence. The gods play funny tricks."* In the simplest terms, AIDS came almost right after the tools for detecting it were discovered. Otherwise, what might our alternate reality be now?

In fact, as you will see later on, the actual flow of events in AIDS research are quite telling[25].

[25] For details see, Gallo R.C., Virus Hunting, A New Republic Book - Basic Books, 1991 -and- Montagnier L., Virus, W. W. Norton & Co., 1999.

5.
A BLUNT REMEMBRANCE OF THOSE TIMES

Before another word can be written, it is important that you remember the world of the 1980's. And if you yourself can't remember, let's go back and see what stage is being set for all of mankind at that time.

Gays were not tolerated, and viewed with great discrimination the world over. Add to that, a mysterious new disease, an unknown disease, was slowly putting mostly homosexual men and hemophiliacs in the hospital. The hemophiliacs are helped with courtesy and care. Gay men were not. In fact, the majority of the general population had no clue, that a problem was even beginning. It was outside their circle of concern or topics of news as more and more homosexual men fell stricken.

Add now, that one thing about this disease was becoming very clear. It was 100% fatal. There was no treatment and there was no clue as to what this disease actually was. It was even called a "divine disease," set loose by God to rid the world of those perverted souls; the homosexuals. And the “straight” world in those early times did not care when they finally began hearing about something called GRID (Gay Related Immune Deficiency). "They're dying, good riddance, they did it to themselves," was a prevalent attitude by the normal public at large.

But the prejudice of hate was far from being contained and knew no bounds. In that very early era, if the disease did strike a heterosexual neighbor, then obviously he had been gay at one time, had an experimental encounter earlier in life, or was a closet homosexual. Because this disease did not affect heterosexuals, right?

Bottom line, if you had this disease, then you just had to be gay.

Conversely, blood banks did what they could with the information of the time; remaining about the only ones trying desperately not to alienate the gay community. Slowing down business was not an option they ever considered. Blood banks attempted to pluck out high-risk donors by taking the medical history of their blood donors; seeking to find out if they had any of the known risk factors for AIDS. But at that time, the only known risk factors were drug abuse and homosexuality. Which led to a very big controversy: Could you ask someone's sexual orientation as part of a medical profile? Blood banks didn't want to do that because members of the gay community were avid blood donors, and blood bankers were reluctant to designate homosexuals as a risk group for blood donation. If they did, they stood to lose a valuable (and profitable) source of blood. Caution led to inaction, as facts about the disease needed to first be made clear (to the satisfaction of Blood Bank policy makers); because no one knew what the cause of

AIDS was at that time. So something that was meant to do good, donating blood to help another human being, ultimately became a tragedy. Thousands who were not before, did themselves become infected, and passed it on.

What was most ludicrous about those times, is that the general population seemingly believed (“hoped” is more accurate) that this whole clinical gay disease, had a communicable agent that would limit itself only to people with a specific sexual orientation. That notion was shattered when soon, this "divine" disease, this "gay" disease, struck enough innocents that there was no choice but to concede something unthinkable – that it had crossed into the general population. Men, women, children, Blacks, Hispanics, Indians, Europeans, Asians, were all suddenly infected and fell ill. With the straight community being struck down, there was a plea for a cure - because what was certain? Only that it was 100% fatal (except for a very small percentage called Long Term Non-Progressors). In almost all the cases (then & now) reported the world over, there are almost none who have survived this disease.

It is airborne? Is it a virus? Is it really a new disease? Why don't we know more? Is it infectious and if so, how is it being passed? What can people do to protect themselves and their loved ones? Who's at risk? Who isn't? What did the gay community unleash upon the world? Why can't medical doctors detect it? Do they know anything about it at all?! All those questions asked every day, in every language man speaks. And the world hung in suspense -and fury- waiting, praying, hoping for an answer. Yet there were none to give. Not then anyway.

Coincidentally, yes coincidentally, one medical researcher was defying the logic of his peers, enduring ridicule and nay-sayers for pursuing a goal in science very few believed in at that time. Why? Because science had been up that tree before, extensively, without any results. Despite that, a different venue of science was born called Human Retrovirology. This new science came about because of the persistence of a single individual, who tirelessly pursued proving what no one else could. And from this discovery that retroviruses do in fact exist in human beings, came a hypothesis that this ever growing epidemic might in fact be just that - a retrovirus infection.

Remember, imagine if you can, a world bereft of any answers up until that point in time. And an urgent, pleading desperation felt the world over by governments, politicians, health organizations, and especially the ordinary masses of people. What is it that is killing so many, so randomly? The one answer anyone knew about that runaway disease was that it killed every single person it infected. If you were diagnosed, you were given a death sentence like no other. The stigmatism associated with the disease at that time, meant you couldn’t ever get a hug from someone disease free. Even from your own family. Paranoia of infection made excommunication a mandatory, precautionary measure.

To quell the brewing firestorm, the government tried to act; but only fanned the flames in the process. Some examples: in March, 1983, the Center for Disease Control (CDC) published guidelines requesting members of groups with increased risk for AIDS to actually refrain from donating blood. And the world tried to guess, “is he/she a high risk person? Maybe we should avoid them, just to be safe.” In that same summer, the U.S. Department of Health and Human Services issued several statements seeking to calm the very fears it had created by stating that AIDS could not be contracted casually. Later, in 1985, a publication finding that the AIDS virus was indeed present in saliva, just

increased those fears all over again. Then something unheard of happened, and people were taken to the brink when every single household in the United States was mailed a copy of a brochure entitled, "Understanding AIDS," prepared by Surgeon General C. Everett Koop (in collaboration with the CDC). Now something was going on. That mailing meant we were in real trouble. Why else notify each and every household in America? The stem of all that confusion and anger directed at the government was simple; "Why don't they know more and just tell us what we should, or should not do? What's taking so long?"

So when this new science of Human Retrovirology proved instrumental in understanding what the disease was, was it any wonder that the eyes, ears, and bated breath of the entire world focused on those with the answers? What is a retrovirus? What is the cause of this dreaded ill killing so many with such vigor, so indiscriminately? How is it killing us?

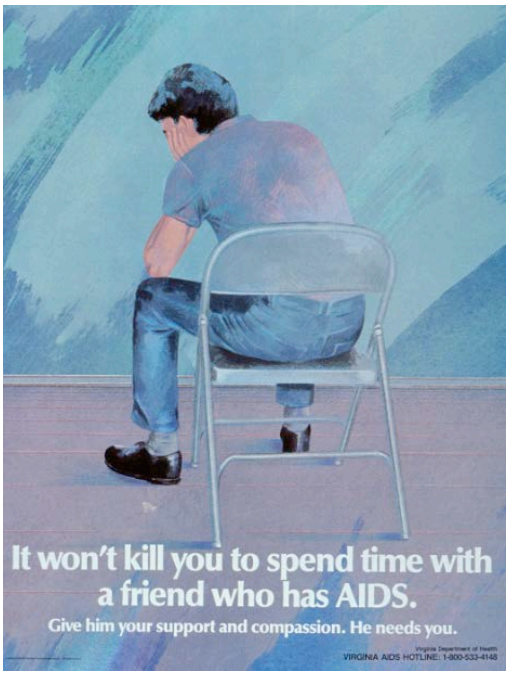
Now here is where coincidence came into play again. The disease is due to a human retrovirus; Human Retrovirology had just become a branch of science, and those three questions above do in fact get answered; from one lab, spearheaded by one person: Dr. Robert C. Gallo.

After becoming the "Pioneer of Human Retrovirology," after discovering the very first and second human retroviruses, after proving causality of what would eventually become known as AIDS, after devising a test to detect the disease, is it any wonder that the world's spotlight found him? That in our desperation for understanding, and at last getting a few answers, we catapulted this one scientist to celebrity status? Dr. Gallo and the few who collaborated with him in those early days, forged ahead, doing much of the work alone. Because many of his peers in those pre-AIDS days, did not believe yet in their work or the theories behind it. No one believed that retroviruses existed in man; that it was a phenomenon exclusive to the animal kingdom alone. But when that work became irrefutable, and validated through confirmations and clear cut scientific evidence, that's when others joined in the research. To help pioneer a new discipline of science and hopefully, make discoveries of their own.

But it was Dr. Gallo who opened the field, and as the world did, so did these new scientists and laboratories, seek out his consul. He became, and was, the leading authority at that time. Meanwhile, the disease just kept spreading and people just kept dying. Yet the discoveries from the work of his colleagues and himself were all key. And remain so to this day!

Remember that against the backdrop of the pages to follow because it is important to understand what state our world was in at that time when the threat of AIDS first revealed itself to us all.

A plea heard round the world,
made from young and old.
Heard and ignored.



Just who is this?
The stricken…or the friend?

Despite assurances, people simply did not believe.

6.
ROBERT GALLO: THE BACKGROUND

With over 23,000 citations in the scientific literature according to the Institute of Scientific Information (see Appendix 1, p.280), Gallo was, in fact, the most referenced scientist in the world during the time period between1981 and 1988, irrespective of discipline. In 2002, he was again. This is based on referred publications in all fields of science. In 1989, The Scientist[26] compiled a list of the twenty most likely scientists to win recognition by the Nobel Committee for Physiology or Medicine. In this list of "Nobel" class scientists, Gallo's name ranked first.

For his multiple outstanding scientific achievements, Gallo has received over the years, more than 60 national and international recognitions and awards. These include 16 honorary Doctorates from universities in the United States, Italy, Israel, Belgium, Sweden, Peru, and Argentina. Add to that, two Richard and Hinda Rosenthal Awards for Cancer Research, two Ciba-Geigy Drew Biomedical Research Awards in 1977 and 1988, Israel's First Otto Herz Prize for Cancer Research in 1982, the Lasker Basic Medical Research Award in 1982, France's Griffuel Prize from the Association for Research on Cancer in 1983, the American Cancer's Society Medal of Honor 1983, the General Motors Award for Cancer Research in 1984, the Armand Hammer Prize for Cancer Research in 1985[27], India's Birla International Award in 1985, the Lasker Clinical Medical Research Award in 1986, Israel's Rabbi Shai Shacknai Memorial Prize in 1987, the Lions International Humanitarian Award in 1987, the Gairdner Foundation Award (Canada's most prestigious award for science) in 1987, membership to the U.S. National Academy of Sciences, the San Marino Prize in Medicine in 1988, the Japan Prize for Science and Technology (Japan's highest science prize) in 1988, membership to the U.S. Institute of Medicine in 1989, The Harvard Medical School's Warren Alpert Prize in 1997, Germany's Paul Ehrlich and Ludwig Darmstaedter Prize in 1999, Spain's Prince

[26] October 2, 1989, p.14.

[27] I (the author) actually attended this particular ceremony and I still remember that although Gallo had been receiving honor after honor, this award was of special interest to him because there were so many in attendance from OUTSIDE the scientific community. In attendance there were celebrities such as Cary Grant, Caesar Romero, and Gregory Peck, and they all had informed knowledge of Gallo's accomplishments. Bottom line, they followed his work and they all wanted to chat with him. Not about Hollywood, not about politics, but about all the advances -and possibilities- in medical research that Gallo was spearheading. At last, people outside medicine were finally, truly, following scientific advancements; and not just his.

Asturias Prize for Science in 2000, and The World Health Award from Russian President M. Gorbochev in 2001.

The highest honor in biomedical science in the U.S. is said to be the Lasker Prize. Unequaled, Gallo has received it twice (see above). Moreover, Gallo holds adjunct professorships in a number of U.S. Universities, serves on more than two dozen editorial boards, and belongs to well over a dozen professional societies.

Robert Charles Gallo, who was born in Waterbury, Connecticut, received his B.A. in Biology, Summa Cum Laude in 1959 from Providence College in Rhode Island, and his M.D. from Jefferson Medical College in Philadelphia in 1963. He spent some time at the Yale Medical School studying metabolic diseases, and then completed his internship and residency in Medicine at the University of Chicago. In 1965, Gallo joined the National Institutes of Health as a clinical researcher in the Division of Cancer Treatment of the National Cancer Institute (NCI).

His destiny to become a physician and devote his life to medical research, rather than pursue medical practice, at least in part, came about when his younger sister, Judy, was diagnosed in 1948 with leukemia. She passed away in 1949. Medicine's inability to help her, coupled with her very rapid and tragic loss, catapulted Gallo in a race to heal through research that remains with him still to this very day. Out of the death of his sister came a philosophy and a drive to not just treat the symptoms, but rather, find ways to eliminate the disease altogether. Medical research was the only answer that could achieve such goals. Other influences were the books Microbe Hunters (by Paul De Kruif, 1966) and Arrowsmith (by Sinclair Lewis, 1925); as well as a biology teaching Uncle who Gallo stayed with while his sister was sick.

When Gallo first arrived at NIH in 1965, he was initially assigned to the caring of cancer patients and later, was assigned to the Pediatric Leukemia Unit, caring for very sick children. Notably ones with leukemia. Sick as his sister Judy once was. The reminders of "why" were daily. The surroundings and the condition of the children were so depressing that one of Gallo's fellow clinical associates took a bottle of morphine to a nearby hotel, named the Governor's House (adjacent to NIH), injected it into a bag of saline solution and there committed suicide.

Gallo's first full time research position began in July 1966 under Dr. Seymour (Sy) Perry, Associate Director for Medical Oncology. Through Dr. Perry, Gallo was given considerable freedom and received solid research training. More importantly, he came to realize that medicine was veering away from crude animal physiology and fast moving into biochemistry; and the newly developing discipline of molecular biology. While most of his research was done in cell kinetics, he soon discovered that he was mostly interested in researching leukemia and lymphomas at the biochemical-molecular level.

Dr. Gallo was promoted in 1972 to Branch Chief of the Laboratory of Tumor Cell Biology (or LTCB), in the Division of Biological Carcinogenesis, at the National Cancer Institute. It was not surprising, therefore, that when he formed his own lab later that year; he centered his research on the abnormalities of blood cells using the newly developed tools of molecular biology and biochemistry. He did this in order to discover and understand the basic mechanisms of disease induction. Soon, Gallo was involved in the research of human cell biology, with interests in the organization and management of research.

Contrary to other published reports, Gallo did not get his inspiration to seek out human retroviruses from a lecture by Dr. Paul Black; a Boston virologist who studied DNA viruses. Rather, it resulted after years of discussions with Bill Jarrett, Ludwig Gross, and Bob Ting. Their friendship and discussions paved the way for Gallo to prove an idea. Howard Temin, also a friend, gave Gallo the first tool (with David Baltimore) in which to begin his search – the reverse transcriptase assay.

In addition to weekly staff meetings in his lab, Gallo additionally holds annual meetings every Fall in Maryland. These meetings began in the early 1970s as a single day retreat with a few domestic participants attending. But over the years it has evolved into a major international conference. These conferences, still called “Bob Gallo’s Lab Meetings," now last to six days and attract about one thousand participants from places even as far away as Australia, Africa, and Japan.

People attend these meetings to report and explain their findings, but more importantly to learn what other scientists are both doing and finding. They do this by freely exchanging information, so upon return to their respective labs, they can make more informed steps in planning their research activities. Research managers attend as well, to recruit promising young scientists. While industry managers attend to pick-up new leads on potential cutting-edge biotechnology products. Even Government officials attend to discuss science politics with domestic and foreign experts.

Researchers then gather in lounges during the sessions for coffee breaks; looking for a chance to meet each other, talk shop, and exchange views. This spontaneous mixing of ideas is as important to the retreat as the main lectures themselves. It gives people the opportunity to build mutual trust, to discuss their projects openly, and to seek fruitful collaborations. Of immense interest to all attendees is, of course, learning in what direction the field has been moving, and particularly, in what direction Gallo himself will be pushing toward next.

As with any researcher and researching effort, Gallo’s entire lab goes through its periodic reviews by various teams of outside experts and consistently passes with flying colors. In 1993, for example, before the accusations against Gallo for scientific misconduct were finally dropped, the reviewers (composed of a group of leading scientists including members of the National Academy of Sciences) called his research lab, “a world-class laboratory led by a distinguished scientist whose stamp of motivation, creativity, enthusiasm, and support of his staff are found in every one of its projects.” They also went on to say that, "the research conducted was innovative, timely, and critically important marked with significant discoveries."

A meeting grows

First Row (left to right)
Bill Haseltine, Dani Bolognesi, Mike Feldman, Bob Gallo, Luc Montagnier, Daniel Zagury, and Maurice Hilleman

7.

1981-1982: WITH THE FIRST STEPS, CAME THE FIRST SIGNS

In 1981, Dr. Michael Gottlieb of the University of California at Los Angeles and, soon thereafter, other clinicians in other urban centers of the country, described an unusual cluster of atypical symptomatologies related to T-cell depletion which afflicted mostly homosexual males. They diagnosed a new disease, which would come to be called Acquired Immune Deficiency Syndrome; or AIDS. On June 5, the first article about AIDS in any medical literature, entitled, Pneumocystis Pneumonia--Los Angeles (by Gottlieb and colleagues at UCLA), appeared in the CDC publication, Morbidity and Mortality Weekly Report (vol. 30, pp. 250-52). Soon after, on June 16, the first AIDS patient was seen at the NIH and admitted under Dr. Thomas Waldmann's National Cancer Institute (NCI) Omnibus Metabolism Branch protocol.

August 1981: The CDC reported 108 cases of the new disease in the United States.

Dr. Max Essex on the CDC then: *"I remember in '81 or so, he (Don Francis) and subsequently one or two others (from the CDC), I suppose at his urging, like Curran, consulted with me to get suggestions on what might cause AIDS. He said, that he thought they should consider it an infectious disease. He was unaware that there were human retroviruses. I know. Because when I told him that, and the rest of the CDC, he seemed quite surprised. Yet the CDC, even by late '82, when they were doing their infectious disease surveys, never considered human retroviruses. I think in part, none of them were coming out of a background in oncology and followed the literature real closely. Secondly, because they, like a lot of others did not want to look at any more human retrovirus claims."*

To be clear, epidemiologist Don Francis was advocating within the CDC that AIDS was (and would turn out be) an infectious disease. At that time, the majority of people at the CDC did not share that view. He wasn't advocating it would be a human retrovirus, just that it was an infectious disease. But he wasn't taken too seriously because he was so junior, having just completed his training.

In late 1981, Gallo first heard about AIDS from newspaper accounts.

Then, in December 1981, with Gallo's collaboration, there was a single experiment[28] done on material from a single patient using HTLV-1 probes to screen DNA from an AIDS patient. This DNA was degraded and no interpretable result came from this effort. This was surely one of the first lab experiments conducted on AIDS and was most certainly the first to seek the presence of a retrovirus in an AIDS specimen.

In early 1982, Gallo learned more about AIDS from informative lectures at NIH given by Jim Curran of the CDC.

It was also in 1982, when CDC officials declared AIDS a new transmissible disease, based on epidemiological evidence they acquired. Then, on January 15, as a snowstorm was shutting down government offices, the second AIDS patient seen at NIH was admitted to the National Institute of Allergy and Infectious Diseases (NIAID), by Dr. Anthony S. Fauci.

Meanwhile, in early 1982, Gallo and Max Essex proposed at the Mt. Sinai conference that a new retrovirus may be the cause of AIDS. Presumably a variant or a mutant of HTLV-1 or -2, on the basis of some similarities: modes of transmission, and the targeting of what scientists called CD4 positive cells. The same cells clinicians reported, were declining in their patients. In fact, Gallo first formally suggested this idea[29] in Medical World News (published August 16, 1982). Gallo even predicted that the AIDS virus would be a recombinant in the 5' end of HTLV-1 (pronounced, five prime end) and something new at the 3' end. Consequently, in 1982 when Gallo and Harvard's Max Essex first proposed that AIDS might be caused by a new retrovirus, one presumably related to the HTLVs, it made rather good sense, yet it was not an idea readily accepted within the scientific community. For example, Dr. Paul Black, Head of the Boston University Cancer Center, argued in the prestigious New England Journal of Medicine that retroviruses caused cancer, but not other diseases (which is not true). There were others who even argued against the infectious course of AIDS (as you will later read).

Also in that time, Francoise Barre -Sinoussi, who would later become a key player in the French group headed by Montagnier, came to Gallo's lab to extend mice experiments conducted in France, to monkeys in the U.S. The intent was to find out whether the use of anti-interferon serum would increase the production of a particular gibbon ape retrovirus known to infect human cells. Barre -Sinoussi spent six weeks in Gallo's lab, working on cell culture technology and learned the art of culturing lymphocytes from Phil Markham in Gallo's lab. Although later she would refuse to admit this to anyone at all. Markham: *"The point here, and maybe it's not emphasized, Gallo has always run a very open lab. I mean, there were always people coming into the lab. Coming and going. Spending the week, spending six months."* In those days, Dr. Genoveffa Franchini, was a post-doc fellow in Gallo's lab[30]. She adds, *"Scientifically, Bob has mentored many, many people."*

In May 1982, Gallo and co-workers started working on AIDS and soon detected reverse transcriptase activity in the cells of an AIDS patient. The techniques used

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[28] From the experimental notebooks of Dr. Edward P. Gelmann, who in 1981-82 was a Post Doctoral Fellow working with Gallo. Today he is Chief of the Georgetown University Medical Center, Division of Medical Oncology.

[29] There were suggestions by others for example, that AIDS was an auto-immune disease, or that it was caused by a fungus releasing toxic substances against T-cells.

[30] Now, she heads her own group and is a very important scientist in the field of Human Retrovirology.

involved growing T-lymphocyte cells from infected individuals in laboratory cultures with Interleukin-2. According to Gallo's thinking (as noted earlier), the likeliest candidate of an infectious agent causing this disease was a new retrovirus. At the time, he logically believed that it was most probably a variant or a mutant of HTLV-1 or HTLV-2. Like the HTLV-1 virus, this hypothetical AIDS variant or mutant, invades T-lymphocytes and, in fact, does so with a specific subspecies called T-4 cells (now called CD4 T cells). Moreover, like the HTLV-1 virus, the hypothetical AIDS variant or mutant appeared to be transmitted by blood. Sex was debatable at that time; as was from mother to infant. But unlike the HTLV-1 virus, which immortalizes T-lymphocytes or at least stimulates their growth in long term cultures, the hypothetical AIDS variant or mutant kills them off. Or, at least, inhibits their growth.

In June, NIH Clinical Center (CC) protocol was approved to study the etiology of immuno-regulatory defects of the new disease; as a collaborative effort among the named CC departments: National Institute of Allergy and Infectious Diseases (NIAID), National Cancer Institute (NCI), National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), National Institute of Dental Research (NIDR), National Eye Institute (NEI) and, the Food and Drug Administration (FDA).

July 15 1982: The CDC reported 413 cases of the new disease in the United States with 155 deaths.

On July 15, during a meeting in Washington, DC, which is attended by federal officials, university researchers, community activists, and others, the name "Acquired Immune Deficiency Syndrome," or AIDS, was selected for the new disease[31].

September 1982: The CDC reported 593 cases of AIDS in the United States with 243 deaths.

Under the guidance of Gallo and Flossie-Wong Staal, the first series of experiments using HTLV-1 probes to screen DNAs from samples of AIDS patients were preformed in September and October 1982.

In October, after conferring with Gallo, Dr. Jacques Leibowitch (a French physician from Necker Hospital) gives a seminar in Paris and introduces there the notion of a retrovirus as the cause of AIDS. Shortly, thereafter, Dr. Jean-Claude Chermann (Lab Chief at the Institut Pasteur in Dr. Montagnier's group) also had the same thoughts after conferring with Gallo as well. Soon, Dr. F. Barre -Sinoussi (from Chermann's lab with experience in running RT assays), Dr. Jacques Leibowitch, Dr. Willy Rozenbaum (a specialist in infectious diseases with access to specimens), and other physicians form a team to substantiate the hypothesis that a retrovirus was the cause of AIDS.

In November, the CDC published formal recommendations for the protection of laboratory and clinical personnel having contact with AIDS patients and clinical specimens. Those recommendations were based on the model for the handling of clinical specimens harboring the Hepatitis B virus.

"I think one of the real tragedies in the whole story is that Bob had this problem solved in 1982[32] but the problem was that he had this guy named Prem Sarin, who was

[31] Even as late as two years after that meeting, Gallo in correspondence (dated 12/27/1984) said that the, "AIDS virus or AIDS related virus is the dumbest name I have yet heard, especially to the clinicians who have to tell people what they have." His feeling was why tell someone they have a virus when 99% of them were going to get the actual AIDS disease?

[32] Specifically, November 11, 1982 was the date of Gallo's first HTLV-3 detection. Only they didn't know what it was because of Sarin's failure to monitor the cultures properly. In fact, the lab had amassed 4 more

not able to do the assays. The consequence was enormous. He didn't do the full experiment and Bob regrets that because ordinarily, he creates redundancy because he didn't trust one person to do something. He still creates redundancy when he can. Gallo had pathology and conceptionalization and insight, which was squandered because critical experiments were reported as (RT) negative when in fact on retesting they were (RT) positive. And in this particular setting there were a lot of people rallying around Gallo, myself included, trying to facilitate the discovery of the cause of this[33]."

Between November 1982 and February 1983, Prem Sarin in Gallo's group detected low-level reverse transcriptase activity in at least five different patient samples. Later however, it becomes known that the reverse transcriptase assays were conducted too late in the culturing process. Blattner: *"Dr. Sarin took the virus and never could produce a lab notebook showing that they had even been tested."* At the very least, Sarin had definitely not monitored the levels throughout the entire culturing process. Just towards its end, this explains the low level counts. This was attributed to Gallo's failure to oversee the details of the culturing process (even though Sarin was himself a senior investigator); a problem that was not corrected until the summer of 1984 when those same samples retested negative for HTLV-1 or -2 proteins. It was a finding suggestive that a new virus was at work. But because of Sarin's failure, Gallo's team did not know this for quite some time. Gallo: *"Prem Sarin really didn't believe me that this would be a retrovirus disease. So Prem would do assays as if it was an HTLV-I. He didn't believe retrovirus was right. He thought it was silly. And so you could call that my sin – an error of not being able to convince him more."* But when Sarin first informed Gallo of those erroneous negative results, did he take him at his word? *"Of course. So you could also criticize me that I didn't explore his notebooks. But you know AIDS was not that important to us at the time in '82. We didn't realize how big a disease it would be. We were doing cancer research. Moreover, Prem was a very senior scientist. He certainly knew how to do reverse transcriptase assays. I trusted him[34]. It only became clear after I moved another person or two into the problem that they were detecting more reverse transcriptase positive cultures - then we questioned Prem in a little more detail. And it turns out he starts the culture at one time, then he assays over here at a different time. Well, that's good for HTLV-I. But if you're killing the cells by a virus, the reverse transcriptase is gone by then. The virus is gone. Do you understand?"*

Dr. Blattner on what caused them to want to run those tests again: *"Well, we believed that the experiments should have been positive because we had objective information on what was going on, which is the disappearance of T-cells that could be exactly recapitulated in the laboratory. That was in 1982. And so then in 1984 we retested supernatants and they were positive."* Still, Gallo and his coworkers had already made several isolations of HTLV-3 later, by mid-1983 and into 1984.

Gallo again, on the irony of another misstep: *"One other thing that held us back was the peculiarity of a French guy who was in Haiti and got double infected with HTLV*

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isolates by February 1983, but still, Sarin's carelessness had cost them the immediate knowledge of those isolates as well. NOTE: HTLV-3 was the generic term Gallo's group used for what would eventually be called HIV.

[33] Dr. William Blattner, in a taped interview conducted on February 6, 2002.

[34] With the trust now fractured, it isn't long before Sarin begins looking for an administrative job outside Gallo's lab, while Gallo himself concurs and writes (4/4/1984), prodding the NCI Administration Officer to move Sarin out of the LTCB.

and HIV[35]. He got in a car accident and he needed a blood transfusion and then he got a double infection. How the hell is one going to know there is a double infection at this point in time? You don't know. And all of a sudden we were getting a virus – its growing well. Cells aren't dying. And we could see aberrant particles, abnormal particles, okay. They weren't abnormal. They were HIV mixed with HTLV-I, which were "the normal particles." And I said, "Oh boy, am I on target," because I was predicting that the AIDS virus would be a new retrovirus. But one part of the genetics of the virus would come from HTLV-I or –2 and another part would be new. We call that a recombinant. We had antibodies from Marjorie Guroff in our lab that reacted against proteins of HTLV that would come from this part. They were positive, but what would be new would be this part because that would give the cell killing activity. That was my thinking.

"You know, I really felt I was predicting everything correctly. But it was purely conjecture. I sent a memo to Dr. DeVita, the NCI Director, predicting the cause of AIDS will be a retrovirus. More specifically it will be partly from HTLV-1 and partly from a new virus, a recombinant. Only later will we learn that the culture consisted of two distinct viral populations; bona-fide HTLV-1 and a new retrovirus. One we would first call HTLV-3; or what would finally be called HIV. But it will over here have HTLV-I or –II and the other end would be a new virus – a recombinant new retrovirus sequence. And so Mika (Popovic) is working and working – days before PCR – a very sensitive hybridization DNA amplification. We could never know there are two viruses mixed together. So we lost, I don't want to say how long because I don't know. My guess would be we lost anywhere from 3-6 months or more. By the summer of '83, the French had now published their one virus, not well characterized and Marjorie Guroff in our lab came to me and says, "Bob, I've evaluated the antibodies testing very carefully and under loose conditions, looking for a related virus, using sera from a lot of AIDS patients, and the answer I get is 5-10 percent are positive. I think they're doubly infected (with HTLV and what would be HIV)." And I have to confess to you, the thought never occurred to me. Sometimes too much information without imagination is dangerous. Because we know in retrovirology the phenomena of interference. Meaning, if you're infected with one, you usually don't get infected with the other retrovirus if there is some relationship between the two. We then began to learn in the field that a single species may be infected by more than one family of retroviruses. So she said, "I'm convinced that 5-10 percent have HTLV-I, not a recombinant, not a mixed virus. It is HTLV-I. The cause of AIDS is something else. And if you're getting reverse transcriptase in all these other samples by other people in the lab, it's another retrovirus. The virus of the French must be from a whole new family." That's when it became clear.

"Then we went back to patient CC (the French patient infected in Haiti) and we cloned out two populations of genes – genomes, HTLV-I, and something else. Later we went back and we were able to prove two different viruses were present. By this time large numbers of isolates were being obtained by Phil Markham, Zaki Salahuddin, and finally Prem and Mika. By the fall, Mika was putting them into permanent cell lines. By the winter we knew the cause of AIDS. And by the end of January of '84, I told that to

[35] In February 1983, the unpublished isolate from this patient, named -CC, his HIV cells grew because his concurrent HTLV infection had immortalized them. They were lucky in that the HIV wasn't killing the cells as fast as the HTLV was promoting their growth. Having an immortalized line was an especially facilitative contribution because Gallo now knew that HIV could be grown in continuous cell line.

Vince DeVita, the Director of NCI. Ironically (do you know) who gave us those (doubly infected) cells? A Frenchman. Jacques Leibowitch."

In November 1982, a new virus from an AIDS patient was detected in Gallo's lab from a blood sample. A month later, in December, the CDC reported a case of AIDS caused by blood transfusion in a previously healthy infant.

Also in December 1982, working with a $68,000 grant, Montagnier began his research on AIDS. He requested and received from Gallo: 1) a bottle with Interleukin-2 (or IL-2) to help him grow T-lymphocytes, 2) a batch of HTLV-1 reagents and, 3) a batch of HTLV-2 reagents; all to help him detect related viruses. Later, in a 1988 interview, in Omni Magazine, Montagnier acknowledged that he based all his beginning work on Gallo's proposal that an HTLV retrovirus, possibly a variant or a mutant of HTLV-1, less likely -2, might be the cause of AIDS. He tested this hypothesis using specific reverse transcriptase assay reagents and the conditions identical to those described for the HTLVs. He found no HTLV proteins present in blood samples from AIDS patients.

Gallo makes clear: *"We had characterized reverse transcriptase and defined conditions to use it for finding human retroviruses very well. Did Montagnier acknowledge that in his paper? Yes. He refers to our paper on HTLV-I for what he did for reverse transcriptase - exactly the same protocol. Did he use IL-2? Of course he used IL-2 and he referred to us again. Montagnier later commercially purchased some IL-2; that was by then commercially available. But his first experiments were done with IL-2 supplied by us. Did we send him any other reagents? We also sent him reagents to discriminate what he had from HTLV-I and HTLV-II. On their side, they sent us LAV as soon as they had it, you know. So there was trust and good will. Good will vanished with success. The problems then extended far beyond that when the patent problem got more serious, ugly, and lawyers got involved. And then it extended, far beyond that when the lawyers in New York, and Dingell, and Crewdson, got involved in the late '80s."*

Meanwhile, Francoise Barre -Sinoussi having completed her research in Gallo's lab, returned to the Institut Pasteur where history awaited.

8.
WHEN APPLES FALL

As this book wants to include the general public as part of its readership, a sideline story becomes necessary to fully comprehend the principles of discovery and credit for modern day scientists. Admittedly, it is oversimplified, and is in no way demeaning to the works of any scientist. But it serves the story with its example and will be referred to by [ ]'s at various points throughout this book. It is something that needs to be in place, in the back of your mind, to help understand various events contained herein. Necessity dictates this book contains science and scientific jargon as they are the only way to state the facts about to be presented. But before we can talk about men, motives, and AIDS, let's talk…apples. Shall we?

Apples grow ripe and delicious on trees everywhere, all over the world. It is a natural event, a cycle unending. But left in their natural state, all the apples, at some point, fall from the tree. And so it is, on apple trees everywhere, over many years, and many generations, apples kept right on hitting the ground. Consider, just how many years it took, just how many apples had to fall before that one apple hit Sir Isaac Newton right on the head? They may have fallen on many others before, but Sir Isaac Newton did something with that apple. He analyzed it until he understood, until he knew, until he could prove why that apple fell from the tree. When he was done, he had discovered the principles of gravity. And that is important.

Suppose we are the tree. That each tree is an individual as are we. Some red, some green, some sour, you get the picture. To keep it simple, let's say that the apple actually falling from the tree -that act- represents disease. So that apple that falls from our branches, that is an occurrence in our bodies; waiting to be found, waiting to be explained. In other words, waiting to hit the right person on the head at the right time.

However, as our story goes, one day an apple falls and does hit a fellow on the head. This fellow has a strong inclination and knew that the apple falling meant something. But what? He really isn't sure. But he held on to that apple because somehow, he knew that apple was special. Still, no matter his inkling, he did not know how to show, or how to prove to anyone else, that his apple was indeed special.

But another fellow had more than intuition going for him when he looked upon that apple. He had imagination and a creative insight that would help him devise ways to test the apple. To see, show, and prove why that the apple was special. Additionally, all those imaginative tests, that he invented, could be explained to others in ways that made

sense, and were in fact logical and true. So if the tests were true and made sense, then the results were true as well. Others could then use those tests, and verify (by obtaining for themselves) the same results again and again.

So what of the first man, cradling the apple? He maintains his apple is still special. But all he can do, all he is capable of at the time, is to just hold on tight to his apple. Telling the world, “it is special. I know it is!” Alas, he can not answer what all scientists must answer; the how, the when, and the why. Can he cut that apple up and describe everything inside that makes that apple special? No. He is dead right in his belief that it is special. But he is only crying “wolf” to a world of scientists who say “prove it.”

So what happens when the first man asks the second man for his help to know, “what does my apple mean?”

What indeed.

9.

1983: WHEN DISEASE, DISCOVERIES, & SCANDAL CAME ALIVE

In January 1983, the CDC reported the first cases of AIDS in the female sexual partners of males with AIDS. In that same month, scientists from the Institut Pasteur began their own experiments on AIDS. It was also when Chermann (an old friend of Gallo's) from Montagnier's group at the Institut, informed Gallo that reverse transcriptase activity was detected in a lymph node tissue sample from a patient with early AIDS disease. Chermann asked for and got advice on how to keep their tissue culture growing. Moreover, he was given a protocol on how to grow retroviruses in human umbilical cord T-cells and sent the necessary reagents (by Gallo) to distinguish new retroviruses from HTLV-1. Working as an assistant under Chermann, Francoise Barre -Sinoussi from Montagnier's group (equipped with the knowledge of techniques learned in America) then detected and isolated a presumed new human retrovirus.

About that same time, Dr. Robert Redfield, with the Walter Reed Army Institute of Research, was first to stage the AIDS infection clinically.

On June 2, 1983, Dr. William Blattner, assisted Gallo by providing liaison to the epidemiology community, and wrote James Curran of the CDC, asking access to their stored sera. Gallo and his group had received sera from other sources, but as Curran remarked to both Science and The New York Times, the CDC clearly had the best defined collection of sera. So Blattner writes, "Given the fact that retroviruses offer an exceptional model for an epidemic such as AIDS, the focus of our efforts is to try and isolate an HTLV-like agent from affected AIDS patients. It may be that an HTLV closely related to the Type I agent could be involved and we are therefore very interested in obtaining biological specimens on patients who have evidence of retrovirus infection." Gallo's request was denied. Notwithstanding, Gallo sent requested reagents to the CDC (Centers for Disease Control), which allowed them to culture their own T-cells.

In February 1983 at the Cold Spring Harbor meeting on AIDS, several scientists from Europe, Japan, and the U.S., convened a session to decide on nomenclature and recommended that new retroviruses be named according to the cell they targeted and according to the order of their discovery; i.e. Human T-Lymphotropic Virus (HTLV) would be the new name for Human T-cell Leukemia Virus; thus HTLV-1, HTLV-2 and

later, the eventual AIDS virus, HTLV-3[36], would be the names of the first three retroviruses discovered. The agreement was formalized by a signed document of this international panel of expert virologists (see page 59). Montagnier was informed of the nomenclature agreement, but does not sign it.

By the late Spring, early Summer, Gallo's group was obtaining several samples from different sources. Of those, Gallo obtains three AIDS samples from Dr. J. Leibowitch which were found positive for reverse transcriptase, but negative for HTLV-1 antigens.

In early 1983, Montagnier makes another request for, and again receives from Gallo, HTLV-1 samples. He wanted to compare the proteins of the presumed new – officially unnamed- retrovirus (isolated by Barre -Sinoussi, Chermann, and himself), with those of HTLV-1 in order to ascertain whether the French isolate was indeed a new virus. Here was where a motive for Barre -Sinoussi to deny she had been trained in Gallo's lab crops up. Dr. Phil Markham hypothesizes Barre -Sinoussi's train of thought: *"The implications are that the aggressive Gallo group is going to claim we stole some technology from them or something, so I'm just not going to commit myself with an admission to technology exposure. In any event, the relevant procedures to culture T-Cells were published procedures at that time."* Independent verification that Barre -Sinoussi trained in Gallo's lab was found in the phone records of Don Francis; where Gallo expressed concern that he gave the isolate to the French - specifically the means for detecting it - because, "Barre trained in my lab[37]."

In March 1983, Montagnier and co-workers submit to the journal, Nature, a paper reporting the detection (by RT positivity), isolation, and tentative identification (by EM visualization) -but NOT characterization- of their new, still unnamed retrovirus from fresh samples obtained from a single patient with early disease (limited to lymph node enlargement). No serology and no identification of viral proteins and/or nucleic acids were presented. However, significant cross-reactivity with HTLV-1 was reported, and then later retracted as a mistake. The paper was thoroughly rejected. It was resubmitted to Science where it still failed to prove causality (meaning it failed to prove that the new retrovirus was indeed the cause of AIDS), and it likewise failed to characterize the new virus biochemically. Nevertheless, Gallo feels that, *"This story needs to be told. I told them (Montagnier's group), (Max) Essex and I would delay our papers being submitted to Science to wait for them,"* and personally urged Science to reconsider. *"That alone should tell my intentions, because I delayed our own publications to get Montagnier's in."* Essex confirmed this in a letter to Gallo dated January 30, 1992; "You asked me if I would agree to delay the publication of my own paper…and that you wanted to do it to help the French group. I know that I was not very happy with the plan to delay but obviously went along in the interest of inter-laboratory and international cooperation."

The French paper on their newly discovered AIDS-associated virus was submitted to Science, but was rejected for publication by Ruth Kulstad, Science Editor of the journal. In the rejection letter to Montagnier on February 2, 1983 she wrote, "I regret to say that that we can not accept the paper as it is….We tend to agree with the reviewers that less emphasis should be placed on the morphology of the virus as seen with the electron microscope and more

[36] So named because the AIDS virus very clearly also infects T-cells.
[37] From Don Francis' handwritten notes recording highlights of a phone call with Gallo; March 27, 1984.

data should be provided on its molecular biology and biochemical characteristics."

Gallo encouraged the French group not to give up but to go ahead and publish their findings, even though they all felt that the results were preliminary. Gallo met with Ruth Kulstad, made her aware of the significance of the French work, and encouraged the publication of the French paper in Science in an effort to open up the field. Moreover, Gallo, together with Dr. Sarin and Dr. Popovic, acted as referees for the resubmitted paper and strongly supported its publication (see letter on p.60). They based their support upon evidence of reverse transcriptase activity. Gallo also wrote the abstract to the paper which the French had forgotten, even though the virus could not be maintained in culture for isolation and characterization. In fact, the French paper came under severe criticism after publication for failing to characterize the virus both biologically and biochemically. Even its EM morphology was disputed. Dr. Siegel at Roswell Park, for example, submitted a letter to Science suggesting that the published EMs looked more like a representation of arena viruses. Behind the scenes, Gallo strongly encouraged the Science editors not to publish that letter because he believed that the French were on the right track and should be given a chance.

All these Gallo actions to help the French, with both promotion and materials, were all made in good spirit. That truth is the exact opposite from the deceptive, malicious, and vicious manner in which the whole Franco-American dispute issue was reported on by the media. The people directly involved knew that too. Surprisingly, even Barre -Sinoussi's statement to the OSI on December 14, 1993, against Gallo, reflects her unpardonable resentment: "Dr. Gallo pushed us to complete our paper as rapidly as possible and transmit to him, with the understanding he would submit it to Science. However, in the rush of events, we forgot to prepare the abstract necessary for our paper to be submitted to Science. When Dr. Gallo received our paper, he called Dr. Montagnier or Dr. Chermann and informed him about the missing abstract, and Dr. Gallo proposed to write the abstract himself. Because of the urgency of submitting the paper, Dr. Montagnier agreed to this plan."

It is of interest to note that Barré-Sinoussi fails deliberately to mention that she had every opportunity to correct any objectionable Gallo statements in the abstract or the main body of the paper upon receiving the galley proofs from Science. Why didn't she? She also failed to mention that she and the French group had previously submitted the article to Nature who rejected it outright. Why blame and hurt Gallo, who went out of his way to help her out? And why hide these important facts from the OSI?

Gallo, now the paper's reviewer[38] (selected by Science), endorsed the publication of the article and wrote the abstract (a summary introduction to the ideas and principles of the paper); which does say that the virus is unique. He reads the abstract to Montagnier over the phone who agrees to its contents. Gallo: *"I read it to him repeatedly. He confirmed every word."* Later the Montagnier group was unhappy that the abstract implied that their isolate was an HTLV variant, whereas the title and the body of the article contradicted this hypothesis. Gallo however, thought it to be in the family of HTLV since the French had first made that initial mistake regarding immunological cross-reaction as reported in their paper. Montagnier himself had agreed to the abstract

[38] Incidentally, it should be noted that when Gallo got the paper for review, the French virus was originally called RUB. Later they called it LAV.

over the phone and again later accepted it as accurate by reviewing -and approving- the galleys sent to him directly by Science, prior to publication[39]. When asked for this book, "why on Earth would you agree to an abstract you were not happy with?" Montagnier replied that it was, *"too late to correct it and afraid it would not get published. But the title of the paper is ours and it is fine."* Barre -Sinoussi would later be quoted as being disturbed and surprised with the abstract when it finally appeared in print. Apparently, Montagnier never shared either the reading over the phone or the galleys with her. An important fact here, the Editor for Science at that time, Ruth Kulstad, testified to the article's history prior to its publication to Suzanne Hadley's[40] investigators (more on her role later in this book). Fourteen months after the article's publication Gallo received a letter (dated July 11, 1984) from the very French scientist (J.C. Chermann) whose assistant (Barre -Sinoussi) had isolated their virus. He writes, "Following your suggestion, we then published our results in Science and we thank you for acting as referee for this paper." Where is the resentment for the abstract in that?

That same month, Gallo received from Montagnier a sample of DNA from cells infected with the French virus and, respectively, on March 23, 1983, has his Chief Molecular Biologist, Flossie Wong-Staal, send to Montagnier the requested HTLV DNA probes.

In May 1983, Montagnier's article[41] was published[42] in Science. Together with one by Gallo[43] and another by Max Essex[44] of Harvard University. Montagnier's article reported the detection, isolation, and EM identification -but still no biochemical characterization- of a new, non-transforming retrovirus and not from a patient with AIDS, but from a patient with lymph gland enlargement (it was later that his illness evolved into AIDS). Biochemical characterization is extremely important in understanding the structure of the molecular components of any virus. Without that, you have no clue as to the nature of the beast. Gallo's own article reported the presence of an HTLV-1 like virus, or a variant, or mutant, in 2 out of 33 AIDS patients. While Essex's article reported the presence of antibodies cross-reacting with HTLV-1 proteins in a small percentage of AIDS patients. Later studies showed that the viruses in Gallo's report were not variants or mutants of HTLV-1; but actually HTLV-1 itself. As was later shown, it was accompanied by HIV because these were doubly infected patients. It would soon be learned later that between 5-10% of all patients are doubly infected. Hence, they were not likely to be involved with AIDS, because of their low percent presence and their known

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[39] So the opportunity for changes (even complaints) abounded then and there. But the paper and abstract went to print without a protest from anyone. One wonders then, why make an issue (and many did) of these facts years later?

[40] For a time, she was the principle investigator at the OSI, in charge of the cases against both Gallo and Popovic.

[41] Isolation Of A T-Lymphotropic Retrovirus From A Patient At Risk For Acquired Immune Deficiency Syndrome (AIDS), by F. Barre -Sinoussi, et. al.

[42] Oddly enough, for helping them get and use the technology to isolate LAV, this May 1983 paper that was published was supposed to be collaboratively published with Gallo's group. But Montagnier changed his mind, saying that a1l the work had to come from France.

[43] Isolation Of Human T-Cell Leukemia Virus In Acquired Immune Deficiency Syndrome (AIDS), by Robert C. Gallo, et. al.

[44] Antibodies To Cell Membrane Antigens Associated With Human T-Cell Leukemia Virus In Patients With AIDS, by M. Essex, et. al.

transforming effect. Consequently, with this serology data, the cause of AIDS was still up in the air.

By late May 1983, Marjorie Guroff and Mika Popovic, both from Gallo's lab, obtained solid serologic evidence that the AIDS virus was indeed new. The evidence was based, first, on the consistent low percentage of AIDS patients (about 7%) testing positive to HTLV-1; while a much lower percentage rate tested positive to HTLV-2. Secondly, the consistently higher percentage of those same patients whose cultured blood cells were testing positive for reverse transcriptase, pointed to something new. These important findings, proving that AIDS was not caused by a virus significantly close to HTLV-1 and HTLV-2, were published by the Gallo team in a letter to Science. Evidence for a new virus was also based on a sample sent from France, named sample CC (from the initials of the patient), which had tested positive with a low percent for HTLV-1. The sample also supplied clear proof that a sub-population of infected cells were fast dying, an effect substantially different from the transforming effects known to be caused by the HTLVs. The fact that a number of cells in culture survived and produced viral particles while others just died and released viral particles, was a strong indication that two distinct viruses were at work. One that causes cell transformation (HTLV-1) and another (then unknown) that causes cell death. Electron microscopy pictures soon proved that this indeed was the case. This was an important fact as it provided clear evidence that some AIDS patients are doubly infected with the above named viruses.

By June 1983, Phil Markham and Zaki Salahuddin had detected and isolated more particles of the new virus, transmitted them to target T-lymphocytes, and managed to grow them temporarily in culture. They also managed to grow them longer by continually adding fresh cord blood mononuclear cells. Supernatant fluids, testing positive to the virus, were frozen and stored. These stored fluids virus particles were subsequently drawn and grown for characterization.

Markham: *"We started getting a trickle of patient samples. Then of course immediately, rapidly, after that, then we started seeing virus. We spent several months trying to figure out what we were seeing. We were seeing reverse transcriptase activity, it would go away. Then we'd go to the next step and then we'd say, well, is it transmissible? And we'd try to transmit it to cells, and basically show that you could. It would also go away. Finally we put the puzzles together and say well, there's something infective going on here that's killing the cells or something. It was an on-going process. And so it took us several months to find out it wasn't following the same pattern as HTLV (-1 and/or -2); which we've had a lot of experience with."* Expanding further, Markham adds, *"By this time period, which you correctly state here, there were several cultures that virus was detected. And you couldn't characterize any further, because there were no reagents to characterize with. The only thing we had to characterize it with, was the reverse transcriptase assay. Which is a general enzyme assay for that particular enzyme, which all retroviruses have. So you can't fault other groups who say, "Ah, you didn't prove it was X, Y, and Z," because there was no way to prove it at that point. You could prove it wasn't other things, which was the process."* What this also means, is that in that time period of 1983 and 1984, viral isolation actually became the epidemiological tool for finding out about virus as in who had the virus, and who didn't. In a lot of ways it preceded the development of a serological assay. Most importantly, it meant that very early on, there were in Gallo's lab, virus isolates, collected on the perspective that

something could be frozen, is recoverable, and was transmissible. As Markham tells it, they had those tools: *"Well before anything came from the French."*

In that same month Gallo met with Montagnier in Paris. According to Montagnier, Gallo still insisted that the AIDS virus was a new HTLV variant or mutant[45]. Gallo elaborates on why: *"Montagnier's paper reported a one way cross reaction between LAV and HTLV-I. What I mean by a one way cross reaction – the serum from the patient they had, had antibodies that reacted with HTLV-I in their assays. I could not know that this was an artifact. They made a mistake. In other words, their data was wrong. That happens. But that's in their paper. I'm reading their paper and the HTLV-I that I sent to them - the serum of their patient is reacting with it. So it suggested it was related to some degree. Secondly, they had a protein – its major protein of the core of the virus and has a certain size – it's almost always in almost all retroviruses, 30,000 – therefore, it's known as p30. P for protein. HTLV-I and HTLV-II are smaller, 24,000, p24. Montagnier described their virus major core protein as a p25. So, the fact that it went into CD4 T-cells, T tropic, like HTLV-I, the fact that it was transmitted by blood, sex, and mother-to-child, like HTLV-I, the fact that its major core protein was 24,000, like HTLV-I, when most other retroviruses were 30,000 and 3) the fact that they published erroneously that there was a cross reaction with HTLV-I, a one way cross reaction, and the logic that there wouldn't be another family of human retroviruses, all made me think it was likely that the new retrovirus would belong to the HTLV family. But it is true if I had to apologize for one thing it would be that I held onto that concept too long, beyond the length of time that the data were telling me. I just couldn't believe it."* The French maintained that theirs was a different class of retrovirus which they started calling LAV.

Professor Daniel Zagury, an expert immunologist from the University of Paris in France, started collaborating with Gallo on a long term basis. The purpose of this collaboration was four-fold: study the patterns of infectivity of the AIDS virus, study the patterns of body defenses against the virus mediated by killer cells, design vaccine trials, and conduct independent vaccine trials.

June 1983: The CDC reported 1,641 cases of AIDS in the United States with 644 deaths.

In July 1983, Montagnier hand carried to Gallo's lab, frozen culture fluid containing LAV-BRU viruses (but not cells producing viruses[46]) named so from a patient code-named BRU. By the account of all the investigators in Gallo's group, later attempts to cultivate and grow this first sample of LAV repeatedly failed; just as they had failed in Montagnier's own lab. During the first working meeting of the NIH Task Force held in Gallo's lab, Montagnier presented material on his AIDS work, including an electron microscopy slide of virus particles. Yet leading microscopists, including F. Hageneou (the head microscopist in France) thought the particles were not retroviruses, but of a different class known as the arena-virus. Present at the meeting was Matthew Gonda, an NIH electron microscopist, who was quick to realize and point out that the Montagnier slide showed a lenti virus, which is in fact a subclass of retrovirus. Gallo resisted this

[45] But…as early as January 1983, Gallo was careful to word his views so that they could not be confused. In a letter to the Director of the Cancer Institute in Heidelberg, he wrote, "It has become somewhat more likely that HTLV may be involved."

[46] The difference is that free virus particles are usually very limited in amount, therefore limiting what can be done with them. As opposed to infected cells which may be able to continuously produce virus.

notion at first; still thinking it was a retrovirus in the HTLV family. It was Gonda who turned out to be right. According to Montagnier, the role of an HTLV-like, or highly related, retrovirus in AIDS was overemphasized at the meeting, at the expense of LAV. Montagnier stated he was *"overcome by exasperation,"* and decides against the continuance of his formal collaboration with Gallo. He returned to Paris with the unsigned Agreement of Collaboration still in his pocket. Up to then, Gallo and Montagnier had agreed that the French isolates would be handled identically to the American ones; both test-wise and publication-wise. But Montagnier called off that collaboration. Even though the two men would continue to share information and materials, Gallo was forced to accept new restraints after the formal collaboration had ended. He was still allowed to experiment with the LAV virus, but was not allowed to publish any results or analysis of LAV without Montagnier's prior approval. [And this is where the apple analogy references mentioned earlier in the book come into play: Montagnier is essentially saying: You can look at my apple, see how special it is, you just can't tell the world about it.]

Gallo: *"I also felt from the discussions with Montagnier, that we were not supposed to do any detailed molecular analysis on LAV. This would be done only in collaboration with his group with agreements of who would do which tests and the tests shared about equally."*

As to the nature of the LAV virus, Montagnier's notion that it belonged to a new retrovirus family, was correct; as Gallo has later repeatedly acknowledged. Don Francis, an epidemiologist with the CDC, claimed to invite Gallo and others to discuss roles and goals in AIDS research on an institutional and individual basis in Paris. Gallo: *"Not True. I set the meeting up with the French group. Francis pushed his way in."* That fact is verified by Francis himself…through his telephone notes of March 26, 1984. Francis, in his own hand writes, "Chermann talked to Gallo." Chermann says, "I think Bob Gallo will come to Paris, April 6." Later, Francis makes this agenda note, "1) Meeting_ I(nstitut) P(asteur), Francis, + Gallo on 6 April 1984." Essentially he hears about the meeting at the top of the page of his notes, and by the bottom of that page, had invited himself to attend. In between all that, he notes his strategy to "finish characterization of LAV and HTLV-3." That meeting ended in disagreement over their scientific functions and their scientific pursuits[47].

For all the negatively reported innuendo, that Gallo was so certain that HTLV was the cause of AIDS, because he knew the French had indeed found the right retrovirus isolate, and then plotted to steal it by changing the name to HTLV-3; one would expect to find a level of certainty or confidence that viral "treasure" had been found in LAV. But that was not the case according to a memo Gallo wrote on August 4, 1983. Addressed to NCI Divisional Director (R. Adamson), the Director of the NCI Cancer Treatment Program (B. Chabner), the Associate Director of the NCI (P. Fischinger), as well as to AIDS Committee Members, and his entire staff at LTCB, Gallo titles this memo, Some

[47] Not to diminish, rather to make the distinction very clear, as an epidemiologist, Francis, and others like him, are statisticians of a sort that predict and study the spread, growth, and contributory factors of any given disease. Whereas Gallo and others like him, are biologists of a sort, dedicated to seeking the causes and mechanisms of disease induction, the natural history of the disease; as well as the detection, diagnosis, and treatment of any given disease. Francis wanted to start doing the job of a biologist (this according to Gallo), whereas Gallo felt Francis' role was different and that he should stick to the job he was trained and hired to do.

Thoughts on the Possible Cause of AIDS by HTLV. Quoting now, the very first sentence reads, "In the most simplistic terms possible, this is my view about the cause of AIDS, **if** HTLV is involved:" He goes on to speculate (correctly too), "that HTLV arose in Africa…," and described the studies he would undertake with outside collaborators to ascertain whether or not HTLV was in fact the cause of AIDS. Hardly indicative of a man who was so certain his view was absolutely right and/or coupled with the knowledge the key was already in his hands, via Montagnier's LAV.

August 1983: The CDC reported 1,972 cases of AIDS in the United States with 759 deaths.

August 24, 1983, Dr. C. Bartholomew (of the University of the West Indies in Trinidad) was invited by Gallo to the Cold Spring Harbor Meeting after he reported the first AIDS cases in the Caribbean.

August 26, 1983, AIDS Investigators Identify Second Retrovirus was published[48], reporting that, "a team of French researchers and clinicians has discovered a human retrovirus that may, they think, may be linked to the etiology of acquired immune deficiency syndrome (AIDS). The virus is similar but quite distinct, the investigators now believe from the first human retrovirus to be discovered, the human T-cell leukemia virus (HTLV)."

By September 1983, almost two dozen different detections and isolations of the new virus were obtained by Gallo and co-workers. Already, they had amassed enough evidence to preclude HTLV-1, or any variant, or mutant, as the cause of AIDS. Gallo accepts HTLV-1's role only as an occasional accompanying infective agent (5 to 8% or so), which merely complicated the clinical and biochemical picture of the actual disease. Although by then, as Gallo puts it, *"in my mind, the new retrovirus was the likely cause, but I would have to prove it."* In fact, the evidence later verified that no higher than 10% of the AIDS victims were doubly infected with both the AIDS and HTLV-1 viruses.

Then Mika Popovic and technician Ersell Richardson in Gallo's lab, got almost two dozen detections[49] and isolations[50] of a retrovirus, clearly distinct from either HTLV-1 or -2, which Gallo names HTLV-3. This name was not arbitrary and, was in fact, the first formal name given to the virus in the peer-reviewed literature; in accordance to the previously mentioned February 1983 international agreement.

September 2, 1983, Marjorie Guroff sent Montagnier 20 blind human sera/plasma samples from Gallo's lab so that Montagnier's team could assay them against the French ELISA approach. Montagnier claimed the values were 30% positive and reported he would do more testing with additional time and help from the CDC.

On September 21, 1983, Max Essex wrote to both Curran and Francis of the CDC, imploring them to begin collecting sera from both donor and recipient transfusions that were HTLV antibody positive in order to isolate AIDS viruses; that doing so was important "from the standpoint of (establishing) potential etiological proof."

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[48] By John Maurice, JAMA, August 26, 1983, vol. 250, No. 8, p. 1010.

[49] Detection means setting up cultures and identifying the presence of retrovirus in non-permanent cultures by positive reverse transcriptase assay.

[50] Isolation, in turn, means either immediate virus capture or delayed virus recovery by freezing cultures that were tested positive and keeping them in readiness for re-growth. In other words, the virus can be produced by the cultured cells virtually at will for a period of time. Through this second process, a number of virus specimens from selected samples were regenerated, grown and used, among other things for genetic sequence studies.

Between September 1983 and April 1984, the documented number of independent isolates of the new virus obtained by the Gallo group (from patient samples) would reach four dozen (Appendix 2, p.282). This was achieved by the cooperative efforts of members of the Gallo team (including Salahuddin, Popovic, and Sarin), and especially by the efforts of Phil Markham. This information, however, was not disclosed[51] until the virus was firmly linked to AIDS as the cause and so published in Science in May 1984; where 48 isolates were reported in all, after evidence of their causative role in AIDS had been amassed by the blood test; which will be discussed later in this chapter. Thereafter, a steady stream of isolates was obtained as more samples kept arriving at the lab.

In September 1983, Gallo invited Montagnier to the Cold Spring Harbor Meeting, where Marjorie Guroff, from Gallo's lab, presented her serological data obtained by late 1983. Montagnier attended this science meeting and reported five more isolates of LAV from patients with early disease, three additional isolates from patients with full blown AIDS (which he called a "Immune Deficiency Associated Virus" or IDAV), and his isolates' selective affinity for the T-4 lymphocytes. But he did not show that they were related to each other. Moreover, the different names plus his own stated hypothesis all indicated that LAV only caused lymph gland enlargement, while IDAV might be the cause of AIDS. Later, it would be shown that those viruses were the same type and were of course the cause of AIDS. But none of that was published in any of the peer reviewed scientific journals. Montagnier also goes on to report the presence of antibodies against his isolates, in patients with early and full blown disease; specifically, in only 20% of patients with full blown AIDS. Lastly, Montagnier repeated his earlier published report and made a claim that all T-Cell Tropic Viruses[52] will be the cause of AIDS. "It is based on the simplest postulate that T-lymphotropic retroviruses are the primary agents of the disease. Among such causative agents, we include LAV-related viruses, HTLV-related viruses, and any other lymphotropic retroviruses to be discovered[53]." This amounted to him saying every human retrovirus (HTLV-1, HTLV-2, LAV, IDAV, etc.) carried the disease; and are all potential causes of the disease. Of course, this turned out to be wrong. So, in this case, Gallo was correct to insist that the cause of AIDS would be a single, new retrovirus. Gallo quips: "*We took so long to convince others that one retrovirus class could exist in man. To think that humans would be one of the unusual species to have two entirely different classes at that time was incredible.*"

By his own account, Montagnier presented all these findings on LAV, to a half empty hall. Montagnier submitted a patent application in Europe, for an AIDS blood test, based on the detection of LAV antibodies and as an assay to diagnose AIDS. Not to protect recipients against contaminated blood transfusions. The application stated that there were no antibodies to the envelope protein, although, as known now, the envelope is the main antigen. Montagnier did not inform Gallo of his patent application submission (nor was he obligated to). However, at that time, the French blood test was highly

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[51] The normal lag time for publishing work done by Gallo's group at the National Cancer Institute was about 1-2 years from the time of actually detecting something new. Example: their publications on HTLV-1, HTLV-2, HTLV-2B, and Human Herpes Virus 6 (HHV-6) occurred 2 years, 1 year, 1 year, and 1½ years, respectively, after their initial discoveries.

[52] Viruses affecting T-cells.

[53] A New Human T-Lymphotropic Retrovirus: Characterization and Possible Role in Lymphadenopathy and Acquired Immune Deficiency Syndromes, L. Montagnier et al., Science, May 20, 1983, p. 378.

inaccurate and, therefore, virtually unusable; detecting about 21% of AIDS cases, and about 38% of lymphadenopathy cases only. Moreover, the test could not be mass produced, given that the French were still unable to grow the virus continually as stated in the application. Additionally, the patent application provided no data that LAV was the cause of AIDS.

Also in September, Gallo received from Montagnier a second sample of LAV virus specimens, and this time his group did succeed in growing them in cord blood cells; even though all earlier attempts to grow the virus both in France and in the U.S. (to any significant degree) had failed. Mika Popovic used the French virus and successfully infected two T-cell cultures for the first time. He then got electron microscopy support to photograph the cultured virus particles, confirming LAV's retrovirus nature. Popovic informed Montagnier accordingly. The sudden ability to grow the French virus in Gallo's lab was, indeed, most curious, especially after the many repeated failures on both sides of the Atlantic (the whys of this are explained further in Chapter 20). But at the time, in fact until 1991, that success would remain inexplicable; as people from that point on, worked somewhat in the dark as details known now, were not known then.

On September 23, Popovic signed an agreement that the viral specimens received from Pasteur would not be used for commercial purposes (see page 65).

September 1983: The CDC reported 2,259 cases of AIDS in the United States with 917 deaths.

By October 1983, it became obvious that the task of proving the newly detected retrovirus was truly the cause of AIDS, would require massive production of the suspect virus in continuous cell culture. Not an easy task given that the virus is cytopathic; meaning it kills the cells it infects. Parallel efforts, already underway in Gallo's lab, were intensified, seeking to put their own different isolates of the new virus into different cell cultures. Cocktails of different isolates were also tried. Soon, the problem of virus transmissibility into cell lines was solved. And it became apparent that different isolates were neither equally infectious to the same cell line, nor equally efficient in making copies of themselves when cultured.

Betsy Read-Connole, a technician in Gallo's lab, succeeded in transmitting the LAV virus (explained in Chapter 20) into some human leukemic T-4 lymphocyte cell lines. The resulting virus growth was low but continuous and, upon testing, proved different from HTLV-1 and-2; as was expected. No significant molecular and immunological analyses of the LAV virus were carried out by Gallo's group at the time, waiting instead for collaboration with the Montagnier group.

Mika Popovic called Montagnier and asked for anti-interferon serum. By Montagnier's account, Popovic mentioned, in passing, that he knew how to cultivate their LAV virus in T-4 lymphocytes; but offers no other details. Conversely, by Popovic's account, after informing him, Montagnier asks for no details, and was already resentful for having been woken in the middle of the night. Furthermore, there was no correspondence or follow-up telephone conversation(s) initiated by Montagnier regarding Popovic's work with LAV.

Dr. Hadley: "Did he (Montagnier) press you to know how you were doing it?"

Dr. Popovic: "No, he did not. Only later we talked about it on the first meeting in Atlanta (1985)[54]."

[54] From the OSI Interview with Dr. Popovic, June, 26, 1990, at 112.

In November 1983, at a meeting in Japan, was where and when the French first called their newly discovered AIDS-associated virus, LAV.

By early December 1983, and in secret, the French group files a U.S. patent request for a LAV-based ELISA blood test for AIDS. They filed it despite their inability at the time to: 1) identify LAV as the cause of AIDS, 2) their inability to cultivate LAV in a cell line, and 3) their inability to produce a reliable blood test. Their filing was based on the still unproven assumption that LAV was linked to AIDS. Essentially, they had nothing to patent. Indeed, their patent application reported only 17% of patients with full blown AIDS to be positive when using their own test. What was most revealing about how incomplete their work truly was, that in their patent application, the French clearly state that, "the LAV virus can not be grown in culture." And not just by them - but by anyone. Clearly that was not the case with Gallo's lab. Yet, that was their position on the subject, at the time. Making things even more problematic was that even though their patent application stated a 17% detection rate, was the fact that their very first paper contradicted that in quite the questionable manner. "The study of the group of AIDS patients gave less interpretable results: Approximately 20% had LAV antibodies, but some of the sera were taken at a very late stage of the disease, with a possible impairment of the humoral response[55]."

So, how is it upon discovery of their isolate, they have a test that detects "approximately 20%" of those with LAV antibodies, yet in their patent application, they disclose a 17% detection rate? Now look at the unaltered Table below from the same page, of the same paper. Notice something missing? There are no recorded tests of patients with AIDS listed. They're missing. The question then becomes, if the AIDS group is not represented in the data, how can other scientists be sure of this 20% detection rate? Are they to take them at their word? And how is it that in the three months between this quoted publication in Science, and the filing of their blood test patent, the detection ratio actually dropped rather than being improved upon? It is curious to say the least. Yet it is not very relevant when compared to its meaning. Whether 17% or 20%, the test clearly was too insensitive and, coupled with the inability to produce virus in a cell line, made it a blood test that quite frankly, was not usable in any practical measure.

Table 4
First Results of Serological Investigations for LAV Antibodies in France

		ELISA-LAV1		ELISA-HTLV-I[a]	
	Total no. examined	no. positive	% positive	no. positive	% positive
LAS patients[b]	35	22	63	5[c]	14
Healthy homosexuals	40	7	17.5	1	3
Control population	54	1	1.9	0	<2.6

[a]The number of positive sera is probably overestimated in this test, since no control of unspecific binding could be done.
[b]28 homosexuals; 3 Haitians (1 woman); 4 with toxicomania (2 women).
[c]Of the 5 LAS HTLV-I positive patients, 3 were born in Haiti, 1 had stayed for a long time in Haiti, and 1 had made several trips to the United States. All of them also had antibodies against LAV.

[55] A New Human T-Lymphotropic Retrovirus: Characterization and Possible Role in Lymphadenopathy and Acquired Immune Deficiency Syndromes, L. Montagnier et al., Science, May 20, 1983, p. 376.

Referring again to the charted results previous, it is important to remember that LAS means Lymphadenopathy Syndrome, which applies to patients with lymph gland involvement; which may be a precursor to AIDS, but not necessarily.

In December 1983, Mika Popovic and Betsy Read-Connole successfully infected a particular cell line (called HUT 78) with a particular Gallo group isolate (code named HTLV-3RF). This allowed them to develop a process for producing large quantities of virus, and was indeed a major breakthrough in that ample supply of materials, for use in meaningful wide scale serological testing, became available for the first time ever. In addition to HTLV-3RF production, the growth of other isolates was also scaled up.

Weeks earlier, Popovic attempted to select an HTLV-3 strain with the highest growth rate in cell lines by mixing 10 different virus cultures from 10 different patients with AIDS (or a seemingly AIDS like disorder). This approach[56] by Popovic was aimed at assuring infectivity by achieving critical virus mass, possibly at the expense of losing track of the patient from which the dominant virus performer came from[57]. An isolate, code-named HTLV-3B, the most dominant virus in the cocktail, grew out of the cultured cells (a sub-strain of HUT-78 called H-9) and lead to high production yields. Dr. Popovic: *"Look, certain things at that point, I was not thinking about it. How unique can be each HIV isolate from each person? Nobody was thinking that back then. At that point (we were thinking) how to get the AIDS virus to grow irrespective from which patient it came from."*

During the same month, Popovic and Sarngadharan (using proteins from whole infected cells extracted by Jörg Schüpbach[58]) carry-out limited serological tests to detect antibodies to the new virus in the blood of AIDS patients; and they obtained preliminary positive results. However, conclusive serological testing could not be conducted until finer and more specific test assays would be developed, using purified viral proteins. Sarngadharan comments on handling live AIDS virus, and the fear of doing so, back in those early days: *"Myself and my technician took normal precautions, but we could have taken more. I was the first to handle concentrated virus, 200cc's in a bottle. No, the fear was a factor later. There were 4000 cases of AIDS in the whole world when we published. So later, when we learned more, yes, I think I was lucky (to have not been infected)."*

Meanwhile, Dr. Dean Burk of the NIH co-authored a book that claimed AIDS was caused by the fluoridated drinking water, and began promoting this on television. Also at this same time, the FDA was theorizing Poppers[59] as the cause; the NIH was claiming there was an autoimmune response happening in the body because of rough sex causing white blood cells to enter the bloodstream and destroying one's own autoimmune system. Even the Walter Reed Army Hospital claimed mycoplasma as the source of AIDS. The influx of rampant speculations did not ever stop.

By late December 1983, Sarngadharan in Gallo's lab immunized a rabbit with the HTLV-3 virus and obtained specific antibodies against it. Soon thereafter, Sarngadharan and Jörg Schüpbach compared all the proteins produced by the infected cells, with all

[56] The Office of Scientific Integrity (OSI), at NIH, later confirmed that this approach was indeed followed.
[57] The dominant virus can come from the combination of progenies of different viruses, each from a different patient or, from the progeny of a single virus from a single patient.
[58] A post-doctoral fellow with Gallo from Switzerland.
[59] Nitrite Inhalants used to relieve pain in angina patients by inhaling their fumes.

those produced by uninfected cells, and singled-out those proteins encoded by the HTLV-3 virus. By then, enough of the virus was produced to allow direct isolation and characterization of all viral proteins.

Between late December 1983 and January 1984, Sarngadharan in Gallo's lab conducted the first AIDS antibody blood tests in two phases. During the first phase, Sarngadharan tested known samples obtained from Popovic to exclude contamination and to streamline the assay. During the second phase, Sarngadharan tested unknown samples obtained from Guroff to validate the reliability of the assay. This collaboration between Popovic (who did the cultures) and Sarngadharan (who did the characterizations) went on. By then Gallo had already begun to receive requests for an AIDS detection assay from other scientists. All he could do was refer them to a commercial kit by Biotech which had been useful in the detection of leukemias and lymphomas, but only 10-15% of AIDS sera scored positive.

By Christmas 1983, Sarngadharan obtained enough serological evidence, which when coupled with the large number of isolates of the new virus from blood cells of AIDS patients allowed Gallo, Sarngadharan, and Popovic, to conclude that HTLV-3 was indeed the cause of AIDS. But equally important, the advantage to having a growing cell meant having enough reagents to be able to develop a reliable test, which in turn, would protect the world. Sarngadharan says to Gallo at a Christmas party, *"I think we have something very interesting here."* However they needed an objective test to be sure. *"Then I asked Bob (Gallo) to get me a serum panel."* To ensure an unbiased result Dr. Sarngadharan tells Gallo, *"…not to tell Marjorie (Guroff). She was custodian of most of the sera. So I asked Bob to get her to prepare a panel. And told him specifically, not to tell her the status of what we have. If you want, tell her it's for testing of HTLV-2."* In January 1984, Guroff made the panel (using between 40-50 sera) and gave the key to Gallo, who then gives the blind panel to Sarngadharan. This panel consisted of varied groups such as; AIDS patients, lymphadenopathy syndrome patients, normal subjects (the control group), sera with HTLV infection, and four sera with infectious mononucleosis. But Sarngadharan did not learn any of this until after he tested the panel.

As soon as he concluded his tests, Sarngadharan returned to Gallo with the results where Gallo says, *"You've done extremely well, but there are four sera here that you consistently failed."* The sera in question were the infectious mononucleosis; a problem sera. Why? Those sera are known to be very reactive with all kinds of things. Unless you have a very specific test, they would always show positive. Once Gallo revealed the type of sera he was failing with, Sarngadharan knew what he needed to do to refine the test. The goal; keep the positives, positive, and get the infectious mononucleosis to read negative. He did. In their laboratory setting, the follow-up test for detection worked as hoped. Sarngadharan then asked Gallo to get blind samples from the CDC to prove the reliability of their assay.

In the months that followed, Gallo requested repeatedly from Don Francis, to be sent CDC reference blood panels, which matches sets of blood samples from donors and transfused AIDS patients[60]. The reason was obvious. The CDC clearly had the biggest

[60] Physicians seeing patients with AIDS (or suspected of AIDS) were requested to send blood samples to the CDC from the onset of the epidemic. Sometimes physicians would call Gallo to see if he would examine the cells or sera, referring him to the CDC. This is what began Gallo's request to the CDC in that early period.

pool of sera at that time because they were the natural recipients of national, unusual disease samples. Dr. Mark Kaplan (from North Shore University Hospital) began collaboration with Gallo's group by supplying it with the samples, when the CDC would not. Kaplan: *"They (Gallo's group) knew there was competition, but it wasn't from the French they were so worried; they were kind of peeved that they couldn't get samples from the CDC. Here they were, an American organization, and they weren't getting samples for their studies. They should be providing samples. After all, he discovered these retroviruses and they're looking for retroviruses, I didn't understand why they didn't cooperate with him. I just figured the CDC wanted to make the discovery themselves. It would have been a great coup to them to have that discovery, you know. Because then that would have put them way up on the map. And here, here's this guy Gallo at NIH, at the NCI of all things, maybe making this discovery."*

In fact, as far back as 1982-1983, Gallo had requested blood samples obtained from AIDS patients from Jim Curran (of the CDC) long before the new retrovirus was detected. Curran assigned this task to Francis, but it took Gallo a year of not only repeated requests, but finally the intervention from the then NIH Director (James Wyngarden) before Gallo would finally receive samples. This *"began very bad feelings"* for Gallo about Don Francis. And telephone notes made by Francis himself (of which the author has copies) clearly say that Gallo is, "Frustrated because: 1) Complaining not getting best material from CDC[61]" and, "Expect to have given us the best primary material – have not[62]." But at that time, again, Gallo received nothing, and now he, himself refused to send his HTLV probes to Francis. Martin Delaney, Head of Project Inform[63]: *"I'm convinced that what that was about (the feuding with Gallo brought on by Francis), is that Gallo and Montagnier were working well together and the CDC was cut out of the picture largely."*

So Gallo flew to the CDC in Atlanta. There he learned that Francis would head a new retrovirology lab and that money had already been allocated for recruitment of scientists from NIH. Max Essex had accompanied Gallo and had this opinion of his former student, Francis, *"At that time, I would definitely say he tried to take more of the credit of the initial observation in our lab, than he deserved (that AIDS was a retrovirus)."* Gallo knowing of, *"Francis's lack of science background and in particular, his lack of knowledge on human retroviruses,[64]"* remarked that at the CDC, *"the blind were leading the blind"* and departs, again, empty handed. Gallo now, is angry. That was when Gallo commented to Vincent DeVita, Director of the National Cancer Institute (NCI), that Francis was not releasing to him the CDC blood panel, and requested his intervention so that he may determine the accuracy of the proposed AIDS antibody test. DeVita and NIH Director James Wyngarden intervened and the CDC finally complied by sending Gallo 205 blind panel samples. After waiting so long, Sarngadharan tested all 205 sera in one day.

Conversely, Francis's dealings with the French were quite the reverse from their onset. In correspondence with the Institut Pasteur, Francis writes, "Thank you for your

[61] From Don Francis' handwritten notes recording highlights of a phone call with Gallo; July 24, 1983.
[62] From Don Francis' handwritten notes recording highlights of a phone call with Gallo; August 25, 1983.
[63] A prominent activist group based in San Francisco and involved with AIDS awareness from the start.
[64] Quote from Dr. Robert Gallo.

request for serum. We are always happy to collaborate with AIDS investigators[65]."

More from Martin Delaney: *"You know, when this all started, the Reagan Administration had talked about shutting down the CDC. In fact, there was a book out at the time, and there was a popular notion that infectious disease had been conquered. And the CDC's budget was disappearing from year to year and they were truly in danger of going out of business. And then to see this new disease appear out of nowhere, and who's taking the lead in it? NCI instead of the CDC. So Don Francis is in there first, to get credit for the CDC, to get them a role in it, and then for himself. I mean Don Francis wanted to be there when the lights went off and the cameras flashed and all of that. He delayed, and I've seen the documentation on this, sending the critical samples to the NCI. The critical samples from the transplant patients, because that's what you really needed to prove that this was an infectious disease. I've discussed all of this, I've said this right to his face and had conversations with him saying, "Don, I really think you've been unfair here, and your motives are personal." And he never in these conversations offered me one wit of evidence to support his point of view. And I gave him that chance."*

In July 1983; with the money in place for the recruitment of scientists, Francis hired virologist Kalyanaraman out from Gallo's lab[66], by offering him a high paying tenured government position that the NIH could no way match (see page 66 for details). Sarngadharan explains, *"That was Francis' way of creating an Institute, a retrovirology lab without having the basis for it. I mean, they had no background (to do such work), and they thought getting Kaly who had published a lot with me (and Gallo) - he was part of the original retrovirology team too - was a way for them to begin. You know, he could do more with LAV then they could (meaning the CDC & the French)[67]."*

Expectedly, the interpersonal relationship between Gallo and Francis deteriorated; and Francis sought scientific refuge in Montagnier's camp, where he was provided all out support. But this quarrel had already begun when Francis wrote a letter (dated June 14, 1983) to Barre -Sinoussi asking for collaboration. Francis, a representative of the American Centers for Disease Control, was asking to join a French laboratory for the, "sharing of information and sharing of specimens." In fact, the CDC, "have begun (to do so) in both these areas already," as stated in that letter. Meanwhile, Gallo was still waiting for the CDC to be kind enough to send him materials too. In a sense, Montagnier's lab became Francis' CDC extension and Montagnier, in turn, got from Francis, technical assistance and samples; including access to the prized CDC blind blood panels. Kalyanaraman: *"It was Gallo who drove Francis to the French by insisting that he (Gallo) should be the one working on science and that Francis should stick to epidemiology."*

The Gallo shut-out by Francis of the CDC is best illustrated by a letter (dated August 17, 1983) written to Francis and Curran by Gallo. "At this point in time regrettably I did not receive sera, nor cells, nor even information that these cases were available. Finally, I hope in the future you will let me and my colleagues know about these very important cases." Still, in desperation Gallo wrote to both Don Francis and Jim Curran (September 28, 1983) because he had just heard from Vince DeVita, the lamest of excuses; "…he told me

[65] Letter from Don Francis to Barré-Sinoussi dated November 3, 1983.
[66] Kalyanaraman would later rejoin Gallo's lab.
[67] Interview conducted July 25, 2003, 12:52 EST.

there have been several occasions that you couldn't send me samples because you didn't know how to get a hold of me." Gallo ends the letter by listing almost everyone with seniority in his lab, and the phone number for each.

What does come in loud and clear from all the correspondence that follows, is that Don Francis never intended to collaborate with Gallo. Instead, his goal was to set-up shop together with the French, preferably alone, in competition with Gallo, and surface as a major player in AIDS research for personal credit. But he lacked the necessary expertise.

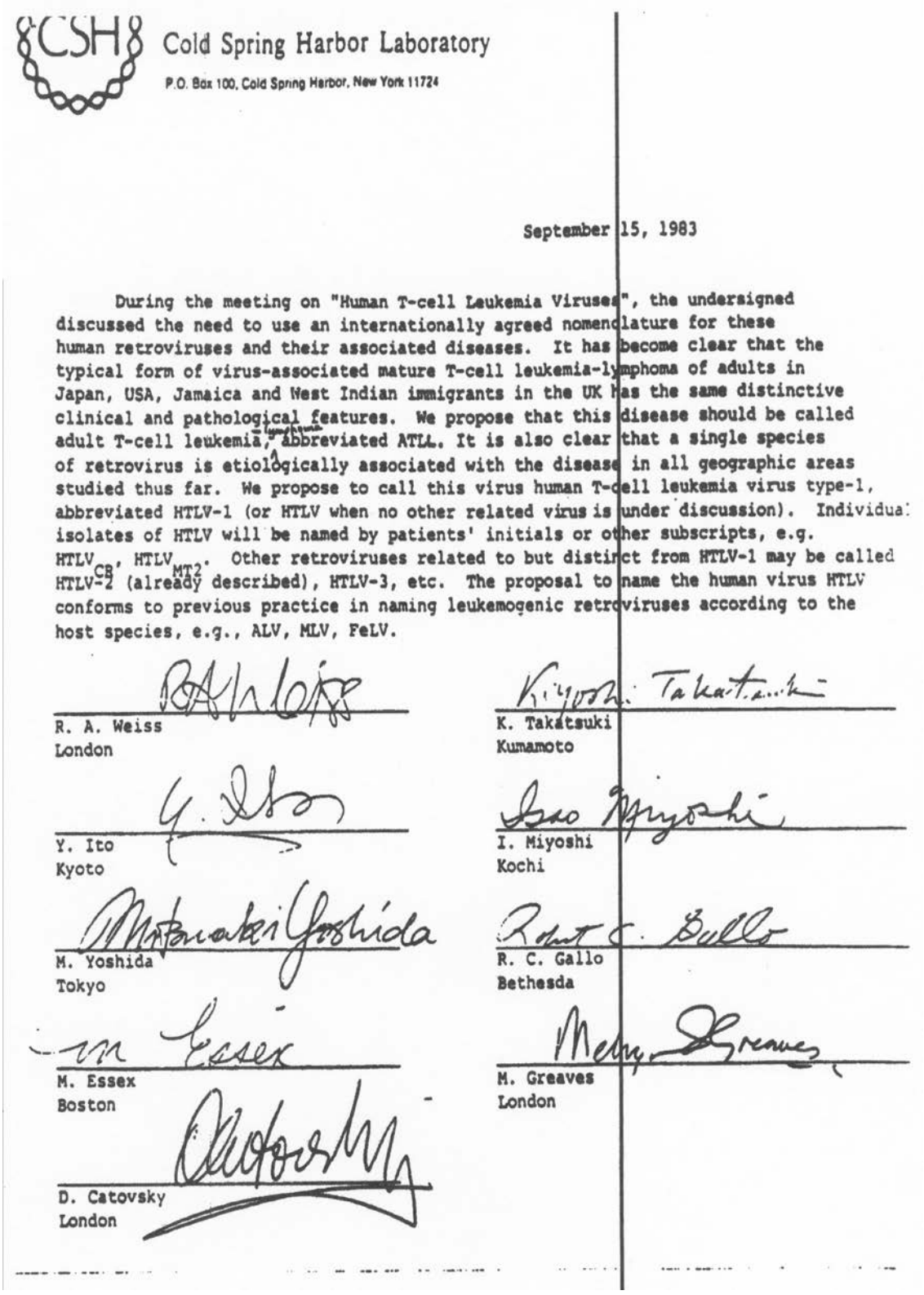
Gallo to Director of the NCI (September 25, 1983): "…CDC uses its increased funds to mimic as closely as they can our laboratory efforts. They can not and will not achieve a sophisticated level of retrovirus research for the simple reason that their leaders don't understand the basic fundamentals of retrovirology. Precious time and clinical material have been wasted…(On the other hand) we never received …(requested) sera (recipients and donors), and since Essex already has positive antibody data on both donors and recipients suggestive of HTLV infection, there can be no greater priority in this whole field than obtaining blood on the antibody donors to determine if…HTLV and/or other related viruses (can be isolated). To this day not only did we not receive any material (but) we did not even know the…material existed except by…chance…"

A later memo by Francis, entitled, Status of Institute Pasteur Studies of Retrovirus in AIDS and Status of CDC Collaboration[68]" chronicled the French getting 30 blind specimens in November 1983, another resending of 30 blind samples[69] in January 1984, followed by "100 serum samples from various patient groups and controls (blinded)" in February 1984. On February 4, 1984, the French rapidly responded to the CDC's liberal generosity by supplying them with a tube of LAV virus, a tube of Human 2 Interferon, and a tube of BRU as positive control serum. This memo (against the French letters of request) emphatically details how whenever the French asked for sera, Francis made sure they got it quick. Whereas Gallo…

Whatever the reasons, while the scientific world and even the French (who were the competition) sought open collaboration with, and advise from, Gallo's lab, the CDC, specifically Don Francis, did not. They merely sought to align themselves with what they perceived to be the winning side. This illustrates how even in Science there are lots of parlayed backroom politics.

[68] This February 16, 1984 memo also details that on January 30, 1984, the CDC received the results of the 30 blinded samples. Results of the detection were as follows: 10/10 LAS patients positive, 3/10 AIDS positive, and 1/10 controls positive. Which illustrates how poor the French detection rate still was. Additionally, their LAV Elisa reported very little difference between LAV (38% detection) & HTLV-1 (22% detection) in more tests with strictly AIDS sera.

[69] And while Gallo was still waiting, Barré-Sinoussi was calling Francis back with the test results of those 30 sera from January 30, 1984 (from Francis' own handwritten notes).



CSH Cold Spring Harbor Laboratory

P.O. Box 100, Cold Spring Harbor, New York 11724

September 15, 1983

During the meeting on "Human T-cell Leukemia Viruses", the undersigned discussed the need to use an internationally agreed nomenclature for these human retroviruses and their associated diseases. It has become clear that the typical form of virus-associated mature T-cell leukemia-lymphoma of adults in Japan, USA, Jamaica and West Indian immigrants in the UK has the same distinctive clinical and pathological features. We propose that this disease should be called adult T-cell leukemia, abbreviated ATL. It is also clear that a single species of retrovirus is etiologically associated with the disease in all geographic areas studied thus far. We propose to call this virus human T-cell leukemia virus type-1, abbreviated HTLV-1 (or HTLV when no other related virus is under discussion). Individual isolates of HTLV will be named by patients' initials or other subscripts, e.g. $HTLV_{CB}$, $HTLV_{MT2}$. Other retroviruses related to but distinct from HTLV-1 may be called HTLV-2 (already described), HTLV-3, etc. The proposal to name the human virus HTLV conforms to previous practice in naming leukemogenic retroviruses according to the host species, e.g., ALV, MLV, FeLV.

R. A. Weiss
London

K. Takatsuki
Kumamoto

Y. Ito
Kyoto

I. Miyoshi
Kochi

M. Yoshida
Tokyo

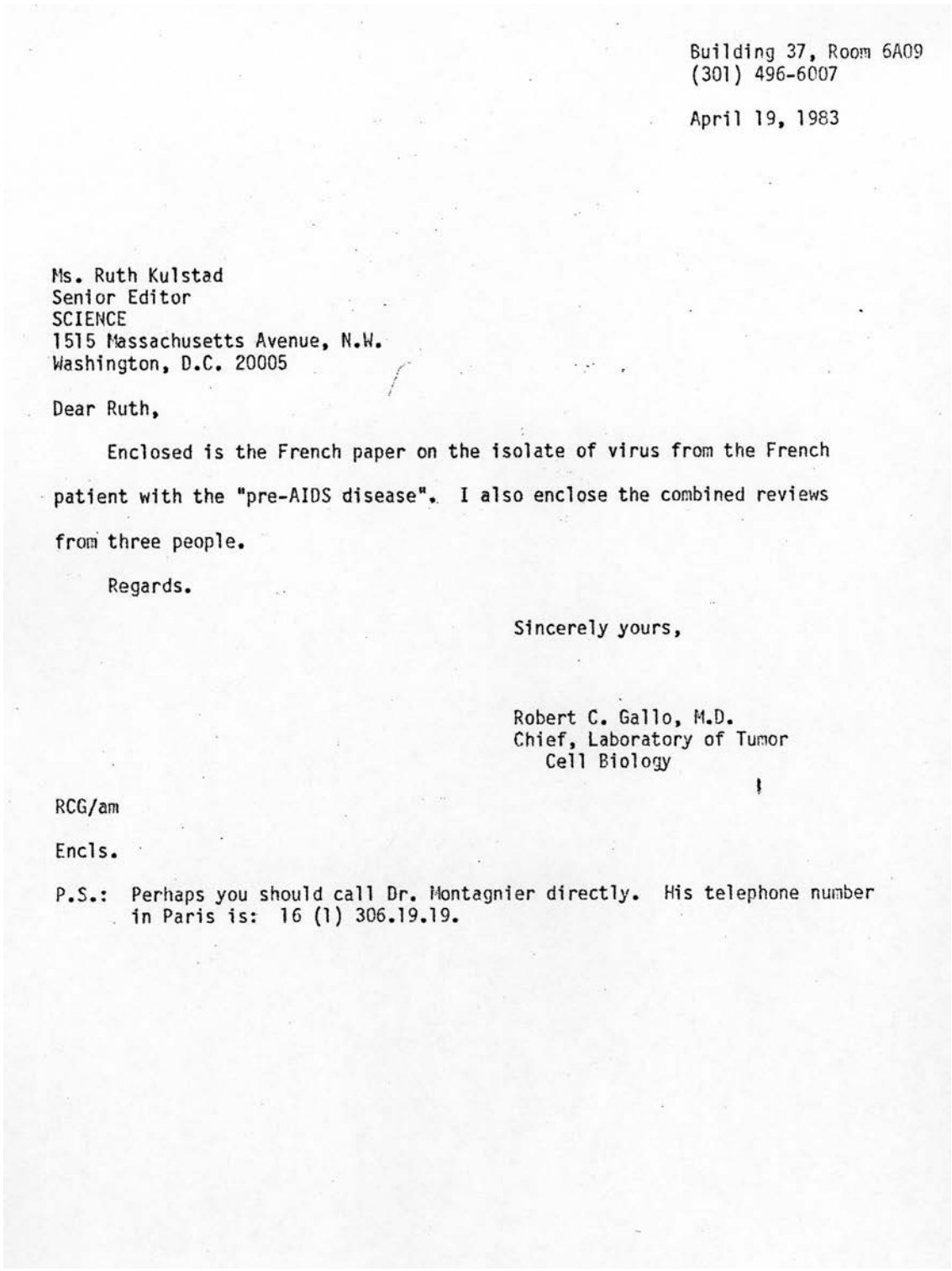
R. C. Gallo
Bethesda

M. Essex
Boston

M. Greaves
London

D. Catovsky
London

The Cold Spring Harbor Agreement on Nomenclature.



Building 37, Room 6A09
(301) 496-6007

April 19, 1983

Ms. Ruth Kulstad
Senior Editor
SCIENCE
1515 Massachusetts Avenue, N.W.
Washington, D.C. 20005

Dear Ruth,

Enclosed is the French paper on the isolate of virus from the French patient with the "pre-AIDS disease". I also enclose the combined reviews from three people.

Regards.

Sincerely yours,

Robert C. Gallo, M.D.
Chief, Laboratory of Tumor
Cell Biology

RCG/am

Encls.

P.S.: Perhaps you should call Dr. Montagnier directly. His telephone number in Paris is: 16 (1) 306.19.19.

Grasping the significance of this new French isolate, Gallo writes to get the all important French paper published…

Review of Science manuscript "Isolation of a T-Lymphotropic Retrovirus from a Patient at Risk of Acquired Immunodeficiency Syndrome" by F. Barre-Sinoussi et al.

This paper is of obvious immediate great importance and relevance. It will be of very great interest to virtually all scientists and clinicians. The work is careful. The discussion is clear and well thought out. It should be published as rapidly as possible.

Our corrections are mainly stylistic and grammatical. Changes are "penciled" in directly on the original. The minor changes have been discussed with the senior author (Dr. Montagnier) and he agrees with all.

Reviewed by:

Robert C. Gallo

Robert C. Gallo, M.D.
Chief, Laboratory of Tumor Cell Biology
National Cancer Institute
Bldg. 37, Room 6A09
Bethesda, MD 20205
(301) 496-6007

Prem S. Sarin, Ph.D.
Deputy Chief, Laboratory of Tumor Cell Biology
National Cancer Institute
Bldg. 37, Room 6C10
Bethesda, MD 20205
(301) 496-4870

Mikulas Popovic, M.D.
Laboratory of Tumor Cell Biology
National Cancer Institute
Bldg. 37, Room 6B13
Bethesda, MD 20205
(301) 496-4923

…never realizing that this first gesture sets events into motion that will eventually help the world, while it almost ruins him.

Institut Pasteur
28, RUE DU D' ROUX, 75724 PARIS CEDEX 15
TÉL. 16 (1) 306.19.19

Paris, February 2nd. 1983

Our ref. : LM/EM/83.12

Dr. Robert GALLO
Chief, Laboratory of Tumor Cell Biology
Experimental Therapeutics
NATIONAL CANCER INSTITUTE
Department of Health, Education & Welfare
Public Health Service
N.I.H. Bldgs 37 Rm 6B04
BETHESDA, Maryland 20014
U. S. A.

Dear Bob,

I tried to get you on the phone, without success.

We -Françoise BARRE, Jean-Claude CHERMANN and I- have detected some reverse transcriptase activity in cultures of T-lymphocytes from a french patient with an immunoproliferative syndroma.

We would like to know whether this isolate has something to do with your HTLV. Therefore, I am writing to ask you if you could possibly make available to us a HTLV cloned DNA fragment (in DNA or bacterial form) and an anti-serum against viral proteins.
If you agree, it would be very convenient for us if you could give these reagents to Dr. LEIBOWITCH who will shortly visit you.

I should like to stress that my inquiry is made only for basic purpose. We would not release your material outside our laboratory without your permission.

Thanking you in advance, I remain,

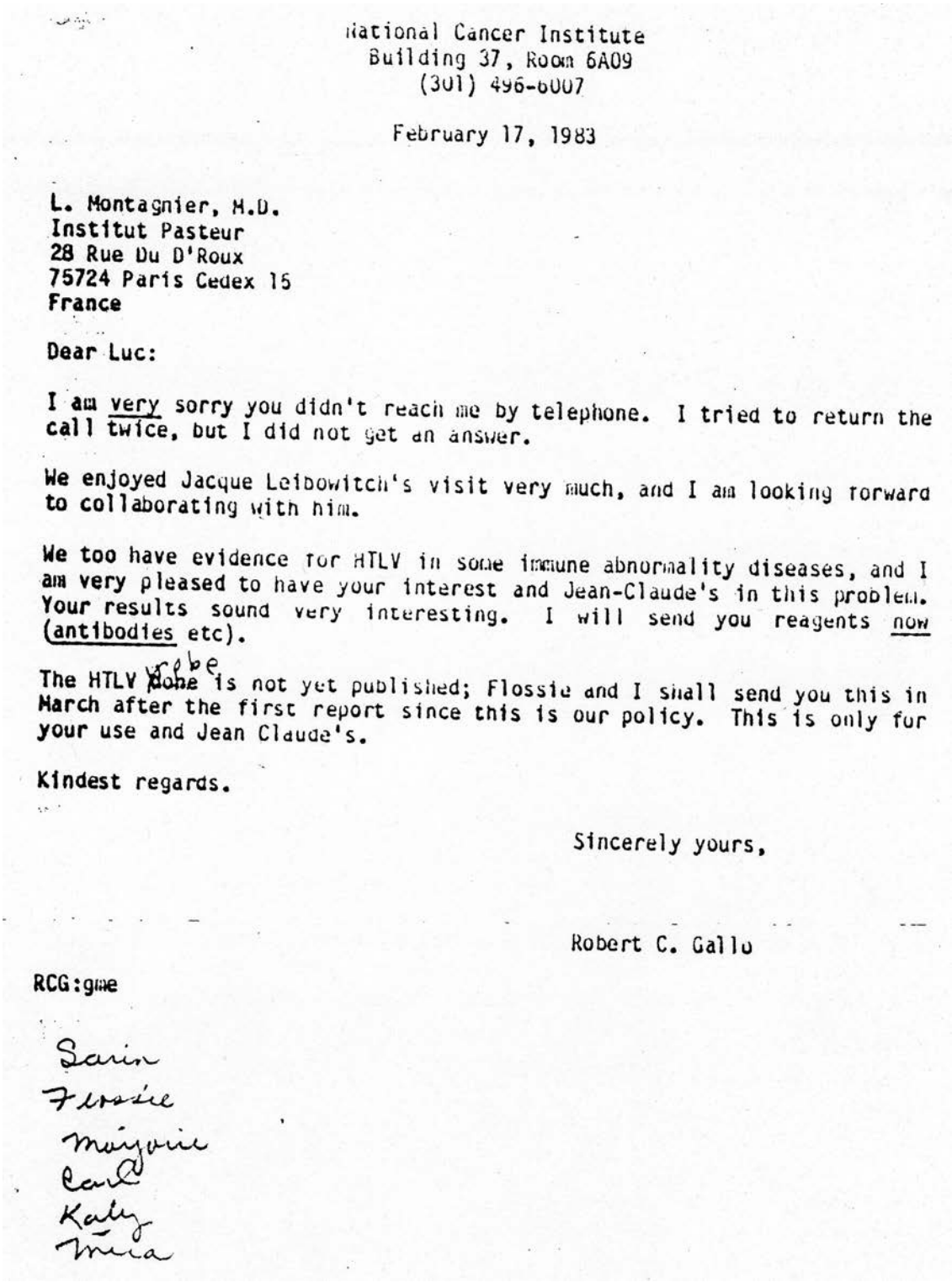
Sincerely yours,

Luc

L. MONTAGNIER, M.D.

P.S. : Did you receive my letter inviting you for giving a lecture on HTLV at the Pasteur Institute in March ?

In the span of just three days (date received) between this letter…



National Cancer Institute
Building 37, Room 6A09
(301) 496-6007

February 17, 1983

L. Montagnier, M.D.
Institut Pasteur
28 Rue Du D'Roux
75724 Paris Cedex 15
France

Dear Luc:

I am very sorry you didn't reach me by telephone. I tried to return the call twice, but I did not get an answer.

We enjoyed Jacque Leibowitch's visit very much, and I am looking forward to collaborating with him.

We too have evidence for HTLV in some immune abnormality diseases, and I am very pleased to have your interest and Jean-Claude's in this problem. Your results sound very interesting. I will send you reagents now (antibodies etc).

The HTLV probe is not yet published; Flossie and I shall send you this in March after the first report since this is our policy. This is only for your use and Jean Claude's.

Kindest regards.

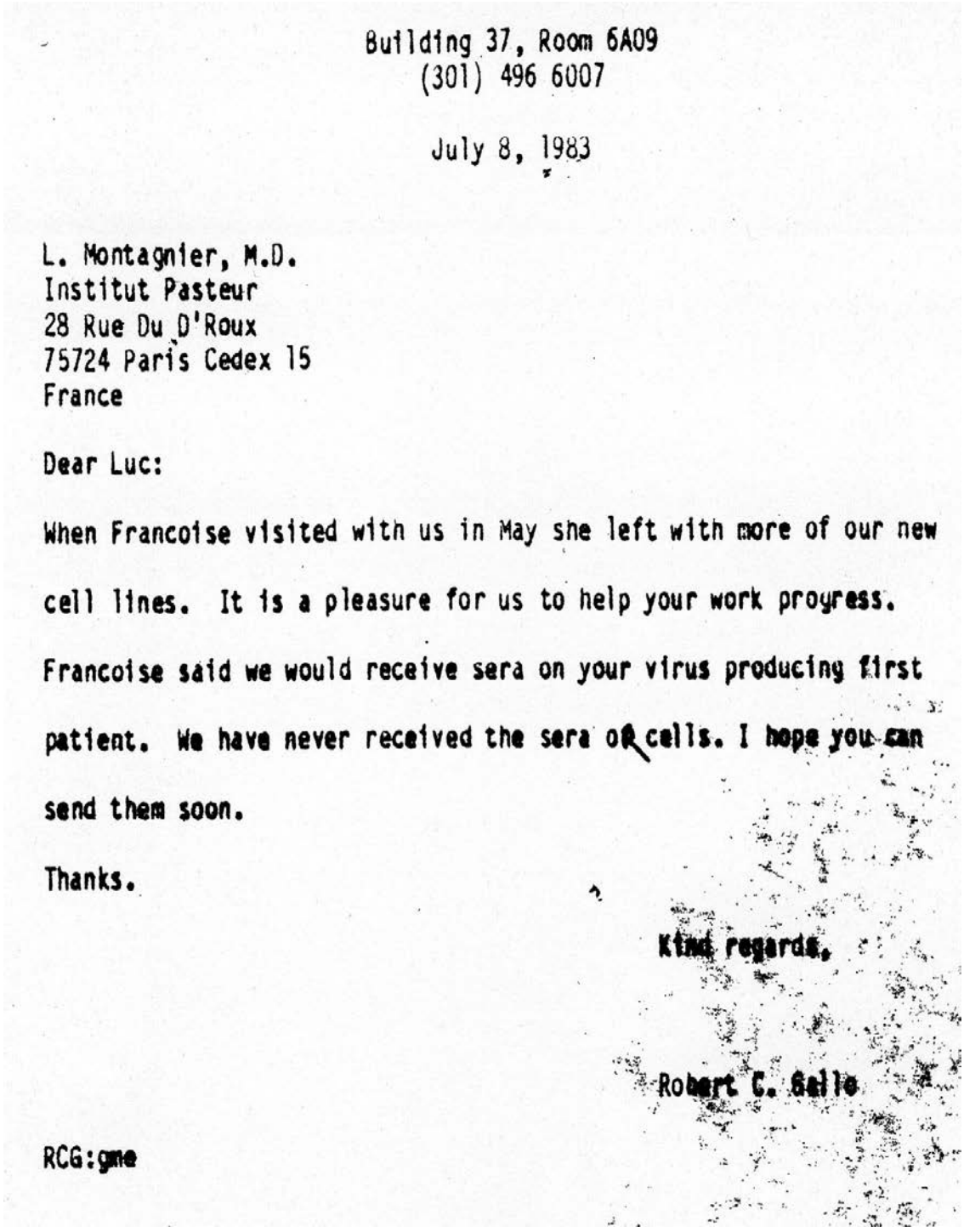
Sincerely yours,

Robert C. Gallo

RCG:gme

Sara
Flossie
Marjorie
Carl
Katy
Mia

…and (writing) this one, is it plausible that Gallo is hatching a diabolical plan…



Building 37, Room 6A09
(301) 496 6007

July 8, 1983

L. Montagnier, M.D.
Institut Pasteur
28 Rue Du D'Roux
75724 Paris Cedex 15
France

Dear Luc:

When Francoise visited with us in May she left with more of our new cell lines. It is a pleasure for us to help your work progress.

Francoise said we would receive sera on your virus producing first patient. We have never received the sera or cells. I hope you can send them soon.

Thanks.

Kind regards,

Robert C. Gallo

RCG:gme

…or seeking a sincere, scientific collaboration?

Institut Pasteur

28 RUE DU Dr ROUX 75724 PARIS CEDEX 15

TELEX PASTEUR 250809F

TEL 16(1) 306 19 19

—

Unité d'Oncologie Virale

Luc Montagnier

40

Virus LAV1 produced by human T lymphocytes n° I-232 deposited on July 15th, 1983 at the C.N.C.M.

The virus LAV1 will be available subject to acceptance of the three following conditions :

1) *The virus will be used by the recipient himself, exclusively, and only for the following research purposes (fill in) :* a) biological; b) immunological and c) nucleic acid studies.

2) *It will not be used for any industrial purpose without the prior written consent of the Director of the Pasteur Institute.*

3) *The recipient agrees not to disseminate the virus in any form (to companies or other scientists) without the prior written authorization of the Director of the Pasteur Institute. The recipient is also informed that the virus LAV1 may constitute a potential biohazard.*

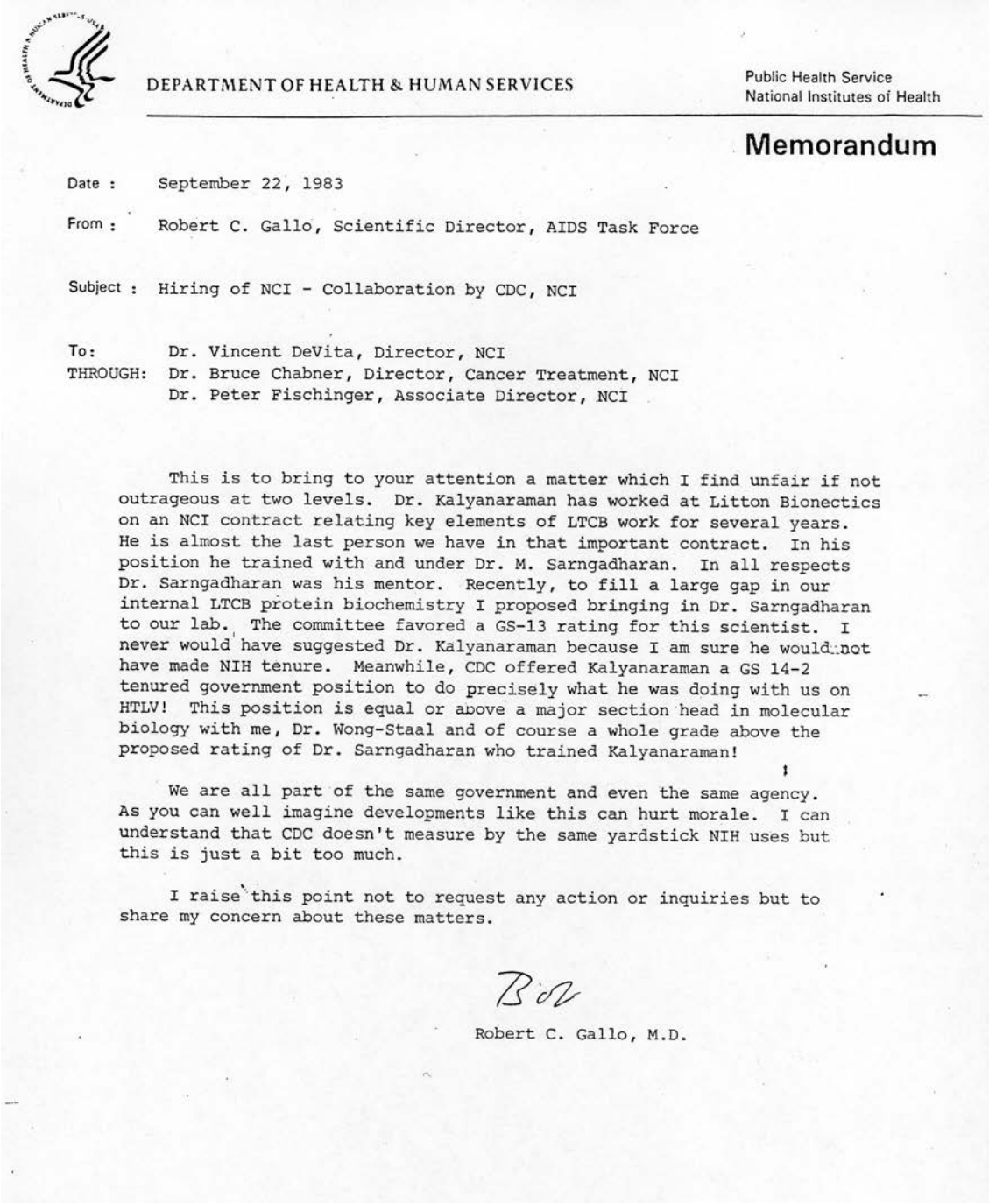
I AGREE TO ACCEPT two samples of virus LAV1 (Mkt-1B and JBB LAV) and anti-interferon sheep serum (2ml)

UNDER THE CONDITIONS LISTED ABOVE.

DATE September 23, 1983

NAME Dr. Mikulas Popovic *SIGNATURE* Mikulas Popovic

The Montagnier-Popovic signed agreement restricting the use of LAV.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date : September 22, 1983

From : Robert C. Gallo, Scientific Director, AIDS Task Force

Subject : Hiring of NCI - Collaboration by CDC, NCI

To: Dr. Vincent DeVita, Director, NCI
THROUGH: Dr. Bruce Chabner, Director, Cancer Treatment, NCI
Dr. Peter Fischinger, Associate Director, NCI

This is to bring to your attention a matter which I find unfair if not outrageous at two levels. Dr. Kalyanaraman has worked at Litton Bionectics on an NCI contract relating key elements of LTCB work for several years. He is almost the last person we have in that important contract. In his position he trained with and under Dr. M. Sarngadharan. In all respects Dr. Sarngadharan was his mentor. Recently, to fill a large gap in our internal LTCB protein biochemistry I proposed bringing in Dr. Sarngadharan to our lab. The committee favored a GS-13 rating for this scientist. I never would have suggested Dr. Kalyanaraman because I am sure he would not have made NIH tenure. Meanwhile, CDC offered Kalyanaraman a GS 14-2 tenured government position to do precisely what he was doing with us on HTLV! This position is equal or above a major section head in molecular biology with me, Dr. Wong-Staal and of course a whole grade above the proposed rating of Dr. Sarngadharan who trained Kalyanaraman!

We are all part of the same government and even the same agency. As you can well imagine developments like this can hurt morale. I can understand that CDC doesn't measure by the same yardstick NIH uses but this is just a bit too much.

I raise this point not to request any action or inquiries but to share my concern about these matters.

Bob

Robert C. Gallo, M.D.

Quoting paragraph 4 of the notarized Declaration of V. S. Kalyanaraman (dated January 8, 1992): “I joined the Centers for Disease Control at the request of Dr. Donald Francis…at that time, in my opinion, CDC was not equipped to perform research on human retroviruses. By that time I had learned through my work with the Gallo group…techniques that are needed to determine whether or not a particular retrovirus is the cause of a particular disease.” This letter illustrates the lengths the CDC reached in order to stay in the AIDS picture.

10.

1984: HOW THE BEST YEAR BECAME THE WORST YEAR

"When I was in the thick of it with Bob (Gallo) and the group down there, we had an important mission. And that was to find out what's causing this disease. And there was a competition going on. Thank goodness there was a competition[70]."

In early January 1984, Popovic had cloned the H-9 cell line from the HUT-78 cell line, and another T-cell line called Ti.304, to assure cellular homogeneity.

January 1984: The CDC reported 3,000 cases of AIDS in the United Sates with 1,283 deaths.

In February 1984, Dr. Chermann went to NIH to give a seminar describing the French work with LAV. It is there that he first heard of the HTLV-3B isolate, but not from Gallo or his people.

By early 1984, Popovic and Read-Connole successfully transmitted several additional virus isolates to cell lines. Francis and others at the CDC began claiming HTLV-2 as the cause of AIDS in a preprint sent around to other scientists. It was quickly retracted to avoid embarrassment.

Meantime, all attempts in Gallo's lab to infect the HUT-78 cell line with the original French LAV-BRU virus, failed. Between late January and early February 1984, Gallo revealed to the Director of NIH, to the Director of the NCI, and to Dr. James Curran, Chief of the AIDS Epidemiology Program at the CDC, that he and his group had identified the cause of AIDS. This was indeed a significant finding because it indicated that the Gallo isolates HTLV-3B and HTLV-3RF (as well as others, such as HTLV-3MN, that were already shown to differ from one another) also differed from the French LAV-BRU virus. Popovic began to grow routinely HTLV-3B in the H-9 cell line. While this was going on, scientists for the National Institute of Allergy and Infectious Diseases (NIAID), led by their Associate Director (the late Ken Sell), announced that a new fungus was the cause of AIDS. This should illustrate to you, the reader, that even after almost a year from the 1983 Montagnier paper, how stubborn the scientific world was to accept that a new retrovirus might be the cause of AIDS[71].

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[70] Dr. Mark Kaplan, telephone interview on October 14, 2002, 6:19pm PST.

[71] On the flip-side, HTLV-3 began being named as the cause of other mysterious ailments. On June 5, 1984, Gallo wrote a response to a woman in Dublin, Ireland who needed to know if a retrovirus was the cause of her psoriasis.

Going back to February 1984, Gallo and the various Directors, decided to keep mum on finding -and proving- the cause of AIDS until all the scientific papers could be written and submitted for publication. U.S. Secretary of Health, Margaret Heckler was herself kept out of the loop and was not aware of the discovery.

By March 1984, Gallo's group streamlined virus production. Large amounts of well characterized virus (isolates HTLV-3B, -3RF, and -3MN) were produced in the H-9 cell culture. The proteins in the envelope and core of the virus, responsible for provoking antibody response, were identified, and specific reagents for their detection were developed. Using the H-9 cell line and the HTLV-3B virus, a prototype screening test (or ELISA) and a prototype confirmatory test[72] (called the Western Blot[73]) were developed by Sarngadharan.

Still in the dark, and very indicative of how far behind the CDC was, Francis wrote to his Director (March 2, 1984): "Retroviruses are associated with AIDS but no etiologic link has been established," then goes on with an untrue and most baffling statement, "CDC has played a major role in making the association of retroviruses with AIDS…" but was quick to add, "a major statement of the nature CDC scientists associate retrovirus with AIDS would be viewed as upstaging our collaborators and would seriously hurt future collaboration…" The last, written solely to prevent attacks from offended collaborators.

Later in March 1984, Dr. James Curran from the CDC, Gallo, and Sarngadharan got together[74] at La Miche restaurant in Bethesda to check the performance of the AIDS blood test against the CDC reference blind blood panel. Curran had the panel list with the answer key and gave Gallo and Sarngadharan each a copy of the list without the key. Gallo called out a sample number, Sarngadharan called out the test result, and Curran marked that result (see page 78). Then Curran broke open the answer code and calculated the reliability of the test to about 88%. He then remarked, "Bob, you guys have a good test." Back at the CDC, Curran will announce that, "it's all done and finished with."

Sarngadharan: *"We knew our own internal panel worked well. It is just validation to the outside world with an impartial panel."* But there was no public announcement made in Gallo's lab of their accomplishment in devising an assay for AIDS virus detection. A decision later much resented by the others in the lab. But the reason for secrecy, rather than a celebration was so that Sarngadharan, Popovic, and Gallo could write their scientific papers for journal publication. Also, no one in the know wanted to risk a leak getting outside the lab before they could get their papers to print. Eventually, the entire lab was notified of the achievement before those papers ever got published.

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[72] A confirmatory test was and still is needed because ELISA is fined-tuned to preclude false negatives, at the expense of false positive results, which are correspondingly increased.

[73] Jörge Schüpbach working with Sarngadharan in Gallo's lab, first thought of using the Western Blot as a backup to the ELISA and developed a workable prototype. In 1985, Tony Kontaratos, who at the time was an executive at Biotech Research Laboratories (partly owned by Bob Ting), led the research team that first standardized the Western Blot, developed it as a clinical kit, got it approved by the FDA in April 1987, and commercialized it world-wide.

[74] This was the second time these men tried to get together. The first time, the meeting was to take place inside Gallo's office at NIH. But there was such a severe winter snow storm, that Sarngadharan (only three miles away at the time) got stranded on the road, trying to get to the meeting. After two hours of trying to drive and getting just a half mile, he eventually pulled into the nearby Pooks Hill Marriott, and waited out the storm. Curran likewise, never made it.

Before that however, back at the lab, Sarngadharan started balancing the sensitivity of the test with its specificity. Using the Western Blot as his reference system, he skewed the assay to assure no false negatives. Doing this meant that in order to get zero false negatives, you allow for more false positives. This was a desired trade off because even with those higher instances of false positives, the much more expensive Western Blot was used later to eliminate them (cost is why it's a second line of testing, and not the primary). The ultimate, most realistic goal was to achieve zero false negatives. But that has yet to be achieved, even in 2006. Dr. Sarngadharan: *"Theoretically, that's what the FDA wants. To get the highest sensitivity means pick all positives, (as) positive; and minimize all negatives becoming positive. You want a high specificity*[75] *means you don't pick up false positives. And you want a high sensitivity which means you don't get false negatives. This is the ideal. That means 100% sensitivity and 100% specificity is always your goal."*

When asked about present day standards for the blood test, Sarngadharan adds at this time, *"You get 99.8% positive sensitivity, and better than 99-plus% specificity. But (when) you are talking about 1985, the first generation Abbott (test), had a lot of false positives. (But) it's okay, because it is being confirmed (by the Western Blot)."* Bottom line, it was better to be suspected you were infected with AIDS, and let the Western Blot[76] say different, rather than be told your blood test came up negative for AIDS, and allow you to live your life without correct knowledge of your condition. Within three months, Sarngadharan's skewed assay would become the acknowledged "gold standard" of clinical serology. This was a major breakthrough in that workable methods for meaningful, wide scale sero-epidemiologic testing were developed for the first time ever; and then applied to protect the nations' blood supply.

"I recall that, while I was in France with (the) Pasteur (Group) in April-May, 1984, I became aware of an announcement by the U.S. Department of Health and Human Services that the Gallo group had positively identified the cause of AIDS as the HTLV-3 virus. This confirmed a statement earlier made in mid-March, 1984 by Dr. Curran, Director of the CDC AIDS program, to me and to others of CDC upon his return from a meeting with Dr. Gallo where the results obtained by the Gallo group using HTLV-3 in tests on a CDC AIDS panel of sera, tested on a blind basis, were reviewed with Dr. Curran. Dr. Curran specifically indicated to us at that time that the Gallo group had determined the cause of AIDS[77]."

Wide scale serological testing of the general population was conducted for antibodies to the HTLV-3 virus in three target groups: symptomatic AIDS patients, people at high-risk and, presumably healthy individuals (the control group). Results confirmed the widespread presence of the HTLV-3 virus in AIDS patients, the

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[75] Specificity refers to the rate of false positive results. Using an ELISA with 98.5% specificity as an example, simply means that 98.5% of all negative test samples are correctly diagnosed as negative, and that 1.5% of the tests produced positive results when antibodies were not present. That is a false positive.

[76] The CDC has set specific guidelines with regards to the interpretation of results when a Western Blot is preformed. Specifically, it involves the reading of several bands of reactivity that appear on a test strip. To be considered positive, reactivity to certain bands must occur. When reactivity does occur, but not to the specific bands required for a positive reading, that test result is labelled indeterminate; and the result is inconclusive. When a test reads as indeterminate, a new blood sample is required. In California for example, that second test is required by law.

[77] Paragraph 10, from the notarized Declaration of V. S. Kalyanaraman, dated January 8, 1992.

opportunistic presence of the virus in the high risk categories, and no virus presence in the healthy controls. Further confirmation came as the Gallo team found in parallel experiments, HTLV-3 viruses in the blood of numerous AIDS patients that had tested positive. This was yet another major leap forward in that the causal link between HTLV-3 and AIDS was firmly established for the first time ever on the basis of wide scale serological screening of the general population. The link of HTLV-3 to AIDS had been conclusively established.

The work of Gallo and his colleagues was described in four landmark papers submitted to Science on March 10, 1984 and published on May 4, of the same year. They were:

- Detection, Isolation, And Continuous Production Of Cytopathic Retroviruses (HTLV-III) From Patients With AIDS And Pre-AIDS, by Mikulas Popovic, et. al.
- Frequent Detection And Isolation Of Cytopathic Retroviruses (HTLV-III) From Patients With AIDS And At Risk For AIDS, by Robert C. Gallo, et. al.
- Serological Analysis Of A Subgroup Of Human T-Lymphotropic Retroviruses (HTLV-III) Associated With AIDS, by Jörge Schüpbach, et. al.
- Antibodies Reactive With Human T-Lymphotropic Retroviruses (HTLV-III) In The Serum Of Patients With AIDS, by M.G. Sarngadharan, et. al.

A fifth paper[78] was submitted to Lancet and published in June 1984 with even more strikingly accurate blood testing (100% of AIDS patients scored positive). These five papers together revolutionized the field of AIDS research. Meantime, the French still could not propagate their LAV virus in a cell line and even their serological testing was still inconclusive in proving that LAV was the cause of AIDS.

Gallo informed Montagnier of his latest results. Montagnier then asks if Gallo had compared HTLV-3 with LAV and gets a negative answer as to any detailed molecular comparison; because Popovic did not have enough LAV on hand to make the comparison. Why? He did not produce enough of it at that point because his efforts were put into growing the various HTLV-3 isolates. Plus, it was Gallo's previous understanding, *"that detailed comparisons should be done jointly in a collaborative work."* And Gallo had been waiting for that to happen from October 1983 (see page 52). According to Montagnier, during that conversation, Gallo was abrupt with him on that subject. Regardless, they agreed that any comparison would be done together…and published together.

At about that same time, Montagnier, by his own account, identified a tumor cell line derived from B-lymphocytes that was producing the LAV virus. Plus, only after the Americans published in May 1984, he reported that his ELISA blood test was performing as good as the American one. However, neither of these claims later proved to be correct. Indeed, according to published data (from all of 1984 thru early 1985) by the French themselves, their LAV-based AIDS blood test could not perform better than 37.5% in detecting patients with frank disease. More importantly, no one today has ever shown (or even speculates) that the AIDS virus can infect B-lymphocytes, let alone suggest that B-lymphocytes could become a source of large-scale virus production. Dr. Phil Markham: *"As far as we know, they never did have it in a B-cell line."* Dr. Marvin Reitz

[78] B. Safai et al., Lancet, p. 1438 (1984).

commenting on growing AIDS virus with B-lymphocytes: *"No. It doesn't have CD-4*[79]*. How are you going to do it? It certainly doesn't produce."*

One month after the four articles to Science were submitted in March of 1984, the French submitted an article which was accepted for publication on April 11. In that article[80], the French remain perplexed as to whether or not their new retrovirus is the cause of AIDS. They write (on page 512 of that publication), "Currently it is not yet known whether this syndrome that some have called an AIDS related symptom complex, which occurs among the same high risk populations, is related to AIDS either as a precursor and/or as a milder form, or even whether it shared the same causative agent." This meant that even as late as one month prior to the four Science papers (by Gallo's group) coming out, the French remained significantly uncertain. They further say in the same paper, the immune anomalies "may reflect the high prevalence within the homosexual population of a putative aetiological agent for AIDS which disputes in vitro immunological parameters of otherwise asymptomatic individuals. However, the absence of any of these immunologic abnormalities in another high risk groups…would argue against this hypothesis." With that, the French questioned whether or not LAV was the cause of AIDS. What is most odd is that in all the media coverage about every little detail of those days, no one ever pointed this out.

In April 1984, Gallo was instructed by NIH officials and DHHS lawyers to file for U.S. patent rights for his AIDS blood test and for his method of growing the AIDS virus[81]. It was the first time any scientist at NIH was named in a patent application[82]. The Government's intent here was to control the manufacturing of the AIDS blood test by imposing specific quality criteria. Abbott Laboratories was later awarded a federal contract to mass produce the Gallo blood test for global use because it met those criteria. Dr. Gallo adds: *"Dr. Lowell Harmison was the head of technology transfer – he's the one who got me the patent. You might say he's the one who brought me this curse, but he was doing it so the blood test would go forward and was very proud of America's role. He was responsible and key in getting this (blood test) out to the companies."* A total of five companies got the same contract.

Gallo then flew to Paris and informed the French of his latest findings, and of his intention to publish them in Science by mid-year. Suggesting that after his results were published, he and Montagnier make a joint statement on the state of AIDS research, and on the relationships and variability of the various virus isolates on both sides of the Atlantic, by jointly publishing papers comparing their respective viruses. This suggestion was well received by the French, so Gallo and Montagnier agreed to compare their various virus isolates.

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[79] CD-4 is one of the key cell surface proteins on the subset of the lymphocytes infected by HIV. In fact, HIV uses this molecule at the beginning of its infectious process to help enter the cell.

[80] Critical analysis of T cell subset and function evaluation in patients with persistent generalized lymphadenopathy in groups at risk for AIDS, Clinical Experimental Immunology, (1984), vol. 57, p. 511-519.

[81] At the time, no one involved in the decision regarding the U.S. patent was even aware that the French had filed their patent application previously. That would not become known until 1985.

[82] In fact, Gallo was the driving force behind almost 80 separate patents filed by the NIH (between 1984 to late 1995) from work and discoveries made within his own lab.

While still in Paris with Montagnier, Gallo also met with Francis from the CDC who had brought with him the results of the French and the American blood tests. Gallo, however, was never given the opportunity to review the French results for an informed opinion. Rather he was only allowed to look at the results *"quickly and casually."* Nor was he allowed a copy. He comments that from the little he was able to see, the cut-off level was set too low for the blood tests to be effective. In other words, it was set so samples would be more easily called positive, but to do this, it would first allow for much too many false positives. More from Gallo: *"Let me tell you I was never allowed to review the data. I saw the data over the shoulders of two people. I don't believe it, okay. I never saw data that's better than ours. I never was allowed to hold it and study it. And why not if it was better? Moreover, why wasn't it published?"*

Gallo disclosed for a broadcast by the BBC, his latest breakthroughs on AIDS to Martin Redfearn, a British freelancer who promised to hold the story[83] until the forthcoming papers were published within two months time. New Scientist[84] got hold of the Gallo disclosure[85] and ran the story immediately, reporting on the discovery of the causation of AIDS and, on the development of an AIDS blood test. The story took health officials in Washington by surprise and Secretary of Health, Margaret Heckler, decided to schedule a press conference on Monday, April 23, to announce the discovery of the AIDS virus by the Gallo group, even though the supporting evidence for this claim was still at least about a month away from being published. Gallo informed the French of this unexpected development where Montagnier asked him to make sure and give credit to the work done by the French on AIDS at the press conference.

On April 20, 1984, CDC scientists, including Francis, alerted the Department of HHS that the French were the first to discover the cause of AIDS. But they were in fact, mistakenly equating virus detection, and temporary culture isolation with proof of disease causation.

On Sunday, April 22, 1984, the New York Times carried an article by Larry Altman, a former CDC staff member and friend of Francis, which also erroneously stated that scientists at the Institut Pasteur had been the ones to find the cause of AIDS. It is important to point out here that the French themselves never made, and could not have made such claim, simply because they had not yet established the linkage of LAV to AIDS. The article, prompted by Don Francis, oddly omits all the achievements in Gallo's lab entirely. Unlike misstatements perpetuated by critics (especially by a journalist named Crewdson as you will later read about), Gallo never claimed to be the first to find the new retrovirus. He and co-workers, on the other hand, were first to have established this retrovirus as the cause of AIDS and had developed a life-saving blood test for it.

On Monday, April 23, 1984, Gallo and Sarngadharan signed the patent application for the AIDS blood test at the Department of Health (Popovic had earlier done so in the attorney's office as he was leaving for a conference in Miami). Following the signing, Secretary Heckler's press conference was held and Gallo announced (under the shadow of the Times article which certainly assured an intense conflict) that the cause of AIDS was a new retrovirus, that all isolates of the new virus on both sides of the

[83] See page 80 for Gallo's reaction to this event.
[84] A newsletter that reported on scientific developments.
[85] According to sources, a friend of Don Francis, Dr. Donald Abrams of San Francisco was the one who leaked the story.

Atlantic are very likely of the same type, and that a blood test had been developed to protect the nation's blood supply. Both Secretary Heckler and Gallo also explained the contributions of the French and the American teams, gave due credit to the French, and outlined plans for further collaboration between the two labs. As Gallo stated at the time, "The laboratory at the Institut Pasteur and my laboratory have been friends for about 15 years….(and) have active collaboration….If what they identified in Science a year ago is the same as what we have now produced ….I will certainly say so, and I will say so with them in collaboration….We think the two laboratories are very likely to come together, although I can not say at this point whether the viruses are identical."

What was most unfortunate however, was that Secretary Heckler, who was suffering from a severe cold, lost her voice in the midst of her presentation, before she could audibly give credit to the Pasteur team. She did however release a summary of her talk, which did include the French contribution. That summary states very clearly: "I especially want to cite the efforts of the Institut Pasteur in France, which has, in part, been working in collaboration with the National Cancer Institute. They have previously identified a virus which they have linked to AIDS patients, and within the next few weeks we will know with certainty whether that virus is the same one identified through NCI's work. We believe it will prove to be the same."

Yet the French did not have the benefit of reading that summary. They were instead watching the press conference live, huddled around the television set…and Heckler's voice gave out. They couldn't believe Heckler did not say more, and very soon, a friend sent them a transcript of the oral portion of that press conference. In their view, acknowledgement of the French contribution was minimal at best; from Heckler and from Gallo. Dr. J.C. Chermann, involved from the start with the Institut Pasteur had this to say: *"You know, I think he (Gallo) was pushed by the American Administration to say that."*

But in the Q & A which immediately followed, and in response to a reporter's question on HTLV, Gallo quickly responded with, "Please do not call the virus HTLV; this would confuse the new virus with the leukemia causing viruses. We call it the third human T-lymphotropic virus; HTLV-3. But since it will probably be closely related to the virus called LAV, previously isolated by the French group, it would be best if you called it for now HTLV-3/LAV." This public statement made to a mass of reporters goes a long way to show, in of itself, that Gallo did not claim to be first to isolate, rather he correctly did claim that the, "work of my group was best."

With the flood of publicity, in immense headline coverage, the Institut Pasteur scientists were justifiably disturbed that credit for them was, at least in the public view, minor. In turn, all those headlines preempted that joint press conference scheduled by Gallo and Montagnier for June, while Gallo himself, largely unknown to the public until then, becomes an instant celebrity.

Nevertheless, negative statements about Gallo follow from first, the French reporters and then Pasteur Officials (but not from Montagnier himself), which provoked Gallo to respond, "Why?" Because up to that time, no one had ever said anything bad about him professionally before, or attacked his integrity as a scientist. So Gallo made counter-statements, the French made counter-counter-statements, and the confrontational snowball started rolling…downhill fast. It is worth noting that Gallo himself never held any press conference regarding any of his work and discoveries before then. In fact, even up to 2006, he has never himself called a press conference.

Wasting no time, on the very day of the press conference, The American Association of Physicians for Human Rights, fires off a letter to the Assistant Secretary of Health (E. Brandt) asking many questions that physicians would have to soon confront from a very frightened public: "Will subjects be told of their test results? Will they want to know if the test is positive? Are we, as practicing physicians required to tell them? If the test is positive, does that mean the individual is immune, is going to develop AIDS, or is a carrier, either infectious or non-infectious?" There were still many more questions not listed here, proving it was obvious the doctors of the day still knew little more about this disease than their patients who had it.

Author's Note - there is an intentional gap of some events for April and May as they warrant an entire chapter; to be found on page 92.

Thursday, May 3, 1984, the DHHS advertised a task/goal to the global medical community in their Request For Applications To Produce A Virus And An Assay System For The Detection Of Antibodies To The Virus Associated With Acquired Immune Deficiency Syndrome.

On May 4, 1984, those four classic papers, considered landmarks in the field by general consensus, were published in Science by the Gallo group. He had delayed publishing his findings till then, until he had thoroughly characterized the AIDS virus and obtained a number of independent isolates. "Our work turned a guessing game into a science. As late as March 1984 there were rampant speculations on the cause of AIDS, most far away from the notion of a retrovirus cause of AIDS, even including an NIH announcement of a fungus cause of AIDS in February 1984. The publication of our May 1984 papers dramatically changed the state of the field[86]." The four papers described all the major findings up to that time on AIDS. Namely, the isolation of HTLV-3 from numerous patients, the discovery of a continuous cell line that can mass produce the virus, the sero-epidemiologic data proving HTLV-3 to be the cause of AIDS, and the availability of a reliable AIDS blood test to protect the world's blood supply. In less than a month, the test's detection ability (in the lab) would reach 100% for frank disease, and about 84% for lymphadenopathy, which is not necessarily an AIDS associated syndrome.

Also in May, in a transatlantic broadcast, Gallo was interviewed and said publicly that his HTLV-3B and the French LAV virus isolates were, "very probably identical."

By mid 1984, the AIDS virus was molecularly cloned with success by the Gallo group in certain bacteria that made multiple copies of the viral genome.

Meanwhile, the French, who still had problems growing their AIDS virus in large enough quantities, turned to a British group for help. The British research group, headed by Robin Weiss, successfully developed a way to grow the French virus, using a T-cell line derived from leukemic cells. This was most curious and inexplicable since the original LAV-BRU did not grow in culture, as all previous attempts from both sides of the Atlantic had shown[87]. Popovic was suspicious of that result *"because the earlier LAV-BRU completely failed to grow in cell line cultures[88]."* But was this achievement

[86] Quote from Gallo himself, during his opening statement before the Richards Committee, April 7, 1990.
[87] Popovic had momentary success with the third shipment of LAV-BRU but had not continued the culture in order to concentrate on his own isolates and those from other members of the Gallo group (especially Phil Markham). This information was never conveyed to either Robin Weiss or Luc Montagnier at that time.
[88] This will become a key issue which is thoroughly examined, beginning on page 169.

based on, or helped by the technology transferred from Gallo's lab via cultures left behind at the Pasteur by Sarngadharan[89]? Yes, it does seem more likely than not. Desperate to produce their virus, Institut Pasteur officials informally promised, in writing, to share the credit and the potential royalties of the French blood test with their British colleagues. Montagnier to R.A. Weiss (June 15, 1984): "…potential use for medical and industrial applications and the Institut Pasteur Foundation will be interested for its application to AIDS and related diseases and to share the property with you and your Institute." Years later, however, there still was no formal agreement signed between the French and the British, regarding the British contribution or, the British share of royalties. So…the British got nothing. Montagnier later claimed that the culture he received from Weiss was contaminated, and that he had to redo the entire process himself.

In June 1984, George Todaro from Genetic Systems (the licensed manufacturing contractor of the French blood test in the U.S.) visited Gallo and threatened[90] to show that, "Gallo has Montagnier's virus." Those words, and the French's feelings of distaste over not getting proper acknowledgement, are the two electrodes that zap the beginnings a controversy to open wide its eyes.

June 1984: The CDC reported 4,918 cases of AIDS in the United States with 2,221 deaths.

In July 1984, a joint study from the Pasteur Institute and CDC, reported positive antibody tests in sera from 41% of AIDS patients.

In the summer of 1984, Gallo received from Montagnier a third shipment of LAV viruses. By late 1984, the genome of the LAV virus was fully sequenced by Simon Wain-Hobson of the Institut Pasteur, and independently by the Gallo team. It was found to consist of 9,749 nucleotides. But the Gallo team did not stop with that, and it is important to be reminded, that they in fact had also carried out molecular analysis of several other isolates of HTLV-3 (including -3B from other AIDS patients) and obtained genetic sequence data on several others still.

Moreover, the separate viral genes of various isolates were thoroughly identified and a number of their functions were determined by the Gallo group. Beatrice Hahn and Flossie Wong-Staal discovered that the genetic heterogeneity from isolate to isolate is significant. Yet, the two viruses, the French LAV and the American isolate HTLV-3B, were almost genetically identical[91], differing by about 1%.

In July 1984, Gallo informed Montagnier of this odd finding, because it could mean that LAV and HTLV-3B are actually one and the same isolate, due to an accidental contamination in one of the two labs. That small difference might be due to different micro-variants from the virus population being selected in cell culture.

Accidental lab contaminants of a virus going into a cell culture was a not an uncommon phenomenon; although much was made of it in this instance to hurt Gallo, and to win arguments over patent rights on the blood test. Yet the issue of contamination will end with extraordinary irony and is further explained in Chapter 20.

By Gallo's account, Montagnier first responded rather indifferently to the whole issue of contamination. Conversely, Montagnier, by his own account, leapt out of his seat

[89] See Chapter 13, page 92 for a full explanation.
[90] See Chapter 16, page 126 for the details of this.
[91] Illustrating distinctly different isolates was painstakingly hard and there was room for doubt. Consider that the Gallo isolates –MN and –SL differed only by a single restrictive enzyme site.

and categorically denied that LAV could have ever been contaminated in his lab with the American virus. If there had been any contamination "it could only have happened at your end," he stated to Gallo bluntly. While Gallo says that he, *"wasn't making any implications as to where it had occurred,"* but he does agree that Montagnier said that to him. Unaware of the actual contamination facts still to come, Gallo wondered, *"Why would anyone care? What is the big deal if contamination had indeed occurred in one of the two labs?"* Gallo already had his own independent, multiple isolates of the AIDS virus which were clearly, genetically distinct from HTLV-3B, but still part of the general AIDS virus family. Also the Gallo group had the capacity to produce several of them in continuous culture. Montagnier by then, also had additional isolates beyond the early LAV. Plus, a laboratory contamination was a credible consideration, when you take into account the scores of cell cultures that were maintained and handled simultaneously in those labs.

Montagnier begins to wonder now whether HTLV-3 was not merely just another name for LAV. A growing skepticism began to develop between Gallo and Montagnier; their main contention being the classification and naming of the AIDS virus. Gallo was criticized by Montagnier for not using the name, LAV. But at that time, Gallo's thinking on this issue was several-fold: (1) until the comparisons were properly made, Gallo was still unsure that the several isolates his group had obtained by late 1983 were of the same precise retrovirus type, let alone identical; (2) the continued failure of the French to grow their LAV made Gallo suspect fundamental differences between the LAV virus and the several virus isolates his group had obtained and; (3) Gallo and Popovic suspected that the growth of one French sample sent to Popovic by Montagnier, might have been due to an accidental contamination by one of the cultures from AIDS samples handled by Popovic. This possibility was enhanced by the French failure to grow LAV in a cell line[92], and by similar failures from Popovic to grow those first samples of LAV sent to him by Montagnier.

Gallo was perplexed because he had told Montagnier that he had already published and made available other independent isolates also growing in cell lines, but apparently the point was not taken. According to the understanding at that time:

- ✓ LAV was a new virus from both the French and the American perspectives;
- ✓ HTLV-3 (the generic name used by the Gallo group for all of their isolates of the AIDS virus), was a novel virus from the American perspective; but one which fell into the context of the HTLV family -or a mutant- from the French perspective, (misinterpreting the American position on HTLV-1 reached by September 1983 that excluded HTLV-1 or any variant, or mutant as the cause of AIDS);
- ✓ HTLV-3B (one of the Gallo group's specific isolates and the first one used for the blood test) was practically identical to LAV from the American perspective; and
- ✓ HTLV-3 was practically identical to LAV from the French perspective, but not from the American perspective simply because HTLV-3 can be any one of a number of different isolates the Americans had made (e.g. -B, -RF, -MN, etc). And -3B was one of those too.

This truly tangled interpretation of virus similarities prompted the French to think that all Gallo had was just one virus, that might well be LAV. Which made them ask, why would the Americans keep calling the AIDS virus HTLV-3, rather than LAV? But

[92] In that sense, the French never really had an isolate that could be continuously maintained in culture.

out of the numerous HTLV-3 isolates obtained by the Gallo group, the fact remains that it is only the HTLV-3B isolate, which is practically identical to LAV. Later, we will examine the paradox in all of this.

It should also be mentioned in August 1984, the Institut Pasteur and Don Francis of the CDC began correspondence to once again change the name of the French isolate to HRV (which stands for Human Retrovirus). With suggestions for prototype isolate identification as either HRV/LAV/BRU or HRV/LAV/CDC-151; thereby brushing aside Gallo's HTLV-3B isolate designation and replacing it with the CDC's own. This plot was abandoned four months later, when on December 10, 1984, Francis in a memo wrote, "We need not enter the conflict of naming. NCI and Institut Pasteur will hopefully arrive at a compromise. In the meantime, it is important that we remain neutral and continue to use the HTLV-III/LAV of LAV/HTLV-III terminology."

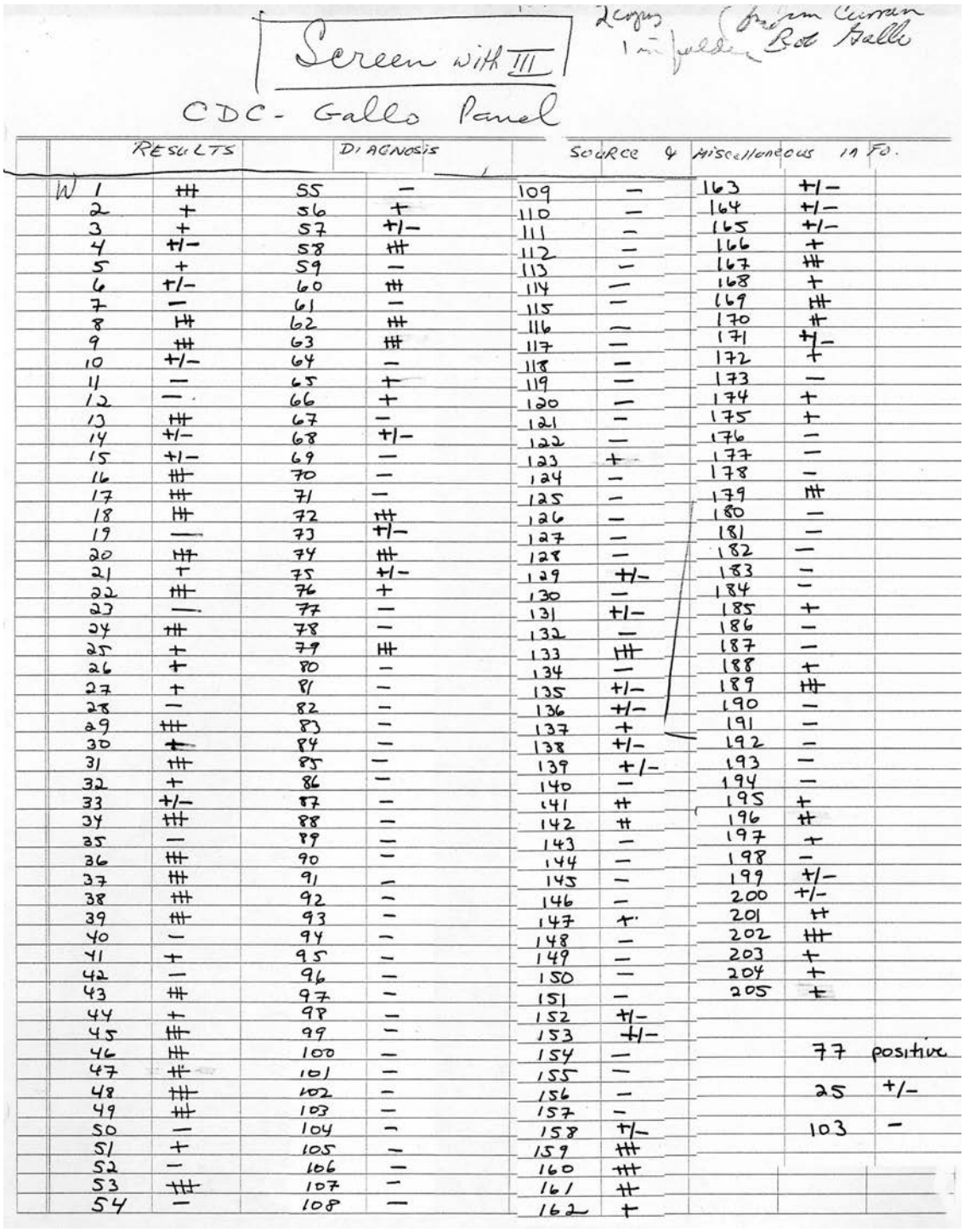
Also in that month, is when Gallo first hears, then confirms that the CDC is in collaboration with the French, even after his friend, Dr. Chermann, assured him otherwise. That the CDC also had the French LAV virus made it all worse.

In September 1984, at a virus meeting in Leriche, Italy, Dr. J.C. Chermann publicly admitted that the French initiated their experiments in January 1983, and got the idea from Dr. Gallo to look for a retrovirus.

November 1984: The CDC reported 6,993 cases of AIDS in the United States with 3,342 deaths.

In December 1984, Wain-Hobson from the Institut Pasteur, formally presented to scientists at NIH that first gene map of the French virus.

On December 11, 1984, Gallo's lab initiated a 14 day experiment to study whether a given AIDS virus isolate changed during passage into different human cells. At its conclusion, they found two viral variants present in the LAV virus stock received from Montagnier in late April, 1984. Something was wrong.



Screen with III

CDC - Gallo Panel

2 cops from Curran
1 in folder Bob Gallo

	RESULTS	DIAGNOSIS		SOURCE #	MISCELLANEOUS INFO.	
W 1	+++	55	−	109	−	163	+/−
2	+	56	+	110	−	164	+/−
3	+	57	+/−	111	−	165	+/−
4	+/−	58	+++	112	−	166	+
5	+	59	−	113	−	167	+++
6	+/−	60	+++	114	−	168	+
7	−	61	−	115	−	169	+++
8	+++	62	+++	116	−	170	++
9	+++	63	+++	117	−	171	+/−
10	+/−	64	−	118	−	172	+
11	−	65	+	119	−	173	−
12	−	66	+	120	−	174	+
13	+++	67	−	121	−	175	+
14	+/−	68	+/−	122	−	176	−
15	+/−	69	−	123	+	177	−
16	+++	70	−	124	−	178	−
17	+++	71	−	125	−	179	+++
18	+++	72	+++	126	−	180	−
19	−	73	+/−	127	−	181	−
20	+++	74	+++	128	−	182	−
21	+	75	+/−	129	+/−	183	−
22	+++	76	+	130	−	184	−
23	−	77	−	131	+/−	185	+
24	+++	78	−	132	−	186	−
25	+	79	+++	133	+++	187	−
26	+	80	−	134	−	188	+
27	+	81	−	135	+/−	189	+++
28	−	82	−	136	+/−	190	−
29	+++	83	−	137	+	191	−
30	+	84	−	138	+/−	192	−
31	+++	85	−	139	+/−	193	−
32	+	86	−	140	−	194	−
33	+/−	87	−	141	++	195	+
34	+++	88	−	142	++	196	++
35	−	89	−	143	−	197	+
36	+++	90	−	144	−	198	−
37	+++	91	−	145	−	199	+/−
38	+++	92	−	146	−	200	+/−
39	+++	93	−	147	+	201	++
40	−	94	−	148	−	202	+++
41	+	95	−	149	−	203	+
42	−	96	−	150	−	204	+
43	+++	97	−	151	−	205	+
44	+	98	−	152	+/−		
45	+++	99	−	153	+/−		
46	+++	100	−	154	−	77	positive
47	+++	101	−	155	−		
48	+++	102	−	156	−	25	+/−
49	+++	103	−	157	−		
50	−	104	−	158	+/−	103	−
51	+	105	−	159	+++		
52	−	106	−	160	+++		
53	+++	107	−	161	++		
54	−	108	−	162	+		

A composite scan of the 4 page checklist Curran himself marked off. With these 205 results against Gallo's new assay to detect the AIDS virus, the global blood supply is about to be saved. The 25+/- result you see in the lower right were called as positive, but since the assay was set-up to avoid false positives with conservative scoring criteria, Sarngadharan wasn't sure he set the levels right. That was not the case. Curran confirmed those 25 blind samples were in fact what Sarngadharan thought they were…positive. Confirmed later by the Western Blot.

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute

Memorandum

Date May 2, 1984

From Associate Director, COP, DCT, NCI

Subject Discovery of HTLV-III

To Chief, Medicine Branch, COP, DCT, NCI

This week marks the formal publication by Dr. Gallo and his co-workers describing the likely etiologic agent for AIDS, HTLV-III. I would be grateful if you would use this opportunity to personally thank the doctors and nurses on your service whose commitment provided some of the critical clinical resources that made this discovery possible.

Dr. Gallo's discovery is likely to fundamentally change how we view immunodeficiency diseases and cancer. We can all take satisfaction in the level of support provided by the Medicine Branch and the Clinical Oncology Program as a whole. Moreover, I know that we all look forward to playing a role in this exceedingly important area of clinical investigation as new scientific developments dictate.

The relationship between the clinical and scientific programs of the NCI in the study of viruses in the HTLV family is an example of the intramural effort at its best.

Samuel Broder, M.D.

cc: Dr. Chabner
Dr. DeVita
Dr. Gallo

Congratulations to all as one of NCI's own is about to publish something historical for which the world has waited to gain knowledge of…the true cause of AIDS.

Building 37, R
(301) 496-6007

May 29, 1984

Mr. John Wilson
Science, Industry & Agriculture Unit
BBC External Services
P.O. Box 76
Bush House Strand
London WC2B 4PH
United Kingdom

Dear Mr. Wilson:

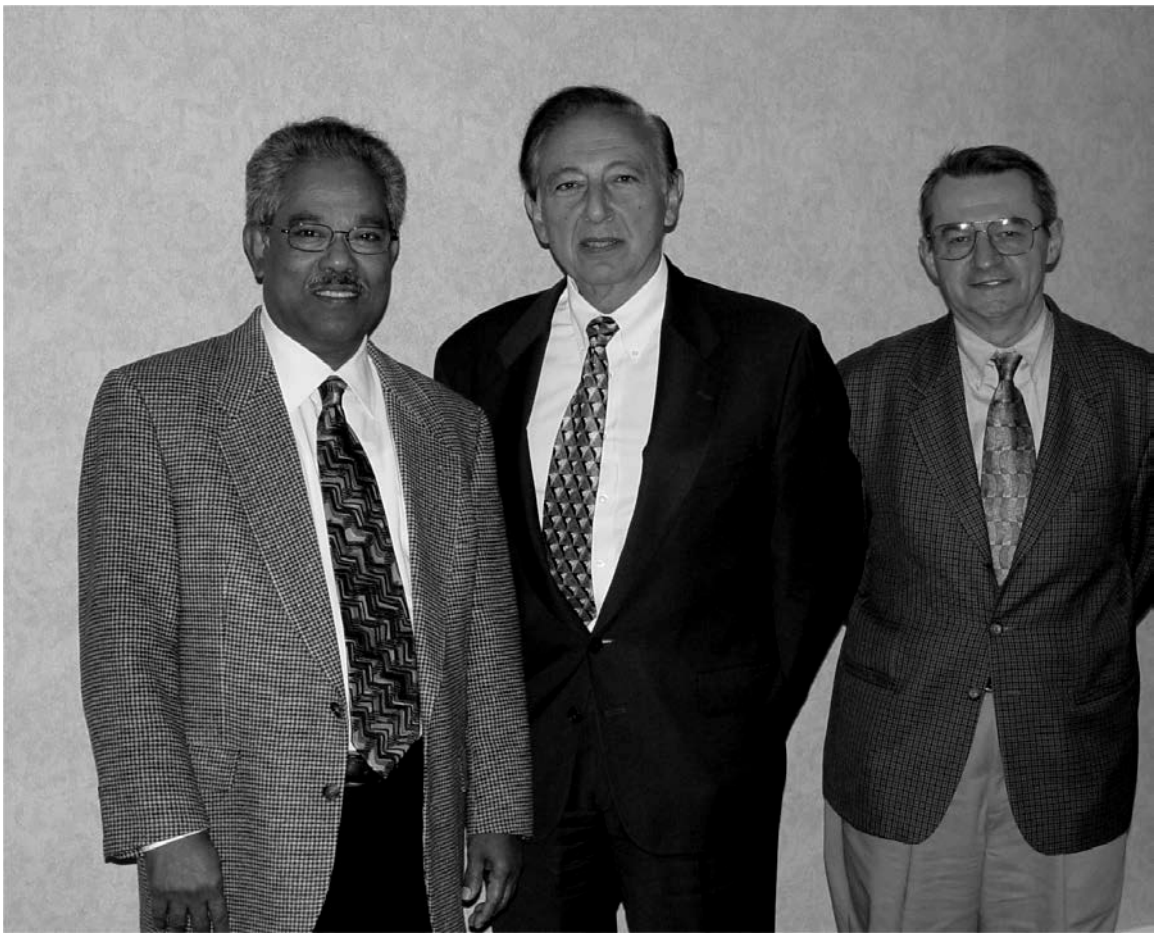
Dr. DeVita forwarded to me a copy of your letter and his response. I would like to take this opportunity to summarize the events with Martin Redfern from my perspective. I was asked to grant an interview on onc genes and HTLV to be used only for a radio broadcast. I was assured that this report would be aired after publication of our Science papers. Martin Redfern had requested material for his own educational purposes, so I included copies of the pre-prints. He at no time mentioned New Scientist nor any publication. The situation he precipitated caused many personal problems and stress for me, my co-workers, and my collaborators. Dr. DeVita may dismiss these events lightly, but I have learned to be infinitely more cautious in the future and far less trusting.

Sincerely yours,

Robert C. Gallo, M.D.
Chief, Laboratory of
Tumor Cell Biology

AHS:tas

Learning a foretelling lesson the hard way: don't trust the press!



The three men who made AIDS detection via blood testing a reality.
Left to right: Mangalasseril Sarngadharan, Robert C. Gallo, and Mikulas Popovic.
Photo taken at the Annual Meeting of the Institute of Human Virology, October 2003.

11.
THE BUSINESS OF BLOOD

In September 1983, the California State Task Force on AIDS, chaired by Marcus Conant released a report. In it, Conant was quoted as saying the risk of AIDS from a blood transfusion is negligible; "less than one in a million[93]." We all know now, just how wrong he was.

While science marched on, trying to get a handle on AIDS, so did business. But one kind of business stood to be utterly shut down. A business that no nation could do without - brokering blood. Blood banks needed plasma. Naturally, as it was quickly becoming quite evident that AIDS was likely being transmitted by blood, the blood banks, the blood brokers, all became uneasy. But until science said unequivocally, AIDS was transmissible by blood, business kept right on going even as concerns behind closed doors grew. On December 15, 1983, Janelle Lynam (Director of Donor Recruitment for the Irwin Memorial Blood Bank) sent a memo to its Director, Herb Perkins. Which stated, "If we implement surrogate[94] testing, we would eliminate 7.3% of our donor population, according to your calculation. Based on a net draw of 120,000 this would eliminate 8,760 of our donors. This would impact drastically on donor recruitment." In fact, how AIDS would affect their industry was a common concern among all blood banks. Epidemic was a word no one wanted to use in those days; however unavoidably numbered they were.

Government was business too. And blood banks worked with them, albeit they proved to be more leisurely than anything else. In a taped interview[95] years later, Dr. Perkins admitted, "at the January 4, 1983, meeting, there was the suggestion for investigating surrogate tests. September of 1983, nine months later, the NIH said, "We'd like to offer some money for this purpose." The money was given in May of 1984,

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[93] Consensus Conclusion and Recommendations of the California State Task Force on AIDS, September 1983.

[94] In 1983, CDC scientists recommended blood collection agencies ask donors about their sexual behaviour and perform "surrogate tests." Surrogate testing seeks to detect something in the blood that is associated with AIDS. For example, one study had found that 88% of people with AIDS had antibodies to the so-called Hepatitis B core antigen. Thus, scientists proposed that testing for these antibodies would be a useful surrogate test to exclude some AIDS-infected donors.

[95] Herbert A. Perkins, M.D., " Director, Irwin Memorial Blood Bank: Transfusion AIDS and the Safety of the Nation's Blood Supply", an oral history conducted between June 11 and July 14, 1993 by Sally Smith Hughes, Ph.D., in The AIDS Epidemic in San Francisco: The Medical Response, 1981-1984, Volume V, Regional Oral History Office, the Bancroft Library, University of California, Berkeley, 1997.

seventeen months later. That's slow. But once it got rolling, we did get funded. But yes, I have to say sure, the American public was concerned disproportionately about transfusion AIDS because it could happen to them, and much less about AIDS among the gays. There's no question about that. The gays are absolutely correct when they say they were discriminated against. Had AIDS been a disease of heterosexuals, it wouldn't have taken so long to get federal funding, or funding in general. There would have been a lot more money there. I agree completely with that."

On why the process took so long, he went on to say, "Well, you see, the specific instance I cited (above) is absolutely classical federal government. That's the way it goes. The staff gets together and they talk about, "Well, maybe we should do this," and then they form an advisory committee, and then they wait for a council to meet and approve the RFA (Request for Application) that they're going to put out, and then having gotten the approval in July, it takes them two months to write it and crank it up and get the OMB (Office of Management and Budget) to approve the use of paper, and that kind of thing. If I see one more piece of paper on how this complies with the Paper Reduction Act of Congress, I shall scream."

You can not have a discussion about AIDS and blood, without talking about hemophiliacs. Tragically, they were the red flag that forewarned the coming catastrophe. In a nutshell, hemophilia is a disease in which the blood lacks one of the clotting factors, or proteins. There was a time when even a small cut could have led to massive blood loss. A method of replacing clotting proteins was developed in the 1960s. In this method you would take plasma, which is the fluid portion of blood, from thousands of individual donors, combine them, and then extract all the blood-clotting factors therein. Hemophiliacs could then infuse themselves with this Anti-Hemophilic Factor (or AHF) from the extract and thereby prevent dangerous bleeding. But, as hemophiliacs are exposed to the blood of millions of people, eventually most (about 80%) became infected with hepatitis. When hemophiliacs began getting AIDS in large numbers so quickly, it was interpreted as a sign that the disease might be transmitted through blood and blood products. By the end of 1982, with more cases of AIDS in hemophiliacs having been discovered, it was a certainty.

In 1982, Congress had given the NIH $3 million for AIDS research on this "gay plague," called at the time, GRID (Gay Related Immune Deficiency). But when the hemophiliac population, got hit so hard, so fast, it was obvious to most that they were just the stepping stone to the population-at-large. The following year, 1983, Congress quickly, and without a fight, anted up more than $21 million in research money[96]. For hemophiliacs, their affliction was their sacrifice, one which paved the way to the expedient federal funding of research. That bears mentioning here.

Across the country, blood banks were left alone to decide policy until federal mandates would force their hand. A few blood banks (like Hoag) instituted various safeguards on their own. Such as not to accepting blood from gay or bisexual men who said they were sexually active. That of course met with controversy and calls of selective persecution. With the information at the time, blood banks could have administered other

[96] On Tuesday, May 27, 2003, U.S. President George W. Bush signed a 5 year, $15 billion Global AIDS Bill into legislation. He did so while challenging the world's other wealthy nations to make similar commitments. But even though the bill itself specifies $3 billion a year in spending, Congress must still approve the actual outlays in their annual budget appropriations process.

tests, including a surrogate test (see footnote 94) for Hepatitis-B, to screen out HIV-contaminated blood. But that was too costly. Plus, there was the risk of simply destroying good, money-making blood in the process. To the people living in those times, Conant's "one in a million" seemed more like fifty-fifty.

Hospitals however began doing several tests, including the Hepatitis-B test, in 1985 to screen the blood of high-risk donors. But the Food and Drug Administration (FDA) and many of the blood banking organizations did not agree with the CDC recommendations. They instead adopted weaker sanctions. These included training personnel to recognize the symptoms of AIDS and ultimately educating the public when those members of high-risk groups should not donate blood. It wasn't until March of that same year that blood banks would begin to routinely screen for HIV antibodies.

In China, AIDS was considered only a "foreigner's disease" and that notion set the stage for a calamity. With blood-bank supplies diminishing, local Chinese governments instigated blood drives paying impoverished farmers in peasant villages for their blood donations. But entrepreneurial middleman anxious to maximize profits used needles that were not sterile. The repercussions were nothing short of full-fledged AIDS epidemics that did not become public knowledge until 1999! These many localities soon came to be known as China's AIDS villages. Central government got involved when this scandal was exposed, albeit too late to do any good as entire families, almost entire villages, died of the disease.

In the U.S., when the first generation of AIDS blood tests came (which would be used to screen the nation's blood supply), it quickly made the news. Those tests (then and now) detect antibodies to the AIDS viruses. Unfortunately, for a brief time after infection, people make too few antibodies for these tests to detect. As a result, their blood would pass all the screening tests, even though it still had the ability to transmit HIV. This period of opportunity for HIV non-detection can last until about 6 weeks. The news organizations reported that fact as well.

The first ELISA testing policies of the time would require all blood testing positive twice, for disease, be destroyed. But calibrating the test to eliminate false negatives meant a willingness to accept false positives. Sarngadharan: *"The blood banks always want to reduce the false positives, because once you have a false positive, according to the guideline, you had to throw the blood away. And that's a lot of money."* They were at issue that Western Blots[97] (not yet standardized) were not being utilized to confirm the presence of disease in their blood donations. Given that false positive test results were a by-product of the ELISA tests, they felt good blood was unavoidably being destroyed and those "healthy" donors would subsequently get blocked from giving blood. Sadly policy, also said if the blood bank discovered a donor had tested positive, they could not reveal that information to the individual. All this was later corrected and standardized when Western Blots became available for commercial use.

Gallo: *"Undoubtedly the people thought we were giving them a tattoo. So at the beginning the gay activists did not appreciate the blood test. I was dumfounded, I didn't understand. Not until later did I understand. That we had no therapy for them. All we were doing was letting the world know they were positive. So they were sensitized by that.*

[97] Originally a research method, the Western blot was remodelled into a diagnostic confirmatory testing tool early in the HIV epidemic. It is rarely remembered today by its original name, EIBT, an acronym for Enzyme-linked Immunoelectrotransfer Blot Technique.

But they didn't also understand that that test allows the epidemic to be followed and is necessary. That test saves the blood supply and that test is the same culture system that enabled the drugs to be tested. AZT was done in that system, in Marv Reitz's lab, by Sam Broder and his people. That was the beginning of AZT; which in turn was the beginning of all primary therapy for AIDS patients."

From March 1985 to January 4, 1988, the FDA only recommended the use of the blood test to the blood banks. It did not require all donated blood be tested until January 5, 1988; three years after the first test to detect AIDS in blood became available. After 60% of America's 20,000 hemophiliacs - 12,000 people - had been infected through contaminated blood-clotting medicine.

But the damage was done by then. Blood donations did drop. Going to the hospital was a frightening ordeal of uncertainty. If one knew they were going to have an operation, they would plan to donate their own blood (or that of family members) and have it frozen for their own use. Anything that could be done to ensure they didn't get the blood of some stranger, was done. The panic was alarming, as patients would deny life saving operations, even in emergency trauma situations, in order to keep donor blood out of their bodies. The hysteria was warranted.

Blood product	What is it?	Its use in transfusions
Whole blood	Blood as it exists in the body. Consists primarily of (red, white, and platelet) cells and plasma	Used in cases of massive blood loss (more than 25% of the body's total volume); usually broken down into components
Red blood cells	Blood cells that carry oxygen	To treat anemia; provide oxygen to tissues; replace blood lost during surgery
White blood cells	Although there are several types of these blood cells, all of them protect the body against infection	Fight infections; also provide stem cells for transplantation
Platelets	Sticky cell fragments which help blood clot	To control bleeding caused by any platelet deficiencies, such as with people stricken by leukemia or cancer
Plasma	The fluid portion of blood that carries proteins, salts, and nutrients	To control bleeding caused by low levels of the blood's normal clotting factors
Cryoprecipitate	A product which is derived from plasma	To control bleeding and treat hemophilia
Concentrated plasma proteins	Proteins which are derived from plasma	To treat genetic diseases (such as hemophilia), dissolve blood clots, treat Rh incompatibility disease. Are also used to protect against certain infectious diseases, depending on the protein

Why blood is so profitable and what it is used for. As you can see from the chart above, there is nothing in blood that is wasted.

12.

CASEBOOK: BEHIND THE DOORS OF THE INSTITUT PASTEUR

Dr. Jean-Claude Chermann was a retrovirologist in the early 1970's, dealing primarily with mice. After training and working at the National Cancer Institute (where he met and befriended Gallo in 1967), he returned to France and the Institut Pasteur in 1974. Jacques Monod[98] set him up in a lab and asked if he would join the Montagnier group. In fact, Chermann was the only staff member with retrovirology training in the entire Institute. Montagnier agreed to the addition of Chermann even though the two men maintained two separate laboratories, in two different buildings, where, Chermann continued his work in Human Retrovirology. Chermann: *"When in 1982, we listened that possible cause of AIDS could be a retrovirus, we make a special group of clinicians and so on, and all these clinician people (such as Leibowitch, Rozenbaum, and others) asked me to come and to explain what it was a retrovirus."*

Following a special lecture, by Chermann, in which he explained the general concepts of Human Retrovirology, these clinicians had further questions. Chermann: *"When they told me the AIDS virus could be a retrovirus, I say okay. If it is a retrovirus, it should be a killing retrovirus, a cytopathic virus. And then we decide to look for a patient not presenting with AIDS, but presenting with a risk of AIDS. That means a French(man), traveling to New York, having a lot of (sexual) fun, and we find one."* Dr. Willie Rozenbaum found the patient, and decided to take a lymph node from this patient, for study.

A brief interruption is in order to clarify one thing. Just where did those scientists at the Institut Pasteur first hear that AIDS could be a retrovirus? Chermann: *"We find out because discussing with Gallo, and because we met a lot of times with Gallo, and because he was publishing something in Nature. At this time, discussing with Gallo, he made the hypothesis that HTLV-1[99] was the cause of AIDS by infecting the CD4 cells and making a down regulation of the CD4. And by making a down regulation of the CD4, when you count, you find no CD4. And secondly, when you make a down regulation of the CD4, the CD4 lose the function."*

On January 4, 1983, the lymph node was brought to Chermann's lab, who took it to Montagnier. He promptly put the node in culture where they began to notice a small

[98] A famous French scientist who worked in the early period of microbiology and received a Nobel for studying the mechanisms that regulate the turning on & off of genes in bacterial systems.
[99] Gallo clarifies, *"...or a variant of HTLV-1."*

amount of positive, reverse transcriptase on either the 15th or the 16th of January. This activity peaked a few days later on January 20th. By the 28th of the same month, they could see that the cells were dying because the AIDS virus was killing them. Chermann had the idea to add fresh lymphocyte to the culture to prevent the cells from dying off. This idea succeeded and gave the French the virus; in what amounted to their first attempt at isolation. Chermann: *"Then I request, in the presence of Montagnier, because I went in the office of Montagnier, we call together Bob Gallo, requesting some antibodies to HTLV-1 to make fluorescence. And what we find, we find there is no correlation."* This was electrifying because the French in the beginning of their discovery had thought they had isolated HTLV-1. At the time, Gallo's lab, which was still at the forefront of Human Retrovirology, had control over the reagents, and wanted to be kept apprised of any work being done on their virus by outside laboratories. So the French were trying to ascertain (or rule out) the existence of HTLV-1 in their culture and the reagents showed no presence of HTLV-1 in their isolate[100]. When Chermann called Gallo to inform him of this find, *"Bob was saying we were crazy. He did not believe. He was still thinking we had an HTLV-1."* That same phone call was put on speaker, so that everyone in Montagnier's office could hear Gallo when he suggested using blood cord lymphocytes[101].

Those reagents however meant something all together different for the Pasteur scientists. It meant, *"We find a different virus, we call LAV. It was a new retrovirus, a new human T-lymphotropic retrovirus. But we did not associate this virus to AIDS because it was isolated from an asymptomatic patient at risk. For that we call LAV. And then after that we isolate the virus from a hemophiliac and we call IDAV, Immuno-Deficiency Associated Virus. And then after that we show that LAV and IDAV were the same. And then after that came HTLV-3-LAV and then after that, we change the name to HIV."* As you see, their isolate had many names.

In the following month of February, the French had room reserved for them to publish their findings in Science. They were asked to *"please"* write their paper so that it could be published with the two papers from Gallo's group and the one by Essex they were to publish on HTLV-1. Chermann: *"And we call LAV, a new human T-Lymphotropic retrovirus. At this time HTLV was human T-Lymphoma Leukemia virus. But for us, it was a new T-Lymphotropic virus[102]."*

A key member of Chermann's team was of course, his scientist, Francoise Barre -Sinoussi. She had been with Chermann as a Pre-Med student, and continued past her earning a Ph.D. For seventeen years Francoise Barre -Sinoussi worked with Chermann, who in turn trusted her with all the important work.

During those three years, 1983, 1984, and 1985, there was still a distinction being made between the Chermann team and the Montagnier team. But the facts are Barre -Sinoussi did the reverse transcriptase tests on the lab cell culture system, which found the first independent presence of a retrovirus, and she was Chermann's assistant as well. Hers was the first name to appear on the French paper documenting their find. As the

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[100] In fact, Gallo had made sure the French were the first in the world to get both his HTLV-2 cell line, personally escorted to France by Barré-Sinoussi herself in May 1983, (see page 64 for proof), and the Antibody to HTLV-3 in order to keep maturing the progress of their collaboration.

[101] Fax communiqué from Chermannn to Gallo July 26, 1989, recalling that first contact after viral isolation.

[102] Fact: that is exactly what the abstract from the paper states as written by Gallo.

collaboration continued, a decision was made to centralize efforts between senior laboratories in both countries. Of course in the U.S., that meant Gallo's lab, but in France, it was Montagnier's lab that had that distinction. Soon afterwards, bad things were beginning. Chermann: *"And then it becomes a fight. It becomes a fight between Montagnier and Gallo. It was a fight between Pasteur and NIH."*

So the question arises, would things have taken a different course if Chermann's group had been chosen to represent the French. On that, Chermann can only speculate: *"I don't know. Like I told you, I knew Gallo from 1967. If they chose me, and maybe I will be wrong, but I will make (would have made) an arrangement with Bob Gallo, we share and we thinking much more about the patient instead of what other people are thinking. That's the only thing I can say."*

Drs. Jacques Leibowitch and Willie Rozenbaum studied infection methods and patterns, trying to isolate virus, by drawing blood from French patients for study. But a sore point was that Leibowitch was giving his blood samples to Gallo. *"He was working for Gallo, against the French*[103]*."* Rozenbaum went to others with sera, but only in France, before the Institut Pasteur said yes. And as you read earlier, it was from a Rozenbaum patient that the French got the lymph node, which in turn gave them their LAV isolate. Later Rozenbaum and Leibowitch would fight and eventually become antagonistic to one another.

Chermann: *"To be recognized when you are (the) French team, you need to convince somebody. And I decide(d) to convince Gallo."* In October 1983, while Gallo was visiting in France, he went on a bicycle ride, on a four-seater tandem bike with Chermann, Guy de Thé, and Francoise Hageneou (who was the leading electron microscopist of France). For two hours during that bike ride Chermann tried to convince Gallo about the individuality of their find when compared with the known characteristics of the HTLVs. It was two hours well spent because by the end of it Gallo became convinced. Chermann relays with humor and a smile that following this two hour bike ride, *"when we're together coming back, walking in the back of this meeting, he pushed me like that in the swimming pool, (with) all my clothes, because after that, he said he was (still) not sure (questioning Chermann's arguments that LAV was really a novel isolate)."* After that, still wet, Chermann continued to persuade Gallo about LAV.

Much has been made about this incident in various published reports (who knows why) by others. The only opinion that matters is from the individual who was pushed; Dr. Chermann. Was he/did he ever get angry about his dunking? *"No. I know him (Gallo) for so long time."* Gallo quips: *"It was quite dark and I really thought it was (Scottish virologist) Bill Jarrett; who loved to joke around. Had I known it was Chermann, well, I probably still would have done it. He was so very close to the edge of the pool and we were all in a fun mood. At least I was."*

The next meeting between Chermann and Gallo was to take place in January 1984, at a conference in Park City, Utah. There, Chermann was going to present up-to-date findings on what the French were calling LAV. Chermann was still pressing Gallo, telling him, *"I will present all the thing, including the key anti-body in patient and so on, and you have to be convinced."*

What surprised Chermann most was that upon his arrival in Utah three months later, there was Gallo waiting for him at the airport for what the French scientist describes

[103] Dr. J.C. Chermann, taped interview September 11, 2002, 1:16pm EST.

as the *"first time"* Gallo had ever been present to pick him up. Chermann goes on to say that Gallo, on the way to the conference, was saying, *"Jean-Claude, you know, you have to demonstrate that you have a retrovirus. That means you have to prove it is a true reverse transcriptase."* Chermann tells Gallo he has done that. Chairing this particular conference session was none other than Bob Gallo himself. As Chermann tells it, *"he (Gallo) start increasing the speaker, put additional speakers, and at the end there was no time for me to present my paper. And Michael Gottlieb say, "Sorry, now stop presenting." And I say, "No, Chermann has to speak," and I present. And it was the first time that somebody was speaking about LAV. Because in the Cold Spring Harbor Meeting, Montagnier was not so strong about the LAV[104]. But in January 1984, all was done."* There are more truths to report as well. Such as the fact that Gallo was not the only Chairman of that meeting and that the Chairmen and the Event Organizer were being inundated with requests by other scientists for 5 minutes to present their findings too. Chermann did present, but he had to wait his turn in line.

That presentation by Chermann was made three months before the publication of the four Science Papers by Gallo's group. The contents of his presentation were likewise published in the UCLA Record Book prior to the Gallo publications. Chermann adds that as the French team were taking the steps that would, eventually become their paper, which in time became that presentation at Park City, Gallo, *"was repeating all our work and he start to be convinced."* But Chermann attaches that Gallo, *"tried to slow what I was presenting in Park City."*

For many, that Park City Conference was very important because many scientists there had read Gallo's 1983 paper on HTLV-1, and were trying to recreate his findings, to authenticate and duplicate them. But they had not, not by then anyway. So new causes of AIDS were being tossed about; such as hepatitis. Now the French were talking about a whole new human retrovirus? Chermann showed those in the audience their retrovirus, that it was cytopathic, and showed it was present in the antibodies of many African hemophiliacs. Chermann further disclosed that on that *"same day the CDC sent us thirty sera negative, (the sera of) thirty AIDS patients, and (the sera for) thirty people at risk[105]. We find the negative, we find the people at risk, and some of the -our tests were not so good- some AIDS patients. That means at the Park City meeting, they call me and I went to the CDC, and they opened the coded serum (the key), that we have done right."*

France was requesting, and getting, sera from the CDC for two reasons. One, there were not too many AIDS patients in France at that time. The second was, Don Francis. Was there a relationship between this American epidemiologist and the French Team? Chermann: *"Yes, absolutely. Don Francis was a very good friend for me. We give the virus (LAV) to him, show him how to isolate the virus, and he was still calling (it) LAV, instead to (of) call(ing it) HTLV-3. And from that Gallo start to fight the CDC and to destroy the retrovirology department of the CDC. That is true. He was saying that the CDC was an inept epidemiology center and not a retrovirology lab."*

Gallo replies that is only partly correct. His position was that the CDC was more than qualified for epidemiological studies, but lacked the sophistication and knowledge necessary to be a true retrovirology center. Of course that all changed with the hiring of

[104] Fact, and quoting from the very Cold Spring Harbor paper Chermann is referring to, Montagnier described his results of LAV and AIDS as, "Uninterpretable."
[105] As discussed back on page 58.

Kalyanaraman.

13.
SARNGADHARAN GOES TO PARIS

It is important to understand how the American and the French saw their two isolates at that time. And that is key to understanding the foundation on which the ensuing scandal was built upon. Forget what science knows now, and go back to the knowledge these two sides had in 1984. What technology and scientific understanding allowed them to know about a new retrovirus that would eventually be named HIV. In those days, it was known as HTLV-3 and LAV. No doubt, whatever its name, it was a tempest in a Petri dish.

Everyone in Gallo's lab agreed, "…it has become extremely important to determine whether this virus (the Gallo group's isolate HTLV-3B) is identical to the virus isolated by Dr. Montagnier and his co-workers at the Pasteur Institute, Paris[106]." They needed to know whether all the -3B isolates and collectively, all LAV and IDAV isolates, were from one retrovirus group. As a result, in April 1984, Gallo agreed, despite tensions, to supply Montagnier with HTLV-3B. And not just as virus particles either; but in a permanent cell line, continuously and permanently producing the virus.

With the Heckler press conference still smarting the French, there had been no face to face interaction between Montagnier's group and Gallo's lab. But that was about to change because the cell line Gallo was sending over needed an escort. And it was Dr. Sarngadharan who was chosen to go. Admittedly, he was, *"very nervous."* He would be the first from Gallo's group to step into the French camp when the hostilities were at their peak. Dr. Sarngadharan recalls: *"April 23rd was the Heckler conference and I left for Paris on May 14. And our papers were published on the 4th of May, and I left on the 14th. It was kind of hostile. The climate was already bad because of Heckler not giving enough (oral) credit to them (the French). I'm the first person they met with after the conference. The conference left an unmistakable taste with them. After I got there, Montagnier took me to a hotel in Paris that cost $12-15 a night. I paid for it of course, but he took me there and registered me. It was terrible. They just made comments, they never asked me anything. They felt they were treated very badly, not given recognition."*

But there was another factor to consider also. Dr. Sarngadharan knew that the man he had trained, the man who left Gallo's lab to work for Don Francis, Dr. Kalyanaraman, was also at the Institut Pasteur at that time. *"I didn't want to go*

[106] Memo to the NCI Contracting Officer for foreign travel request dated April 26, 1984.

immediately because I knew Kaly was there. The fact that he had left me to go to the opposite camp left a little bit of tension." So Sarngadharan coordinated his schedule so that he would arrive a few days after Kalyanaraman left Paris.

Still, Kalyanaraman, had a purpose for being in France. "I was aware at the time that Pasteur considered a p25 protein to be the significant viral fraction of LAV, and that they believed this protein was reactive with sera from some AIDS patients. However, it was evident to me that Pasteur had not done, or been able to purify and label the p25 protein sufficiently to determine the specificity of the reactivity of this protein with AIDS sera. Without such isolation, purification and labeling, it was clear to me that the significance of LAV to AIDS could not be definitively determined. I stayed with Pasteur for about three weeks disclosing to them my assay, purification, and labeling techniques. Until I disclosed my purification methods and reagents to Pasteur during my visit in April-May, 1984, it was is also my understanding that Pasteur had been unable to obtain anything significantly higher that about 30-40% positive results when using their LAV with sera from AIDS patients[107]." The reason Montagnier's assay hovered about the 80% false negative mark was due to the fact the purification procedures he used stripped off a key element in the virus envelope; one which provoked the production of most of the antibodies in HIV-infected subjects. Conversely, this envelope remained preserved in virus preparations preformed at Gallo's lab.

Kalyanaraman had been sent by Francis from the CDC, to transfer radioimmunoassay technology to Montagnier's lab. Francis did this because Kalyanaraman had the needed experience to prepare proteins for comparison, and to streamline the protein assays. Before his trip to Paris, Kalyanaraman was handed the French LAV virus to both grow and purify its proteins. He set up a radioimmuno assay using the LAV protein he had previously purified while at the CDC, and took it with him to Paris. He also left behind enough purified proteins with Barré-Sinoussi before returning to the CDC.

On May 15, 1984 (from the groundwork laid down in the April 1984 agreement to trade and compare viruses), Dr. Sarngadharan arrived in Paris and hand carried to the Institut Pasteur, a 50cc Blue Cap Tube containing the highly efficient H9 line producing the HTLV-3B virus; as well as protein samples of the same virus. Sarngadharan: *"I carried it in my pocket and was going to personally hand it to him[108]. He said, "No, no, no." He did not want me to give it to him in the office. So we walked to the lab and I gave it to the technician. And I never saw the inside of that lab a second time after I gave Montagnier the culture. It (the lab) was locked and he produced a key, I think from around his neck. Anyway, he took a key and opened it and his technician was inside. That door closed and locked again when we were inside. She (the technician) took it (the culture) and put it in the hood (biosafety cabinet). He (Montagnier) never touched it. He gave instructions to the technician to culture it. Barre -Sinoussi did the comparisons*

[107] Quotes from paragraphs 5 and 7 of the notarized Declaration of V. S. Kalyanaraman, dated January 8, 1992.

[108] Sarngadharan adds more about his meeting with Dr. Montagnier: *"He (Montagnier) was surprised I had with me (the tube containing the virus culture), right there in my pocket. It was still properly sealed. I was careful. I didn't want to crush the tube. I was very tired. I didn't sleep on the plane, because I didn't want to do anything to the culture. It was there in my pocket, so I just sat there, straight in the seat until we could land."*

with her technician, Francois Rey. We would (then) discuss the results of the tests each morning. But Francois Rey did all the hands-on tech work."

This marked the very first time the French saw a culture, producing viruses in abundance. Comparative experiments between the LAV and the HTLV-3B viruses were conducted which showed that protein-wise, the two viruses were closely related. A genetic comparison was then scheduled to take place later in Gallo's lab; and in fact was done by Flossie Wong-Staal.

The results of all the comparisons were recorded on two pages written by Montagnier himself (see page 99). As Sarngadharan describes, *"This is not comparing the results. This is the state of our understanding of the virus at the time."* They agreed that via the p-24 and p-18 protein make-up, HTLV-3 and LAV were the same or related. To avoid any confusion to you the reader who might be examining those pages, you should know that back then, what the Americans called p-17 (protein of molecular weight 17,000), the French called p-18. But p-17 and -18 are actually one and the same. On the second page, last entry of the 'We Agree' column, it says: "p41-43: there is a band in viral preparations" Which means both sides agree that there is a protein p-41 through p-43. Sarngadharan: *"But beyond that I said p-41 (is) likely to be a viral protein; a glycoprotein (a protein containing sugars)."* However Montagnier thought there was actin; which was of no consequence. See second page of the Montagnier papers; first entry under the 'Do Not Agree' column.

Follow down that same column, under that same MS entry (MS are Sarngadharan's initials) where it reads, "recognized by most AIDS patients by Western Blotting." Sarngadharan there is saying that p-41 is a glycoprotein, something that reacts with the sera of AIDS patients. But the next entry by LM (Luc Montagnier) reads, "not seen…" and "not seen in Western Blot." It's not seen by the French team for one reason; they didn't have enough virus particles in their cultures (and therefore the viral proteins) to see the reaction with the anti-bodies in the sera. *"Otherwise there is no way in the world you'd miss that protein. Because this is the most immunologically prominent band in (the) Western Blot."* Continuing, Sarngadharan adds, *"This is the major point, this is the one big difference. This is not to mean that their LAV was different from our HTLV-3B by this point. It is their inefficiency to get enough virus to perform the immunological assays (ELISA and Western Blot). The virus was the same but they couldn't see it. We saw it, and we saw this as a major protein. That's the only difference."* Simply put, the French could not see the p-41 because there was not enough virus particles in cultures to detect it. And p41 is exclusive to HIV. All the French found at that time was actin; which is not a viral protein. It is found/made in every cell and is a key component in the architectural make-up of every cell. How little virus did they have? Well, even when culturing with radioactive precursors (S35 methionine and S35 cystene), which means you introduce those radioactive amino acids in the protein as they are made, even with those very sensitive culturing techniques, Montagnier wrote, "Not Seen."

A note here: 20-30% of the total protein of the AIDS virus is p-24. Other than being a core protein, it is also the most abundant protein in the virus as you prepare it. Whereas p-41 is a trans-membrane protein which is part of the envelope of HIV and exclusive to HIV.

So after that, the 'Decide' column was created (as in what we have decided to do next in order to test the isolates further). As you see, the two men agreed on eight more

tests that the French wanted to conduct. The 50ccs of virus culture Sarngadharan had brought was more than enough to accomplish this, because as stated earlier, it was a permanent cell line; continuously and permanently producing the virus. Sarngadharan commenting on the number of tests Montagnier could perform with the original 50ccs he had brought to France with him: *"He can do anything and everything beyond, with just that. Because everyday it becomes - you can make a factory with that."*

The documents examined in this chapter were drafted and completed only a few hours before Sarngadharan was to leave Paris. An EM takes more than a day on average, plus several of the other tests would have taken overnight. Yet, when Sarngadharan stops by to greet his host adieu before his flight, that's when Montagnier asks if he should destroy the culture Sarngadharan had brought him. Before any of one of those tests was ever performed, Montagnier actually asked whether he should destroy the H-9 cell line! He gets a negative answer. Sarngadharan: *"At this time, (Montagnier asks) "Shall I destroy what you brought?" I said, "No. I brought it for you to use."* Sarngadharan figures that if he replies in the affirmative, he would have had no guarantee that the line would indeed be destroyed. Sarngadharan: *"It is a hollow question to (ask to) destroy because we already agreed that he was going to use this to make the EM pictures. I went (to Paris) to give it to him. I had nothing to prove. He's the one who didn't have it."*

Gallo concurs that the report to him was that Sarngadharan told Montagnier, *"Gallo and the whole group wish him to have it (the H-9 cell line) for scientific purposes as he wishes."* Remember, Sarngadharan's sample was the first time the French saw a culture, producing viruses in abundance. More from Sarngadharan about Montagnier's question as to whether or not the cell line should be destroyed: *"I don't think he even meant that. Because I used to say, it's almost like having the first kiss, the first time. You yearn for it, you're looking forward to it, and when you get a chance, you do it. You'll never forget (it), right? He had been looking for a long time for a cell line that produces his virus. He hasn't been successful in doing that. And I brought one to him. He's not gonna leave it, he's not gonna destroy it so…in my mind there is not even a remote possibility he (ever) meant it. But he did ask me that. And that only reflected the tensions between the two groups."*

Obviously by leaving the culture behind, Sarngadharan had transferred more Gallo technology to Montagnier, leaving him with two very important tools: the virus itself and the culture producing the virus continuously. Within a week after Sarngadharan left, the French's previously problematic assays suddenly begin to work[109], and within just a month, the French blood test improved drastically to better than a 90% detection rate. It seems that coincidentally, just after Sarngadharan had left, the French team made their first major advances in the more detailed studies of the virus.

Sarngadharan tells that years later, Dr. Rachanee Chiensong-Popov told him at a conference: *"I was struggling…I was struggling for more than a month to get an assay done (referring to the immunological antibody assays she was conducting). But I couldn't see any virus." But to get any kind of reaction, you need antigen. And to have antigen, you need virus produced in the cultures. So she was saying Montagnier would give her*

[109] Personal communication to Sarngadharan from Rachanee Chiengsong-Popov who was at Pasteur at the time. Chiengsong worked in Robin Weiss' lab in England, and was on a short assignment at Pasteur at that time. It was later at Robin Weiss' lab where the French virus was finally grown in permanent culture for the first time.

samples, and she hardly found anything to be able to do an assay with. And she said, "One week after you (Sarang) came, I got a sample and I could just do an assay so fast (now). It was so easy." So she knew something changed."

Dr. Chiensong-Popov (presently at the CDC) does not recall nor deny those events. In a phone interview for this book[110], she calmly, softly stated: *"I have a disease and don't remember much about the past. I'm not interested in this. I'm moving on to my future now and I don't wish to talk about the past."*

However, when Montagnier was asked for this book, what happened to the material Sarngadharan left behind, his reply was, *"Nothing. I didn't touch it."* This of course means that he did not destroy it.

After this comparison was done, Gallo called Sarngadharan to let him know, *"You know what Montagnier is saying? He's calling your protein p-41, actin. And he's saying you are going after an artifact[111]. Are you confident your protein is viral?"* Sarngadharan replied, yes. A year later, when Sarngadharan presented at Cold Spring Harbor, he showed how the p-41 protein is synthesized in the cell; its genesis. That it was made as a 160,000 molecular weight protein first, then it breaks down into two proteins: p-120 and p-41.

Had the French ever been able to produce the virus at that time, then, as Sarngadharan says about those two pages, *"We would agree on everything and disagree on nothing."* And that may have been enough of a stepping stone to quell the imminent controversy.

The French were supposed to bring to Gallo's lab their molecular clones for study. But Montagnier said that everyone on his team was too busy for travel. However, in those next few weeks, the French had lectured three separate times on the NIH campus, right near Gallo's lab. The Americans pressed their desire to compare the isolates again in more detail. "As we both agreed by telephone on a few occasions it would now be nice and perhaps essential to compare the molecularly cloned genes of HTLV-III and LAV…Several of your collaborators are pressing me for an answer on the comparisons. I want them, you, everyone at the Pasteur Institute, and any one else who is interested to know that we are ready and waiting for the final experiments[112]."

In the same month that letter is sent, Francis and Montagnier quickly publish a joint paper (Kalyanaraman et. al) which reported their serology improved from 18% in AIDS to 40%.

In fact, in November 1984, on the last day of the Princess Takamatsu Symposium (in Tokyo), Gallo called Sarngadharan and told him to meet with Montagnier who was waiting for him, to go over the particulars of the comparative study. Sarngadharan met him in his hotel room and went over the data. Sarngadharan suggested that some experiments, e.g., Western Blot, be repeated to obtain cleaner data for publication. A short time later, after that meeting, Montagnier changed his mind and he, not Gallo, refused the joint study, citing that all work would be done in France. So it never happened. *"We tried."* Gallo said.

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[110] Conducted February 7, 2003, at 10:47am PST. Note: She refused to be tape recorded, so quotes come from Author's handwritten notes taken during the conversation itself.

[111] If you are looking for a viral protein and seeing actin, and you believe it is a viral protein, you have an artifact.

[112] Letter to Dr. Luc Montagnier, from Robert C. Gallo, dated July 3, 1984.

Unaware of these attempts by Gallo for a comparative study, other scientists start suspecting that a theft had taken place and a cover-up was being attempted. Dr. M. Martin in a memo (November 28, 1984): "At 4.30 today I received a telephone call from Dr. Jay Levy. He was quite upset because of pressure being put on Dr. Murray Gardner by the NCI staff not to publish data presented at the Montana workshop. He likened the situation to "a Watergate cover up" and stated that all data pointed to apparent theft of the French AIDS virus by Gallo."

But the truth of the matter was that Gallo wanted all comparison data be published from his and Montagnier's lab first; since the isolates in question came from their two labs. In fact, he explicitly states so in a letter to D. Francis (dated December 12, 1984): "…comparisons of the viruses would be published first by the Pasteur group and our lab. This is in progress now. Until this occurs neither you nor anyone else should be making serological comparative papers..."

In fact, final results of the comparison were obtained by the Gallo and Montagnier groups in September 1984. No one knew this because Montagnier had called off the collaboration, tying Gallo's hands. But not before that collaboration culminated with the authoring of two papers; one from each group, each with the aid of the other group. Nonetheless Montagnier halted their publication when he insisted that the work come out of France...solo. "While time is passing, it is clear that our planned joint paper on proteins is as obsolete as the other one. Flossie should not have been surprised by my letter since at the NCI meeting of December 6 (1984), I told her we might not co-sign her paper[113]."

Soon, two articles are published, one by each laboratory. The Americans published their genetic sequence of their HTLV-3 virus, while the French did the same with their LAV. But if both those collaborative papers, which in fact were written, had not been called off by Montagnier, those papers would have instead been papers co-authored by both groups coming to one conclusion; that LAV and HTLV-3B were identical to each other. And that would have happened not much after November 1984! Still, at that time, no one could begin to fathom how enormous and complex the coming controversy over those two viruses would become.

Regrettably, even if those papers had been published, Sarngadharan doubts it would have really changed any of the events that followed. *"This never was about LAV or HTLV…it was about the money."*

Still, so that what might have been, not ever be lost, those two aforementioned, unpublished papers will be cited now so the world could know the conclusions the French team did not wish to collaboratively publish. The following are highlights of the findings contained therein.

From the first paper[114], primarily authored and reporting results from the French team, it states on page 4, first sentence under RESULTS: "Several reports on the characteristics and the properties of either LAV or HTLV III suggest that these viruses are probably the same or closely related viruses. As shown on Figure 1, by electron microscopy, LAV and HTLV III can not be distinguished; they both show characteristic morphology , distinct from HTLV 1 and HTLV II, …" On page 5, first sentence under DISCUSSION: "The data

[113] Personal correspondence from Montagnier to Gallo, dated March, 4, 1985.

[114] Comparative Immunological Properties of LAV and HTLV-3, J.C. Chermann, F. Barre -Sinoussi, F. Rey, and L. Montagnier in France -and- M.G. Sarngadharan, M. Popovic, F. Veronesi de Marzo and R.C. Gallo in the U.S.

presented here show clearly that the major core protein of HTLV III is antigenically identical to LAVp25." On page 6, still under DISCUSSION, the final sentence of the paper: "Molecular hybridization and nucleotide sequence have been investigate(d) and suggest also they are clearly related."

From the second paper[115], primarily authored and reporting results from the American team, it states on page 2, middle of first paragraph under SUMMARY: "Restriction enzyme fragments totaling 9.0 kb were detected even under conditions of high stringency, suggesting that LAV is highly homologous to HTLV-III." On page 7, last sentence under RESULTS: "We conclude that LAV and HTLV-III are independent isolations of the same virus." On Page 7, under DISCUSSION, the last sentence of the paper: "Therefore as can be expected logically, there is only one etiological agent of AIDS, namely HTLV-III/LAV."

So they agree. But had the papers been published jointly, in collaboration, what would that mean? Quite simply, the French and American laboratories were working together to figure out what was going on. That meant being allies at a time when the French and American governments were not. Earnest, honest efforts, publishing the same results, and agreeing to them before a settlement was reached, would have hurt the accusations and the outcome of the French case to come. Better to publish alone and say, "See, HTLV-3B is our virus. Look at the test results. We (and only we) proved it. So, the Americans must have stolen it."

You think the French government wanted to hear instead, "Drs. Montagnier and Gallo, in the spirit of cooperation, and in an effort to settle the issues, jointly conducted studies on their isolates and came to the following conclusion. LAV and HTLV-3B are…"

As you will read, a couple of hundred million dollars annually says, no.

[115] Different Isolates of HTLV-3 and Lymphadenopathy Virus (LAV) are Genetic Variants of the Same Virus, F. Wong-Staal, B. Hahn, G. Shaw, M. Popovic and R.C. Gallo in the U.S. –and- S. Wain-Hobson, F. Barre -Sinoussi, J.C. Chermann, L. Montagnier, and M. Allison in France.

The following two pages are copies of…

The results of the Comparative Tests conducted on May 20, 1984 in Paris by Sarngadharan and Montagnier. The tests compared LAI with HTLV-3 and the results were broken down into three categories:

1. We Agree
2. Do Not Agree
3. Decide (…what the next step will be to settle the differences)

The pages you are about to see are handwritten by Dr. Luc Montagnier himself.

M.S = M. Sarngadharan, NCI — L.M = Luc Montagnier

We agree	do not agree	decide
I Virus morphology : 3 types of pictures : - budding - immature virus with lucent core - mature virus with dense, eccentric core	LM : 2 immature virions of LAV with dense crescent, not circular	Protein : EM sections of Hg / HTLV3 infected cells
I Proteins 1) p24/p25 – p25 of LAV and p24 of HTLV3 antigenically related (closely) by RIA competition. - recognized by same patient sera (Western blot) - relation to HTLV1 p24 : distant By RIA competition : more distantly related to HTLV2 p24 than HTLV2 p24 is to HTLV1 p24) p18	Migration in 1d PAGE : MS : not different from HTLV1 p24 LM : 1,000 difference in ~~MW~~ apparent MW with HTLV1 p24 MS : not seen in HTLV3 (in PAGE after Coomassie Blue staining) LM : detected by silver staining, labeling with AA(14, I 125 labeling - In some patients : antibody to p18 by Western Blot and RIPA	To Compare radioactively labe (35S) proteins in the sam gel with the same M marker Compare both protein by 2 d (O'Farrell) exchange positive and negative sera

LM: ... was routinely technique of western blotting of M.S.; she will send it as soon as possible to LM.

LM, MS: media purification of GP, independently. make and exchange specific antibody, when available.

- do BLIPA of cell lysate (355 labeled)

LM: - compare physicalities of respective (western blot BLIPA) on purified LAV and HTLV3, and mock virus from uninfected H9 cells. - remove actin

MS: send the uninfected H9 cells from this purpose

M 41-45: these in an action band in final preparations

M45: M41 labeling to be of viral region (GP), in

recognized by most AIDS patients by Western blotting.

LM: - not seen after labeling with 119 AA, 535 methionine or 535 system labeling - not seen in western blots

- seen only actin by 2d

14.

1985-1994: DRUGS & A BLOOD TEST GET TO THE WORLD

"The beginning of anti-viral therapy was a phone call from (Dani) Bolognesi to me, to go down to Duke University to talk at a nearby place called Burroughs Wellcome. We talked to the people, I gave a lecture, they had some compounds on the shelf that were there, not used, that were tried for cancer, but (were) not so effective. We went back, (Sam) Broder said (he wanted to pursue this). I said it's a reasonable idea, go ahead. So Marv (Reitz) let Broder come to his lab to use our cell systems. I'm a co-author of the first paper on AZT, but the credit is Broder's, his Japanese coworker Mitsuyai, and the Burroughs Wellcome group[116]*."*

In January 1985, Montagnier's sequence of the LAV virus was published in Cell and Gallo's sequence of the HTLV-3B virus was published in Nature, showing in comparison the identity of the two viruses.

At various times throughout 1984, Abbott Laboratories, ElectroNucleonics, Biotech Research Laboratories, Litton Bionetics, and Baxter-Travenol/Genentech, all received U.S. Government contracts to develop the Gallo blood test for industrial use. However, Baxter-Travenol/Genentech was the only commercial venture that dropped out and did not seek FDA approval for its efforts. It was rumoured that they had fallen behind in development of the test. But it wasn't until February 1985, Abbott Laboratories in the U.S., and Diagnostic Pasteur in France (the latter assisted scientifically by Genetic Systems, Inc., in the U.S.), each respectively got their FDA approval for the American and the French AIDS blood test. However, it was presumed that Genetic Systems, Inc., obtained and used the Gallo virus-producing cell line, either from (1) the culture left behind by Sarngadharan during his visit at the Institut Pasteur, (2) from clones provided by Marv Reitz, from Gallo's lab, or (3) indirectly from the NIH repository of materials deposited by Reitz.

By early 1985, Gallo, Mika Popovic, and Suzanne Gartner showed that the AIDS virus could infect not only CD4+ T-lymphocytes, but macrophages as well (which is another type of white blood cell). Furthermore, Gallo, Beatrice Hahn, George Shaw, and Flossie Wong-Staal discovered AIDS viruses in brain tissue. An important finding suggestive that macrophages, can cross the blood-brain barrier, bringing the virus into the brain, thereby causing the neurological disturbances observed in many AIDS patients.

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[116] Dr. Robert C. Gallo, taped interview, September 11, 2002, 7:32am EST.

In March 1985, the FDA approved the manufacture and marketing of the Gallo AIDS blood test (ELISA) by Abbott Laboratories, based on the demonstrated capacity to mass-produce the test for worldwide distribution. The commercial version of the ELISA blood test was optimized to assure zero false negative results at the expense of false positives. To confirm seropositivity, therefore, a Western Blot assay was/is required on all positive ELISA results.

Gallo clarifies the initial difficulties facing Abbott: *"Ours (the test in a laboratory setting) was a research tool. We hardly had any false positives. But you have to understand that in defense of Abbott, the ELISA equipment was all over the world because Abbott is a diagnostic company. The Abbott ELISA machines were in hospitals all over the world because there were earlier diagnostic tests that they were doing before you give a blood transfusion, like for some types of hepatitis. So, the ELISAs were all over the world. We had already published ELISA was not accurate (by itself). Not adequate enough because of false positives. Do writers who presumably and self-righteously criticize this, know that? Of course. Are they aware that the Western Blot couldn't be used on a global scale right away by Abbott? Of course. Are they aware that the Abbott test is not me or my group? Yes.*

"Okay. If you wanted to save lives you would go into operation as fast as you could, even if you had some false positives. Abbott had to be aware (of that) because they knew (from) our papers that ELISA was going to give some false positives alone and you need verification by the Western Blot. (With) The Western Blot you look at a pattern – alone the Western Blot we didn't think in some cases was not quite sensitive enough. But you (first) combine the ELISA and its screening, and then you verify with the Western Blot and you got it. You miss very, very few. Sarang will tell you that because Sarang had a lot to do with this. You couldn't get a better test than (that); we had a double test. To this day it's as good as anything ever developed, okay. But now when it becomes global, how can Abbott ask hospitals all over the world to do a Western Blot when it has never been used in clinical medicine by anyone before? Do you understand? This is the first time the Western Blot was adapted to a clinical test. Abbott wasn't ready for the Western Blot. They themselves did not have that technology yet. But you can say somebody else did. Yeah, in their own little laboratory. But how can you test laboratories in Africa or Greece? The hospitals don't have it (there yet). It was ridiculous. And, so of course you can't blame Abbott for not using it - because they couldn't get it to the world. They (Abbott) had to settle on the ELISA at the beginning. I had some trepidation when they did – not for my reputation, but because, you know, you're going to get false positives. When would a place like Santorini[117] have a Western Blot? But every hospital has ELISA type equipment. Thank God they went forth or there would be a lot more dead people now."

In May 1985, two HHS/Gallo U.S. patent requests for an AIDS blood test were granted. The first was on the test itself, and the other on the method of growing the virus to produce the test.

May 1985: The CDC reported 10,000 cases of AIDS in the United States with 4,942 deaths. Dr. William Blattner commenting on the high attack rate of the disease when the numbers for 1985 started coming in: *"Which were much higher than people appreciated. We were seeing 60-70% of people who were HIV positive going onto*

[117] A small island located in the Cyclades of Greece.

develop AIDS over a 5-8 year period. That provided the first evidence of the high attack rate."

In June 1985, the French AIDS blood test manufactured by Pasteur Diagnostics was approved for commercialization in France.

Phyllis Kanki, under Max Essex's leadership, and others (such as N. Letvin and R. Desrossier; all from Boston) described a monkey virus in Asian macaques, which is closely related to the AIDS virus, and from which the AIDS disease in humans may have originated. Interestingly enough, the same group of investigators detected cases of human infection by viruses almost identical to this monkey virus in West Africa. Later, this virus in humans would be called HIV-2.

Going back to Essex for a moment, it has been whispered that he had HIV-2 first, but fell victim to what else? Contamination. Specifically, by the monkey virus SIV (or Simian Immunodeficiency Virus), which is the possible progenitor of HIV-2 in humans. Essex, using the monkey virus got reaction via antibody positive results. But he didn't get it with HIV-1, which predicted that there was a virus in West Africa different from HIV-1. Unfortunately, there was that contaminant in the monkey virus and that caused great confusion. As Pasteur Institutes are located all over the world, the Pasteur Institute in Africa heard about this research, quickly amassed a lot of samples and jumped right on it. Montagnier is in the middle of that paper as a co-author and received shared credit for HIV-2, but it was really Essex's discovery. Essex to Gallo (June 10, 1991): "As you know I never underestimated LM (Luc Montagnier) after he managed to steal credit for our discovery of HIV-2." However, in science credit goes to those who prove and publish first. In this case, that was the French.

In July 1985, the American AIDS blood test manufactured by Abbott was approved for commercialization in France, five months after its approval in the U.S., and six months after submission for approval in France. This intentional delay of about half a year to approve the Abbott AIDS blood test in France resulted in a heavy human toll among French transfusion patients (see Chapter 28.for more on this story).

But even that was not enough to shift the noose of scrutiny targeted upon Gallo as allegations were becoming strongly voiced by the enemies Gallo had made. Francis to Curran (September 5, 1985): "Enclosed are some of the material which documents collaboration between the Institute Pasteur and CDC. …I am sure I am not alone in believing that Bob Gallo exceeded ethical bounds in his dealings with the French…. The French clearly found the cause of AIDS first and Dr. Gallo clearly tried to upstage them one year later. He knew that CDC-supplied sera from patients reacted to ELISA antigens in a similar manner[118]…he actively prevented the comparison which is required by ethical scientific practices[119]. He was reluctant to send his virus to Paris[120]."

Gallo was being publicly accused of misappropriating the French LAV virus and renaming it HTLV-3B. So on September 6, 1985, the DHHS sent a letter to Pasteur Director Dedonder concerning the issues regarding the discovery of the AIDS virus, in order to avoid litigation. When Dedonder wrote back he was willing, the Assistant Secretary of Health wrote a memo (October 2, 1985) asking for all concerned to sign

[118] Did he now? The published data clearly indicates otherwise!
[119] Untrue, since Gallo agreed with Montagnier to do the comparisons jointly and in fact did. See page 102.
[120] Wrong. He did send Sarngadharan to Paris with the virus producing cell line, which was left at Pasteur. See Chapter 13.

their agreement of Dedonder's terms and make public acknowledgements as soon as possible. Not all would.

In 1985, Gallo and co-workers also undertook the task of finding the cause of the B-cell lymphoma which afflicts, with extreme frequency, HIV-infected people. B-cell lymphomas are, of course, cancers whose induction involves the transformation of a B-lymphocyte into a malignant cell. In Africa, EBV (or Epstein-Barr Virus) is the cause of Burkitt's lymphoma, a B-cell lymphoma which greatly resembles the one established in AIDS victims. Yet, many of the AIDS-associated B-cell lymphomas are EBV negative. This suggested to Gallo that another virus was involved in these lymphomas; so a search to find it was initiated. Later that year, Zaki Salahuddin, Dharam Ablashi, and Gallo, identified a new herpes virus from one such patient. It was given the name HHV-6 (Human Herpes Virus -6) because there were already 5 other viruses in humans belonging to the same herpes virus family. They are…

1. Herpes Simplex 1
2. Herpes Simplex 2
3. EBV
4. Cytomegalovirus and,
5. Herpes Zoster (also known as Shingles).

HHV-6 then became the first new human herpes virus that had been discovered in over twenty-five years. Further studies revealed, that HHV-6 was a very old infection, widespread in the human population. Most people test positive for HHV-6 antibodies, but the virus remains dormant and well under control in healthy people. Though no conclusive evidence was obtained that HHV-6 was involved in causing B-cell lymphomas, some surprising results with other implications for HHV-6 soon followed.

Paolo Lusso, in Gallo's lab, showed that HHV-6 infects primarily T-lymphocytes and, in particular, the CD4+ T-lymphocyte subspecies. He also showed that HHV-6 kills these cells even more efficiently than does the AIDS virus. When AIDS infection progresses to produce immune suppression, HHV-6 is activated from dormancy and then both viruses seemingly act synergistically to kill more CD4+ T-lymphocytes together than they ordinarily do alone. Lusso and Gallo further showed that HHV-6 actually turns on the gene for the CD4+ T-lymphocyte receptor of the HIV virus and, thus, increases the number of cells susceptible to AIDS infection. Thus, it appears that HHV-6 may contribute to a more rapid progression to AIDS in HIV infected individuals whose HHV-6 has become activated. It was also shown by Japanese scientists that HHV-6 is the cause of the infant disease Roseolla infantum, or Exanthem subitum.

January 1986: The CDC reported 16,458 cases of AIDS in the United Sates with 8,361 deaths.

In February 1986, the FDA approved the manufacture and marketing in the U.S. of the French AIDS blood test (ELISA) by the American company, Genetic Systems. Even though the test was still not covered by a U.S. patent and, remained exposed to patent infringement entanglements by manufacturers of the American blood test.

In the Spring of 1986, a Nomenclature Committee renamed both the LAV and the HTLV-3 AIDS viruses, HIV (or, Human Immunodeficiency Virus), thereby halting the confusion of the same name given independently to the same infectious agent. So by necessity, the original AIDS virus was re-designated as HIV-1 and the second AIDS virus designated HIV-2.

AIDS Heterosexual Threat Grows was the headline[121] in April 1986[122]. "Concern is mounting about the spread of AIDS into the heterosexual population, the head of the federal AIDS effort (Dr. Walter Dowdle) said."

April 11, 1986: During a private meeting, HHS lawyers are told by Ira Milstein (an attorney representing the French), that another public relations firm had been hired whose, "purpose is to cause problems and set-up investigations[123]," for Gallo.

December 1986: The CDC reported 28,098 cases of AIDS in the United States with 15,757 deaths.

In April 1987, the FDA approved the first Western Blot blood test; a more specific HIV diagnostic test. Then, in May 1987, the American Red Cross awarded Abbott a new, two year contract to supply all of their AIDS blood tests.

The accomplishment of creating a blood test to screen for AIDS was a source of pride; not just for Gallo, but for others who contributed to the task. Dr. Mark Kaplan explains why: *"It wasn't for HIV, it was for allowing a blood test, to make the blood supply safe. And I feel very good about that because it meant that people could get transfused and people could be safe from this (disease). That we essentially eliminated the transfusional HIV. We stopped that disease dead in its tracks. And that's something that's irrefutable, and came from his (Gallo's) lab because of the H-9 cell line."* Later, in 1988, Dr. Kaplan and other collaborators will come home to find a package from Gallo waiting for them. Inside each was a beautiful silver plate, inscribed with these words: "Thank you for allowing us to develop a blood test to make the blood supply for the world safer against HIV."

August 1987: The CDC reported 40,051 cases of AIDS in the United States with 23,165 deaths.

By October 1988, the structure and function of the AIDS virus was made fully clear; mainly through the work of Bill Haseltine and Flossie Wong-Staal. An array of regulatory genes was identified and the intricate control function of each was explained.

Also in October 1988, Scientific American, published a single topic issue on AIDS. In that issue, Gallo and Montagnier co-authored a detailed history of (1) the scientific efforts leading to the discovery of the HIV virus, (2) the role of the virus in causing AIDS, and (3) its use for the development of a blood test. Both agree on the historical facts, on their respective contributions, and yes, even on their place as co-discoverers of the AIDS virus.

On the complex issue, what credit goes to which team (French or American), one can sort things out as follows: The Gallo team first developed the biochemical probes and reagents that made rapid progress in the field possible. The Gallo team was first to prove the existence of human retroviruses and to accumulate transferable hands-on experience, which allowed the handling of retroviruses possible. And, with Essex, was the first to propose the idea that AIDS would be caused by a new human retrovirus. The Montagnier team first reported the discovery of a new virus, subsequently shown -by Gallo- to be the cause of AIDS (the French report did not contend formally, let alone prove, that their

[121] U.S. Medicine, vol. 22, page 2.
[122] Notice how the heterosexual public is alerted only after the new, non-group specific name "AIDS" is adapted; revamping it as a disease befalling all mankind, and not just those in the homosexual community?
[123] HHS internal memo, dated April 15, 1986.

retrovirus was the cause of AIDS). The Montagnier team was also first to recognize that the new retrovirus killed the T-cells, and were first to present preliminary low efficiency blood-test data [In other words, Montagnier found the apple, Gallo dissected it, and found out how it worked. Thereby proving to all that the apple was indeed special].

Likewise, the Gallo team first proved that the new retrovirus first isolated by the French was the cause of AIDS, first managed to mass produce the AIDS virus in continuous culture, first developed a working blood test to protect the world's blood supply, and to diagnose the disease in sero-positive patients. These distinct roles of the two teams were agreed to, in the two co-authored statements (Nature,1987, and Scientific American,1988) by their respective leaders. It is appropriate, therefore, to name these two teams co-discoverers of the AIDS virus.

By March, 1988, a total of 136 countries or territories reported a total of 84,256 cases of AIDS to the World Health Organization (WHO), Global Program on AIDS.

August 1988: The CDC reported 72,024 cases of AIDS in the United States and estimates that 1 to 1.5 million Americans are infected with HIV.

September 1988: The World Health Organization reported 111,000 cases of AIDS had been documented worldwide. Authorities at WHO place the actual number of cases, including those unreported, at 250,000.

In November 1988, a CDC study revealed that 3 of every 1,000 college students were infected with HIV.

In February, 1991, Gallo published a short note in Nature reporting that, the LAV virus strain coded BRU (LAV-BRU) in the second and third shipment of viruses he received from the French, was not actually LAV-BRU, but a different strain altogether.

In May 1991, (pressured by that note in Nature) Pasteur reanalyzes their isolate and reports that, what they thought to be only LAV-BRU in those last two shipments of virus sent to Gallo was, in fact, LAV-BRU (which does not grow in culture due to three mutated accessory genes) plus LAV-LAI[124] (which does grow in culture). This was due to an accidental contamination of LAV-BRU, by LAV-LAI, that had occurred back in the Pasteur lab. Gallo acknowledged in Nature that HTLV-3B is a variant of LAV-LAI, due to a secondary, accidental contamination in his lab of the HTLV-3 cocktail by LAV-LAI. As luck would have it; it is that same exact second contamination which would later plague Popovic and Gallo (expanded on later as the story unfolds).

Interestingly, Birgitta Asjo and Eva Marie Fenyoe in Sweden (Lancet 2, 8508, 1986, p.660-662), had already shown that the slow-growing, low-titer LAV-BRU virus was prevalent in early-stage disease, while the fast-growing, high-titer LAV-LAI virus becomes prevalent in late-stage disease.

In subsequent years, Gallo's team concentrated its efforts on the molecular biology of the HIV virus and of the AIDS disease, on its trigger mechanism(s), on the biological effects of cytokines, on the molecular aspects of AIDS prevention, and treatment. Even on discovering additional new human viruses.

In 1994, AIDS becomes the leading cause of death for all Americans between the ages 25-44.

[124] Unintentionally pronounced "lie."

15.
THE FRANCO-AMERICAN DISPUTE

How did these many cresting events look, from the eyes of a young post-doc working, living, and learning science, in Gallo's lab in those days? Dr. Genoveffa Franchini: *"It was very exciting, it was very competitive as you might expect. I learned a lot. Extremely lucrative in terms of science; particularly in terms of biology. Overall, it was exciting at the beginning. Then later on, it was also hard during all of the issues raised about the virus. We were all swept by that."*

Unfounded accusations against Gallo started appearing in the daily press by about 1985. In the U.S., accusations were made by organized homosexual groups fearing that the blood test would be used for unfair purposes; such as to discriminate against the gay community and further the claim that an "evil" homosexual disease now threatened the "innocent" heterosexual population. Their fury was not unfounded, once you remember the mindset of those days. The animosity against them was total and they had only each other to count on for protection and care. But more and more, things began coming in Gallo's direction; all of it negative. Gallo appreciates: *"If it wasn't for having good people around me, I would have died in that period."*

In Europe, and in other parts of the world, accusations were made by Eastern Bloc critics who actually went so far as to say that Gallo himself had created the AIDS virus in his lab; to be used as a weapon of biological warfare[125] intended to wipe out the population of Africa. Even the Internet abounded with cockamamie theories. As Gallo so rightfully states, *"That's the problem with the Internet. Any person with a first grade education who can write his name, can be equivalent to any one else on the Internet. I used to call the media the great equalizers. They said, "What do you mean?" I say, "You'll take any person who talks about AIDS and write about his or her statements as the equivalent of someone who's educated about it." And that was true with the media in the early years. But it may be more of a problem now because of the universal access to the Internet."*

The hysteria to make sense and understand this disease in its early days ran amok in wild theories and propaganda schemes. But this happened only after the disease hit the general population; not before. If you remember, when it just affected the homosexual community, some were quite content in their belief that God was responsible for the

[125] The flaw in that view is this: wouldn't the military also have created a contingency antidote before unleashing something so lethal and rampant in its own country?

plague on those gay "sinners." But when innocent children and decent folk became as easily afflicted, there had to be another reason, another person to blame. Anyone, but God.

Little did Gallo know, that the very blood test he had developed to save lives would now be used as an instrument for his destruction; by the lawyers and PR firms representing the French and, ultimately, by Congressman Dingell and his (as Gallo puts it), *"his witch-hunting henchmen."*

Interviewed for this book, Luc Montagnier stated, *"Pasteur was not paying much attention to the development of a blood test as if there was no vision. Pasteur was making hepatitis vaccines at the time and the only concern was getting contaminated blood that would destroy the product. This was true until Gallo's four famous papers appeared in the scientific literature on May, 4, 1984. Then, Pasteur realized that a blood test could make money and got extremely interested in it."*

Expectedly then, enormous tensions arose between American and French Government Officials over royalties when Gallo's blood test was granted a U.S. patent (No. 4,520,113) in 1985, while Montagnier's test still had not. Despite the fact that Montagnier had filed first[126]. Why did that happen? Because there was a condition in U.S. patent law that the French failed to meet. Dr. Robert Redfield explains: *"The fact is, that Montagnier's test was not demonstrated. Gallo's test was. The U.S. law says that in order to award a patent you have to demonstrate. (But with) the French law at the time, you didn't have to demonstrate. You could just say I invented it and you can write it on a piece of paper and (under) the U.S. law, you can't do that."* In the many reports which have been published, this one important fact has almost always been omitted. Undoubtedly to stoke an angry fire (started by the Heckler Press Conference) kept spreading, by those who insinuated that the U.S. Patent Office played home-team favoritism when granting the U.S. scientists their patent first. But even in lieu of that required condition in Patent law, the French patent (No. 4,704,818) was in fact later granted by the U.S. – not denied. Even though they still could not demonstrate a working test. As Dr. Redfield puts it, the ploy was to present through the media, the French side of we-filed-first-got-our-patent-last was a, *"sort of a creation to cause controversy. It's a creation to cause controversy."*

Albeit prestigious, the Institut Pasteur is not unlike other facilities of its caliber, in that it utilizes two primary sources of income to keep itself going; government funds plus, the income from the commercialization of its own Research & Development products. The French Government matches almost dollar for dollar the Institute's income. This of course requires that the Institut Pasteur have an output of products to receive monies from the government in the first place. This drives people up and down the line to generate income which the government would match. Moreover, the Institute has developed over its lifetime, strong political influences within the press and the government. One example, the former Science Editor of the French Newspaper, Le Monde, Claudine Escoffier-Lambiotte, was one such Institute supporter. Another was Francois Gros, Director of the Institut Pasteur, who eventually became advisor to the Prime Minister, then Chairman of the French National Ethics Committee, and finally becoming, permanent Secretary of the French National Academy of Sciences. More on

[126] Key events leading to the Gallo and to the Montagnier blood test patent applications are given in Appendix 3, p.287.

those two later. But for now, it is sufficient to say that this triumvirate worked as a team.

In an effort to ease tensions, Gallo met with Nobel Prize winner, Francois Jacob, then President of the Institut Pasteur in France. At the dinner (arranged by Escoffier-Lambiotte, and hosted in her home) Jacob requested that royalties collected by the U.S. Government from the sales of the Gallo blood test in the international market, be shared by the Institut Pasteur. He argued that both Gallo's and Montagnier's groups had contributed to the discovery of the AIDS virus [but…we found the apple first]. So it was only fair that part of the royalties from the patent should go to the Institut Pasteur for the pivotal role its own scientists played. Keep in mind that the Institute had only recently (1981) lost the Hepatitis B Virus (HBV) patent rights to American Nobel Prize winner, Baruch Blumberg. According to officials at the Pasteur, Blumberg, in their viewpoint, had cheated them out of their discoveries on HBV, and had appropriated for himself, patent rights that otherwise would have been theirs; including all the monies associated with that patent. Fearing a repeat of both financial and prideful loss once more, Jacob had strong reasons to personally meet, and speak, with Dr. Gallo. He further proposed that Gallo, as the patent holder, should work out the deal by acting on behalf of the U.S. Government. According to Gallo, Jacob otherwise cautioned, the Institut Pasteur would have, *"no option but to pursue legal action against the only identifiable person in the patent,"* namely Gallo himself. Adding that Gallo would be badly hurt. Although personally, Jacob did not want it to come to that; he would have, *"no choice because the issue would go to the Board of the Institut Pasteur, then into the hands of some very aggressive lawyers and their PR contacts."*

Gallo thought the point valid and agreed that the royalties should be shared and even told Jacob so. Gallo tried to achieve that end, but failed. This decision, however, was never in Gallo's hands to begin with. Rather, it was in the hands of the U.S. Government, which chose to ignore Jacob's proposal. A privileged legal paper obtained for this book states, "…Gallo informed HHS officials upon his return to Washington. The officials told Dr. Gallo that this was a legal not scientific issue and was none of his concern." Now pause for a moment to consider what just happened. On one end of the rope is Jacob, warning Gallo that his reputation would be hurt, while on the other end, are Gallo's superiors instructing him to ignore the French. Both sides were hiding from each other, and they were both using Dr. Gallo as their shield and as their intermediary messenger of intent. With such strong forces fortifying their positions, there could only be one outcome.

In early August 1985, a top level French delegation flew to Washington, D.C. and met with officials from the Department of Health and Human Services. The purpose of the meeting was to discuss the delay in awarding the U.S. patent on the French blood test, to suggest that Montagnier and other key members of the French AIDS team be included in the U.S. patent of the American test, and that the Institut Pasteur together with the United States DHHS share the royalties. Gallo's past good deed of pushing Science to get the French paper published, came back to bite him with the interpretation that Gallo had key French information 1 year prior to the U.S. patent application[127]. Then Pasteur Administrator, Dr. Dedonder, "…unequivocally stated that the IP (Institut Pasteur) can not accept the current U.S. Patent Policy" and they

[127] But then so did every scientist in the world who read the article.

demanded, "Montagnier be recognized as the true inventor of the virus and the basic testing methodology leading to the current test[128]."

No agreement was reached by the end of that meeting. Following the breakdown of those informal negotiations, the lawsuit Jacob had threatened Gallo with[129], began. Pasteur sued the DHHS in December 1985 claiming that the HTLV-3B virus used in the American blood test was actually the French LAV virus. The lawsuit lasted almost two years and taxed the patience of the international research community. The key accusation in this dispute did not hinge on which party found the virus first; or which party made the greatest overall contribution to the AIDS test; or even which AIDS test was better. It did hinge, however, on whether or not the American side had used the French strain of the AIDS virus to devise and patent its own blood test for the disease.

The reason for that is likely this…using the core protein, p25, in their patent, the French claimed 20% of AIDS patients tested positive for antibodies. Soon thereafter, a CDC-French paper[130], lists 41% positive. The paper was submitted May 4, 1984 and accepted June 8, 1984. A note was added in the proofs (and this is key), "A specific ELISA test with total LAV proteins detects LAV-specific antibodies in 95 percent of LAS patients and 70 to 95 percent of AIDS…" Somewhere between May 4th and the galley stage of their paper, they realized they were using the wrong antigen (p25); subsequently finding that when using techniques similar to those described by Gallo and colleagues in the already published Science papers of May 4, their results improved dramatically.

But on the matter of explaining the key difference between the Gallo and Montagnier patents: Gallo's patent used a gp41 based antigen preparation. The Montagnier patent used a p24/p25 based antigen preparation. It is now known that p24/p25 antibodies appear early in the course of HIV infection. Yet the level of these p24/p25 antibodies decreases over the course of the infection. Whereas antibodies to gp41 have been identified consistently in sera of patients during the course of HIV infection; both in pre-AIDS and AIDS patients. Montagnier did not ever try to introduce into his patent, a claim involving the p42 antigen until July 18, 1985 – that's two months after the Gallo patent had been issued (May 28, 1985)! Finally, on October 10, 1985, Montagnier cancelled all of his pending claims and substituted them all with diagnostic assay claims based on the p25 core antigen. Prior to Gallo's work, there was really no way of predicting that gp41 antibodies would be present in the majority of AIDS and pre-AIDS patients; nor that these antibodies could be used as the basis for a reliable diagnostic assay. Remember, Montagnier was wholly unable to detect any antibodies which reacted with the gp41 protein and was only able to detect a non-specific cellular protein, actin, contaminating his viral preparation (which is approximately the same molecular weight as gp41).

So in the beginning, Montagnier never or in any way enabled an assay based on the gp41 antigen; but rather teaches away from it, and even disclaimed detection of

[128] August 7, 1985 HHS memo from P. Fischinger reporting on the meeting with the French.
[129] …and apparently planned for ahead of time. See memo on page 122 for more.
[130] Antibodies To The Core Protein Of Lymphadenopathy-Associated Virus (LAV) In Patients With AIDS, published in Science, July 20, 1984.

antibodies to that particular envelope protein. Yet did they accuse that Gallo's method constitutes patent infringement of their French assay? They did.

Litigation lawyers, comprised of registered[131] legal agents in New York (of the French Government) were mobilized to investigate Gallo's lab records in search of wrong-doing to support their case in court. Public relations firms were also utilized to bend public opinion by distorting facts and events in daily press reports. The aim of the PR firms was to discredit Gallo while simultaneously promoting Montagnier (still an unknown at the time) as an international figure with scientific prestige. Gallo was the vulnerable person to hit because he was the patent holder and patent royalties, not science, was always the real issue in this legal dispute. Obviously, the Institut Pasteur (and the French Government), had a lot to gain from a favorable resolution of the dispute (not just financially, but in national pride). They spared no expense in legal fees or in their public relations campaigns.

Montagnier: *"Pasteur first turned to a law firm in Philadelphia to handle the case, which proved not aggressive enough for the job. Under the advise of Sanofi, a huge state owned company handling the commercialization of the Pasteur's patents, Pasteur then turned to a law firm in New York, which was the registered legal agents for the French Government. They got the job and Sanofi assumed the payment of the legal fees."*

Yet, during those first two years of dispute (and during the entire subsequent Gallo inquiries), the scientific collaboration between Gallo's and Montagnier's laboratories never stopped, never degraded to such a point as to affect the pace of their research, to the credit of both men -and that bears mentioning here. An important point to keep in mind is that the legal dispute was between Institutions all along and never between the scientists. In fact, the reported clash between Gallo and Montagnier was quite temporary, and was completely over by the 1987 period. Its continuation as an item of controversy was entirely fabricated by several in the media.

Gallo: *"Late '82, 1983 and until the late spring of '84 we exchanged things, were friendly and collaborative. We get into that tension because of the patent and because of our press conference, that there was animosity for a while. The animosity was essentially over in '87. And then there was an agreement with Chirac and Reagan and everything was fine. However, at that time Dingell is entering my life without me knowing it and Crewdson is set up to make a tremendous attack on me, which was the 50,000 word thing in the Chicago Tribune."*

It was true that the personal relationship between Gallo and Montagnier had its many ups and downs, but never to the point of becoming anemic. *"Of course it crossed my mind at one time,"* admits Montagnier, *"that the Americans could have stolen our virus. Certainly not Gallo himself, but maybe someone in his lab was pushed to produce results fast. Retrospectively, I don't believe that to be the case at all. There is now the explanation that LAV-LAI unexpectedly jumped from one lab to another, contaminating cultures."*

Through a well thought-out campaign, orchestrated by hired public relations firms, the press on both sides of the Atlantic, supported Montagnier and boosted his public image by making him out to be a low-key, fair-playing, dedicated scientist, totally disinterested in money or glory. Conversely, Gallo's public image was unfairly distorted

[131] This is an entity in the United States that represents foreign interests.

by the press, irreparably damaging his reputation, eroding his scientific effectiveness, and slowed down his work. He was depicted as a ruthless character who would do anything; and stop at nothing for glory and money. Thus, they attempted to turn him into a villain, who hid his true, petty motives behind a veil of pretentious altruism. He was pictured as a fraud who misappropriated information from the French and, who even stole their AIDS virus for his own gain. Additionally, most of the press in Europe treated Gallo as a big, government-bought American, victimizing an innocent, little Frenchman named Montagnier. As a result, sometimes when Gallo traveled to parts of Europe, he would be followed by activists protesting against him on the streets and passing out denouncing leaflets. All his prior accomplishments and scientific discoveries were forgotten in these characterizations, as if they never even happened; or mattered. And yes, even at home in the U.S., Gallo became the target of threatening anonymous phone calls and hostile letters (see page 125). Yet, through it all, Gallo was (and still is) in the AIDS fight to stay. Tarnished though his public image was, he remained one of a handful of researchers who could further understand, even control the disease. Regardless of all that was going on and alleged, the world (and the scientific community) recognized this above all else. His contributions were still *"mostly welcomed in this period"* as Gallo himself puts it.

Back in 1984, James Curran correctly prophesized, "I'd like to sound more upbeat about this, but there are some unavoidable facts we need to face. AIDS is not going away. Gay men don't want to hear that. Politicians don't want to hear that. I don't like to hear that. But for many of us, AIDS could well end up being a lifelong commitment[132]." How true that was. Not just for Gallo, but for many others in the field, it seemed that quote was now a fact that applied to them all.

It is of interest to note here, that throughout his ordeal, Gallo was left totally unprotected by his own Government, even though he was a public servant; a Government Employee. Martin Delaney, head of Project Inform: *"I felt that a lot of what he (Gallo) was being blamed for, and this is even true to this day, a lot of the stuff that gets dumped on his lap, is really the activity of other people in Government. Like he's forever beat up about the press conference. "How dare he call a press conference." He didn't call a press conference. He was dragged back from Europe to attend a press conference set up by Margaret Heckler. Basically, it was the Reagan White House that was pulling all this crap. Yeah, I did think that (the American) Government should have stepped forward and defended him more because they got him into a lot of these spots. But it was my first exposure to that kind of behavior by Government."*

In fact, NIH did not provide Gallo with any representation when the accusations and investigations first began. He had to research and find an attorney…all on his own! This did not go unnoticed by scientists around the world, who were appalled that the American Government was not supporting its own research scientists. As Dr. Jonathan Gershoni (from the Tel Aviv University in Israel) reflects[133], "This unwillingness to support prominent scientists of proven integrity and stand behind their work has generated an atmosphere which is stifling creativity and endangering America's ability to maintain its leadership in Medical Research." Dr. Gallo's only advice from his employer came just after the onset of his

[132] The San Francisco Chronicle, December 1984 issue.

[133] Has Freedom Abused Been Killing America?, an open letter to the NIH and other scientists written after the initial, informal OSI inquiry.

troubles, that he was, "big enough to take it." In a formal plea, to four different Directors (including the NIH and the NCI), on December 23, 1985, Gallo wrote: "I would like to request that an office at NIH or NCI take responsibility for inquiries relating to the lawsuit filed by the French Government. My office is overburdened by this, and we are not sure how to handle these inquiries." The response, like the protection his Government Employers offered him, was nil.

Gallo: *"The (only) help I got was from Maxine Singer (currently President of Carnegie Institutes). Her husband's a lawyer. She brought me to her husband to give me advice. (At first,) I thought it was funny. Lawyer? What do I want a lawyer for? He's like, "You don't' understand. This is serious."*

But Gallo not defending his lab more back then, despite being ordered not to, has had an effect that has lasted to this very day. Even from the very closest of associates. Dr. Popovic: *"When the discovery was clear…I think it was his duty to protect and defend our work more. That is one of the jobs I think should be with the Lab Chief and keeps the (working) environment in (a) proper political (climate). I still today have this conflict."*

Dr. Robert Redfield: *"Bob could have helped his cause and I might as well say this. If Gallo had been more aggressively cognizant, he could have modulated this, okay. By giving Montagnier a little, you know what I'm saying? If he had just said, "Listen, it was really Dr. Montagnier (who) was the first to discover this virus in a patient like this. And (that) it really was, in retrospect, this was an important thing because later we were able to show it was the cause of AIDS. If he had handled it differently this wouldn't have happened."* But the fact was that the Pasteur cared about money and it was the success of the Gallo blood patent that grew to be the primary source of problems.

No U.S. official ever came forward to clarify that Gallo was not the driving force behind the blood test patent, that the patent had, in fact, been requested by the Government, that Gallo never questioned this Government request and that, as the law stood at the time, there were absolutely no financial benefits from the patent for Gallo because of his status as a Government Employee. Only later did this last condition change when President Reagan allowed government scientists to make up to $10,000 per year on all patent royalties to the NIH. Years later that amount was increased to $100,000. This key point was conveniently left out of the reports written by the negative journalists of that time, led by John Crewdson of the Chicago Tribune. And he knows that because this author has a copy of the letter sent to Mr. Crewdson, by the NIH's Freedom of Information Act (FOIA) Director, Joanne Belk (dated June 6, 1989) which clearly reads: "As for payments for fiscal year 1989, if sufficient income is received by NIH from NTIS, the maximum allowable amounts of $100,000 will again be paid." There is also another letter, again to Crewdson from Belk (dated July 29, 1988) that reveals the sum of all royalties paid to Gallo up until 1988 totaled less than $75,000. The two factors to consider are the initial $10,000 cap put in place by the Government, and the fact that it wasn't really until 1988 that the blood test found wide-scale use. Hence, before then, Gallo, Popovic, and Sarngadharan, all got less than their maximum allowable compensation as the blood test had not yet achieved extensive sales to generate that income. So where are the Gallo riches Crewdson alludes to?

Fact: Gallo was instructed by Dr. Lowell Harmison; the newly appointed technology transfer expert, whose responsibilities included enacting new policies. One duty was to ensure Gallo and his colleagues patent the blood test in order to protect

against the emergence of any fraudulent tests that were sure to follow; as well as to induce the larger pharmaceutical companies to advance the test globally since they could be selectively licensed by the Government.

Gallo and colleagues never considered, or expected, any compensation for their work. In fact, with the selective reporting of facts, Crewdson repeatedly committed what the famous Spanish author Cervantes calls the worst lie of all; reporting half-truths. Seemingly, he did this for the purpose of defaming and playing down the significant achievements of Gallo and his colleagues.

Gallo: *"When I think about it, I say to myself, there was the (French) Mitterrand Government, one of America's most powerful law firms, the public relations industry, a writer (Crewdson) full-time on me, and a Congressman (Dingell) who knows no end of power. And I was in a vacuum in the Government, with people scared out of their boots; including the NCI Director, Sam Broder. Sam Broder told me, "You don't understand, these guys that work for Dingell want you physically dead."* As for Crewdson's climb up the journalistic pole (and some of Dingell's staff as well), Gallo comments they were, *"Getting ahead by getting a head."*

Finally, in March 1987, peer pressure and political diplomacy working synergistically, brought the dispute to an end, although it was strongly suspected that certain third parties were not at all happy to see a settlement reached. Jonas Salk (a polio vaccine pioneer) was instrumental in precipitating the Franco-American agreement. During the winter of 1985, Gallo visited Salk to find out more about vaccine science. According to Salk, Gallo was the first person ever to ask him for help on an HIV/AIDS vaccine. Later, when Salk realized that Gallo was hounded by reporters generating negative publicity and, appreciating the pressure Gallo was under, vowed to help and advise since he was acceptable to both sides (the French[134] and the Americans). He did and, from that day on, he devoted considerable time and effort to end the dispute.

Additionally, the late Nobel Prize Winner, Howard Temin, also used his influence to push for an agreement and a settlement in the matter. Gallo has never before told or published this story of what Dr. Temin tried to do for him; until now. *"Howard Temin was a Nobel Prize winner. He was also rather well known as a man of the utmost integrity. He was like the model. During the worst of the period for me, when the Dingell gang was really going crazy, Howard Temin said he wanted to help. And the best way was to take on any and all accusations, implications, whatever the innuendos were, because there were never really formal charges before me. He said, "Let's confront it all; every accusation, every insinuation. You come in with documents and evidence and we'll hold a press conference on the NIH campus and we'll do this for a day – two days if we need." I was excited. Said that would be so helpful, wonderful because we can shed light on this darkness. The day was planned when Howard was coming to Washington, in the morning, to receive the President's Medal, the highest honor that our country can give. And on the day he's receiving the President's Medal, in the afternoon he was supposed to do the press conference, but because of Dingell pressure on HHS, the Chief Consul, lawyer, for HHS, a man named Astrue, wrote quickly to Temin that if he came on the NIH campus and did this, he would be prosecuted. A Nobel Prize winner who just received the President's Medal, and that's the threat! Now Astrue was just (making this threat) because of the pressure by Dingell. Temin said that we ended up not being able to*

[134] Salk's wife was herself French and the former wife of famed artist Pablo Picasso.

do it, prohibited, formally, by HHS. And Temin just went to his hotel room (named, The Governor's House at the time), and had a little press conference himself with a few reporters[135]. Which had no effect. Before he died, Temin, told me it was one of the few things in his adult life he really regretted. What could they have done to him? A Nobel Prize winner who just won the President's medal? What a scandal it would have been for Dingell. And for HHS. HHS was just complying to the pressure. HHS was not the enemy, you know. But they sure weren't a courageous group.

"As for Temin, in my mind he was a gem, and a key advisor to me on multiple levels. Though we were of the same generation it felt like the loss of a father, a second time, when he died."

In fact, David Baltimore, Renato Dulbecco, and Salvador Luria (all of them Nobel Prize winners themselves) urged President Reagan to end the distracting dispute; and to do so quickly.

In April 1985, with the encouragement, and the insistence, of Dr. Daniel Zagury (Professor at the University of Paris), Bob Gallo, and Dr. J.C. Chermann (from the Institut Pasteur) met to write the history of the American and French contributions toward the discovery of AIDS. Gallo: *"Chermann and I looked at each other, we hated not being friends. I said, "What the hell?" and we sat down and started to write (that agreement)."* In it, details of who did what, where, and when were documented in 14 points. The job was completed in forty-five minutes and with total agreement over what had been written. Gallo: *"We each wrote what we felt we had contributed. He wrote, I wrote, then we just put it all together."*

However, the next day, Chermann called Zagury, informing him that if that history were ever to be published, he himself would be in trouble. Chermann asked if Zagury would step in, and convince Gallo not to proceed with the publication of the agreed to history. Telling him, *"Please, you must stop it. Otherwise I will have big problems with my administration[136]."* Zagury did. Within hours, Claudine Escoffier-Lambiotte (the Science Editor of the French Newspaper, Le Monde) also called Gallo and alerted him that Chermann's career would suffer if that history were to see publication. She asked Gallo not to publish. Gallo feeling outside forces are essentially holding Chermann's career hostage, complied out of respect (see the correspondence on page 123). Zagury says that Gallo right away, without hesitation, told him, *"I will not use it."* What is now known is that the Director of the Institut Pasteur forbade Chermann from signing the document. This action by the Director begs the question whether the signing of such a document, before any economic settlement was reached, would have been premature.

"Gallo called me and we met at Zagury's house. But we did not write anything. We were trying to find an agreement," responds Chermann, who denies ever writing

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[135] This in fact did happen on June 24, 1992. In his statement Temin recounts, "I was hand-delivered a letter from Michael J. Astrue, the General Counsel of the Department of Health and Human Services, dated June 23: "This letter is to reiterate my oral advice to you which is the meeting you have scheduled for tomorrow to review matters relating to allegations of misconduct against Dr. Robert Gallo exceeds the authority of your committee and therefore must be cancelled…You need to be aware that unauthorized expenditure of federal funds may expose you and others to various types of liability."….I would like to wonder about why such a statement, about such a meeting…was so threatening and illegal that it called for such a letter and had to be cancelled?"

[136] Quote from Zagury, interviewed for this book.

anything, only adding that, *"Zagury was writing something. And I took that and the Director of the Pasteur Institut disagree completely to that. He said, "you have not the right." I was an employee of the Pasteur Institute. I have not the right. I never say I disagree, I said the Pasteur Institute gave me the order not to sign. (And that is…) Not the same. I never write something. Never. They were writing something, Gallo and Zagury."*

That is not true and Chermann's own words contradict that. Because of the great friendship between these two men, which endures to this day, Gallo had asked Chermann to write the preface[137] for the French edition of Gallo's book, Virus Hunting - AIDS, Cancer, & The Human Retrovirus – A Story Of Scientific Discovery. In it, Chermann writes, "…we decided to meet and straighten out the situation by trying to write a "history" of the discovery of the virus, at a beautiful Parisian villa, in front of witnesses. The following morning I was called before the Director of the Pasteur Institute, who, furious, strictly forbade me to sign anything. I called Gallo, who immediately sent a letter confirming that I had not signed anything." Additionally, Zagury verifies, that he was acting as a secretary at that meeting, jotting down the points which Gallo and Chermann wanted to address in that history.

When asked did he himself disagree with what was written, regardless of the fact that the Institut Pasteur did, Chermann had this to say, *"If you know me, I much more involved about the patient than about the fame, okay? I am a scientist, not a political (meaning politically motivated). If you want, the agreement, I mean the points that we were discussing, trying to find an agreement - for the patient - it was much more better not to continue to fight than to fight. That was my opinion. Secondly, at this time, I have the position to decide because Montagnier was not the leader. And I did not disagree, I'm sorry, that is a word I will correct. I did not disagree, as (opposed to being) ordered not to sign a paper like that. It's completely different."*

Gallo on why Chermann was not allowed to sign: *"They (the French Government) didn't want the settlement because there wasn't the money! They needed a…look, if we won the patents fair and square, we reduce to practice, we did all of this, (and) they don't have a working test, then how else can they attack? The only way they can attack is by somebody doing something wrong in America. So to have this as a controversy with me, was their only play. That's what Jacob warned me about in '85. He told me it would happen to me."*

A chronological history of the scientific events leading to the discovery of the AIDS virus was then later agreed to, this time between Gallo and Montagnier. A scientific accord, which was an indispensable prerequisite to the settlement, was written jointly by the two scientists and, was subsequently published in Nature in April 1987 (see Appendix 4, p.290). According to the publication, Montagnier is credited with the first isolation of a new retrovirus [I found the apple first] subsequently shown to be the cause of AIDS; by Gallo no less. While Gallo is credited with the demonstration that the new virus, first isolated by the French, was in fact the cause of AIDS [I can show you why the apple fell from the tree]. Additionally, an agreement was signed in Washington D.C. on March 31, 1987, by French Premier Chirac and President Reagan in which equal percentages of the royalties from Gallo's blood test would be allocated to the NIH and to

[137] Written August 13, 1991.

the Institut Pasteur for research purposes, while a third percentage would be channeled to the new, World AIDS Foundation[138] (legal accord).

But was that chronology that was published with Montagnier essentially the same as the unpublished one written previously with Chermann? Gallo: *"Yes."* The differences were few but significant. *"We (the Gallo Team) were going on to show etiology, Montagnier never says that."* The most important element however was the timing. Had the Chermann history been agreed to and signed, the whole thing would have stopped then and there. Only after the French received their financial settlement, was a history of events agreed to. This alone makes their motive rather transparent. Gallo once more: *"If they settled this early, there's no money for the lawyers and no money for the Pasteur Institute. I wouldn't agree to the settlement myself unless the history was written, and published, at the same time (as the settlement). So that's what happened. And that history (with Montagnier) was in agreement on both sides and yes, was about the same as the history before."* This issue of the history is examined in greater detail beginning on page 199.

After the settlement, the American and French scientists did not end up getting equal shares. Gallo, Popovic, and Sarngadharan started receiving $100,000 annually while the French scientists (because of French policies at the time) received nothing until 1991. Then, when the first monies at last started coming into the Institut Pasteur, the financial share given to the French scientists was considerably less than what was given to their American counterparts; due to an internal decision made solely by the Institut Pasteur. Also a factor was the restrictive language in the agreement. Essentially the actual amounts due each country was based on the sales by licensees in each country, which was not placed into the joint pool. Which meant that France got their part of the money based on the sales of their own test kits (mostly in France) and that created an imbalance since the Abbott test dominated sales in the rest of the world; and those sales were the basis for the U.S. revenues under that formula.

As we're talking about money, one needs to get an idea of just how much the Gallo patent was worth. Fact: The United States government received more money from his one patent than all the other patented discoveries in biomedical sciences combined! These monies even built one new NIH building in Frederick, Maryland. Between 63-68% of the annual, total patent money coming into the U.S. Treasury, was from the Gallo patent. Of that, Gallo got $100,000 a year. As did Popovic and Sarngadharan. Then in 1998 their payments increased to $150,000 annually; due to increased patent revenue collected by the government. In 2002, they all got their last bi-annual payment on a patent that generated hundreds of millions of dollars annually, since the government has a time restriction of just how long a scientist in their employ can collect patent money. After 2002, their $150,000 became zero, and they now collect nothing.

On the issue of patent money, which has been brought up in previous attacks of integrity, many times, it is just -and only- this simple: As the law stood at that time, there was to be no expectation of personal profit[139] for Gallo, Sarngadharan, or Popovic from the issuance of the patent in their names. That would not change until two years later

[138] The idea of creating a new World AIDS Foundation (where most of the royalties would be channeled) was brought up by Gallo during a soul searching meeting at Alfonso's restaurant in downtown Washington D.C., in early 1987.

[139] Except for a U.S. Government inventor's award of $2,000 awarded to each.

when the Government began to share (albeit a limited portion) the money generated for the achievements made by discovering, inventing scientists in their employ. Gallo: *"That came out later. That's exactly right!"* This change in policy was made by the Government itself. In the case of the Gallo patent, its life span was 17 years (ceasing when 2002 ended). When the policy change was made and put into effect, two years had already passed (1984 and 1985). So when the royalty money began, there was no back-pay to these scientists for the lost two years. They simply began to collect in 1986, and would collect as long as the patent had life. In this case, 15 years[140]. Before that nothing; after that nothing.

2002 likewise marked the end of the American and French Governments receiving their royalty payments, and opening the blood test market up to third parties. Which meant that when the year 2002 ended, there could be no more issue over patent royalty monies. Also, if you remember, part of that money pool went into funding the World AIDS Foundation whose existence was wholly contingent on that patent money. So when the money stopped, that Foundation closed.

On March 10, 1987, just days before the Franco-American settlement, Gallo was informally interviewed by Harry Rosenthal and Warren Leary, both reporters with the Associated Press. In a nutshell the following is what Gallo had to say. "There is no fight between Montagnier and me. There never really was. I can not think of anything I or he might have done that would start a fight. Montagnier knows exactly what I have done because everything I do is published in the open literature, and I know what he has done because everything he does is also published in the open literature. Moreover, we collaborate and we do not hold important information back from each other…. Our group at NIH opened the field of (human) retrovirology back in the early 1970s. The French came into the field in early 1983 and found a virus that we later proved to be the cause of AIDS. From the very beginning and ever since, we have helped the French move along because we wanted the field to grow…. Yet, I am confronted with innuendoes, even accusations, that I have done something wrong. It is demoralizing. It sets me back, it sets my lab back. It is interfering with my mental ability to think and innovate. I find it distracting and wasteful to have to spent enormous amounts of time with lawyers when I could be in the lab doing something useful. I can not take this crap."

Following the enactment of that formal agreement, Gallo and Montagnier met in the French restaurant La Ferme (oddly enough, owned by a man also named Montagnier), not too far from NIH, to celebrate over dinner the end of the Franco-American dispute. Present to this dinner were Dani Bolognesi and Tony Kontaratos. During the course of the dinner, while spirits were flying high, Dani Bolognesi suggested that Gallo and Montagnier sign a formal agreement of continuing collaboration; and Tony Kontaratos drafted the terms and conditions of this collaboration on a paper napkin - to which the two interested parties immediately agreed. Unfortunately, the very next morning when the terms and conditions of the collaboration were typed up, neither of the two parties was willing to sign. Rather, they chose to continue their collaboration on an opportunistic

[140] If you do the math, from 1986 to 2002 is actually 16 years. But they were paid for 15 years worth of sales. The reason the numbers don't add up, is because the patent dividends were paid to the scientists for past sales. In other words, the first annual payment of any given year, was based on the sales for the latter part of the previous year. So the payments are a delayed catch-up for their entitlement of a previous sales period, hence that extra year.

and informal basis instead.

Years later, Montagnier will give his own personal account of his unsettling relationship with Gallo in an interview to T.A. Bass[141]. In this interview, Montagnier retained for himself the distinction of having isolated the AIDS virus first, but admitted that, at the time, he had no proof that his virus was the cause of the disease. He also admitted that Gallo contributed significantly to the discovery of the virus by being the first to push the idea that AIDS was in fact caused by a retrovirus, then by being the one to prove causality and finally, by growing the virus in continuous culture. All of which led Gallo to the development of the AIDS blood test. He further admitted that, "Gallo is not someone who merely perfects other people's discoveries, but someone who generates a lot of creativity; and from whose lab many important findings have come." He finally admitted that he was particularly furious when Gallo's blood test was accepted, while his went on to be largely ignored. But his fury was not against Gallo, so much as against those in control of the system. That was the one fact that eventually pushed him into endorsing legal procedures. His position on the issue was clear. There could be no compromise simply because no one should be made to look as if he were loosing face. And Montagnier felt that was happening because another party was commercializing his product. A criticism he had of Gallo was that after the HTLV-3, strain B (or HTLV-3B), and the LAV viruses were found to be practically identical, HTLV-3B was never renamed LAV.

To be clear, HTLV-3 is a generic term (like HIV which has many strains) used by the Gallo group for all of their isolates. It was only strain 3B that was contaminated. HTLV-3(MN), HTLV-3(RF), and many others, were not.

Gallo is sympathetic with all these views but holds firm against the use of the LAV nomenclature (designation), believing it to be a misleading misnomer (LAV means Lymphadenopathy Associated Virus), and incompatible with the nomenclature structure agreement signed in 1983 by the majority of scientists involved in human retrovirus research. He immediately acknowledges, however, that Montagnier had not, at the time agreed to the new nomenclature; and was not one of its signers.

Still, it should also be noted that the name LAV never appeared in any scientific literature until 1984. In fact, no name was used even in the Institut Pasteur's 1983 case report. But it was used in oral presentations as a name for their particular strain by mid-July, 1983. Oddly enough, Montagnier named his next isolate IDAV (Immune Deficiency Associated Virus). Lymphadenopathy (swollen lymph glands) is a sign in many diseases; like Strep Throat. Thus, the designation LAV had no precedent in retrovirology. Perhaps then, IDAV got its name when Montagnier realized the shortcoming of LAV as a name or, he didn't believe his two isolates were really the same virus. On the other hand, those were his isolates to name any way he wanted.

Montagnier concedes, *"We were indeed prepared to do the work, but we were also very lucky. Our first patient, BRU, from which we isolated the LAV virus, was infected only with the AIDS virus. Consequently, unlike Gallo, who was initially confused by samples doubly infected with the AIDS and the HTLVs viruses - we were not. Expectedly then, Gallo's HTLV-1 variant hypothesis became a cause of dispute. On the other hand, our second sample came from a doubly infected patient and we, then, got the*

[141] Bass T.A., Reinventing the Future: Conversations with the World's Leading Scientists, Addison-Wesley Publishing Co., 1994.

same messy results as Gallo did. We were also unlucky in that we tried many times to grow the LAV-BRU virus but consistently failed."

Gallo adds: *"No doubt he (Montagnier) saw the virus first, no doubt he cultured the virus first, no doubt he got the idea from me -me and Essex- but he says me. No doubt we helped a little in the technology, and no doubt he did those experiments themselves in France, and no doubt that they wondered if it caused AIDS. But, no doubt that they didn't, nor could they show cause - they didn't have the data to say so. So it wasn't that they were totally bungling, but they couldn't produce it (their virus isolate) to characterize it."*

August 13, 1985

Chief, Laboratory of Tumor Cell Biology, DTP, DCT, NCI

FOR THE RECORD

Associate Director, NCI

Peter, for your records. As I told you, I received a call on Monday, August 12, from a Mr. Corky Johnson (telephone in DC 483-1442). He told me he works for columnist Jack Anderson. He told me he was given information from someone who attended an Institut Pasteur/NCI-NIH meeting regarding a possible law suit on HTLV-III concerning patent rights, and he told me of the slimy statements of possible accusations. My response was I was not at the meeting and I knew nothing about it. Also that "I know nothing about patents and what could I possibly say." I talked perhaps two minutes about science. He seemed to understand the truth and appeared sympathetic.

Robert C. Gallo, M.D.

A scandal unlike any other was now looming. This was the warning shot.

Bldg. 37/Rm. 6A09
(301) 496-6007

March 28, 1986

Dr. J. C. Chermann
Institut Pasteur
28, Rue du Dr Roux
75724 Paris Cedex 15
FRANCE

Dear Jean-Claude:

I heard from our mutual friend Daniel Zagury that the possible scientific history caused some trouble for you at the Pasteur. You have my word that I will make sure that this is ended.

Warm regards.

Sincerely yours,

Robert C. Gallo, M.D.

RCG/bj

Gallo acts for friendship, amidst swelling controversy…

Bldg. 37/Rm. 6A09
(301) 496-6007

March 27, 1986

Docteur C. Escoffier-Lambiotte
Le Monde
5 Rue des Italiens
75427 Paris Cedex 09
FRANCE

Dear Claudine:

It was a pleasure to speak with you. Please reassure Dr. Dedonder that Dr. Chermann did not agree or sign anything and that I have not "used" the "history" in any way except to seek advice and input from very few select scientific colleagues in France and in the U.S. In no way is Dr. Chermann responsible for anything but his good will, and I would feel terrible if his position is in any way reduced or harmed by a normal and friendly discussion. If science and NIH-Pasteur relations come to this, we have miserable problems for the foreseeable future. Jean-Claude should be congratulated for scientific contributions, fairness, honesty, and his desire to seek common good will and scientific progress.

You have my word that the older "history" will never again be used by me. I wonder, however, why there was a reaction against it?

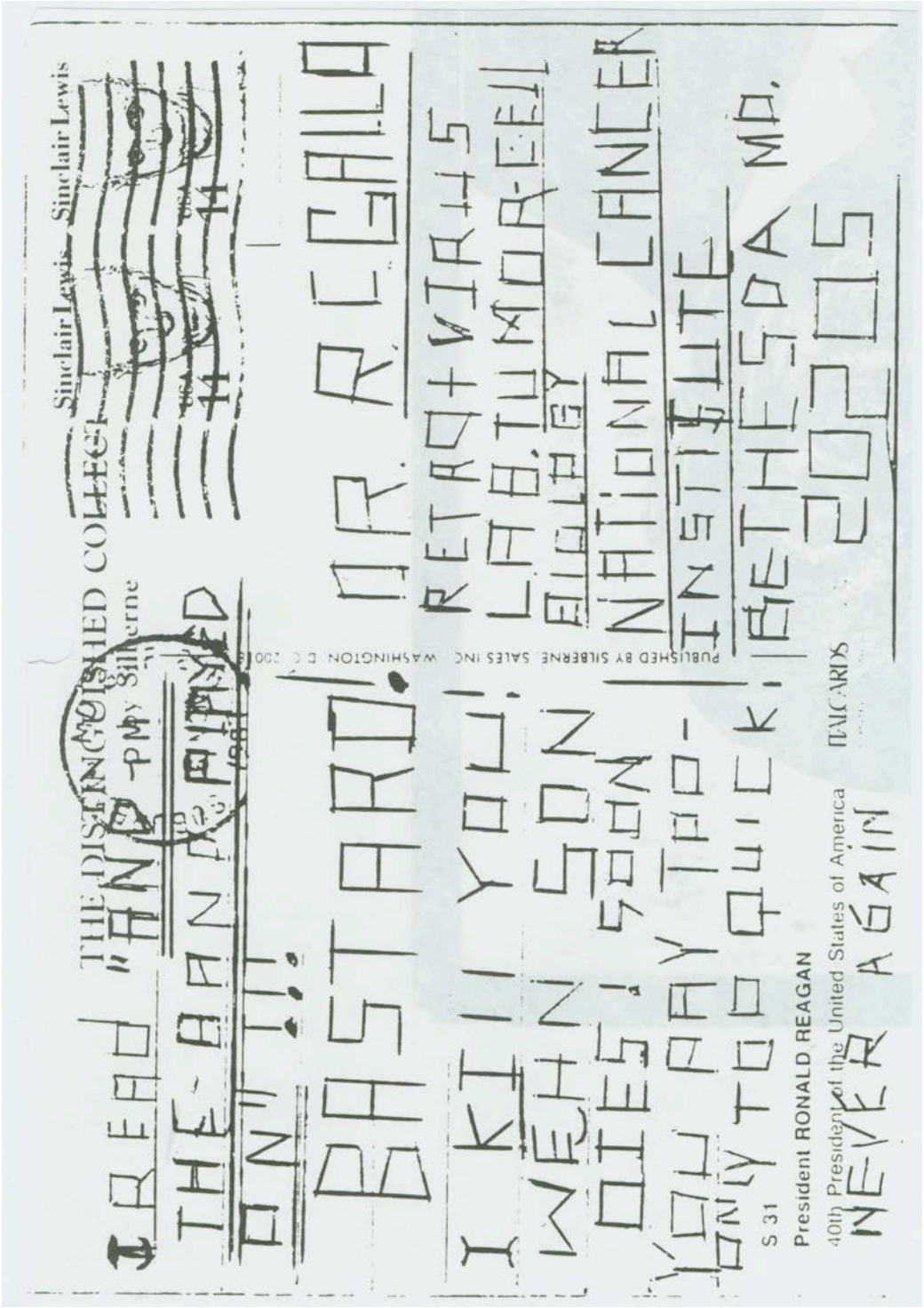
Warm regards.

Sincerely yours,

Robert C. Gallo, M.D.

RCG/bj

…and a history of events is effectively erased.



An example of what the French PR firms accomplished: branding Gallo as the AIDS bad guy in spite of all he had accomplished to the contrary. This hostile letter even threatens to kill Bob Gallo. Needless to say, there were many, many others which were supportive and complimentary.

16.

GENETIC SYSTEMS & THE PATENT INTERFERENCE ACTION

On July 3, 1985, Mr. Ferris from DHHS, sent a letter to the Associate Director of the NCI, bringing to his attention another involvement in the Franco-American dispute; that of Genetic Systems: "Mr. Bert Rowland called today regarding the subject patent (the Gallo patent on the AIDS blood test). He stated that he represents a company (Genetic Systems), a licensee of the French investigators who have been working on HTLV-III in collaboration with Dr. Gallo and his group and who have an application pending before the FDA for a license to market an AIDS blood test. Mr. Rowland stated that he has reviewed the French documentation and feels that there is conclusive evidence that the French are the first inventors of the subject invention and that an Interference should have been declared while the Patent Application was still pending. Mr. Rowland had expected that an Interference would be declared and that all the information as to who did what when would come out during the Interference. Instead the subject patent issued and he is faced with the problem of how to best protect his client's interests."

On July 17 1985, Mr. Ferris put the following additional information on record:

"Mr. Rowland called and advised that, upon instructions from his client Genetic Systems, he is canceling the meeting that was scheduled for 23 July to discuss the subject patent. …Mr. Rowland advised that the patent examiner in the U.S. Patent Office will probably declare an Interference between a pending French application and the subject issued patent before the end of the year….Genetic Systems will continue to explore[142] the facts surrounding the development of the AIDS technology by Gallo et al and the French investigators. Mr. Rowland asked me what I thought the Government position might be regarding enforcement of the subject patent should Genetic Systems attempt to enter the market without having obtained a license from the Government. I told him that I did not know what action the Government might take against an infringer."

On November 8, 1986, Gallo appeared at the U.S. Patent and Trademark office and made a sworn declaration on the Interference. A number of important points of this declaration follow: "…At the time the Gallo patent was filed, my colleagues and I did not consider LAV and HTLV-III to be the same, or even substantially the same virus. Quite clearly the data available to us indicated that the two viruses functioned differently and

[142] And they could afford to as they had received enormous endowments from the Bristol-Meyers Corporation; investing in hopes of reaping in the rewards of a winning French test.

reacted differently. One such difference was shown by the fact that we could grow the HTLV-III using the H9 cell line, and we could not do this with LAV…A fourth difference was that the sera of 20% or less of AIDS patients reacted positively with LAV. We found 88% to 100% of these sera positive to HTLV-III…I do not know and can not determine if the LAV I received from Pasteur in September 1983 was the same as, or different from, the isolate referred to in the Barré-Sinoussi paper, the isolate referred to by Montagnier in his presentation at Cold Spring Harbor in September 1983, the isolate referred to in the Montagnier patent application, or the isolate deposited at the C.N.C.M. …"

On September 9, 1987, Gallo filed an amendment at the U.S. Patent and Trademark Office: "In accordance with provisions…please correct the above identified patent by adding the following twelve individuals as joint inventors…" The names of twelve newly added French scientists then follow.

On September 17, 1987, the U.S. Patent and Trademark Office re-declared the Interference: "The inventor-ship of the Montagnier et al application…is corrected by adding as inventors thereto:" (then the names of three American scientists follow). "The inventor-ship of the Gallo et al patent… is corrected by adding as inventors thereto:" (likewise, the names of twelve French scientists also follow).

And that's the story of how the American AIDS test patent was changed which allowed the French government first, then its scientists, to share in the on-going wealth of its sizeable monetary potential.

17.
MISCONDUCT WITHOUT DEFINITION

Knowledge and know-how in biomedical sciences truly exploded during the last third of the 20th century. Correspondingly, the business prospects of biomedical research, in terms of wealth generation, multiplied. The competition for a "piece of the action," in terms of access to finite research resources, became tougher. Likewise, the pressure to publish or perish, as a means of increasing one's share of research resources, increased. Scientific misconduct, as a way to survive that competition, became more prevalent.

As it turns out, the Gallo affair was but a small portion (but generated the most noise) of the attacks that befell the scientific arena. It seemed that as soon as science was targeted, it became a mission to take down the leaders in the different disciplines. Science and Government became oil and vinegar. Although science was doing good things for the people of the world, Government tried to throw itself into the mix and questioned the motives and practices behind the advances. In that period of time, a lot was going on behind the scenes, and its scope was far reaching; its totality intricate and complex. The history of scientific misconduct in the biomedical sciences[143] is expectedly then, only about at least as long as the present period of explosive growth in knowledge and know-how. Its highlights are represented here in the following text in an attempt to clarify what some of those targeted had to muddle through.

In 1974, a core number of biologists called for a moratorium on research in recombinant DNA experimentation[144], pending an investigation of its potential hazards.

In 1975, 140 biologists participated in a conference at Asilomar to assert the need of morality in biological sciences and produce recommendations for the conduct of recombinant DNA research.

By mid 1976, the NIH issued guidelines, based on the Asilomar recommendations, to govern the conduct of federally funded research in recombinant DNA. In the same year, the City Council of Cambridge, Massachusetts, imposed a moratorium on recombinant DNA research, pending a better understanding of the hazards involved.

By 1981, cases of scientific misconduct and fraud appeared in the press with

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[143] This information is based on Kevles D.J., The Baltimore Case – A Trial of Politics, Sciences and Character, W.W. Norton & Co., 2000.

[144] This is a process where you to transfer biological properties of one species to another by transferring genes of one species (plant and/or animal) into the DNA of another.

enough frequency to set off alarms. Virtually all the cases reported, involved biomedical research at leading institutions of learning and research.

In early 1981, U.S. Representative Albert Gore, Jr., Chairman of the Subcommittee on Investigations and Oversight, held the first hearings ever on misconduct in biomedical sciences, exposed several disturbing incidents of scientific fraud, and revealed the alarming frequency of sinful research practices.

The press continued to report additional cases of scientific fraud at various intervals following the hearings. The scientific community itself was obviously disturbed by the findings and became very concerned over the possible enactment of government controls.

As a result, by mid 1981, Yale University was the first to establish scientific fraud handling procedures that took the inquiry out of the hands of the involved scientists. In contrast, the NIH had yet (as of then), no formal fraud handling procedures in place; including the exercise of oversight during inquiries of grantees by their own host institutions.

However by 1982, the NIH started developing policies and procedures to govern the handling of alleged scientific misconduct within the Public Health Service. It established an ALERT system designed to inform and share confidential information about ongoing inquiries and sanctions imposed. Colleges and Universities followed suit and started developing their own procedural mechanisms for handling alleged cases of scientific fraud.

In the fall of 1983, Walter Stewart and Ned Feder, both staff members of the NIH, ran across a case of scientific misconduct. They conducted an impartial case study, wrote a critique on the subject and submitted it for publication. No scientific journal accepted their paper on the grounds of possible legal entanglements as the subjects of the paper were still under investigation.

In 1984, Representative John Dingell was appointed Chairman of the Energy and Commerce Committee (with jurisdiction over the NIH), and Chairman of the Subcommittee of Investigations and Oversight. Dingell tenaciously went after fraudulent federal contractors, corrupt government bureaucrats, and illegal decision-bending peddlers. His successes earned him fame which helped him enlarge the scope and authority of his Committees, as well as the size and finances of his investigative staff.

In 1985, Congress revised the Health Services Act, requiring that any applicant organization for federal research funds from the biomedical and behavioral sciences have a process in place to handle charges of alleged scientific misconduct.

In early 1986, William Broad and Nicholas Wade[145] published a book titled, Betrayers of Truth, in which they claimed that fraud is practically commonplace in Science.

In February 1986, Stewart and Feder testified at the House Judiciary Subcommittee on Civil and Constitutional Rights on the substance of their fraud study, and on the practical conflicts between the free press and the laws of libel.

Around the same time period, the ethics and responsibilities of authorship become hot subjects of debate in the open scientific literature and at scientific meetings. Policies on misconduct were also formulated and offered by scientific journals and scientific societies.

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[145] Later, Wade will write a magazine article in the New York Times, defending Gallo during his ordeal.

In May 1986, Stewart and Feder testified to a Congressional Task Force on Science Policy about their fraud case study and declared that scientific misconduct may be more prevalent among biomedical scientists than was generally realized.

In June 1986, the Public Health Service, the mother agency of the NIH, defined misconduct in science as "serious deviations from practices which are reasonable and commonly accepted within the scientific community for proposing, conducting, and reporting research; the deviations include, but are not limited to fabrication, falsification, plagiarism, and deception."

In the meantime, more cases of scientific misconduct continued to surface in the press along with accompanying evidence of inadequate institutional responses. Dingell and his investigative staff concluded that scientists are no more honest than the average lay person. That the institutional procedures the scientific community themselves had established to deter scientific fraud, or to deal with alleged fraud, were wholly inadequate. Congressional criticism mounted over the competency of safeguards against scientific misconduct, which was based on peer review, with a perceived likelihood to cover-up, rather than a willingness to expose wrong-doers. Dingell soon turned his investigative resources to search for fraud in federally funded biomedical research. The NIH responded by looking into mechanisms and procedures aimed at handling cases of alleged scientific fraud.

In the fall of 1988, the NIH announced its intent to create an office dealing exclusively with scientific integrity.

In late 1988, Representative Dingell prepared a draft bill to legislate the creation of an office of scientific integrity within the NIH; with powers to conduct random audits of laboratory records kept by NIH employees and NIH grantees.

On March 8, 1989, the NIH created, on its own, the Office of Scientific Integrity (OSI), in response to Dingell's initiative. It appointed as Acting Director, Dr. Brian Kimes, a research administrator on loan from the National Cancer Institute and, as his Deputy Director, Dr. Suzanne Hadley, a psychologist on loan from the National Institute of Mental Health. OSI was given the power to conduct its own inquiries on its own NIH scientists, as well as to monitor on-going inquiries by host institutions on NIH grantees; and to discontinue federal research funds to offenders.

OSI was burdened immediately with about one hundred pending cases of alleged scientific misconduct. For Congressman Dingell, however, the prosecution of Imanishi-Kari (with Nobel Laureate David Baltimore in the background) was the one single crucial test case to show how the fraud handling system of the NIH was still in need of reform. Consistent with this aim, was Dingell's decision to go after high profile cases and make his point in a most dramatic way so that everyone in America would get the message that he meant business. Expectedly, then, he soon went after Gallo (see Chapter 19), another high profile case that could serve his purpose well.

Gallo: *"At the beginning (of the controversy & ensuing investigation) I thought this was a farce. A joke. I thought they just wanted to make sure we had some isolates*[146]*. I didn't even understand why they were doing it. But I took it as something trivial, and something very minor in that it was levity, it was lightness, and we'll get through this*

[146] To prove Gallo's claim of previous multiple isolations of virus to his accusers, many of the early isolates done by Phil Markham, were retrieved from storage, thawed from their frozen state, and retested by independent review.

quick, and we did. The inquiry…well, it wasn't quick but they thoroughly examined everything and they found everything to be in order. They called it the "Inquiry," which was a misrepresentation. In fact the so-called inquiry was the only time a group of qualified individuals evaluated the entire story and records and no one was found guilty of anything. That was the whole investigation. Hadley would bring in new people again and again, each group was trying to find something to get us for." All manner of tactics were tried. No matter how absurd they were. Gallo continues: *"And then Hadley had her cookies, she makes some homemade cookies, and gives me some to eat. While she's attempting to put the last spear into a guy hanging on the cross."*

From the very start, the OSI came under severe criticism for three main reasons.

i) First, for its lack of formal procedures, which could not safeguard due process for the accused. Obviously, the greater the threat on the reputation, livelihood, and freedom of an accused, the more legally rigid -more justly structured- due process protection needs to become. However, conventional privilege of due process was never an issue at the OSI. As a matter of fact, it was considered totally unnecessary under the pretence that investigations of misconduct were scientific rather than legal. Given that due process was never an issue, a number of evils were apt to follow, and they did.
    a) The investigative process could drag on for years, which was more likely than not.
    b) The name(s) of the person(s) who brought the charges against the accused could be concealed, and were.
    c) Access to accusatory evidence could be denied to the concerned, and was.
    d) Cross-examination of accuser witnesses could be prohibited, and was.
    e) Confidentiality could be breached, and was (sensitive information was continuously fed to the press in violation of the Privacy Act).
    f) Reputations could be tarnished, and were.
    g) Finally, livelihoods could be destroyed, and indeed were.

ii) Secondly, the OSI was criticized for Hadley's mentality to consider the accused guilty until proven innocent[147]. Even placing the burden to prove innocence on the accused, rather than on the OSI to prove guilt in their cases. The common perception on this was that Hadley was influenced by Dingell's investigative staff into believing that was the right way to handle matters. Thus, Hadley actually reversed one of the fundamental principles of American Justice, all by herself, right from the onset of her investigative career. An odd note, Hadley was a psychologist with zero experience in the science she was investigating; specifically cancer, virology, molecular biology, and endocrinology. But as Gallo puts it, *"She always had people she could go to, to get help, who wanted us (him and Popovic) dead; like from the Pasteur's lawyers side."*

iii) Thirdly, the OSI was criticized for decision-bending, in the direction desired by Dingell's investigative staff, to protect itself from Congressman Dingell's potential wrath. The OSI remained in constant scrutiny under the watchful eyes of Dingell, as well as under the constant watch of Dingell's allies in the

[147] Kevles D.J., The Baltimore Case, W. W. Norton & Co., 1998, p. 228.

press[148]. It was virtually impossible for the OSI, therefore, to keep its investigations outside Dingell's influence.

In midsummer 1989, the Public Health Service issued its regulations on scientific misconduct and stipulated that "honest errors or honest differences in interpretations and judgments of data" did not constitute misconduct. In other words, "intent to deceive" became the differentiating factor in ascertaining misconduct verdicts.

In 1989, Daniel Koshland, the Editor of Science, noted in an article published in the New York Times (Aug. 19, p.13) that "scientists have lost their ability to run their affairs as a cozy collegial group that rewards the good guys and agrees to throw out the bad guys with a minimum of formality."

In January 1990, Dr. Jules Hallum, a biologist with experience on scientific ethics and, on the responsible conduct of research, was appointed the new Director of the OSI.

In June 1990, Bob Charrow, former Deputy General Council of the Department of Health and Human Services, by then in private practice, blamed the OSI in an article published in the Journal of NIH Research for operating without a formal set of rules and procedures.

In August 1990, Judge Barbara B. Crabb ruled that the OSI was in violation of the Administrative Procedures Act. The Crabb ruling brought wider attention to the OSI's investigative practices, and encouraged the filing of several due process lawsuits by scientists already accused of misconduct. Mounting criticism forced the OSI to undertake a revision of its policies and procedures to better protect the rights of both the accusers and the accused. The attempted revisions, however, still gave the OSI freedom to deviate from any particular policy or procedure, if it was in the best interest of the United States.

In the fall of 1990, NIH began a campus-wide property inventory. Pressure to keep all things looking on the up and up, targeted Gallo's LTCB as the first laboratory to be so inventoried.

In March 1991, Suzanne Hadley, Deputy Director of the OSI, at odds with Jules Hallum, Director of the OSI, resigned. She was then assigned to the Office of Science Policy and Legislation of the NIH, but remained authorized by the then Acting Director of the NIH, to personally keep charge of the Imanishi-Kari (Baltimore), Popovic, and Gallo cases to complete her reports on them all. Presumably because of her familiarity with those specific cases. Hadley then exceeds her authority and conducts follow-up and other investigations as the Director of the OSI lost supervisory control over Hadley's on-going activities, on a day-to-day basis. Most probably due to her continued collaboration with Congressman Dingell's staff. A bit later you will read how these actions had consequences for Hadley.

In April 1991, Dr. Bernadine Healy became the new Director of the NIH.

In June 1991, Healy completely shut down Hadley's investigative operations, after it becomes apparent that she essentially established herself in competition with the OSI.

On July 1, 1991, Hadley wrapped up her investigative activities and her reporting responsibilities, and took a leave of absence.

There was general agreement at NIH by then, that Hadley was in fact, Dingell's agent, suspected of carrying out clandestine activities on his behalf, and that she had created a real mess while working at the OSI. Healy was appalled to discover that the

[148] Kevles D.J., The Baltimore Case, W. W. Norton & Co., 1998, p. 232.

OSI operated outside the margins of due process, suffered from judgmental subjectivity (meaning, it could not/would not distinguish between intentional fraud and honest error), and violated privacy rights (by deliberately leaking confidential information to the press, thereby smearing reputations). To clean up this confusion, Healy ordered a review of the OSI's operational procedures to protect the rights of the accused against violations of due process, and from breaches of individual confidentiality.

On July 15, 1991, Healy gave a talk to an NIH Advisory Board on Scientific Misconduct and noted that the breach of confidentiality was among the biggest failings of the OSI, which, in of itself, could even be viewed as much -or more so- a misconduct charge just as the alleged misconduct of the accused. She further noted that the Privacy Act should apply to records and information concerning people under misconduct investigations; and that the obligation of confidentiality was only exceeded by the obligation of due process.

On July 19, 1991 several of Dingell's staff arrived at NIH to review the recent developments at OSI, in preparation for a hearing of the Subcommittee called by Dingell himself. Healy would state later that Dingell's staff behaved like "thugs, absolute thugs[149]," cursing, intimidating, and threatening. Also, they were considered scrappy, brutal, and vicious. According to Brian Kimes, the previous Acting Director of the OSI, Dingell's staff was "totally unethical[150]," leaking confidential information to journalists just to hurt people still under investigation. Also, according to Kimes, Hadley knew only too well that Dingell and his staff were denying elemental protection of -and going after- the accused very publicly. Therefore, she herself did not care about fairness, objectivity, due process, or confidentiality.

Dingell will later admit, "congressional hearings are rather blunt instruments, poorly suited to making fine distinctions of fact[151]."

In July 1991, the President of the Federation of American Societies for Experimental Biology urged its members to protest in writing the OSI policies which afford little, if any, procedural protection of scientists accused of misconduct. By September 1991, NIH policymakers were inundated with letters of protest. An independent protest campaign was also mounted by the academic associations of the nation asking for procedural reforms in handling alleged misconduct cases, and for the separation between investigation and adjudication functions.

"We need investigators that are independent, not intimidated. We need investigations that will be factual, not friendly. We need investigation procedures that are fair and efficient, not toothless[152]." With those opening remarks, on August 1, 1991, Congressman Dingell held a hearing on scientific misconduct, with both Healy and Hadley present. He further declared that Healy had "virtually obliterated" all progress made at NIH in dealing with scientific misconduct, not to mention that she had deprived the OSI of Hadley. Healy responded by elaborating on the lack of (and the necessity to assure) confidentiality and due process in misconduct cases.

Healy's response attracted the attention of the press and her position was

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[149] Kevles D.J., The Baltimore Case, W. W. Norton & Co., 1998, p. 303.
[150] Kevles D.J., The Baltimore Case, W. W. Norton & Co., 1998, p. 232.
[151] In his 1992 Shattuck Lecture, Misconduct In Medical Research, New England Journal Of Medicine, 1993:328:1610-5.
[152] From the, Opening Statement Of The Honorable John D. Dingell, Chairman, Subcommittee On Oversight And Investigations, Thursday, August 1, 1991.

enthusiastically endorsed by the scientific community. A week after the hearing, Nature (Aug. 8, 1991, p. 457-458) observed in an editorial that, "Healy's instincts are correct, that the constitution of the OSI as it stands is thoroughly unsatisfactory, and that there is ample reason to believe that people against whom misconduct is alleged, might be unjustly pilloried." Healy knew only too well that she could be hurt by going against Dingell, who had already threatened her (see Chapter 19). Bruce Chafin, one of Dingell's investigators, made a most relevant and revealing statement after the hearing. "She's (Healy) got her mind made up…and the only way to deal with this woman is a collision course. Some people you can threaten, or cajole, and you can influence them. I'm convinced we're not going to be able to influence this woman until she fears us. She's going to have to start listening…or they'll be another train wreck, and another, and sooner or later she'll be carried out in a body bag[153]." Much later, Healy would make a public statement (reported by the Chicago Tribune on January 19,1995 , see Appendix 5, p.293) as to the witch-hunting methods employed by the misconduct handling machinery to assure convictions. "Immune from the Freedom of Information Act and the laws against libel and slander, Dingell and his staff operated in virtual secrecy, withholding any document that displayed their methods of operation, or contradicted their fabricated story line. This gave them carte blanche to make reckless and unsupported statements about people or institutions. To these charges against the accusers one can add humiliation, intimidation, and threat of both the accused and their defense witnesses. As Supreme Court Justice Robert Jackson stated about a half century ago "the most odious of all oppressions are those which mask as justice."

In November 1991, OSI Director Hallum, met with Dingell's staff to discuss progress on its investigations. Strangely, Hadley was also present in a supportive capacity to Dingell's staff, following her return from her leave of absence at the NIH.

By March 1992, a comprehensive proposal for reorganizing the entire scientific misconduct handling system was submitted by NIH Director Healy to the Secretary of Health and Human Services. The proposal recommended moving the office of investigations out of the NIH and creating a Board of Appeals governed by all the conventional rules of due process. This last recommendation was pivotal in guaranteeing the rights of the accused for impartial justice.

"Shortly it became apparent to me that she (Hadley) was not conducting the business of OSI out of OSI offices in Building 31, but rather had an office in Building 1, where she maintained sensitive and highly confidential OSI related records and files separate from OSI. On a day-to-day basis, she was carrying out OSI investigations physically separate from the other OSI personnel and without the day-to-day supervision of the Director of OSI[154]."

In March 1992, still with no formal ties or position at the OSI, Hadley somehow obtained confidential OSI documents regarding on-going investigations, and leaks them to Dingell's staff. Hadley's unauthorized action was investigated and she was rightfully (and duly) reprimanded. Hallum had been told by an informant on the weekend of March

[153] Science Fictions: A Scientific Mystery, a Massive Cover-up and the Dark Legacy of Robert Gallo, John Crewdson, Little, Brown & Co., 2002, p.427.

[154] From the, Statement Of Bernadine Healy, M.D., Director, National Institutes Of Health, Before The House Energy And Commerce Committee, Subcommittee On Oversight And Investigations, August 1, 1991.

7, 1992 that Hadley was getting those confidential OSI documents from two members of its support staff. After Hallum reported this to Healy, she turned to the Inspector's General Office, who determined that her actions violated Federal law, and her case was sent to the FBI for further action.

Enough was enough and the locks were changed on Hadley's office, so that she could not gain entry without first being chaperoned by watchful supervision. FBI Agent Alan Carroll soon spoke with Hadley for 45 minutes, after getting admissions from both her accomplices; the two support staff members. Hadley would never admit either to Agent Carroll, or to Science reporters (doing a story at the time) that she ever received the documents in question. She also declined to say whether she had ever given OSI documents to Dingell's Subcommittee.

The FBI brought the case to the U.S. Attorney in Maryland, for possible indictment. The U.S. Attorney wrote a letter to Healy explaining the reasons he would not prosecute; that the Subcommittee could have gotten those documents through legitimate means if they wanted. But more than that, the U.S. Attorney also made sure to send a copy of that letter to Dingell himself. Hadley, Dingell, the OSI, and, a Congressional Subcommittee had now, positively, been tied together for all to see. The secretive, underhanded relationship of impropriety had been found out. Dingell started running to Hadley's aid. Not surprisingly, Dingell then protests the censured acts against Hadley, which he (ironically and amazingly) considered an attempt of intimidation and harassment.

One of Dingell's aides had this to say of the whole thing, "This is the craziest thing I've ever seen. Leaking documents is clearly not a federal crime[155]." Does that make it right?

In May 1992, Dingell attacked Healy for unjustifiably attempting to start a misconduct investigation against Hadley; confirming all suspicions regarding Hadley's role as Dingell's agent even after her departure from the OSI.

In June 1992, the Office of Scientific Integrity (OSI) was abolished and replaced by the Office of Research Integrity (ORI) outside the NIH, but within the Office of the Assistant Secretary of Health (in line with Healy's March 1992 proposal mentioned previously). The Director of the ORI was instructed to design policies and procedures protecting the accused. Moreover, any accused, found guilty of misconduct, was now given the right to appeal the verdict at a hearing in front of a panel of lawyers; known as the Research Integrity Adjudication Panel. Note - at the time, the ORI had eight guilty verdicts pending, but lost all eight of those cases when each of the accused appealed.

The ORI was given the task, to regulate the behavior of scientists under the assumption that different research institutions could not exercise adequate self-control on those accused of misconduct. But the ORI was not an agency, not even a full-fledged office. Rather it was an office within an office, within an agency and, therefore, could not convict anybody for anything. It could only collect evidence and to that end it had broad subpoena authority and virtually unchecked power to investigate, judge, and reach a verdict on alleged scientific misconduct. The ORI did not need a motive to pronounce a guilty verdict, never looked for a motive, never came up with one, and never burdened itself with proving intent. Prosecution and conviction were the prerogative of Dingell's Oversight and Investigations

[155] FBI Investigates Leaks At O.S.I., by David P. Hamilton, Science, vol. 255, March 20, 1992, p. 1503.

Subcommittee where the ORI's evidence and rulings were presented. Convictions meant anything from reprimand, being cut-off from federal funding, even imprisonment.

In October 1992, the Public Health Service called for further reforms to the ORI's policies and procedures, as well as for a more precise definition of scientific misconduct.

In December 1992 and again in January 1993, Dingell requested from Healy, that Hadley be assigned to his Subcommittee in an assisting capacity. Healy refused.

In late spring 1993, Dingell appealed the Hadley assignment issue to the Secretary of Health and Human Services, who reversed Healy's decision, and authorized the move.

In July 1993, Hadley (a psychologist by trade, remember?) arrives at Capitol Hill for a six month, full-time detail and joins Dingell's staff, for whom apparently she had been working for all along. She remained in that position until April 1994; making those six months, last nine. Afterwards, she remained in touch with the Subcommittee.

In 1994, Congressional elections bring into political power a Republican House and Representative Dingell was demoted down to the ranking minority leader on his Committees; so ending the open season witch-hunt on scientists. But cases of alleged scientific misconduct did continue to surface at a rate of about two dozen a year, flooding the system.

In late 1995, the ORI's misconduct procedures were still vague and were still in draft form. A Federal Commission on Research Integrity, headed by Dr. Kenneth Ryan, was appointed by, and proposed to the Secretary of Health and Human Services, thirty-three measures for dealing with misconduct. Within months the National Academy of Sciences and the Coalition of Biological Scientists denounced those measures.

In late spring of 1996, an interdepartmental group headed by Dr. William Raub was appointed by the Secretary to review and revise the Commission's proposal. The group endorsed about two thirds of the proposal.

In March 1998, while all of the proposed measures for dealing with scientific misconduct were still under advisement, the Presidential Office of Science and Technology Policy, took it upon itself to streamline the fraud handling system in regards to scientific research; to redefine scientific misconduct in a way acceptable by both the Government and, the scientific community. On December 6, 2000 they released their Federal Policy on Research Misconduct as the final word on the matter (see Appendix 6, p.295).

In January 2002, Dr. Irving Weissman of Stanford University, chaired a national advisory panel that called for a ban on the cloning of human beings, but for the continuation of cloning human tissues for therapeutic purposes. Senator Sam Brownback (R-Kentucky) and Senator Mary Landrieu (R-Louisiana) introduced a bill to ban the cloning of human embryos. The House of Representatives likewise passed a similar bill.

So, in view of all this turmoil, who then can claim that scientific misconduct is easy to define? Who can claim that the system of judging misconduct is easy to establish? Who can assure that the individuals investigating misconduct are always impartial and just? And, who can claim that the existing system of judging misconduct operates in a logical and fair manner? No wonder many scientists accused of misconduct suffered inexcusably for no good reason. Guidelines were a whim at best in those days. Rights, nonexistent. Whereas, the ambitions of Congressional Committee staff members, were monumental.

As documented throughout this book, Gallo's ugly prosecution (persecution in reality), documented further in Chapter 19, was intended to serve as a high visibility showcase that would have earned for the accusers (bureaucrats and journalists alike) many high marks. As you will soon read, unfortunately for them, but fortunately for science, the Gallo case exploded in their faces, much to their chagrin and embarrassment.

18.
HOW THE BAND PLAYED ITS MUSIC OUT OF TUNE

And The Band Played On is the title of a book[156] written by Randy Shilts. Since first published in 1987, the book sold over a million copies and has been serialized in various magazines. The author, a reporter, who at the time was covering the gay community for the San Francisco Chronicle, described events and personalities during the early days of the AIDS epidemic against the backdrop of a rising death toll. No doubt, the book became a dominant force in the late 1980s and early 1990s, shaping public perception of the AIDS predicament.

The underlying theme of Shilts' book was that America's Institutions had failed to cope with the problem. The Government had failed because politicians and administrators did not grasp the urgency of the situation, did not recognize the universality of the disease, ignored the many pleas of the gay community for help, and remained otherwise preoccupied with conservative ideologies. The research establishment had also failed because scientists and clinicians were slow in showing interest in a disease that primarily affected the gay community, instead becoming enmeshed in battles over research thrusts, over research priorities, over research funds, over personal achievements, over personal power, and over personal glory - while the epidemic just kept right on sweeping through the nation. Finally, the media itself had failed because reporters labeled the epidemic a gay affliction, focused themselves on its morbid aspects, addressed issues of moral retribution, and even cultivated the early public revulsion of the disease and its victims.

In order to support these views, Shilts twisted statements, distorted events, got innumerable facts wrong, identified wrong people in certain events, and even misidentified institutions. In addition, he demeaned personalities with both conviction and passion, even those he never met and never spoke to; like Gallo. He even went so far as to report hearsay as fact, gossip as truth, and myths as history. More importantly, however, he totally ignored the scientific literature as an irrefutable historical record of who the real contributors were, and what contributions each one of them had really made. It is not surprising, therefore, that Shilts' characters and story plots were carefully redesigned to support his thesis of indifference, selfishness, and bigotry.

Under his novelistic style and spotlight, Shilts' story is unkind to both NIH and Gallo. NIH is portrayed as an intellectual country club where detached, middle aged scientists, with strong interests in basic research (and only an indirect concern for the sick),

[156] Published by St. Martin's Press.

hope to stumble across discoveries that will glorify them and perhaps benefit mankind as well. This perception in of itself reveals Shilts' inability to grasp the process of scientific inquiry. Scientists do not just stumble onto discoveries. They precipitate them through imaginative thinking and creative doing; while in constant cooperation, and competition, with each other.

Against this backdrop, Gallo is again depicted as a villain. As a man bent on personal glory with no scruples when it comes to stealing ideas, results, and credit from others; all in order to feed his own ego. His discovery of the first human retrovirus is mentioned as a second rate scientific achievement with little or no relevance to AIDS research. Yet, it was this very discovery that led to the idea of a retroviral cause of AIDS, provided the framework for how the AIDS virus replicated itself (a far harder achievement than its isolation) and, even how to grow the virus too. In retrospect, the HTLV-1 discovery was far more difficult than HIV - which then became much easier to detect because of the foundation and credibility given to human retroviruses based on that initial HTLV detection[157]. Moreover, Shilts propagated the innuendo surrounding the scientific conflict between Gallo and Montagnier, and leads the reader to believe that the allocation of credit to Gallo, for the co-discovery of the AIDS virus, was entirely undeserving and was only the result of political compromise. Even the development of an assay that (still) protects the world's blood supply, the genetic mapping of the AIDS virus, and proving the cause of AIDS (all achieved by Gallo's group) were simply brushed aside.

After a volley of letters between Shilts, Gallo, and publisher St. Martin's Press, Inc., the publisher yielded to give Gallo a very hollow victory. In a letter dated January 27, 1988, Michael Denneny of St. Martin's Press, Inc., writes Gallo to say, "Nevertheless, Randy Shilts and we have determined to make a few additional changes in the text of the book." But before he can enjoy his victory, Gallo further reads, "However, I should add that I do not believe that any books were printed after these changes were made."

Martin Delaney, Head of Project Inform: *"I knew Randy quite well. He was actually a friend of mine. And when that book first came out, that's where you first saw some of these implications (against Gallo). I mean frankly, I blame Randy for what started (John) Crewdson down this path in some ways. A lot of the things Randy had wrote about were things that I had lived through, and the way he wrote about them wasn't true. There was a lot of false and misinformation in there, on things that I personally knew and was involved in."* Delaney never did confront Shilts about the book's inaccuracies, out of respect for their friendship. For by that time, Shilts had become very ill as a result of AIDS, and was close to death.

In the last quarter of 1993, Shilts' book was dramatized on television and released as an HBO movie[158]. Although the movie claims to be based on facts[159] and actors played real scientists, the script commits grave errors in its reporting of scientific history; even more negligent than those contained in the original book. What actually happened in real life is -to an overwhelming extent- radically different from what was shown on screen. Not only are many episodes entirely false, but the whole film is in gross violation of the factual

[157] In fact, Gallo had already received his first Lasker Award for this work prior to AIDS.

[158] Scientists Say HBO Movie Distorts History of Fight Against AIDS, Boyce Rensberger, The Washington Post, Sunday, October 3, 1993, p.A6.

[159] During the film's ending credits, it reads, "Some dialogue, events, and characters have been created or combined for dramatic purposes." That is an understatement.

record. Moreover, the movie depicts Gallo as a cartoon-like monster who accomplished nothing on his own, but somehow managed to get all the credit for himself.

Yet, HBO spokesmen called the movie "fair and accurate." Shilts, himself, called it "substantially accurate," but admitted that several different incidents shown in the movie are either not in the book at all, or are downright false. Actually, Shilts himself had "been voicing similar concerns (to HBO) for quite some time," and that "HBO publicity had mistakenly promoted the notion that Randy was extremely happy with the film, which I now know is not true[160]."

Don Francis, an obscure public health researcher with the CDC, and an ex-Montagnier collaborator, who was wrongly depicted in the movie as an imaginative originator of key advances against AIDS, agreed[161] that "the movie was not all factual" but "in a thematic sense, I think it captured him (Gallo) rather well." This from a scientist who in 1982 had never even heard of human retroviruses before, according to Harvard virologist Max Essex; whom Francis studied under at that time. Essex: *"He was there (in my lab) for two and a half years. He left before HTLV. There's no question whatsoever in my mind, he was assuming all kinds of credit he didn't deserve. And that's crystal clear."* Even as late as March 1984, Francis was advised by Gallo himself, "Don't jump off Max's band wagon – he's right (about a retroviral cause)[162]." And this is the movie's hero? In fact, in that same month Francis stated in a memo to his superiors that there was no linkage of any retrovirus to AIDS.

Gallo relates that not only did Don Francis never make any contributions to HIV/AIDS research itself, but (as documented earlier) deliberately blocked Gallo from getting blood specimens from the CDC, which James Curran of the CDC had promised to send. So the torch of animosity between the two men had been lit for quite some time. It should be noted here that some years earlier Francis himself was the target of Gallo's blunt and open criticism; calling him a, "carpet-bagger." Gallo's use of that term for Francis was because Francis wanted to join in on publications with Gallo and the French group after the cause of AIDS had already been determined. After he retracted his own claim (and pre-print) that named HTLV-2 as the cause of AIDS. Gallo believed Francis had no role other than that of a self-serving desire to gain involvement, without serious contribution. At a meeting in Paris, Gallo expressed all this to Francis and Francis vowed he would, "destroy Gallo." It is a comment Don Francis would make to more than one NIH investigator.

Gallo on Francis: *"(He) became the hero of 'The Band Played On' without doing a single scientific experiment[163]. Yeah, I did call him a name. He behaved like a carpetbagger looking for something with nothing. I called him a carpetbagger when he came to Paris for that meeting. He wasn't supposed to be there. I find him there and ask, "what the hell are you doing here?" And the one thing in the movie that is true was that I threw him out and that's true, I did. "You're a carpetbagger, you don't have anything to contribute, yet you want to put your name with ours? What are you doing here? What did you do?" So, you know, he got me back."*

Interestingly enough, Francis was allowed to read the developing script and

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[160] Letter to HBO's CEO, Robert Cooper, from Martin Delaney dated May 12, 1993.
[161] Scientists Say HBO Movie Distorts History of Fight Against AIDS, Boyce Rensberger, The Washington Post, Sunday, October 3, 1993, p.A6.
[162] From Don Francis' handwritten notes recording highlights of a phone call with Gallo; March 27, 1984.
[163] Gallo expands, *"When is he first author and when is he last author on an HIV paper? Those are the critical people."*

comment on it. He was even paid for the rights to tell his side of the story. In contrast, none of the true key scientists intertwined in the history of AIDS science (Curran, Essex, Gallo, Montagnier – or their many colleagues) were ever consulted on their story. In fact, Gallo (and the others) were never entitled to the same consideration and, *"did not even know the film was being made. A repeat of the experience in the book."* Point being, Bob Gallo, Luc Montagnier, and James Curran, the three indisputable key players in AIDS research, were never ever interviewed for either the book or the film! But not being interviewed, or approached for either input or clarification was a mute point anyway. Because Gallo was already under orders by NIH officials not to discuss the movie, or to comment publicly on it.

Gallo: *"I was a Government worker. I was forbidden. You have to understand, I was forbidden to protect myself! Sam Broder, the NCI Director, he demanded I sign a document*[164] *that I wouldn't talk to the press. I couldn't comment, I couldn't do anything. You could have called me a rapist, killer of children and I would have had to sit there and say, " Yes, thank you." That is a fact."*

There is a scene, even Shilts agreed was wrong: in which Movie-Gallo orders Movie-Popovic, "And while you're at it, find out how they keep the cells alive." In other words, find out how the French made the breakthrough that allowed them to grow the AIDS virus in the lab. Again, it was Gallo who had made that breakthrough; who also later helped the French do it when they themselves could not. The movie also names Luc Montagnier of the Institut Pasteur in Paris, France as the discoverer of the cause of AIDS; and then insinuates strongly that Gallo stole the virus from the French. As you have already read, Gallo was the first to prove causality. Plus, by then he already had just about four dozen isolates of the AIDS virus prepared. The movie further suggested that Gallo patented his blood test out of pure greed. Yet nothing is further from the truth. The patenting decision was made by HHS and NIH officials, not by Gallo.

Yet these are the least of the movie's sins. The most perverted scene of the movie has the Movie-Gallo giving a speech (with feigned tears!) about his battle against AIDS for "the smile of healthy children," and afterwards, cynically telling Movie-Francis, "I've used that line 50 times and they still believe it." It is unthinkably sad that the media arranged for the public at large, to present a false, and quite evil image of one of the greatest medical minds of our times. Then twist it beyond the realm of truth - and yes, even fact. Especially of a man who lost his only sibling, his sister Judy, at age 6, to leukemia…herself one of the "sick children" for which scientists the world over fight for.

"It is evident that HBO is not telling the truth. I spoke to Professor Montagnier. He received a copy of the script and certainly does not agree with the statement of HBO that "our docudrama is a fair representation of the events portrayed" in And the Band Played On. He wrote a letter to HBO stating that they should drop the project[165]."

Finally, in an interview with a French news-magazine, the film's director, Mr. Spottiswoode, in the presence of several French scientists, including Montagnier (who commented on the unfairness and inaccuracies involving Gallo; as well as various other

[164] To fully appreciate just how suffocating the Gag Order was to Gallo, read Appendix 7 (p. 299). It is not the Gag Order itself, rather a report of Gallo's compliance and enforcement prepared by the Associate Director For Biological Carcinogenesis; E. Tabor. See for yourselves the many denials/exclusions from professional participation his employers imposed, which were tantamount to sanctioned harassment.

[165] Fax to Dr. Gallo from Genevieve Clavreul, dated December 13, 1992.

events and facts), admitted that the film had numerous (19 or so) developments or themes it could have followed. But for drama's sake, this was the one (Gallo, the virus thief) which made the best story. The best profit-making story, no doubt.

After the movie's release on cable television, Gallo received a call from top Dingell aide, Peter Stockton, and was asked the unbelievable by a man seeking to ruin him. Gallo: *"He tried to get me to watch, And The Band Played On, with him. How about that for sadism? He said we could watch it together and I could tell him what was wrong with it."*

It is worth mentioning that Martin Delaney, the San Francisco activist, and head of Project Inform, saw a preview of the movie and tried to set the record straight. He went to see the head of HBO, prior to the release of the film, brought him evidence of the falseness of various scenes, and got assurances that corrections would be made. Nothing of course was ever done. Delaney: *"Don (Francis) was a salesman, he was known as a big self-promoter, let's just put it that way. And he still is today."*

Later, Gallo carefully employed correspondence through his attorney (Joe Onek) to either correct or halt the movie's video release due to the dark light it cast on him. Attorneys for HBO Daniel Waggoner and Robert Joffe were only too happy to write back on May 2, 1994 and threaten: "…HBO stands behind the movie and would defend it vigorously if Dr. Gallo chooses to initiate litigation," adding, "that the volume of truthful and negative information that is available to HBO which was not directly shown in the movie, but would be at issue in the litigation and Dr. Gallo's cross-examination."

In 1989, two years after the publication of Shilts' book, there was a scientific meeting in Montreal, Canada, with thirteen thousand attendees from all over the world. That meeting ended with a presentation by Shilts. In his closing remarks to the audience, Shilts warned scientists that even if they did make any great progress or advances in AIDS research, if it wasn't done before 1996, it would be considered a failure because most of his friends (and lovers) would most likely be dead by then. Shilts then threatened to cut off research funds if he and his group did not approve of the kinds of experiments scientists were engaging in. That somehow he controlled or raised the research money which scientific endeavor needed.

Well, 1996 came and went. As of 2006, we're waiting still. The best minds have tried then for a cure, as they are trying now. Which only illustrates how very complicated the AIDS disease is.

OCT 16 1987

San Francisco Chronicle

THE VOICE OF THE WEST

October 14, 1987

Dr. Robert Gallo
Laboratory of Tumor Cell Biology
Building 37, Room 6A09
National Cancer Institute
Bethesda, Maryland 20205

Dear Dr. Gallo,

I have directed my publisher, St. Martin's Press, to make additions and further context in my AIDS book, as we discussed in our conversation last week. I have added new material you discussed with me to the anecdote on p. 350, the sentence to which you objected on p. 367 and the Paris story on p. 445. I also deleted the statements about Dr. Kaly (specifically, "I will destroy you) on p. 368 and about being "fond" of talking about Don Francis on p. 599. Moreover, I added more context to another section of the book that we did not discuss, one that concerns the various contributions that you and the Pasteur made in the discovery process of HIV. Essentially, I point out that the French clearly could not have made their LAV isolate without your pioneering work; in fact, it was your comments about a possible HTLV link to AIDS that first set them on the trail of a human retrovirus in the disease. I think this point is implicit in other parts of the book, but, in fairness, I want to make sure it is utterly clear to the reader.

Again, I appreciate the constructive nature of our discussion last week. Let me assure you that these corrections not only will appear in all future editions of the book, but that they also will appear in any Book Club editions that will come later, all foreign editions and in any paperback release. I will send you the first edition of the book that includes these contextual statements. I also await the documents you mentioned in our conversation.

I will be out of town for most of October and November. If you need to reach me, however, please leave word for me at the office of MIchael Denneny at St. Martin's Press, 212-674-5151.

Warmly,

Randy Shilts
Reporter

Even though only a few will ever see the changes, Shilts made these modifications as science fact forced him to concede to the truths of the story. But catastrophic damage was already done by then.

HARVARD SCHOOL OF PUBLIC HEALTH
Chairman, Department of Cancer Biology

HARVARD AIDS INSTITUTE
Chairman

M. Essex, D.V.M., Ph.D.
Mary Woodard Lasker Professor of Health Sciences

May 27, 1993

JUN 04 1993

Dr. Robert Gallo
Chief, Laboratory of Tumor Biology
National Cancer Institute
National Institutes of Health
Building 31, Room 6A09
Bethesda, MD 20892

Dear Bob:

Concerning any role that Don Francis played in a retroviral hypothesis for AIDS, I believe it was minimal. I also believe that he did not have any significant role in inducing either you or I to look for a human retrovirus. Let me describe the history of my own interactions with him.

(1) Francis came to Harvard in the late 1970's as a CDC employee, to do a research degree. He came to work in the general area of STD epidemiology. After his arrival he decided not to do human STD epidemiology but to work in my lab doing feline leukemia retrovirus (FeLV) epidemiology for leukemic disease. Although my lab had shown that FeLV was highly immunosuppressive 2-3 years before he did not work in that area. Instead he worked on salivary FeLV transmission, virus stability and inactivation, and the duration of incubation period for leukemia.

(2) After leaving my lab in 1979 he went back to the CDC to do hepatitis B epidemiology.

(3) During early 1982 I was investigating the possibility that HTLV, the virus that you discovered earlier (which we now call HTLV-I) could cause immune suppression. I also investigated the possibility that a variant of HTLV, or a cross-reactive related but distinct retroviruses, might be even more immunosuppressive and cause AIDS. I know that you were also independently investigating that latter point at that time or before. Thus, I believe that we were both independently looking at a retroviral hypothesis for AIDS by early 1982.

(4) In the summer of 1982 Don Francis called to discuss the AIDS epidemic with me, and to emphasize his feeling that it was an infectious disease (at the time most emphasis was on non-infectious causes such as amyl nitrate poppers or sperm antigen overload). I assured him I agreed with the infectious hypothesis and we discussed the types of infectious agents that might be considered. He suggested viruses such as hepatitis B, cytomegalovirus, and Herpes simplex. I told him that the "new class of human retroviruses" should also be considered. He replied that he and his colleagues at CDC were not aware of these viruses and I told him about them and why they should be considered (T cell tropism, same epidemiology, etc.).

(5) He mentioned that he was working on an "infectious hypothesis" AIDS epidemiology paper with Jim Curran and asked if I'd join them in that endeavor. I agreed. They sent me a first draft which contained no mention of HTLV and I added a section on HTLV. The paper was eventually published (JNCI 71:1, 1983). The CDC's own studies to evaluate infectious agents was also eventually published. It did not include anything on retroviruses (Ann. Intern. Med. 99:151, 1983).

(6) All of the lab research that was done to evaluate a human retrovirus association with the CDC was done in my lab, at least until 1983. This included all the results in any of the papers I co-authored with them (Science 220:859, 1983; Science 221:1061, 1983; Lancet 2:732, 1983; Science 223:1309, 1984). The only major role the CDC and Francis played was in supplying coded serum samples from AIDS patients and high risk individuals and to inform me about the valuable sets of human sera available for analysis.

While all this was going on you and I were obviously speaking very frequently about human retrovirus hypotheses and results and you were organizing your NIH think tank sessions. In summary, I do not believe that Don Francis even considered a human retrovirus until he heard it from me and I don't recall his expressing any particular insights on a human retrovirus during the course of the research. Thus, it seems absurd to suggest that he somehow influenced you to pursue a human retrovirus hypothesis. I was well aware of your commitment to this approach before he became involved.

As you know, I'm not eager to get involved in any public debate on credit. However, I do believe that Don Francis has portrayed his own role in "And the Band Played On" in a very misleading and inaccurate way.

Sincerely,

Max

M. Essex

This letter is from the one who knew best the extent of knowledge Don Francis had in those days…his college professor.

19.
GALLO IN THE CROSSHAIRS

The attacks against Gallo continued sporadically after the release of Shilts' book, but unexpectedly intensified in the late 1980s. In fact, his accomplishments became the center of a lengthy controversy and the focus of an unprecedented investigation; completely unheard of in the entire history of modern science.

It all started in February 1987, when Steve Connor, published two articles[166] in the British Journal, The New Scientist on the Franco-American patent dispute. These articles raised some questionable issues; namely the tampering of scientific data and the misappropriation of credit by Gallo.

Later, John Crewdson, an investigative reporter with the Chicago Tribune, interviewed Gallo by phone regarding his work on AIDS. According to Gallo, the kinds of questions Crewdson asked revealed strong negative bias with an intent to discredit him. In fact, Crewdson was all set to *"get me"* from the very start, Gallo insists. Gallo says that he never insulted or argued during the interview, kept a calm composure during the questioning, and never did send Crewdson on the warpath, as some have suspected.

Backed by strong editorial support, Crewdson started a well planned crusade against Gallo, by first publishing on November 19, 1989, an unprecedented 52,000 word article entitled The Great AIDS Quest: Science Under The Microscope. It was an article which took up sixteen full-sized pages of the Chicago Tribune. Its goal? To present in its entirety the resurrection of the same old controversy over the discovery of the AIDS virus. Moreover, it made strong allegations that Gallo stole the virus from the French, misappropriated the credit of its discovery from Luc Montagnier, deliberately deceived the scientific community into believing that HTLV-3 and LAV were two different strains of the same virus; while all along he knew they were one and the same; and then delayed progress in France for a whole year by failing to go on record that it was they who had found the cause of AIDS. Gallo: *"That starts the whole thing. Based on Crewdson's article, which was fed by Dingell, Dingell now has an excuse to begin the investigation. The French tell me, "Hey boy, this is not ours – this is your American problem." So then the real action starts. Dingell sends a woman from his staff to the NIH, predating Suzanne Hadley. Nobody at NIH knows she's working for Dingell at that time until Healy finds out.*

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[166] AIDS: Science Stands on Trial (February 5, 1987, p. 49-58) and AIDS: Mystery of the Missing Data (February 12, 1987, p.19).

"Look, as it relates to what was done to me, the villain in this is not really the French. The villains are more Americans than there are French. I want you to understand that. As I see it, the villains in this are the New York lawyers; the villains in this are Dingell, Crewdson; and the number one villain in this is Don Francis. That Don Francis set a lot of this in motion."

As to misappropriating credit, and renaming LAV as HTLV-3, what no one seems to mention anywhere is that Gallo's group was the first to describe how each isolate of HIV varied, and then published the sequences of those isolates. So if they knew they had LAV, they would also know that its sequence would likewise show up. Add to that, his other isolates (that some would lie and say he never had at all), where in fact used all over the world by scientists as prototype HIV-1 isolates.

It turns out that out of the entire universe of isolates; only HTLV-3B and LAV-LAI are identical to one another. And the reason they are identical is because of an accidental, DOUBLE contamination. The first in Montagnier's lab, and a second one occurring in Gallo's lab.

In regards to delaying progress in France, the evidence is clear that Gallo was indeed helping the French, by giving them materials and know-how all along. How could Gallo delay scientific progress in France, for a whole year, by not saying the French had found the cause of AIDS? Did scientific progress in France hinge on the words of Bob Gallo? If it did, wow! Even the Acting Assistant Secretary for Health, James Mason, addressed this issue in a July 16, 1985 memo in which he concludes he, "can not identify anything that has or will inhibit the French's ability to conduct or to collaborate with us in research." It bears mentioning here, that Gallo never went on record by saying that the French had found the cause of AIDS. The fact is they never did. They had only detected a virus.

Plus, Gallo never had to misappropriate any credit for no other reason than he himself already had enough credit to his name for his contributions to science and public health care. Besides he -not the French- was the one who proved that the virus first detected by Montagnier was indeed the cause of AIDS -and the scientific record is very clear on that!

What is known for sure is that when Crewdson went to the Pasteur Institute, its Director, Maxime Schwartz, did not greet him at all. Nor was Crewdson allowed to rifle through any files, and that Schwartz drove him away from the campus after a few days. Why? Crewdson had asked Schwartz for a permit to consult the Archives there, in order to study, he said, the history of the Institut Pasteur. Schwartz agreed, but when Crewdson got to the Archives, he asked to see the files on AIDS and said he had authorization from Schwartz to do so. The Chief of the Archives called Schwartz to confirm. Schwartz got so mad, he said not to show Crewdson anything. Besides, the Institut Pasteur was still very happy with the 1987 agreement since, as a French source states, *"as you might know, its patent was not solid at all. Political pressure finally obliged the Pasteur Institute to move."* In fact, the only person who did talk at length with Crewdson was Luc Montagnier.

It is noteworthy that Montagnier's name does not appear in the list of the first 100 science superstars (see Appendix 1, p.280). Conversely, Gallo's name is listed first. Logically then, Montagnier's claim to fame (at least in those early days) is based more on notoriety, not on peer recognition. According to The Scientist (October 2, 1989 issue, p.16) "…the French researcher (Montagnier) does not occupy the same high ranking as Gallo does in terms of citations…." Yet, according to page 117 of

John Crewdson's book[167], "…the French (i.e. Montagnier) had published a major paper in The Lancet reporting the isolation of the AIDS virus…. The Lancet paper (claims Crewdson), the most important publication on AIDS from any laboratory, opened the first window onto the epidemic to come." To the contrary (later, on page 323) he forgets himself and states, "But when the ISI calculated which scientist had been most cited by others during the 1980s, the hands down winner was Gallo, who has been an author on each of the four Science articles published in May 1984, at least one of which was cited in virtually every subsequent article about AIDS – a whopping total of 36, 789 citations in just six years." That statistic alone makes it very clear, which is more regarded among scientists; The Lancet paper or the Science articles?

Some facts need to be mentioned, that clarify the French position on their own LAV isolate, which had a very tangled start. In the May 20, 1983 paper (referred to as the Barre -Sinoussi paper) the French report on a retrovirus in which they claim a cross-reaction to HTLV-1, that the virus is a member of the HTLV family, and called their virus a type-C RNA tumor virus. A second paper published by the Pasteur group in 1984, reports their virus was a type-D virus. Then, in 1985, the Pasteur group reclassified the virus as a lenti type of retrovirus. Add now, that the French published a paper[168] (Science, July 20, 1984) that stated further studies had shown LAV to be more closely related to HTLV-2, than to HTLV-1. These disclosures, all inconsistent, demonstrate that their own morphology (of their own virus!) was quite baffling to them. Either that or, they did not have the same virus in each instance as type-C, type-D, and lenti are all three very different classes of retroviruses.

Yet, to support his allegations, Crewdson spared no resources, worked hard for many years, and published many follow-up articles, including an overall "Perspective" of the case against Gallo[169]. He traveled all over the world looking for, and interviewing, anyone he thought harbored a grudge; or could offer allegedly incriminating evidence against Gallo…and he did this with a seemingly endless financial budget.

One strange fact in all this is that Crewdson, for his many articles and book on the Gallo matter, has never met Gallo the man. Or any of his key co-workers; except for Zaki Salahuddin (a laboratory technician) who (in Gallo's words), *"had a notorious hostility and jealousy of Popovic. Zaki was hostile because Mika was taking over what Zaki wanted to do."* In other words Salahuddin was getting a lot of isolates of HIV at the time, with Phil Markham, simultaneous to Popovic. They were doing the work for the Gallo, et al. paper[170] important towards providing evidence that you could detect and isolate the HIV virus frequently from people with AIDS. This was one of the two approaches used by the Gallo group to prove causality. The second was the use of the blood test in large scale epidemiological studies. So that paper was not intended to illustrate how to grow the virus, then mass produce it for the blood test. Rather, simply, how to detect it. Gallo: *"But when Mika was starting to be able to grow the virus in a cell line, he (Salahuddin knew) that would be big, and became hostile to him thereafter."*

Popovic adds: *"Of course, during January-March 1984, Zaki made a lot of various accusations such as "You, Mika, do not have anything, only the French virus," in spite of*

[167] Science Fictions: A Scientific Mystery, a Massive Cover-up and the Dark Legacy of Robert Gallo, Little, Brown & Co., 2002.
[168] Antibodies To The Core Protein Of Lymphadenopathy-Associated Virus (LAV) In Patients With AIDS.
[169] Published December 6, 1992.
[170] This was the first of the four papers published in Science (on May 4, 1984).

the fact that not only HIV-RF, but also the HIV-1MN isolates were put into the permanent H9 T-cell line by me and not Zaki or Phil. This HIV-1 isolate was recovered by Phil Markham and Zaki Salahuddin from a boy with AIDS. They provided me with RT positive culture fluids after failed attempts to grow the HIV-MN isolate in a T-cell line. Zaki and Phil did try very hard to have an AIDS isolate in a T-cell line but they were not successful. Thus, the story that "I had only a French isolate and nothing else" was created in the LTCB by Zaki Salahuddin and not by John Crewdson."

Frantically, Crewdson also probed into Gallo's lab records and correspondence under the Freedom of Information Act (FOIA), and even peeked into Gallo's personal finances. Conversely, he never sought access into Montagnier's lab records or correspondence; he never obtained access to documents from private labs where much of Gallo's work was conducted under contract (no documents can be released from private sources under the FOIA); and got nowhere with Gallo collaborators who declined to be interviewed -even when pressured with thinly veiled innuendoes and downright threats of negative publicity. They too were convinced that Crewdson was not out to seek the truth, but to discredit Gallo globally. Which he did in fact do. For the next four years, his one-sided headlines published in the world media continued to appear, influencing articles, publications, and broadcasts with his take on the AIDS matter. In the process, immensely hurting Gallo's public image again and again.

It seemed as though Crewdson avoided interviewing those close to Gallo and close to the truth. In a letter, dated August 10, 1989, Dr. Dani Bolognesi[171] wrote to Gallo, "I then called Mr. Crewdson and told him that if he truly wanted to write an accurate account of the history he must contact the individuals…and others who were an integral part of it. His reply was cold and straight forward. He said he knew our telephone numbers and when he needed to, he would call. The call never came, at least to me." From the World Health Organization, Gallo got a letter dated May 28, 1990, from Dr. Jose Esparza[172] that read, "At that point in the discussion I suggested to Mr. Crewdson that he contact Dr. Zagury directly. He indicated that he was an investigative reporter and that preferred to use his own methods."

One of the worst allegations of premeditated bias against Crewdson comes in a confidential memo (which this author has copies of) written by Michel Baur, Head of France's General Inspection and Internal Control Department. In this translated communiqué, dated April 24, 1991, it states,

"Following your request and making an exception, I am sending you the account of a meeting that I and Dr. Chedru had with Mr. Crewdson April 8, 1991.

I confirm what I told you on the phone:

- During this meeting, Mr. Crewdson told us he was in France for reasons other than the inquiry on clinical experiments done at the Saint Antoine hospital.

- While leaving, Mr. Crewdson added explicitly that the goal of the inquiry he has been pursuing for four years is to put an end to the activities of Mr. Gallo and researchers working with him, people that Mr. Crewdson considers as noxious[173]."

[171] From the Duke University Medical School.
[172] Acting Chief, Biomedical Research Unit, Global Program on AIDS.
[173] Noxious - meaning harmful to living things; injurious to health; harmful to the mind or morals; corrupting.

Crewdson's articles against Gallo, with their strong allegations of wrong-doing, were too biased, left too many informational gaps, and had too many flaws of logic. In fact, they gave such a partial and misleading picture of the actual events that they were not taken seriously by most of the scientific community. Neither could these articles justify an official Government investigation, but alas, they did. "The real origin of the current claims of misconduct remains obscure, but the most visible whistle blower is an investigative reporter, Mr. John Crewdson of the Chicago Tribune[174]." Influenced then by Crewdson's reporting, congressional science watchdog Rep. John D. Dingell (D-Mich) pressured NIH officials to investigate the matter thoroughly and take appropriate action. Thus, in January 1990, the then acting NIH Director Dr. William Raub felt compelled to mobilize the Office of Scientific Integrity (OSI) with instructions to investigate Gallo's scientific conduct.

Once again, Gallo was left unprotected as many hundreds, perhaps even thousands, of copies of the original Crewdson article were mysteriously and anonymously sent to scientists and science administrators all over the world in order to discredit Gallo. As a Government employee, Gallo was even obliged under the FOIA to turn over to Crewdson all sorts of written lab records he had on file. Crewdson's requests for information counted literally in the hundreds, and, in his hands, the Freedom of Information Act became an instrument of personal harassment. Costing Gallo and his staff an enormous amount of distracting man-hours[175] to respond to his questions and requests; at the expense of all their on-going research.

To get a proper perspective, one must realize (and the author has copies of these) that most requests Crewdson made under the FOIA were in questionnaire form. Many of these questionnaires had on average over a hundred questions. Together with my own FOIA request[176] regarding Crewdson himself, I conservatively estimate Gallo and his team had to answer over 19,000 questions posed by just this one reporter alone. Conservatively! Nineteen thousand! Not to mention the other FOIA requests from other journalists and investigators[177] conducting their own probes. Did this stifle AIDS research? You bet. And you'll read later in this book by how much. When the truth is there, and there is collaborative, independent evidence to support it, it doesn't take anyone 19,000 questions to see it. On the other hand, if you want to skew or slant that truth, 19,000 questions are more than enough to get someone so dizzy their answers will lose decisiveness.

Interestingly too, Crewdson never used in his articles any information from Gallo's lab records that contradicted his own twisted reconstruction of events. Knowing full well the internal turmoil he was causing, and the ruckus he was creating, Crewdson decided to check on who else but himself. No doubt to use as fodder in future articles, by becoming

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[174] Response To The Charge To The Consultants To The Director Of The National Institutes of Health Concerning The Investigation Of Drs. Gallo And Popovic, General Comments, signed Frederic M. Richards, January 29 & 30, 1992.

[175] The unpleasurable task of answering Crewdson's questions, and the demands from the French lawyers, went to Nancy Miller & Howard Streicher. Truth be told, all those written replies you see quoted from Gallo, back then, were in fact, Miller and Streicher answering as Gallo.

[176] This was in fact the only FOIA request made at all for this book. You should know that all the cited internal documents, correspondence, memos, lawyer communications, and the like, were given freely to this author, by both sides of this story.

[177] Another investigation on January 13, 1986 amassed a $53,300 bill for reproduction costs of documents secured through the FOIA at 10 cents a page!

part of the story rather than simply reporting it. In a letter[178] to then NIH FOIA Director Joanne Belk (dated December 28, 1988), the very last item he lists as an outstanding FOIA request is, "Copies of all documents in which John Crewdson of the Chicago Tribune are mentioned." And again on June 7, 1989 (letter to same), item 18, "All documents in the custody or control of LTCB, NCI, and not previously supplied in which John Crewdson or Chicago Tribune are mentioned."

Still, Gallo was prohibited by his superiors to comment on his own behalf, make statements, or give interviews to the press, while the investigation on his alleged scientific misconduct was on-going. This explains why, although normally unrestrained, Gallo suddenly disappeared from the spotlight only to return to public life in 1991, with an outspoken autobiography entitled Virus Hunting - AIDS, Cancer, & The Human Retrovirus – A Story Of Scientific Discovery (published by Basic Books and released after the inquiries against him had begun).

Not to be outdone, on April 14 of that same year, Crewdson published 3 Dead In AIDS Vaccine Tests, and attempted to implicate Gallo in some clinical trials done in Zaire and in particular, sought to tie him to the fatalities associated with that study. Did it stop there? No. Remembering that by this point Gallo had undeniably proved the cause of AIDS, had developed a blood test to detect it, lived through the nightmare of the 1987 settlement, with newly barbed investigations awaiting him on the horizon, he now gets…what? A letter from Montagnier that must have read like salt in his old wounds, "I regret that you ought to spend time again in details aimed at increasing (uncorrectly and unnecessarily) your contribution to our 1983 work[179]."

The NIH investigation itself began in January 1990, headed by Dr. Suzanne Hadley, then Deputy Director of the OSI. She opened an "informal" inquiry into Gallo's research practices. Already, NIH officials were worried that reopening the Franco-American dispute a second time might threaten the Gallo patent; as well as the royalty settlement already in place, if damaging new evidence were to come to light.

In February 1990, Dr. Raub informed Dingell that he would, and did, ask the National Academy of Sciences to oversee the Gallo inquiry so as to ensure its impartiality. The Academy responded favorably to Dr. Raub's request by forming a special blue ribbon Review Committee under the chairmanship of Dr. Fred Richards. This Richards' Committee, however, deliberated consistently behind close doors while being fed selected information, strictly of Hadley's choosing, by Hadley herself. Also unfortunate, the participants at the Committee meetings were spending time *"mostly gossiping about Gallo and never really focusing on the scientific issues of the case"* (quote from Dr. Bernadine Healy, former Director of the NIH, in an interview for this book). To make matters worse, the entire Richards Committee did not have on that panel a single member that was in any way involved in the field of HIV research. Nor was there anyone who worked in human viruses, just like there were no members who worked in immunology. Yet these were the people put in place to piece together an investigation that centered on human retrovirology.

The members of the Richards Committee were: Jack Stobo, the tough Chairman of John Hopkins who did not like Bernadine Healy. Alfred G. Gilman, a pharmacologist who had won a Nobel Prize for medicine in 1994 who was (according to Gallo), *"the most vicious"* member of the panel who, *"made his opinions felt from a distance."* Mary Jane

[178] Sent on Chicago Tribune letterhead.

[179] Personal correspondence dated December 29, 1989. The entire quote, including the parenthetical, are Montagnier's own words to Gallo, and presented here unaltered by the author.

Osborne, a biochemist from Connecticut. The only virologist on the panel (for a time) was Arnie Levine. Finally, Fred Richards was himself a crystallographer. It seemed that the odds were stacked well against Gallo via who Hadley (and Dingell) had put on that panel. Gallo's one comment: *"They knew what they were doing."*

In truth, the Richards' Committee was seated to only oversee the investigation against Gallo and Popovic, and give advice even though Gallo was never found guilty of anything. Making matters worse, they denied Gallo all opportunities to address his situation. Does that make sense? The very Committee put in place to oversee the Gallo case, resisted meeting with their principal: Gallo himself. They actually denied him any chance to present his response to Hadley's insinuations; even when Gallo confronted Richards personally by phone on the issue. Why refuse to see or hear from the man they were investigating? Gallo: *"It was Hadley's rules."* All the information given to the Richard's Committee came solely from Hadley, who had already shown herself to be (as Gallo says), *"more than a little flawed in the David Baltimore / Imanishi-Kari case."*

Later, after demanding an audience with the Richard's Committee, and with help from both Bernadine Healy and Sam Broder, Gallo was granted a ten minute audience. Gallo: *"And all Gilman did…we got into a shouting match as I was leaving. He says, "You grew the French virus!" And I said, "Well Mika (Popovic) actually succeeded in doing some growth, although the original samples couldn't grow. We couldn't understand it." Then I said, "What were we supposed to do? Eat it?"*

During the actual course of the inquiry, exhaustive interviews were conducted, painstaking analyses of records were performed, and a detailed reconstruction of key events was made. Gallo's own opening statement before the committee, on April 7, 1990, was most illuminating on how unfounded the accusations really were: "One particular allegation that has been most distressing to me is his allegation of "the lost year," i.e., that I personally caused a year to be lost in the fight against AIDS. It is difficult for me to understand this charge when it was our success with the blood test and evidence for causation that led to the controversy. Even by March 1984, the Montagnier group had not convinced the scientific community." (see Appendix 8, p. 306 for full text).

Gallo now: *"On the personal side, it was my great disappointment with a few of those people, because they were scientists and yet, they behaved in a manner that was the antithesis of science. So I have absolutely no respect for some who served on that Committee. A notable exception was Arnie Levine. To assume that Hadley was right when they already knew her misbehaviour with (David) Baltimore was outrageous and shocking."*

Gallo endured much by this point, and it began to take a toll on him. *"I didn't have too many nights of rest. I used to go to Roberto's (a Mexican restaurant) and eat by myself there. It was a terrible period, (I was) thinking I don't really want to stay around here anymore. A lot of thoughts like this; like what kind of life is this? I don't understand this world. But of all the things, the biggest disappointment to me was that Richard's Committee. Because they were scientists, and the only noble one on that Committee, or I should say the only one with a combination of nobility and intelligence, was Arnie Levine. He called me up and said, "I'll help you anytime day or night." He said, "I'm getting out of this Committee." He resigned from the Committee because he didn't like what we saw."* Levine in fact did resign from the Richards' Committee after its second meeting.

In October 1990, nine months after the opening of the informal inquiry, the NIH

announced that the OSI had cleared Gallo of all charges for any wrong-doing including misappropriation of the virus from the French, unduly taking the credit of discovering the AIDS virus, or misleading respectively the scientific community. The investigators confirmed that Gallo had in fact, numerous viral isolates of his own from several different sources at the time and, therefore, had absolutely no reason to steal the virus from the French. Moreover, since he had those numerous isolates already, the development of the AIDS blood test would have been possible with, or without, the French virus.

Dingell and his staff, unhappy with the verdict (as they were with the high-profile Baltimore Case and later again with the Fischer Case), seemingly influenced Hadley to the point where she would later announce (with the Academy Panel at her side) that the OSI, had again assessed the evidence, set aside their own verdict of innocence, and had decided to upgrade the "informal" inquiry to a "formal" investigation of alleged scientific misconduct by both Gallo and Popovic (see page 164). This was based on the supposed "new" findings that his laboratory records seemed inconsistent with published claims. In December 1990, Popovic was officially charged of suspected discrepancies and false statements in his landmark Science papers published back in May 1984. In addition, the Richards' Committee criticized Gallo for not sharing materials freely with other researchers. It was a statement which *"shocked"* Gallo, *"his whole team, and most at the National Cancer Institute."*

But before all that, Gallo was again found "Not Guilty" of any wrong-doing by another, separate panel of inquiry.

As announced, a second cycle of investigations started, in which records were reexamined and witnesses were recalled. In March 1991, however, Hadley, at odds with her own administrative supervisor, Dr. Jules Hallum, Director of the OSI (and a virologist), leaves the OSI – at her own request. "Dr. Hadley said she wanted a career change so Dr. Raub temporarily assigned her to an area of her interest[180]," specifically the Office of Science Policy and Legislation of the NIH.

In April 1991, during the course of the second investigative cycle, Dr. Bernadine Healy was appointed the new Director of the NIH and the Gallo case became her problem. She was astounded to learn that the Dingell staff considered the Gallo inquiry their own investigation (although the NIH, through the OSI was officially conducting it), and that they considered Gallo guilty and expected, therefore, that he would in fact, be found guilty. She was further astounded when she heard Dingell's staff boast about having taken down two of the biggest names in science; namely Nobel Prize Winner David Baltimore and Robert Gallo. When Healy questioned the independence and impartiality of the inquiry both in private and in public, she was subjected to heavy fire by Dingell's Subcommittee and was asked to "repent" (see Appendix 9, p.312). Moreover, Dingell's staff resorted to overt tactics of humiliation, intimidation, and threats in order to pressure Healy into endorsing an unqualified guilty verdict on the Gallo matter. Peter Stockton (Dingell' s chief investigator) would later admit to associates, "we pretty much humiliated her" following Healy' s appearance before Dingell's Subcommittee.

In her interview for this book, Healy corroborates that there was absolutely no doubt that she was intimidated, pressured, and threatened in order to back-off from the Gallo case and to stop questioning the investigative process. *"Otherwise (she was clearly warned),*

[180] From the, Statement Of Bernadine Healy, M.D., Director, National Institutes Of Health, Before The House Energy And Commerce Committee, Subcommittee On Oversight And Investigations, August 1, 1991.

there would be severe repercussions; up to and including a Dingell indictment." Another pressure tactic employed was that she was asked to submit receipts for incurred expenses for the upkeep of the NIH house, which she was provided with by the Government to live in. The Dingell gang wanted to know whether she (or the Government) was paying rent, whether she was paying the gardener, whether she was paying the bills for receptions she held, and/or whether she was paying for the furniture she ordered. They discovered that yes, Dr. Healy did in fact pay for all those things…out of her own pocket.

The OSI reached its second verdict in June 1991. Popovic was found guilty of scientific misconduct for misrepresenting data in his 1984 Science paper and for keeping sloppy lab records[181]. Conversely, Gallo was again cleared of all charges but, was criticized once more for not freely sharing materials with other researchers. That was their best shot at Gallo after reviewing, *"all my personal files back to high school."*

With regards to the Popovic ruling, it must be clarified that Dr. Popovic always treated LAV and HTLV-3B separately in all his work. Just as he did with the isolate MOV, which was later discovered to be LAV-LAI. Proof of that is quite simple. After completing an assay using MOV, he repeated the SAME tests with HTLV-3B. Why do that if he knew they were one and the same? Answer: he did not.

Unhappy with both the first and second OSI conclusions, Dingell asked NIH for the evidence upon which the decisions to condemn Popovic, but to acquit Gallo, had been based. He also had his staff launch an investigation of its own. So to tally – there's the French lawsuit, the OSI "informal" inquiry," that other panel of inquiry which followed, the OSI's immediate and subsequent "formal" investigation, and now another investigation by Dingell. All the while Gallo, his collaborators, and science as a whole wanted just to move on and get back to work. Because AIDS did not stop. Not for Dingell. Not for Crewdson. Not for anyone.

For his own investigation, Dingell further asked that both the General Accounting Office and the Inspector General of the Department of Health and Human Services, look into the case for possible wrong-doings by Gallo (now add them to tally too). But it doesn't stop there. Additionally, he asked the Justice Department to examine whether Gallo had committed perjury on his sworn declaration of the AIDS blood test patent, and to recommend whether there were grounds to prosecute him for knowingly making false statements. Dingell it seemed searched every venue and utilized any and all offices of the Federal Government to find something on Gallo; especially since the score -up to then- was three victories for Gallo, and three loses for Dingell. These new efforts fared no better. The response of the Justice Department was negative; there were no grounds to prosecute for perjury. Determined, Dingell continued his own investigations and accused the OSI for failing to properly discharge its responsibilities by deliberately suppressing evidence and by allowing Healy to interfere with, and soften, the final OSI report on Gallo.

Still, Dingell had tightened the screws to an intolerable point. Every miniscule action and/or word was excruciatingly scrutinized. So on July 19, 1991, Gallo had to sign a "Gag Order" imposed on him in the form of an official Memorandum from both Drs. Healy and Broder. Fourteen points were detailed, curtailing Gallo's behavior and response to the on-going investigation and very public allegations against him. Collaborations and

[181] In an internal memo to Dr. Streicher (August 19, 1985), Popovic wrote that he was more concerned with developing an accurate assay for HIV antibody detection for use in blood banks, than in keeping a carefully documented notebook.

consultations were halted; even memberships into to professional organizations were denied. He could not even lecture without official approval; much less speak to the media in any manner, ever.

Expressing the sentiments of a great many scientists, Marshall Goldberg, Professor of Medicine at Jefferson Medical College in Philadelphia, sent a letter of protest to The Philadelphia Inquirer which was published as a commentary on April 25, 1992. In this commentary, entitled Stop Knocking AIDS Scientists, Goldberg argues that the "media blasts at the Gallo team are unwarranted, hamper important research, and ought to stop." Also, Martin Delaney, the San Francisco activist and Head of Project Inform, wrote a factual letter to Congressman Dingell (others did too) in defense of Gallo, unfortunately to no avail. Other letters were also written to news agencies, pleading that they print true facts in their coverage of the story. Not just opinions (Appendix 10, p.316).

So what motivated this AIDS activist to help Gallo, when so many others would not? Delaney: *"I didn't know Gallo up to this time (1989), I knew the story, I read the same things in the paper everybody did and I thought, "God, this guy is a monster." I didn't want to meet him or ever deal with him. I was sitting, talking with Sam (Broder – Head of the NCI) and he started explaining to me that Gallo wasn't this character that you were reading about. He wasn't what the public was being led to believe. Most importantly, Sam was worried that this whole process was destroying his (Gallo's) productivity. Having to dig out old records, rerun experiments, and respond from one inquiry to another. And he was also concerned that Gallo's spirit was breaking down. And that this was a loss that was going to be felt by people with AIDS. That this did matter to people. This wasn't some nobody. This was one of the most important people working on the (AIDS) project. And he wondered if there was any way that I could help. And I remember telling him I would do anything I could but I really needed to know more. Because everything I had read up till then had been such and such.*

"So I went to see Tony Fauci about it. And I said, "Do you think I should engage Gallo?" And he encouraged me to. He said, "Yeah, you'll actually enjoy meeting him. He's not the monster, and he could probably use a friend in the activist community right now," because so many people were blaming him for everything. Because that was the bizarre thing; if you go back and look at newsletters, community newspapers, and all that; every mistake that (the) government made about AIDS, they were blaming on Gallo. They had this impression that Gallo was running the whole government's research program, Gallo created it (AIDS) in a military experiment, and it was as if Gallo was advising all the policies, and he had nothing to do with any of that stuff! He had no involvement with these policy decisions or any of this stuff. So I did get the sense that at least that much was clearly unfair. So I called him up and said I'd like to meet and I'd like to talk.

"And I talked with him (in Gallo's house) for hours and hours and hours that night, and I looked him in the eye, and asked him what was true and what wasn't, and kind of began to learn the story. Got his view, what he would say to me, straight, eye to eye, and then I asked him to back it up. (That) I'd like to see the documentation. So he just began sharing with me all this stuff that was being collected for the committees and the investigations and that. And as I read it, my view began to shift from what I had been reading, like all this other stuff had been coming, basically from two people; it was coming from John Crewdson and Don Francis. And I knew Don Francis and I knew he wasn't the straightest shooter on two legs. And I found Gallo, not just charming, but a really kind of interesting character. Of all the AIDS researchers I met, I thought, if I had to go out

drinking with one at night, this would be the one."

In June 1992, the OSI was abolished and replaced by the Office of Research Integrity (ORI) outside the NIH, but within the Department of Health and Human Services. The first order of business of the newly formed ORI was to charge -yet again- Gallo and Popovic for alleged scientific misconduct. This time the ORI started its own independent investigation, including an inquiry of a possible cover-up by the NIH. But the issues of alleged fraud and possible cover-up were completely unfounded. Why? Look at the evidence. During the critical period (1983-1984) Gallo's lab had identified and isolated numerous strains of the AIDS virus, each of which was undeniably different from LAV-LAI, and each of which could have supported the Gallo claim of possessing his own virus. Having those, there was no need to commit fraud, hence no need for a cover-up.

Behind these new accusations stood one Dr. Suzanne Hadley, the former Deputy Director of the OSI. Evidently, she prepared a report for the Dingell Subcommittee, reviving all the same charges against Gallo, and now contending that the NIH and the Department of Health and Human Services were involved in a massive cover-up of Gallo's fraud to protect the patent rights of the U.S. Governments on the American AIDS blood test. Needless to say that behind Hadley was Congressman Dingell, pushing for convictions. And that was common knowledge throughout the NIH campus.

At this point one needs ask an important question. Which is…why was Congressman Dingell so obsessed with Gallo, and was so stubbornly set against him[182]. After tracing back and connecting people and relationships, the answer becomes clear. The New York law firm representing the French (Weil, Gotschal, and Manges) was, at the time, also representing[183] the General Motors Foundation; whose President, coincidentally enough, was Congressman Dingell's own wife. It suspiciously appears that the law firm used its relationship to influence Dingell's wife on behalf of their French clients, and in turn, Dingell's wife was influencing Dingell himself, to go after Gallo. Dingell then apparently also leaked information about Gallo to selected reporters, such as Crewdson.

This new ORI investigation lasted until late into the winter of 1993, under Dingell's watchful eye, and probed into the same issues as thrice before addressed (during the 1987 French lawsuit, the 1989 OSI/NIH informal inquiry, and the 1990 OSI/NIH formal inquiry). Once more, pressure and influence from outside the investigative process went to work behind the scenes to succeed where they had failed before. Namely, to convict Gallo. For example, Peter Stockton (Dingell's chief investigator), was quoted by Crewdson himself for making the following statement: "The trick is going to be to push him (Gallo), but not panic him so that he flies out the door, either literally or figuratively. If he just goes crazy then nothing is accomplished." Stockton had gotten the impression that Gallo might be ready to point a finger at Mika Popovic "and point it strongly enough, and in front of enough people, so that we then could go to Mika directly and say, Here's what Bob told us. That's our only hope to get Mika to crack[184]."

In August 1992, Barre -Sinoussi from the Institut Pasteur testified against Mika Popovic. She found the excuse and the opportunity to do so while attending that year's annual Gallo lab meeting on AIDS, in Bethesda (interesting enough, she was invited by

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[182] The same could also be asked with regards to the David Baltimore witch-hunt.
[183] Specifically, Ira Milstein, the head of the law firm, was the Chief Counsel to the Board of General Motors.
[184] Science Fictions: A Scientific Mystery, a Massive Cover-up and the Dark Legacy of Robert Gallo, Little, Brown & Co., 2002, p. 467).

Gallo who was paying her expenses so that she could attend). During her questioning, she testified that Dr. Popovic confessed to her in a taxi ride, which they shared on their way to the Gallo meeting, that he had deliberately put the LAV virus into his pool. Popovic vehemently denies that he ever made such a statement. Gallo himself called Barre -Sinoussi in Paris on several occasions to demand an explanation. Even though he never did reach her, he nonetheless, soon found himself now accused of harassment. A curious fact here: his last call to her at the Pasteur, was not answered by anyone in Paris. Rather it had been diverted directly to the French lawyers in New York.

Much later, Barre -Sinoussi sent a fax[185] to Gallo trying to present the whole incident under a different light. Gallo: *"She does say she denies that Mika said it, "deliberately." What she's doing is trying to get out of the statement (her testimony). She now says she didn't understand Mika's words because of his Czech accent. She was undoubtedly angry because she got in trouble. So what she's saying to me is that Mika acknowledged it was most likely a contamination. And she was trying to get the word(s) (during her testimony) exactly straight."*

Later, one of Gallo's post-doc students (without Gallo's knowledge) wrote, and asked the numerous laboratories around the globe to verify for his defense his freely sharing materials with them. Genoveffa Franchini explains: *"We (the people in Gallo's group) decided to do something. We felt, many of us, that it was unfair what was going on, that it was a kind of persecution, we felt we could do something. I don't like situations of victimization, so I felt my contribution could be that (mailing)."*

So petty and so great was the determination of Gallo's accusers (notably the Dingell gang) to get him convicted on any excuse they could find, that Gallo was immediately (are you ready?) charged for mail fraud. More specifically, for using official NIH stationary without authorization. Shake your head because on this, no one told Gallo a thing. Gallo tells how he found out about his latest charge: *"I'm looking through the 'A' section of the Washington Post, and I end up about two-thirds of the way through the paper and I see a little headline; A pioneer under investigation for possible criminal activity for mail fraud. And I read it's me. And I say, what?! My first reaction is, what the hell did I do now? Before the day is over I find out that (it was) Veffa Franchini."*

Those charges were dropped only after an exasperated Gallo produced evidence that his co-worker (Genoveffa Franchini, the post-doc in question) had obtained prior permission from the Administrative Director of her division, Dick Adamson, to use the NIH stationary, to write Gallo's colleagues an official correspondence, and request their factual testimony. Genoveffa Franchini's reaction to Gallo's charge of mail fraud: *"I couldn't believe it partly because I didn't know those rules, which by the way, I think are made up as we go along. For me, it was proper to do that (mail those requests on official stationary), because it was part of defending the reputation of somebody that represents and that works for the government. It was not to personally help Bob, it was for all of us. All of us. It was the way in which the public would look at us. Which I think is important."*

But if making that immediate charge of mail fraud seemed important, investigating it was not. Not the OSI, NIH, NCI, Hadley, Dingell, or his subcommittee pursued the matter once Franchini's lone role came to light. Genoveffa Franchini expands: *"Let's put it*

[185] "It is true that I never said that Mika made a direct statement that LAV (LAI) had been put deliberately into the pool. However, since I assumed that LAV had indeed been added to the pool…" Fax from Barré-Sinoussi to Robert Gallo, March 14, 1994.

this way. I didn't feel that anybody felt really so strongly about that, because nobody came and asked me, "Why did you do that?"

Incidentally, out of some three hundred letters sent to labs all over the world, they received back 297 responses of support[186]. The rest simply did not respond. But the response Franchini got was enough; to a degree. Gallo explains: *"And she gets letters back that are so supportive that they can't do anything to me about the reagents. The NCI shows (these letters to) the crazy Dingell gang and Hadley and, of course, they're pissed off. Because it ends their claim about reagents. Do they retract anything? Of course not. Does Crewdson retract anything? Of course not. He still does it in the book, okay. Does he tell you about these letters? Of course not. Does he know about it – of course he does. And he's working like this with Hadley. So…he knows and he omits. He knows and he omits."*

Not to be deterred, Dingell's aides (not the ORI investigators) Peter Stockton and Bruce Chafin travelled all over Europe, at taxpayers expense (of course), to interview people in search of incriminating evidence. Gallo only found this out when one of his ex-post-docs (all the way from Prague!), Peter Stockbauer, phoned him after a visit in his lab from both Stockton and Chafin. Gallo was also called by another former post-doctoral (Mandy Fisher), from her London office, telling that she also found Crewdson waiting in her office.

Gallo was trying to make sense of all that was going on, with his boss, Sam Broder: *"His parents were in Auschwitz in World War II and they got out, but they were in Auschwitz – I guess they got liberated. Sam used to say to me - yell at me - when I said I don't understand why they're doing this; why do they want to hurt me? "Don't you know there's evil in the world?" he used to scream at me and say that. He told me "Bob, these people are the same as the SS" – that's what Sam Broder used to say."*

According to personal communications to Gallo, from Mike Astrue, a lawyer with the DHHS, and Dick Adamson, Gallo's immediate administrative supervisor at NIH, Gallo's personal files at the DHHS and the NIH were also investigated by Dingell's staff looking for any skeletons in his past. Gallo: *"Adamson told me at 9pm, they were still badgering (Sam) Broder, intimidating him to find Baltimore, Fischer, and me guilty of something. Did he ever get threatened? Of course."* Adamson further relates that the Dingell's staffers became enraged, having not found anything incriminating in the records. Those are but a few of the things that Gallo knows of Dingell's investigative practices. As he himself puts it, *"God only knows what I don't know. Had they found something bad about me, such as cheating on a test in high school, it would have become instant headlines for sure."* One of the things that Gallo did not know (until this author shared it with him), was that in late 1989, Intelligence Agents had covertly met with key people asking if there was any information in Gallo's past that would make him vulnerable to blackmail. The excuse for those interviews, and that question, was that Gallo was being considered for a position as a White House Advisor.

Unexpectedly, Dingell then actually solicited the help of the Institut Pasteur lawyers (tally that) in New York to amass damaging information against Gallo and, thus, facilitate his conviction. So if Dingell enlisted the aid of the French lawyers, can the ORI be far behind? Well, "the next stop for the ORI lawyers was Manhattan, where their request for a

[186] This author has personally read through hundreds of correspondence letters asking Gallo for reagents; hundreds of letters of thanks for said; and just as many which later referred scientists to the NIH repository because of the unending requests hindering the lab's on-going research.

meeting had left Jim Swire (the lawyer representing the French interests) slightly nonplussed by the fact that the United States government, which only a few years before had been defending Gallo against the Pasteur's claims for reparations, was now asking for Swire's help in proving that Gallo had deliberately concealed Popovic's use of the French virus[187]."

This questionable alliance undermined U.S. interests by encouraging the French to request reallocation of the royalties from the AIDS blood test by questioning the validity of the original 1987 Franco-American agreement. They justified their request upon the identity of HTLV-3B with LAV-LAI, which proved that the American AIDS blood test was being manufactured using the French virus. Upon closer examination, it is not unthinkable that an additional motive for Dingell, known as a very partisan Democrat, was trying to attach controversy to government scientists making important discoveries during a Republican (Reagan) Presidency. Essentially, to keep the press from touting the good while it blindly, and wrongly, sought only to task science on the bad.

In fact, that historic agreement between the French and U.S. governments, reached in March 1987, did begin to unravel little more than five years after it was signed. But even as far back as 1988 Gallo had been warned that future trouble was coming; this time not from the French side, but from the American side. In a privileged communication to Gallo from Ashley Haase (a Professor at the University of Minnesota, with access to inside information), Gallo learned that the lawyers handling the French case over the patent dispute were unhappy because of inadequate compensation out of the Franco-American settlement. So they put together a plan to reopen the case with the help of Congressman Dingell[188]. Gallo had believed everything was fine with the previous history of events he had published jointly with Montagnier. Gallo: *"Of course, that's settlement number one. Then as soon as it occurs, I think everything is over now, what a horrible period of my life, and then I find out I'm going to get it all over again because the lawyers in New York are unhappy. I'm warned by Ashley Haase. Milstein (a lead attorney representing the French side) had a plan. The plan was obvious. Milstein was Chief Consul for General Motors, Debbie Dingell (the Congressman's wife) – President of (the) General Motors (Foundation), got Dingell involved. And then that became the focus that the virus we used for the blood test was from France. And we were told on the settlement that time, we would never be able to talk about this again. You understand? I could never talk about this again. Sure, I could take all the negative stuff and everything else, have a defaming movie made, have all those other attacks, and I should never talk about it again. I know why they don't want to talk about it again, <u>because</u> <u>they</u> <u>knew</u> <u>they</u> <u>had</u> <u>that</u> <u>contaminant</u>! That's what I think[189]."*

In his interview for this book, Bob Charrow, former Deputy General Consul of the Department of Health and Human Services stated (in line with Haase's previous disclosure), *"there was a fundamental misunderstanding as to what this new investigation against Gallo and Popovic was all about. It was not about the virus, as the accused thought all along; it was about patent rights and royalties."*

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[187] <u>Science Fictions: A Scientific Mystery, a Massive Cover-up and the Dark Legacy of Robert Gallo</u>, Crewdson J., Little, Brown & Co., 2002, p. 477.

[188] One of the contentions the Pasteur lawyers made was that they would not have signed the first settlement if they had known of Popovic's first draft manuscript. But this was nonsense since they had ALL of Popovic's notebooks in 1985.

[189] See next chapter for more on this.

In early 1992, the French Government made an official request that the March 1987 agreement be renegotiated since the virus used in the U.S. blood test was proven to be a French isolate. In June 1992, a panel of experts commissioned by the Department of Health and Human Services concluded that there was no substance to the French request. They argued (and this is true) that the description of the U.S. patent claimed a method for detecting the presence of antibodies to the virus. It did not claim the virus itself. Therefore, the source of the virus in the American blood test was irrelevant to the patent case. Besides, the French application for its own U.S. patent never did describe in it, a workable blood test. They also, very clearly stated that the virus can not be grown in a cell line; meaning that no large scale production was possible.

Toiling in top level secrecy, NIH was hatching its own plan in the summer of 1992. They wanted the nuisance of the French to end once and for all. Confidential and privileged documents prove that NIH had commissioned the law offices of Allegretti & Witcoff, LTD. (of Chicago, Illinois), to study the feasibility of their one grand scheme to stop the French claims against the Gallo patent permanently. How? By removing all of the NCI co-inventors from both the Gallo and Montagnier patents! An incredible stratagem to say the least. Remember, in the 1987 settlement, Montagnier and his team were added to the Gallo patent just as Gallo and his team were similarly added to the Montagnier patent. Officially removing Gallo and the other American scientists would invalidate both patents, thereby rendering all claims against both patents unenforceable! The answer to why is simple: lack of common ownership of the two patents. Additionally, a change in ownership nullified the terminal disclaimer filed in Montagnier's patent. But a change of inventorship would not affect that disclaimer, so the importance of exact wording and clear distinctions becomes crucial to the NIH scheme. Now comes the most cunning facet of the plan; how to get around the doctrine of double patenting[190]. Lawfully, a new, second patent would not be invalid if a terminal disclaimer had been filed with it, which provides that the second patent expires on the same day as the first issued patent. So they were seeking to invalidate the original Gallo patent, then file new patents listing the same American-side inventors effectively rendering all challenges against Patent No. 4,520,113 (the Gallo patent) impotent the moment it ceased to exist. This would allow NIH to re-create the second patent in a new filing with concise wording that unquestionably described simply the process for detecting HIV infection in the blood; absolutely without naming any isolates because that process works irrespective of any strain. Simply put, HIV is HIV, regardless of any individual isolation; whether it comes from the U.S., Africa, or even France.

But the stumbling block was Claim #4 of Montagnier's patent: "The method of Claim 1 wherein the biological fluid is from a patient with pre-AIDS." The patent attorneys looking into this matter for NIH, concluded, "…Montagnier could have a position with regard to detecting antibodies to p24/p25 for pre-AIDS patients in such a test;" even though he never demonstrated that in his patent. Nevertheless, the last sentence on the last page of that 71 page study[191] for NIH, concludes with the lawyers agreeing, "Claim 4 of the Montagnier patent, properly construed is valid." NIH quickly abandoned that effort.

[190] The reasons two patents can not be issued for the same invention is that Congress intended that the period of exclusive rights to an invention be limited to 17 years and, a second, issued-later patent would extend the period of those exclusive rights beyond that 17 year period.

[191] Dated June 30, 1992, written by John J. McDonnell, Esq. and Edward W. Remus, Esq.

Unaware of all that, in September 1992, French officials, and lawyers representing the French, resubmitted and defended to U.S. Government Administrators their request for a bigger share of the royalties from the American blood test, and of course, threatened to take their case to court once more. So, a new agreement reached out of court, was signed in July 1994 (see page 166), which was financially more attractive to the French side at the expense of the American side. According to that new agreement, the Institut Pasteur would now receive two thirds of the royalty pool after each side gets an equal share of 20%. Meaning that the entire sum of royalties would be collected first by the U.S. government, then twenty percent of that sum goes to the U.S., another twenty percent goes to the French, and two-thirds of what remains after that, is likewise given to the French. The remaining one third went to the World Foundation for AIDS Research and Prevention, for funding international projects on the disease. Additionally, the French got an acknowledgment by the American authorities that the LAV-LAI virus isolated by the French was the same one used for commercial purposes in the U.S.

In the meantime, after yet another cycle of penetrating investigations into Gallo's scientific practices, the ORI reversed the conclusion of the OSI's investigation, and this time, did find Gallo guilty of scientific misconduct. But not for stealing anything from the French. Rather, for a single ambiguous sentence he wrote in a paper entitled: Detection, Isolation, and Continuous Production of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and Pre-AIDS. This was one of the four papers published in the single topic issue of Science, in 1984. In that paper, Gallo failed to acknowledge that his laboratory had managed to grow the French virus in his own producer cell line. That according to the ORI's interpretation, but not according to Gallo - who meant that the French themselves had failed to grow the virus. But how could one sentence be so misconstrued, especially in light of the fact that other scientists concurred with the Gallo interpretation when that statement was taken in context with the paragraph it was written in. An interesting fact about all this, is that Gallo was/has never been found guilty of anything by any scientific body ever –and in fact, the ORI never was/has been a scientific body. Gallo: *"They didn't have the courtesy, the politeness, the decency to tell me anything. You know how I found out about the misconduct? I got it in the mail."*

Waiting, wanting, wishing, to testify in that round of hearings, was Suzanne Hadley. She had herself injected into the ORI's Witness List of "Experts" to testify against Gallo. She testified. But instead of being a happy nail on the Gallo crucifix, a jury of her peers judged her and wrote, "Not accepted as an expert witness[192]." The former Deputy Director of the OSI, who led the investigation against Gallo, who continued to personally oversee the case even after leaving the OSI in 1991, was deemed not to have any expertise on the matter and that her words, whatever they might have been, carried no weight. In fact, of all the names on that ORI witness list, Hadley's was the only one not accepted by that Board of Inquiry. Then there was Dr. Mal Martin. The one scientist Gallo did not send reagents to, which he did eventually get but, *"with more restrictions than on others."* He showed up to testify against Gallo too; as a key government witness. But the court found him to be "highly-biased" and "un-objective" because of his own personal dispute with Gallo (which is discussed in more detail later in this book).

Still, the ORI found Gallo's co-worker Mika Popovic sloppy in his record keeping

[192] DAB Decision No. 1446, In re: Mikulas Popovic, M.D., Ph.D., Docket No. A-93-100, Appendix C at 1 and 2; see also Transcript of DAB Hearing (TR), June 8, 1993 at 139-140.

obligations, and was likewise found guilty of scientific misconduct for ambiguities in the description of his experiments in the same paper; but they conceded that these ambiguities were relatively minor. Gallo: *"Popovic was found guilty in what would turn out to be some very small and irrelevant inaccuracies."* However, under pressure from the Dingell staff, in December 1990, the non-scientist administrators in the Health Department found Gallo "guilty of one-half of one statement in the discussion of the Popovic paper." Gallo adds that it was, *"a sentence which was correct in its inference, supportive of the French scientists, but taken literally could be viewed as inaccurate."* It was then recommended that increased supervision be given to requests for federal funds from either scientist for a period of four years, and that Popovic's "misconduct" should not preclude his employment in the Federal Government as a scientist. Popovic had been out of work for almost two years because of the investigation, and had incurred a debt in excess of $250,000 in legal fees[193]. Mika Popovic, "who worked night and day…This was one of the true heroes of AIDS research, the man who helped figure out how to detect the (AIDS) virus in blood and, as a result, saved thousands of lives[194]." In 1998, Mika Popovic finally paid off all his legal fees.

And just what was that one sentence that did so much damage? As much as it is talked about, it is rarely presented anywhere. That sentence (untouched by the author) reads as follows:

"The concentrated fluids were first shown to contain particle-associated RT [reverse transcriptase]."

It was the words "concentrated fluids" and "first shown" that the ORI pinned its case on. The ORI read "concentrated fluids" to mean samples from individual patients (or pooled before concentrating) and, "first" (again, according to the ORI) was used to mark a priority in the timing of the RT tests when compared to the infection. But to Popovic, and the Appeals Board, "concentrated fluids" meant the fluids were first pooled then concentrated for each of the three infections of the same cell line, just as it was recorded in Popovic's notebook.

It is important to note here that none of the instances of scientific misconduct cited by the ORI ever called into question the conclusions of that very same 1984 paper co-authored by Gallo and Popovic. Nor did it invalidate Gallo's claims that his lab

- was the first to biochemically characterize the AIDS virus,
- was the first to prove that HIV is the cause of AIDS,
- was the first to grow the AIDS virus in large quantities in culture and,
- was the first to develop a workable blood test.

Truth be told, stealing the French virus was never a charge leveled by the OSI; although it was constantly implied. And no one ever, at any time, in any of the many investigations, attacked or challenged the science Gallo had published. His scientific work and the resulting conclusions were in effect…untouchable.

When Gallo was informed of the outcome, he called the ORI's investigation "endless" and "incompetent;" based on the distorted interpretation of the sentence and the statement in question. In fact, when attorney Arthur Liman (who represented A-bomb

[193] While Gallo himself lost all of his late father's estate (nearly a 1 million dollar value) paying over $600,000 in his own legal fees, plus other expenses incurred defending himself. The U.S. Government on the other hand, did not spend a penny defending Gallo and/or Popovic. Keep in mind these were scientists under their employ whom they were advising and ordering; just not defending.

[194] Science Friction, by Malcolm Gladwell, The Washington Post, December 6, 1992, p.W18

inventor, J. Robert Oppenheimer against Sen. Joe McCarthy in what was later dubbed, "The McCarthy Hearings") read about the sentence in the newspaper, he called the beleaguered scientist. Gallo: *"Liman became convinced I was a victim of another Joe McCarthy. I had never met the man and out of the blue he calls me, he told me who he was, and says he wanted to become a part of my legal team and he wanted to make a speech. Pro Bono. He said (for that one ambiguous sentence) he was going to start by bringing the Head of the Department of English, from Columbia (University), who he said was the best English linguist in the country, to prove, definitively, that the statement (sentence) could only be interpreted the way it was meant."* But that never happened because of what you will read later with regards to November 5, 1993.

Both Gallo and Popovic were requested by the ORI to respond to the guilty verdict even as both had decided to appeal; should their response to the ORI not reverse those guilty verdicts.

Instead of receiving deserved admiration and gratitude for all his discoveries and breakthroughs, Gallo was still facing doubt, criticism, and now suspicion of scientific fraud. But in essence, the case against Gallo was ultimately whittled down to a mere ambiguous statement in a sentence published in a scientific paper eight years earlier.

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Geisinger
THE TRADITION CONTINUES

HOWARD E. MORGAN, M.D.
Charles B. Degenstein
Distinguished Scientist

June 29, 1990

Dr. William F. Raub, Acting Director
National Institutes of Health
Building 1, Room 126
Bethesda, MD 20892

Dear Dr. Raub,

I am writing on behalf of the Panel of Consultants Concerning Research Conducted in the Laboratory of Tumor Cell Biology, National Cancer Institute by Dr. Robert Gallo et al. The Panel met on June 27 with the following members in attendance: F.M. Richards (Chairman), J. Areen, A. Gilman, A.J. Levine, H.E. Morgan, M.J. Osborn, J.D. Stobo, and J. Sambrook. Dr. Richards is away for the next month and I am serving as Acting Chairman. The Inquiry Team consisting of J. Hallum, S. Hadley and P. Parkman presented a portion of their findings centered on the work of the laboratory in the period from April 1983 to August 1984. The Panel considered these findings and the 4 papers that were published in Science on 4 May 1984.

After considering a) the current status of the Inquiry, b) the internal NIH procedures and regulations, c) the significance of the change in status from an inquiry to a formal investigation of possible scientific misconduct, and d) the importance of public perception of NIH and Panel actions, the Panel voted unanimously to recommend the following action to you: termination of the inquiry phase of proceedings and institution of the formal investigation. This decision was based on the review of material presented at the meeting. Some data appeared to be missing from the data books. There is a possibility of selection and/or misrepresentation of data. There is a need for the Panel to plan experiments on the viral samples that have been sequestered or that can be located. These

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How the Gallo matter moved from an informal inquiry…

experiments will be arranged by the Office of Scientific Integrity.

In the opinion of the Panel, this situation fits the stated requirements to proceed from the Inquiry Phase to a Formal Investigation. In this regard, you should charge the Panel as to its role in the formal investigation, for example whether the Panel should interview certain persons who participated in data collection and analysis. The Panel recommends that you proceed with a formal investigation and that you define the role of the Panel and the current Inquiry Team in that investigation.

Sincerely,

Howard E. Morgan

Howard E. Morgan, M.D.
Senior Vice President
for Research

Acting for
Frederic M. Richards,
Chairman
Sterling Professor of
Molecular Biophysics and
Biochemistry, Yale University

HEM:dmm

…to a formal investigation.

NIH News
National Institutes of Health
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STATEMENT ON DIVISION OF HIV TEST KIT ROYALTIES

The following statement was issued by Harold Varmus, Director of the National Institutes of Health (NIH), upon the conclusion this morning of a meeting of the French and American AIDS Foundation (FAAF):

"I am pleased to announce that, as part of a meeting of the French and American AIDS Foundation, an agreement was reached to put an end to the Institut Pasteur's request for additional patent royalties from the sale of HIV test kits.

"The agreement aims to equalize the amount of royalties each country will receive from the worldwide sale of test kits over the lives of the patents, and to normalize the sometimes rocky relations between the parties.

"The reallocation of royalties is being made because the U.S. has been collecting significantly more in royalties than France. This resulted from an anomaly created by greater U.S. test kit sales, a fact not taken into consideration in the 1987 settlement agreement. The settlement agreement and subsequent action by the FAAF board should have provided approximately equal revenues to the Institut Pasteur and the U.S. as co-patent

- MORE -

History rewritten: The second agreement between the U.S. & France over royalties.

holders, under terms intended to recognize the critical contributions made by both sides to the development of screening tests for HIV.

"The Department of Health and Human Services and the NIH also officially acknowledged, in light of the current state of knowledge and, in particular, as a result of a well-known independent study published in 1991, that scientists at the NIH used a virus provided to them by Institut Pasteur to invent the American HIV test kit.

"The technical details of the royalty reapportionment appear in the resolution adopted, copies of which are available to you. The new formula was developed so that the U.S. and France would receive approximately equal shares of the test kit royalties over the lives of the patents.

"Under the settlement reached in 1987, each side keeps the first 20% of royalties from the sales of its test kit. This will not change. Also, as under the 1987 agreement, the remaining 80% of each side's royalties will be pooled. Under today's agreement, the annual pools, beginning in 1994, will be divided as follows: 50% to Institut Pasteur; 25% to the U.S.; and 25% to the World AIDS Foundation, which funds AIDS education and research in the developing world.

"The new formula is intended to remedy an imbalance that has given the U.S. approximately $20 million and Institut Pasteur approximately $14 million in royalties since the 1987 settlement

agreement. The U.S. has received a disproportionate share of the royalties because the American test kit greatly outsells the French test kit. If past experience holds, the new formula will give the French several hundred thousand dollars per year more than they would have gotten under the old formula. The old formula distributed 25% to the World AIDS Foundation and 37.5% each to France and the U.S.

"Today's agreement is fair and equitable; it is also in the best interests of science and of the American and French people. It reflects a sincere commitment by both sides to bring this matter to a close. I look forward to putting this distraction behind us and continuing our collaboration with the Institut Pasteur in an atmosphere of mutual esteem."

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OH GARCÓN…THERE'S A LITTLE LAI IN MY BRU

"This is how it was presented to me," Popovic said. "If we lose a few weeks, more people would be infected[195]." Bad luck was coming and when it did, it hit fast. By the Spring of 1984, Popovic had HIV producing in two different cell lines. One from pooled blood samples taken from a number of patients, and the other cell line infected with the virus taken from a Haitian (residing in Philadelphia) known only as RF (his initials). Popovic wanted to use that RF[196] cell line for the blood test he, Gallo, and Sarngadharan would later create to save millions from ever becoming infected. But the RF cell line would take many more weeks to prepare for use in the test; because it was a few weeks behind HTLV-3B in development. That, and Gallo said they had to rush a blood bank assay, arguing that every day more and more people were being transfused using blood contaminated with HIV; that any delay would cost lives. As Mika Popovic told the OSI, for "clear-cut science data," RF was the better choice. But Gallo chose instead to use the pooled cell line for two reasons:

1) Gallo had a real concern that due to patient RF being Haitian, his RF virus strain might be slightly different from the virus strain(s) predominating in the United States; and would thereby compromise the usefulness of the blood test in the U.S.[197], and

2) to get a test out as soon as possible and try to halt the rampant ascension of disease to epidemic.

Gallo: *"I said take 3B (to make the blood test with). Mika came to me and wanted to use RF. And I said, "Well, why? 3B is two weeks ahead of it and we'll save that many more lives." That's all I was thinking about. Mika says, "Well, RF is from one patient, one lineage, we understand everything about it." But 3B was from pooled samples. So I asked him under every kind of circumstances, "DID YOU ADD LAV TO IT TOO?" Mika said, "No, I never added the LAV to it. I tried to keep that completely separate and at that time I stopped working with LAV."*

There was a problem however, lying in wait. A fuse the size of a virus lay in that pooled cell line; one lit with L-A-V. Unbeknownst to any, that pool line had become contaminated in early 1984 with an HIV strain sent from France; LAI. And with it, a

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[195] Science Friction, by Malcolm Gladwell, The Washington Post, December 6, 1992, p. W18

[196] By July 1984, Gallo's lab had also created the Southern Blot confirmatory assay for the RF cell line. This way, it didn't matter which way they decided when finalizing what test they would present to the world to screen blood; RF or 3B. They both worked.

[197] Transcript of DAB Hearing (TR) June 18, 1993 at 2085.

controversy came alive. The French never even knew about the existence of Gallo's RF cell line, nor did they ever know about the choice Gallo had made between the pooled versus the RF cell lines. Or, the reason for that choice. What they did come to learn was that the virus strain in the assay used by the Americans, looked a little too much like theirs. So much so in fact, that they filed a lawsuit in 1985 and put the whole "Gallo Case" into motion. They assumed the worst. But a surprise was coming for the French too, because there was another lie (or is it LAI?) unbeknownst to them; sitting in that same pooled cell line. More on that soon.

On October 25, 1984, Gallo relays in memo to Director of NCI (DeVita) and Associate Director of NCI (Fischinger), the record of a telephone conversation with Montagnier on Aug. 23, 1984 where he reports: "Montagnier was informed that we routinely find genomic diversity in our isolates of HTLV-III... He (Montagnier) stated that he has cloned his virus and finds no variation among isolates… We went back to the original LAV that they had sent to us and when analyzed it was found to be different from the virus growing in the culture they recently sent." This bit of news however, was not enough to motivate the French into taking a more in-depth look at exactly what was in those viral samples they had been shipping out.

But, with the lawsuit, the French vented to anyone and everyone. Soon, the word "steal," hit the winds. Did the Americans "steal" our virus, "steal" our accomplishment, and "steal" our credit? That decision to use the pooled cell line instead of the RF line brought up questions and accusations that took more than eight years to sort through. "But this much is clear: Had Gallo and Popovic chosen to put their own interests ahead of the public's health – and taken the extra month to prepare RF in place of the cell culture infected by the pool – none of the resulting controversy would have ever happened. Had they used RF, there would have been no international outcry over the discovery of HIV, no patent fight, no Congressional investigation, no NIH science fraud inquiry, no destruction of reputations. Popovic would still be working [198]. Gallo might well be a Nobel Prize winner[199]." Then there's this little tidbit of knowledge to share. Even into late 1986, there was a greater difference between RF from LAV-1 than any known isolate of this family of viruses. Also, you should be aware the very different RF isolate was also immediately patented by the U.S. Government.

But why pool the fluids at all? Well, Dr. Popovic had his reasons, which were rooted in science. It is known that most retroviruses exhibit a degree of heterogeneity with respect to biological behavior. He then reasoned that an efficient way to find an AIDS variant(s), one(s) which could infect, and more importantly, replicate in neoplastic CD4 T-cells, would be to pool virus from different sources (patients), concentrate them, and use the resulting viral inoculum to infect CD4 cell lines. Criticized for even doing this by his detractors, he nevertheless reasoned correctly, and thereby successfully infected the cell lines. He used his ingenuity to overcome a problem, and later, that ingenuity was used against him.

Fact confirmed by the OSI investigation: the pool that ultimately grew -3B contained several genuine HIV isolates that were different from -3B and LAV. Which meant Popovic had no reason at all to believe that the virus production he saw in the pool was the result of contamination by LAV.

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[198] Because by that time Popovic had lost his job and was barred from working for the Government again.
[199] Science Friction, by Malcolm Gladwell, The Washington Post, December 6, 1992, p. W18.

The main criticism was that the specific patient origin of the virus would not be known. But the precise knowledge of a patient's identity (the virus origin) is important for different, more precisely narrow investigations (such as the evolution of HIV-1), but not for serological studies, diagnostics, or even a virus' role in the development of AIDS. Moreover, the very first pooling (mixing) of HIV-1 from two different patients was done by Luc Montagnier. On page 372 of his paper[200], he describes, "double infection and induction of polycaryons (multinucleated giant cells)." Additionally, in the classic works of science with Rous Sarcoma Virus (RSV), stock preparations pooling was performed by lumping together sarcoma tissues from 15-20 chickens with virus induced tumors. The virus as stock was extracted from this pooled mixture of these chickens. So there was precedent and continued use of this method known as pooling.

Later, Hadley, still untrained in virology or any laboratory work, would attack Popovic on the pool as well; claiming that the pool never even existed to begin with. This theory was hers and hers alone. With her allegation, she accused the pool was nothing but a cover-up to introduce LAV into his experiments from which Popovic would then claim the new discovery of a (LAV) virus, and thereby call his independent discovery, HTLV-3. The official record on this is very clear. The only "evidence of such a notion (the supposed nonexistence of the pool) in the entire HHS record of this case is the testimony of Dr. Hadley herself, at the hearing before the DAB in June 1993. After having spent the first several years arguing that Dr. Popovic should not have established a pool in the first place, Dr. Hadley changed course at the last minute and suggested that perhaps the pool never existed[201]." Citing from page two of the Response To Investigative Memorandum No. W-90-00066-4 (Drs. Gallo and Popovic), "Her (Hadley's) reasoning was that since a few cultures were discarded because of mold contamination following the relocation of Dr. Popovic's lab, he could not have used those viruses to establish the pool. As Dr. Popovic testified, however, he made several flasks of his cell cultures and also had viable primary samples stored in the freezer for later use. Thus, the disposal of one flask of a culture clearly did not exhaust his supply of any one virus sample…Were it not the case that specimens were maintained in the freezer, Roche Diagnostics would not have been able to analyze, nine years later, each of the ten samples that comprised the pool, as ORI's witness Dr. Shaffer conceded."

The DAB (an independent panel of three Administrative Law Judges) unanimously rejected Dr. Hadley's assertion that the pool never existed. Of the many reasons cited, two stand out. The experts, on whom the ORI relied for its report, did not draw the same conclusions as Hadley (that the pool never existed) and, the existence of the pool is solidly established in Popovic's notebook[202]. Further, it referred to pooling in the protocol for those series of experiments and, pooled as a culture in the laboratory after infection.

A key component must be considered: during that very sensitive stage of experimenting and attempting to grow his cultures Popovic encountered something completely unforeseen and potentially catastrophic to his work in progress. Gallo: *"The NCI Director, Vince DeVita, gave an order to Popovic to move his (entire) lab to make room for some administrator. And gave him 48 hours (in which to do so). I tried to*

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[200] A New Human T-Lymphotropic Retrovirus: Characterization and Possible Role in Lymphadenopathy and Acquired Immune Deficiency Syndromes, L. Montagnier et al., Science, May 20, 1983.
[201] Transcript (TR) June 10, 1993 at 878-886, 890-893.
[202] H-19 Popovic Notebook at 16-17,33,34,40,44,58.

convince him otherwise, but it didn't work. That's one thing I remember that DeVita did, that was wrong. Because if it's accidental (the LAV contamination), Mika lost all control. DeVita gave Mika 48 hours to move labs. So Mika had to rush dozens of (working) cultures from one end of the corridor to the other. You ever had to move a lab in two days? When you have dozens of cultures? There's tissue cultures, media, flasks, and plates like this that you're carrying around. And you got to put it another place? Dozens?! As samples were coming into our lab – dozens! Papers, 200 pieces of glassware, 50 of which have growing cells in them, all the stuff in your freezer, and all your reagents, and your chemical things, and your equipment, and getting it to the other lab."

One other event to mention as told by Gallo. *"I had Betsy-Read (Connole) come in crying one day. That the tubes in Mika's lab were a third full higher (meaning somebody adding something to it…or perhaps was told to?). Mika left his labs wide open. The lady was crying cuz she said, "The tension is so great and now I can see somebody played with my cultures." Betsie clearly was implying that she thought somebody tampered with those tubes in the lab. And those were key samples of virus cultivation."* Were the contents of Connole's tubes ever analyzed? Not right away. But there are factors in regards to that. There really was no way to analyze the contents of those tampered tubes because HIV was not yet known, and there were no molecular probes. They would only come later, and of course after any virus was isolated. But from this incident, Gallo obtained a key to his lab so his team could lock the doors when they were away. And they did. Ultimately, Connole's tubes were analyzed because they became part of Popovic's pool which came to be HTLV-3B.

With the advent of PCR technology, by late 1990, evidence amassed in Gallo's lab revealing that something was vitally wrong with the HTLV-3B = LAV-BRU hypothesis (remember, LAV-BRU was the only French virus Montagnier claimed to have repeatedly shipped to Gallo). In fact, in a short article published in Nature[203] (from work done and authored by Marv Reitz) in February 1991 (refer back to page 107), Gallo disclosed that the genetic sequence of the LAV-BRU still in his freezer, was dissimilar both to that of his HTLV-3B virus and to that of the French AIDS virus which appeared in Cell in January 1985 (page 102). The publication of the Nature article forced the French to investigate the American allegation. Did the French want to? Marv Reitz explains: *"No, I think they didn't want to, but that (article) made them have to. I mean, they wanted to do damage control until they were able to come out with something."*

As shocking as this is to report, the next development has now been verified. Montagnier and the Pasteur had a huge problem. They couldn't even begin to address the assertions from the Nature article for one simple fact…they didn't have any samples of LAI! They were forced to ask colleagues (who provided them with the initial samples) Gluckman[204] and Klatzmann[205] for them.

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[203] Sequence Analysis Of Original HIV-1, by Guo, Chermann, Waters, Hall, Gallo, Streicher, Reitz, Popovic, Blattner, published February 28, 1991, Nature, issue 349 (6312), pages 745-746.

[204] He was first author on an early AIDS paper (published in Nature) that claimed the French team of which he was part, did all the work regarding the LAV virus and even though the Pasteur scientists played only a minor role at the end of the discovery process, they somehow managed to claim all the credit. In a later 1994 Nature article, he and others would argue the French patent was invalid, even fraudulent, for forcing the inclusion of several names of people who played no role in the discovery, in an apparent attempt to exaggerate the role of the Institute.

[205] Was the first to show how the virus infects, then kills T-4 cells.

Expectedly, this Gallo paper added more confusion to an already messy picture. Was LAV-BRU contaminated by HTLV-3B? Or was LAV-BRU contaminated by an altogether different virus, also named HTLV-3B by Gallo? If so, where did this other contaminating virus come from? Most importantly, where did the alleged contamination take place? One thing was sure at the time. HTLV-3B was identical to another AIDS virus the French had already sequenced!

Yes, by Montagnier's own admission (three months after the Nature article) in May 1991 (page 107), the second sample of LAV virus sent to Gallo in September 1983 was not actually LAV-BRU (which does not grow in cell lines at all). In fact, what the Pasteur had inadvertently delivered (and they say was completely unbeknownst to them at the time) was in reality LAV-BRU plus LAV-LAI. And LAI does grow in cell lines. This virus mixture, discovered much later, was due to an accidental contamination of LAV-BRU by LAV-LAI first in Montagnier's own lab, sometime in early August 1983. Popovic: *"If they didn't know from '83 until '90 that the mix up occurred…how could I know in '83-84 that they did this?"* Gallo: *"He (Popovic) got the last sample of LAV, he played (experimented) with it, there's no question. That was LAI."* End result, the French analysis showed a 5% contamination; the 5% being LAV-1 (BRU) and 95% being LAI. Those percentages should illustrate just how well LAI grows, how dominating, and how overpowering it is.

In the French paper[206] response to Gallo's Nature letter, after agreeing with the finding that –BRU was contaminated by –LAI, in their lab and their fault, they wrote, "Contamination is a recurrent problem in microbiology. There is no reason to suppose that experiments with immunodeficiency viruses are any more susceptible to contamination than experiments with other viruses in culture." Dr. Marvin Reitz repeats: *"Contamination is not uncommon. The only inconsistency was that they were in effect saying, "Our contamination was accidental, but the LTCB contamination was deliberate."* That French article ends with a sentence designed to throw suspicion back at the American team; instead of just keeping the paper on the topic of the contamination in their lab and its subsequent effects. "Might not the fate of the M2T-/B sample have some bearing on the relationship between LAV and HTLV-3B?" You'd think that two papers coming to the same conclusion, the mere fact that a proven contamination had occurred in France, would ease some of the pressure off the backs of the Gallo team. But that was not the case. Reitz explains: *"Both articles presented the same data, with the same conclusions; that JBB was not what it was purported to be[207]. We were accused of magnifying the differences by sloppy or questionable methods, possibly even fraud. The (French) Science paper was considered to prove that the viruses really were different, so in effect, that part of the heat was off. On the other hand, the Science paper showed that M2T-/B (grown in bone marrow cells), which we had received in 1984, was in fact the real LAV[208], proving it as the origin of -3B, and suggesting that this indicated misappropriation of the virus."*

And because his Nature article had swung the pendulum back to France, Reitz further adds, *"I got a lot of flack to the point of nearly being accused of fraud in the newspapers. A lot of it came from Gerry Myers at Los Alamos and from Wain-Hobson*

[206] LAV Revisited: Origins Of The Early HIV-1 Isolates From Institut Pasteur, Wain-Hobson, et. al, Science, May 17, 1991, vol. 252, pages 961-965

[207] JBB had virus from the patient BRU.

[208] M2T-/B probably had BRU, with LAI being the virus that would grow out in cell lines. But by some later point it probably had only LAI since that strain dominates so.

(from the Institut Pasteur; both worked closely together). However, when the Pasteur came out with its own paper several months later with the same data, they drew the same conclusions. Namely that BRU and LAI were different viruses."

The second shipment of the supposed LAV virus came in two samples (see page 178). The 5 milliliter sample is what was believed to most likely be the LAI contaminated material. While the 8 milliliter sample was BRU. It was the RT (reverse transcriptase) count that gives credence to the identification of the contaminated sample. The larger, 8 milliliter sample had an RT of 16,000 counts per million/per milliliter, while the smaller sample with just 5 milliliters of the supposedly same virus had an RT of 60,000 counts per million/per milliliter (meaning it is obviously replicating). As you know by now, the strain of HIV from patient LAI does grow in cell line culture, whereas the culture from patient BRU does not. Since that is a fact, the proof is in the numbers as written by Montagnier himself. Besides, no scientist would question the wide range in the RT count as it would likely mean that the samples were harvested from the same culture, but at different times; making that RT range a common sight they were used to seeing.

Additionally, that LAI isolate contaminated samples at other Institutions, including its place of origin - the Institut Pasteur. Of significance, after LAI was found to have contaminated cultures in Robin Weiss' laboratory (in London), that's when Dr. Montagnier reported in Science that he was certain the contamination was accidental. Soon afterwards, laboratory records given to NIH investigators proved that in 1984, other virus samples (not just HTLV-3B) had become contaminated by the LAI isolate. Yet Gallo's lab was the only lab that got the full torrent of insinuations hurled against it, along with the finger pointing of allegedly misappropriating the virus.

But to prove this contamination of LAV-LAI, the Gallo team faced an unflappable wall of non-cooperation from who else?...the French. From 1986 until 1991, Gallo unsuccessfully tried to get his hands on the source virus whence his second shipment of LAV had come. September 19, 1986, the Administrative Director (Y. Cerisier) of the C.N.C.M.[209] in France, wrote, "I ought to inform you that C.N.C.M. is not authorized, in compliance with the regulation in force, to take your demand into consideration." On November 5, 1990, Gallo reached out to his long-time friend Dr. Chermann and asked him to, "kindly send me a sample of the cells infected with LAV-BRU that were sent to me in 1983," and further requested, "to divide the material into two or three parts, and send only one part to me. Later someone else may ask for the remaining information to verify results."

The letter was forwarded to Barre -Sinoussi, whose November 15, 1990 response was short and to the point: "After your request, I have contacted Maxime Schwartz, Director of the Pasteur Institute, who wishes not to give this kind of sample now." The letter ends, "I am then very sorry by the fact that I can not transmit actually the samples to R. Gallo." Chermann then attached his own letter to the reply by Barre -Sinoussi to suggest Gallo write Cerisier of the C.N.C.M., not knowing that road had already been tried.

Tenacity being one of his hallmarks, Gallo did indeed write Cerisier again, two months later, on January 29, 1991. This time Gallo rightly pointed out he was a co-inventor[210] of the Montagnier patent #4,704,818[211] and as said joint inventor, would like a

[209] National Collection of Cultures of Micro-organisms, a branch of the Institut Pasteur.
[210] He was listed as such, per the terms of the 1987 settlement. Just as Montagnier was put on Gallo's patent.

sample, "of the original 1983 deposits NO. I-232, NO. I-240, and NO. I-241; not "equivalent" material supplied at a later date." That did it. Stating he was co-inventor of the patent was the only legal footing Gallo had. He never asserted that in all his previous correspondence, and doing so then, left the French with no choice but one…compliance. Which came in the form of a letter dated February 15, 1991. Where Cerisier still posed one last hurdle (proving that fate denies Gallo any clear-cut victories, ever) and wrote, "Anyhow I seize this occasion for telling you up to now, that I need a permit of importation set up by your authorities for proceeding to the relevant shipment." So why all the resistance and delays? Did they beforehand know what Marv Reitz was going to prove? Nobody asked for this book would answer that question. Thirteen days later, Reitz's Nature article revealing the French contamination was published for the world to read.

Keeping objectivity in mind, what happened next can really only be called one thing; suspicious. Pasteur Director, M. Schwartz, wrote Gallo (letter dated March 20, 1991), "In view of the results you recently published in Nature, we are making some verifications on our side." Nine days later, all the requested material, each and every one, that had been asked for by name were all suddenly deemed to have "insufficient stock." So on March 29, 1991, new deposits were made to the IDAV-1 and IDAV-2 virus stocks. But what about the LAV-1 virus stock, you may ask? Beginning on page 180, you can see for yourselves that new deposits were made there as well – just two days after Gallo asserted his rights as co-inventor! So American scientists waited four months from that February 15, 1991 letter, until Cerisier sent a letter to NIH on June 17, 1991 and deals this blow; "Furthermore, I ought to inform you that owing to the fact that the remaining stock of the original material of these three deposits is reserved for eventual expertises, the samples which are sent to you, belong to relevant subcultures." And with that, the Americans are denied any access to the original source material. Eight days after the French broke this news regarding the subcultures, Bobbie Brandon of the American Type Culture Collection, verified that new deposits had been made to C.N.C.M.

On September 9, 2002, at the Annual Meeting of the Institute of Human Virology, Professor Luc Montagnier presented data on the physical association of HIV with mycoplasma which enhances the transmissibility of the virus; and that the virus hides in the mycoplasma and is transmitted. To illustrate his case, he used the accidental contamination of LAV-BRU with LAV-LAI, which apparently occurred via a mycoplasma vector[212], as his example. Montagnier: *"This is probably what occurred with regard to our contamination of BRU, with LAI."* At last, an admission to, and an explanation of how he feels the contamination occurred. It was a calm statement, refreshing to hear in an open forum. Also, it is admirable for him to come to terms with it and discuss it candidly, even at that late date.

But as one scientist[213] puts it, *"It could also mean sloppy culture practice because mycoplasm tells you that this is a non-viral infection. You test for mycoplasma in cultures. And when you see mycoplasma, you start worrying about it, you start curing it. There are ways to cure the bacterial contamination. You can cure the mycoplasma with antibiotics*

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[211] Officially known as, "Human Immunodeficiency Viruses Associated With Acquired Immune Deficiency Syndrome (AIDS), A Diagnostic Method For AIDS And Pre-AIDS, And A Kit Therefor."
[212] A bacteria-like microbe.
[213] He/she wishes to remain anonymous.

and antibodies, and at the end of that exercise you'll see cultures that are clean."

What is important to realize now, is that if the original contamination by the French had NOT occurred, then the subsequent contamination in Gallo's lab, would not have mattered. Why? Because the isolate the French had originally sent to Gallo for testing was LAV-BRU. As this isolate does not grow in culture[214], it would not have ever surfaced as a candidate for culture by Gallo; irrespective of any accidental contamination. It would have remained in limbo. On the other hand, with the French accidentally contaminating LAV-BRU with LAV-LAI in subsequent samples, and LAV-LAI being a producer (meaning it could grow in culture), it appeared to all that LAV-BRU had now, inexplicably, somehow, become a producer. And with the second contamination of LAV-LAI, occurring with Popovic's cocktail (in Gallo's lab), the producing LAV-LAI took off. Adding to the confusion of just where and how LAI got into Gallo's lab, it was discovered that the actual patient LAI visited the United States several times between 1977 and 1979. Unlikely, yet a last possibility nevertheless, is that an isolate from a patient infected by LAI (or who infected LAI) could have contaminated HTLV-3B.

Dr. Marvin Reitz: *"Another thing that was sort of interesting I was puzzled by - because I thought probably that the sample that they had sent to me had the other virus in it, and that at some point they had a contamination with that virus. And so I called Wain-Hobson at the Pasteur, I think the day before the paper came out and explained what we were going to publish and asked him whether the sample that they reported - the whole sequence of LAV - had he obtained that from the primary blood cells of the patient or, that had been put in culture to amplify it and then he sequenced what had been grown? He said, "Oh no, it came from the primary blood cells of the patient," because they were worried about change occurring in culture. A couple days after the paper came out I called up to verify the same thing and then he said, "Oh no, we transmitted the virus from primary cells from normal PMBCs[215] from a person in the lab here." And so from that I kind of concluded that they probably knew all along what had happened."*

Until 1991, nobody could figure out why, what they knew as LAV-BRU, suddenly began to grow in culture, when it never did before. Barre -Sinoussi and the Pasteur had the original material from which BRU and LAI had come. Yet, it wasn't until Gallo's lab -not Montagnier's-, trying to be thorough, sought to understand why BRU first wasn't infectious, then was. So, how could Gallo suspect that HTLV-3B was the product of a double contamination? Besides, at the time, there was no way to know those two isolates were identical until after they were genetically sequenced. That could not be done until a more sensitive technology called PCR became available years later. Only then could accurate work be carried out in the very small samples of LAV-BRU particles kept in the freezer by the American group.

Any retrospective claims to the contrary are without basis or merit.

Oddly enough, years later, while Popovic was away at a conference in Switzerland, the American's sample of BRU that was contaminated with LAI, was misplaced and to this day, not ever recovered. Gallo: *"But in any case, Montagnier acknowledges that it (cross*

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[214] It wouldn't be learned until years later (1995-1997) that almost all isolates of any early HIV infected patient, those HIV strains at that early time cannot be grown in cell line culture. That happens only with strains that arise late in the course of the disease. Meaning the vast majority of isolates can not be grown in a cell line.

[215] Peripheral Mononuclear Blood Cells (basically, white blood cells taken directly from a blood sample).

contamination of LAV-LAI with other samples) happened in his lab first. It happened in everybody's lab. So whether or not somebody did it (intentionally), whether or not Mika had to move or not, it was a common contaminant." This means something stupefying, yet true: with PCR technology now in place, one could go back with small amounts of material from patient BRU, compare it to all the Pasteur laboratory samples ever used over the years for study, and actually prove that pure BRU has never, ever been in any of the scientific literature! Essentially, it's never been published!

Dr. Marvin Reitz adds this irony: *"One thing that occurs to me from time to time is that the virus that came from LAI grew so well that it really enabled a lot quicker progress to be made. The fact that people had contaminations with it really was a good thing."*

But also, it was used to launch the most unrelenting, the most oppressive, the most outrageous attack ever recorded in medical science.

Unité d'Oncologie Virale

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ATTACHMENT E

Paris, September 21st, 1983.

Drs. GALLO and POPOVIC
Laboratory of Tumor Cell Biology
NATIONAL CANCER INSTITUTE
Bldg 37 Rm 6B04
N.I.H.
BETHESDA, Maryland 20014
U. S. A.

Dear Bob,
Dear Mika,

Enclosed, two samples of virus LAV1 :

- Mkt-1B 29/08/83 5 ml
  RT 60,000 cpm/ml

- Pool JBB LAV 10/07/83 8 ml
  RT 16,000 cmp/ml

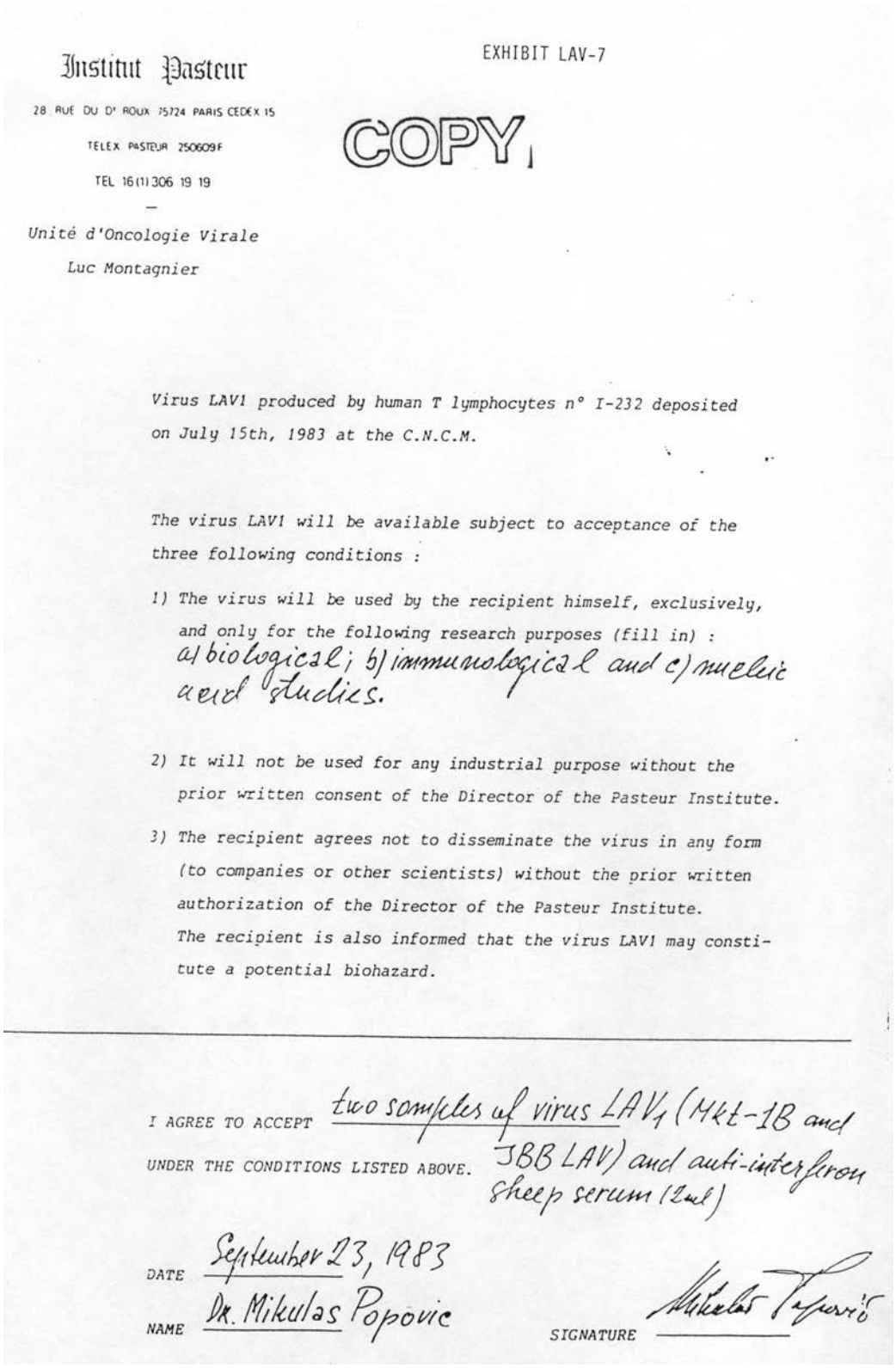
- Anti-interferon sheep serum : 2 ml
  (filtered and 56°C heated)
  to be diluted 1/100 final

I have been also requested by the Direction of the Pasteur Institute that you sign and return to me the enclosed form.

Good luck,

Luc

It took eight years…



Institut Pasteur

28 RUE DU Dr ROUX 75724 PARIS CEDEX 15

TELEX PASTEUR 250609F

TEL 16(1)306 19 19

Unité d'Oncologie Virale

Luc Montagnier

EXHIBIT LAV-7

COPY

Virus LAV1 produced by human T lymphocytes n° I-232 deposited on July 15th, 1983 at the C.N.C.M.

The virus LAV1 will be available subject to acceptance of the three following conditions :

1) The virus will be used by the recipient himself, exclusively, and only for the following research purposes (fill in) : a) biological; b) immunological and c) nucleic acid studies.

2) It will not be used for any industrial purpose without the prior written consent of the Director of the Pasteur Institute.

3) The recipient agrees not to disseminate the virus in any form (to companies or other scientists) without the prior written authorization of the Director of the Pasteur Institute. The recipient is also informed that the virus LAV1 may constitute a potential biohazard.

I AGREE TO ACCEPT two samples of virus LAV1 (Mkt-1B and JBB LAV) and anti-interferon sheep serum (2ml)

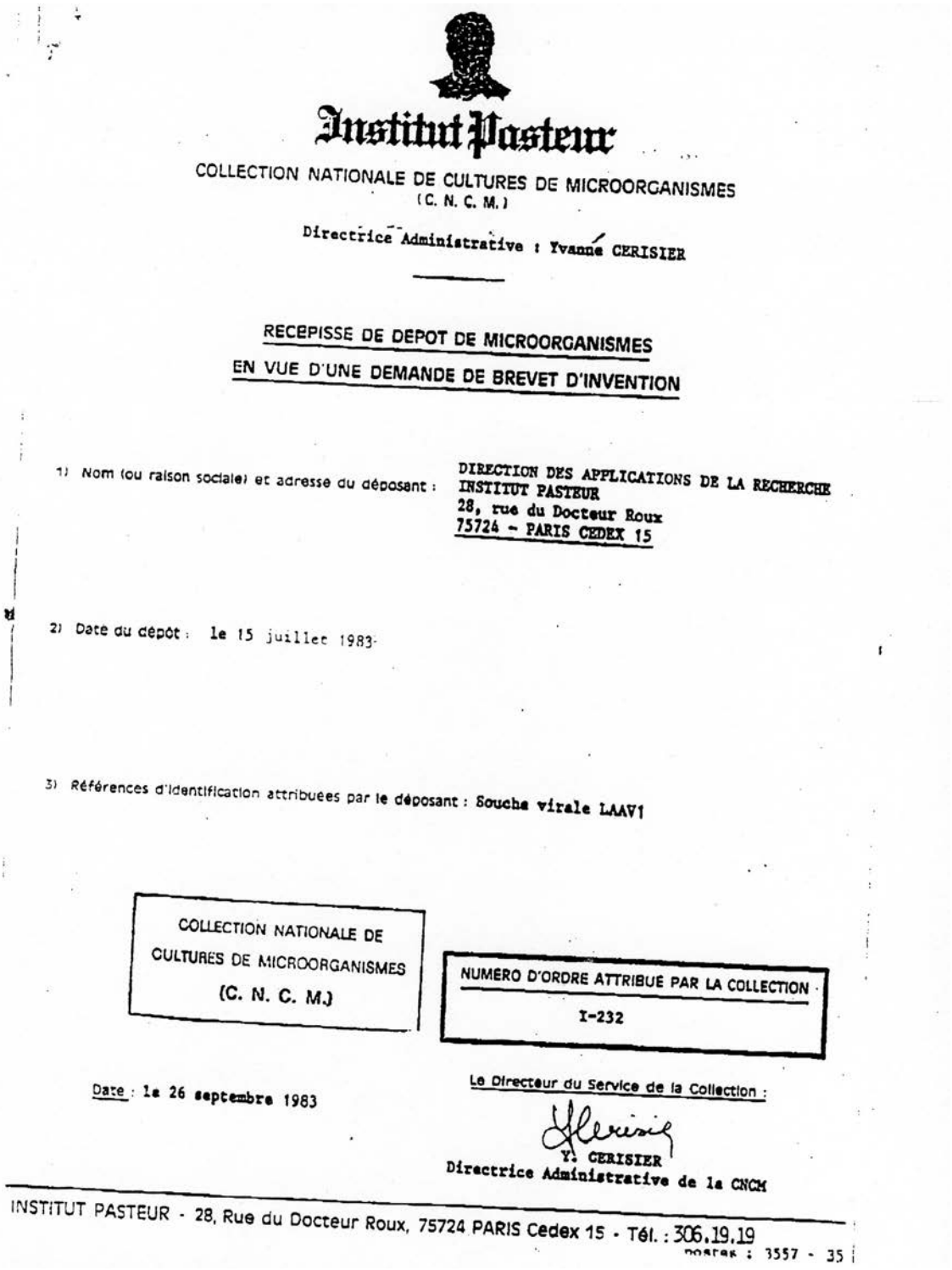
UNDER THE CONDITIONS LISTED ABOVE.

DATE September 23, 1983

NAME Dr. Mikulas Popovic

SIGNATURE Mikulas Popović

…to straighten out the “LAI” in these papers.



Institut Pasteur

COLLECTION NATIONALE DE CULTURES DE MICROORGANISMES
(C. N. C. M.)

Directrice Administrative : Yvanne CERISIER

RECEPISSE DE DEPOT DE MICROORGANISMES
EN VUE D'UNE DEMANDE DE BREVET D'INVENTION

1) Nom (ou raison sociale) et adresse du déposant : DIRECTION DES APPLICATIONS DE LA RECHERCHE
INSTITUT PASTEUR
28, rue du Docteur Roux
75724 - PARIS CEDEX 15

2) Date du dépôt : le 15 juillet 1983

3) Références d'identification attribuées par le déposant : Souche virale LAAV1

COLLECTION NATIONALE DE CULTURES DE MICROORGANISMES (C. N. C. M.)

NUMERO D'ORDRE ATTRIBUE PAR LA COLLECTION
I-232

Date : le 26 septembre 1983

Le Directeur du Service de la Collection :
Y. CERISIER
Directrice Administrative de la CNCM

INSTITUT PASTEUR - 28, Rue du Docteur Roux, 75724 PARIS Cedex 15 - Tél. : 306.19.19
postes : 3557 - 35

LAV-1 is known as Isolate-232 by the C.N.C.M. From it's original date of deposit, July 15, 1983, it remained without problems…

TRAITE DE BUDAPEST SUR LA RECONNAISSANCE
INTERNATIONALE DU DEPOT DES MICRO-ORGANISMES
AUX FINS DE LA PROCEDURE EN MATIERE DE BREVETS

FORMULE INTERNATIONALE

DESTINATAIRE :
Unité d'Oncologie Virale
Bureau Brevets et Inventions
INSTITUT PASTEUR
25, 28 Rue du Docteur ROUX
75015 PARIS

RECEPISSE EN CAS DE NOUVEAU DEPOT,
délivré en vertu de la règle 7.1 par
l'AUTORITE DE DEPOT INTERNATIONALE
identifiée à la page suivante

NOM ET ADRESSE DU DEPOSANT

Unité d'Oncologie Virale - INSTITUT PASTEUR
25, 28 Rue du Docteur ROUX - 75015 PARIS

I. IDENTIFICATION DU MICRO-ORGANISME

Référence d'identification donnée par le DEPOSANT :	Numéro d'ordre attribué par l'AUTORITE DE DEPOT INTERNATIONALE :
LAAV1 (espèce HIV-1)	I - 232

II. RAISON INDIQUEE PAR LE DEPOSANT POUR EFFECTUER LE NOUVEAU DEPOT

[1] Le micro-organisme faisant l'objet du dépôt antérieur n'était plus viable.

[1] L'envoi ou la réception d'échantillons du micro-organisme faisant l'objet du dépôt antérieur était empêché :

- [1] par des restrictions à l'exportation, ou
- [1] par des restrictions à l'importation.

[1] L'autorité de dépôt internationale auprès de laquelle avait été effectué le dépôt antérieur a cessé d'avoir le statut d'autorité de dépôt internationale ou a cessé d'exercer ses fonctions, et le micro-organisme n'a pas été transféré à une autre autorité de dépôt internationale qui est en mesure d'en remettre des échantillons.

[1] [XXX] Autre raison[2] : Stock insuffisant (cf. notification du 06 Novembre 1990).

[1] Date de réception de la notification visée à l'article 4.1)a) :

[1] Date de la publication visée à l'article 4.1)e) :

[1] Cocher la case qui convient.

[2] Indiquer la raison.

Formule BP/5 (première page)

when suddenly there is need to make a new deposits due to “insufficient stock…”

III. DESCRIPTION SCIENTIFIQUE ET/OU DESIGNATION TAXONOMIQUE PROPOSEE

En rapport avec le dépôt antérieur, le déposant a indiqué.

[XX] une description scientifique

[XX] une désignation taxonomique proposée

(Cocher ce qui convient)

IV. AUTORITE DE DEPOT INTERNATIONALE AUPRES DE LAQUELLE LE DEPOT ANTERIEUR A ETE EFFECTUE

Nom : COLLECTION NATIONALE DE CULTURES DE MICROORGANISMES
INSTITUT PASTEUR
Adresse : 25, Rue du Docteur ROUX
75724 PARIS CEDEX 15

V. NUMERO D'ORDRE ATTRIBUE AU DEPOT ANTERIEUR

I - 232

VI. RECEPTION ET ACCEPTATION

La présente autorité de dépôt internationale accepte le micro-organisme identifié sous chiffre I, qu'elle a reçu le 30.01.1991 (date du nouveau dépôt).

VII. AUTORITE DE DEPOT INTERNATIONALE

Nom : COLLECTION NATIONALE DE CULTURES DE MICROORGANISMES

Adresse : INSTITUT PASTEUR
25, Rue du Docteur ROUX
75724 PARIS CEDEX 15

Signature(s) de la (des) personne(s) compétente(s) pour représenter l'autorité de dépôt internationale ou de l'(des) employé(s) autorisé(s) :

Date : Paris le 31 Janvier 1991

Y. CERISIER
Directeur Administratif de la C.N.C.M.

Pièces jointes : Copie du récépissé relatif au dépôt antérieur

Copie de la plus récente déclaration concernant la viabilité du micro-organisme qui faisait l'objet du dépôt antérieur et indiquant que le micro-organisme est viable

…2 days after Gallo invokes rights as co-inventor to access this virus stock for study.

21.
POPOVIC: THE MAN IN THE MIDDLE

Gathered together to talk about those times, Dr. William Blattner recalls[216] to Dr. Popovic: *"And they were just trying to squeeze you enough that it was so painful that if you, in fact, had entered into a bargain with Gallo, then you would have owned up to the malfeasance and would have saved your own skin and then (they would have) landed the big fish."*

The OSI had a strategy. Lean hard enough on one fellow to incriminate another. So to get at Gallo, they put the pressure on Popovic. To try and get him to save himself by incriminating Gallo - voluntarily. For their effort, they get an 'A.' Circumstance and coincidence made the Czechoslovakian native a perfect candidate for this tactic. Dr. Popovic was in the United States on a year-long fellowship for study, which had expired. He had applied for a second year extension, but the authorities in Czechoslovakia rejected the application. He then sought to remain as a political refugee after his apartment back in Bratislava had been seized by police. When that failed, he applied for a Green Card and found himself in the purgatory of waiting for American bureaucracy to make up its mind and come to a decision. The OSI also sought to take advantage of the fact that Dr. Popovic grew up in a communist country, and was highly protective of his work. If you walked into his office or lab, out of sheer habit, he would turn papers over so they could not be seen. He still does that today. Plus, he was known to keep notes in his head because you could not ever steal that. But that was not the way things were done in a procedure laden, U.S. Government lab. So while all this was going on personally, his professional life was coming under attack as well. The looming question for him: Did you knowingly put LAV into the blood pool to hide it, and then rediscover it? Add that Hadley being in charge of the investigation, her tactics and demeanor were reminding Popovic of the totalitarian system he had left behind in his native land. But at the time, he had no idea what was coming, or even that he was a target for the NIH investigators. Not a clue.

What bears mentioning here, is that the investigation against Popovic did verify one very important detail. That the protocol for AIDS virus isolation was detailed by Popovic in his notebook[217] before he ever received the second LAV sample. But even if you wanted to argue the first shipment; let's. Stating only facts now, Popovic gets Montagnier's first shipment of virus on September 24, 1983. It contained an extraordinary small amount of

[216] Taped interview conducted on February 6, 2002.
[217] Popovic Notebook: entry dated September 10, 1983.

virus; 11,000 CPM reverse transcriptase. Popovic developed the H9 cloned cell line in early November 1983. These were the target cells ultimately used for continuous and large scale production of the virus. Is it then possible to obtain the necessary mass production of the virus needed to accomplish such a thing…in just 5 weeks? No. Keep in mind that Montagnier himself did not have a virus producing cell line until July 1984.

In February 1991, Dr. Popovic spoke with Hadley and other NIH investigators for over two hours regarding that all important work he had done in 1984; figuring out how to detect the AIDS virus in blood. But March 19, 1991, was the day Mika Popovic found out the OSI was coming after him. Per his rights, Popovic was allowed to receive a taped copy of his interview session. Realizing his English was not very good, he asked for a copy of the interview tape to check for mistakes against the written transcripts. Popovic: *"Until then I didn't perceive the investigators as enemies, I didn't perceive that there were people who want(ed) me for certain purposes. I considered they wanted to find the facts and that was my attitude. Now I learned that it was one of the greatest stupidities the first time I went in without the lawyers, without anything, and talked. And then they pulled out what was good for them in order to accuse. On the tape I learned it."*

March 19, 1991. His wife Marta signed for a package messengered over by the OSI. It sat on their living room table until 10pm when Dr. Popovic finally opened it. He was immediately puzzled by the fact that instead of getting one tape, he got three. Which is what he is referring to in the above quote. This day would be what some others have labeled the "deliberate accident." Because those tapes Dr. Popovic received were not of his interview session at all. Rather, they were the discussions the investigative panel had about him, after he had left the room. Popovic: *"When I was listening to the tape I think in the first 15 minutes it turned out to be clear that they wanted to find a guilty person. And then I started to fight. Then I realized that they don't care."*

During his taped interview, one investigator had told him, "the fact that you are here, the fact that there is an investigation, doesn't mean you are guilty, not at all." Imagine what ran through Dr. Popovic's mind, when he heard that same voice on those tapes, say behind his back, "Sometimes we find it (misconduct) because someone is so flaming bad we don't want them around the lab for a certain amount of time." Then the voice laughs. He also heard discussions that he lied about the work he did, that the results from his work were more lies, that he should not be in science at all, and finally, that he was guilty of scientific misconduct.

On June 25, "In the course of the briefing it came out accidentally, and without Dr. Hadley's intention to divulge it to me, that someone working for her while she was still located within the OSI had inadvertently mailed to Dr. Popovic's lawyer the full tape recording of the final meeting of the investigation committee, the one in which individual panel members expressed their own conclusions on the investigation. This error represented a serious breach of confidentiality of both the committee and the accused[218]."

The pressure was on. But Mika Popovic was not the objective. He suspects it was to scare and agitate him, so that he would turn against Gallo. Then, one evening, Dingell's right arm lieutenant, Peter Stockton, telephoned Dr. Popovic and *"wanted very much to talk with me (in a private meeting). I think that was (their) attempt (to get me alone, to give them Gallo), but I don't have evidence."* Stockton, himself a lawyer, knew he could not

[218] From the, Statement Of Bernadine Healy, M.D., Director, National Institutes Of Health, Before The House Energy And Commerce Committee, Subcommittee On Oversight And Investigations, August 1, 1991.

speak ex-parté with Popovic as he was the subject of an on-going investigation; and that his lawyer need be present at all meetings and interviews. *"The irregularities were very clear."* Not taking 'no' for an answer, Stockton called a second time, and spoke with Popovic's daughter; getting the same negative answer. Despite requests, Stockton declined to make any comments for this book.

If the tapes did get sent to Popovic by accident, why is there no record of any OSI secretary and/or investigator getting any discipline or reprimand for sending out the Panel's private discussions? If the tapes were sent by accident, how come the OSI never asked that they be returned? Asked, did the OSI ever ask for the tapes back, Popovic replied, *"Well, no. What I did – I gave it to the lawyer. They (the OSI) made a copy and they returned the original to the office (of his lawyer)."* It is peculiar to say the least, when an investigative panel does not ask for the master copies of their own private deliberations to be returned to them. That the investigative panel would willfully keep copies, not originals, in its archives. Especially when it is their own property containing privileged communications. It totally destroys the authenticity of that particular piece of evidence as they can in no way ever vouch that the master (in possession of the very person whom they are investigating) was not altered in any way before they were made their copy.

So if the OSI did not demand its own original tapes back, then those tapes had no value to them to begin with. Rationale then begs the question, what if those tapes were intentionally sent? What if their only value was to intimidate Popovic? That they did not fight for their return because they never really wanted them back at all? Perhaps the ploy was simply nothing more than a "save-yourself-Mika,-give-us-Gallo" tactic.

Mika Popovic never did that. There was nothing to confess to, no revelation of any Gallo complicity to offer. And he finally did get a copy of his interview session, *"but the quality was very bad."* Odd, since it was recorded by the same tape recorder as the Panel's private discussions. The guess would be Popovic heard exactly what he was supposed to hear.

It wasn't much later, that Dr. Popovic found himself guilty of errors in his 1984 Science paper that added up to a charge of scientific misconduct. Popovic: *"It was the best work of my life and now I am going to be destroyed (by it). This paper opened the field."* But the OSI did not just give value to the published paper, but to the drafts written to get there. One draft was written just before Popovic left to attend a conference in Park City, Utah; when he believed he would have a month to put the polish on his paper. But upon his return, Gallo informed him he had only days to get his paper ready, as the three other papers were completed and ready for publication. Popovic: *"I was in Park City, Utah when they decided to go ahead (with publication) in the end of March. So I came back Monday and they told me Friday the manuscripts have to be downtown. And the draft what I wrote up – it was only for me to work (on)– it wasn't for (others)– and Gallo took the draft and in my absence … wrote in the paper so much … and later (I) tried to jump on it – (catch) each and every error."*

But between writing the four Science papers, and their publication, came an unexpected hardship which Popovic was oblivious to, as he was away at the conference. So his paper suffered the most, for what could only be called a bad time to be absent from the office. Dr. Redfield, who was a co-author on one of the papers, and familiar with the data and had seen the manuscripts (more accurately, the papers in progress), began talking about them during his clinical rounds at the (U.S. Army) Walter Reed Hospital. One of his

associates then leaked what he had been told at a cocktail party where it eventually found the ear of a reporter. As things quickly got out of control (leaks, partial leaks, conjecture as to what the forthcoming papers might say), everything got pushed up. Where they once had two months to finalize their papers for publication, they now had days. Hence, the reason outside hands worked on Popovic's paper during his absence. As for Redfield, he went straight to Gallo's office and apologized.

As there have been many crooked acts already presented in this book, there is yet another to report. File No. W-90-00066 (Drs. Gallo and Popovic): Apparent Tampering with Evidence: On July 6, 1994, Popovic's attorney, B. Mishkin, requested the return of her client's notebook and eight drafts of his manuscript (Popovic, et al.). But the notebook was missing from the evidentiary materials retuned to the NCI in July; and remained unaccounted for several months thereafter. Until October 12, the same day when Dr. Suzanne Hadley visited Dr. Sam Broder on the NIH campus. Mishkin immediately compared the lost-then-found original to her own copy she made prior to her initial surrender of the notebook to the investigative committee. She quickly discovered that at least one page was missing[219] from the original and two other pages had been re-numbered and interchanged. A search for the missing page revealed that an earlier NCI copy of said notebook contained two more additional pages that were also missing[220]. Records confirmed that notebook was removed from Gallo's laboratory by Hadley in March 1990. Lastly, some "green dot" numbers affixed to the notebook by Hadley concealed the original pagination on some of the notebook pages, which according to Mishkin, "suggested that even more pages may be missing."

Much has been made of those early drafts of the 1984 Science paper written by Mika Popovic. Their value of course being that these early drafts were edited by Gallo himself (and others) in an effort to get it published with the three other papers which were being submitted. The treasure they were seeking was simple; was there anything incriminating written in Gallo's own hand? No. But those early drafts had seemingly disappeared and for a time, were not produced by Popovic. So the question had arisen, in August 1984, when the charges against Popovic had already begun[221], what happened to these early drafts?

Popovic: *"After this "Hadley's manuscript fiasco" most likely she via others from OSI and particularly Mr. Crewdson tried to portray it that I was "running with manuscripts" to Czechoslovakia to "hide" them. This is crap! Manuscripts were with other documents (family stuff) in our Pooks Hill apartment (Bethesda) in the closet until August, 1984. My wife Marta with (our) children went to Switzerland and Austria in August, 1984 for family reunion. And when she packed the "family stuff," by mistake she included an early version of my manuscript as well. I was in England at that time participating on International Leukocyte Conference meeting in Cambridge and joined my wife and children in Switzerland, from where we went to Austria. The family package that contained an early version of my manuscript was given to my sister who has been living in Bratislava. The*

[219] This happened between February 1983 and October 1994.
[220] This happened between March 1990 and February 1993.
[221] The propaganda was that Dr. Popovic's Green Card to continue working in the U.S. was still a pending issue at the time. But that is false. The reality is that Dr. Popovic became a U.S. citizen in December 1989, and the investigation against him did not begin until 1990. But even colleagues in his own lab were so confused by this erroneous information; they too were asking him about his Green Card status even after he received his citizenship. Should it matter, Dr. Popovic was given his Green Card in 1984.

problem was that when Ms. Barbara Mishkin wanted to see the manuscripts I did not have the early version. It took time to get it back. That's why it is known that the "manuscripts" were in Czechoslovakia for "hiding purposes[222] *behind the Iron Curtain." Funny, Crewdson's gangs were looking for those "manuscripts" in Prague. And again, during my appeal, OSI wanted to make out an issue of "the manuscripts in Czechoslovakia" and that's why my wife Marta came to testify. In the end, the counsel representing OSI (Mr. Godek) told (me) that he is not interested how the "manuscripts" got to Czechoslovakia and my wife did not testify at all*[223]*."*

Yet, this version of events contradicts an earlier, published, account also given by Popovic back in 1992. That article[224] reports that Popovic, "took early drafts of the research paper that would later get him in trouble with the OSI – drafts that had been heavily edited by Gallo – with him to a family reunion in Europe. There he gave them to his sister, who in turn hid them in her house in Czechoslovakia." Popovic himself wrote a confidential memo to Suzanne Hadley on May, 15, 1991 and admitted, "During my interview, I also told you that during my trip to Austria in August 1984, I gave my sister manuscripts #4 and #5 for safekeeping. Naturally, you wanted to know why I gave them to my sister…but I did it in this case because I believed that sometime in the future, I might need them as evidence to prove that I gave fair credit to Dr. Montagnier's group[225]."

It is strange that these accounts differ so. And since copies of those early drafts have surfaced, been examined, and were never enough to conclude a guilty verdict, it is curious all the more.

[222] The implication being that Popovic could hurt Gallo with those drafts; which was never really the case.
[223] Mika Popovic, in his interview for this book, conducted July 19, 2002
[224] Science Friction, by Malcolm Gladwell, The Washington Post, December 6, 1992, p.W21
[225] OSI Ref. 89-67: Comments to April 10, 1991 Interview Regarding The Early Versions Of The Manuscript Of The May 4, 1984 Science Paper By M. Popovic Et Al.

22.
ACQUITTAL EXAMINED FROM ALL SIDES

On November 5, 1993, Popovic appealed his ORI verdict and was cleared of all misconduct charges, when the conclusion, as to the ambiguous meaning of that one sentence reached by the ORI, was subsequently reversed.

In fact, according to the Appeals Board, the ORI failed to show that the paper in question contained untrue statements, let alone intentional falsifications. The Board said, the whole case "focused essentially on the meaning which we should give a handful of words and notations contained in one heavily edited paper written by a scientist with limited English skills during a volatile period of scientific discovery a decade ago[226]." In fact, the official findings of the Departmental Appeals Board[227] go on to say that the: "ORI did not establish that Dr. Popovic drafted the "first shown" sentence, that his attention was drawn to it during the editing process, or that even if he noticed it he would have recognized that it might have been misinterpreted by others. ORI gave an importance to the matters at issue here which is not justified when the paper is examined as a whole. This paper and three companion papers published in the same issue of Science are regarded as a "tour de force" of science. The paper in question is regarded as a seminal work, possibly the most important paper in virology in the 20th century."

Dr. Popovic filed suit against Hadley, the ORI, and the Government for its handling of his case, and the damage it did to his career. But because the case against him, took so long to conclude, the statute of limitations had run out before he was even able to file the papers. So the lawsuit was dismissed.

As for the six notorious "ND" entries, which the ORI interpreted to mean "Not Done" (as in, Not Performed[228]), the Board deemed that the ORI had failed to prove its position that "not done' could only mean "not performed." It also bears mentioning here that the OSI confirmed that the virus samples Dr. Popovic put in that pool, which did grow HTLV-3B, were in fact also found to contain several other genuine HIV isolates that are different from both LAV and HTLV-3B. That is a very important fact because it clearly

[226] The New York Times, November 5, 1993

[227] Department of Health and Human Services, Department Appeal Board, Research Integrity Adjudications Panel, Docket No A-93-100, Decision No 1446, November 3, 1993, Case: Mikulas Popovic.

[228] Popovic all along meant it as "Not Determinable." Still, those notations are trivial and not substantive to the work.

proves that Popovic had no reason to believe that the virus production he saw occurring in the pool was the result of LAV contamination.

Expectedly, the ORI, anticipated its defeat in the Appeals Board on the Gallo case for two main reasons. The first, Popovic's earlier acquittal for the reasons stated above and, second, Gallo's own responses to the verdict. So, on November 12, 1993, the ORI dropped the misconduct charge against Gallo (see page 194 for official press release). It was a most embarrassing reversal of events. Most revealing in an article later published in Science[229], was an admission from a member of the ORI's advisory board, that there was tremendous pressure from (who else?) Dingell to come up with anything incriminating; hence the guilty interpretation of that single sentence in Gallo's paper. "Congress drove them into proving they're (the ORI are) tough." Even the assistant Secretary of Health, Phillip Lee, is quoted in the same article as conceding the ORI was under "tremendous pressure." Anyone care to guess who turned up the heat on the ORI by conducting a parallel, Congressional investigation?

Thus, ended an unprecedented four-year investigation into Gallo and his lab's scientific practices by three separate investigative teams who had worked long and hard, and…

- examined a 13 foot high pile of Gallo's lab records; including all the lab books
- devoted some 10,000 man hours interviewing witnesses, evaluating findings, and deliberating the case
- spent millions of taxpayer dollars in legal fees
- drained enormous intellectual capital from the fight against AIDS and,
- slowed down scientific progress against the disease.

Despite all that, when rightfully examined up close, the alleged sins of Gallo and other scientists disappeared altogether; as it did with all those other high profile cases. Yet there was a cost to these men and women labeled 'defendants.' By his own estimate, Gallo spent between one third to one half of his time over a period of about eight years responding to investigative demands. Gallo: *"Dingell took away the peak years of my career. I had a strong lab, good people, but he really caused a lot of damage."*

"One might anticipate that from all this evidence, after all the sound and fury, there will be at least a residue of palpable wrongdoing. That is not the case[230]." wrote the Appeals Board justifying its landmark decision which cleared Popovic of that one and only official charge, and forced the ORI to drop all charges against Gallo as well. In fact, the decision to clear Gallo of all charges was summarized in different ways, in different publications (see page 198). Here are some samples...

On November 14, 1993, an article in The Washington Post called The Fraud Fraud: "…no one ever claimed that the disputed sentence changed, undermined, or altered the substance of the paper itself which is widely considered the most important in 20th-century virology."

On November 22, 1993 an article in Time[231] entitled Victory at Last of a Besieged Virus Hunter: "Nine years ago, Dr. Robert Gallo was one of science's supernovas. When the National Cancer Institute researcher unveiled proof

[229] The Aftermath of the Gallo Case, by Christopher Anderson, January 4, 1994, vol. 263, p. 22.
[230] Department of Health and Human Services, Department Appeal Board, Research Integrity Adjudications Panel, Docket No A-93-100, Decision No 1446, November 3, 1993, Case: Mikulas Popovic.
[231] Page 61

that a virus caused AIDS, he had every reason to look forward to fame….and, down the road, maybe even a Nobel Prize. Instead he soon faced doubt, criticism, and accusations of fraud….But with the charges of wrong-doing dismissed, Gallo has the right to proclaim "I have been completely vindicated." He can now hope that history will be kinder…."

On December 1, 1993 an article in The Washington Post called Dr. Gallo: A Vindication: "Dr. Gallo may not be known for his modesty or retiring nature, but he is, without a qualification, a dedicated and accomplished scientist who has been subject to a great deal of personal attack, the most recent example being the TV movie "And the Band Played On" in which he was portrayed as an overbearing villain. His work along with that of others at NIH is extraordinarily important and is conducted under great pressure…"

And on December 26, 1993, an article in the Sunday Magazine Section of The New York Times called Method and Madness - The Vindication of Robert Gallo by Nicholas Wade (then, science editor of the Times), referring to Crewdson's article, "was relentlessly hostile to Gallo, interpreting one complex event after another to his discredit. It gave little weight to the possibility that Gallo's fierce competitiveness might have had something to do with the brisk pace of discovery. And despite every paragraph's insinuation that Gallo was capable of stealing the French virus, it failed to offer proof he had done so…….From Crewdson's article to ORI ignominious collapse took four years – four years in which Gallo was diverted from fighting AIDS to fighting the ill-will and narrow vision of various accusers…In Gallo's rush for the AIDS virus, he has bruised many competitors. His critics mistook his sharp elbows for itchy fingers. They were too slow to correct their misjudgment of the one scientific hero who has yet emerged in the fight against AIDS."

The long-running inquiry into the practices of Gallo was supposed to culminate with a report from the U.S. Congress, to be prepared under the auspices of Representative John Dingell, and rumored to deliver the final blow in a case that had failed repeatedly to substantiate wrong-doing. When the Gallo case was dropped by the ORI, one Dingell staffer called a Congressional report "more necessary than ever[232]." That report, running hundreds of pages, was finally released, in yet another breach of confidentiality, via the Internet on January 1995 by Walter Stewart[233], an NIH scientist turned investigator (refer to Chapter 17) and, affiliated with Dingell's House of Representatives Subcommittee on Oversight and Investigations. The report was critical of Gallo -as expected- but also alleged a massive cover-up by U.S. officials in an effort to protect the U.S. Government against further claims by the Government of France.

Hindsight allows one to see things in a new perspective, especially with the knowledge of information that comes to light, piece by piece. Viewed in its totality, is it not unreasonable to hypothesize a conclusion with the asking of this one question. How could the ORI investigators justify soliciting the French to help "nail" Gallo? Who could NOT have known that would have led to the re-opening of the patent case resulting in an increase of the French royalty share? That single act worked against American interests; and it all happened under the veiled excuse to expose an alleged massive cover-up that allowed the

[232] Scientific Misconduct: ORI Drops Gallo Case In Legal Dispute, by Christopher Anderson, Science, November 19, 1993, vol. 262, page 1203.

[233] He, previously and tenaciously, worked hand in glove with both Dingell and Hadley to try and bring down Dr. David Baltimore.

door to open (the intent all along?) through which the royalty issue could be re-visited and re-negotiated. Or does that seem too far-fetched?

Unexpectedly, however, Congressman Dingell disavowed that report. "In short, neither Dingell nor full time members of his investigative staff stand behind this report which is essentially the work of Suzanne Hadley[234]." Who was probably still smarting from her snub as an Expert ORI witness. Hadley in the meantime had much to say, but no credible forum from which to throw her barbs. Not in an ORI inquiry, and now, not from a report with the name of a disapproving Congressman attached to it either. In a letter dated February 3, 1995 to Harold Varmus (the then Director of the NIH), Dingell has this to say of the report (see page 197): "We can not vouch for the authenticity or accuracy of the papers provided to you. They were not reviewed, much less evaluated by the staff director, the Chairman, or any other Member of the Subcommittee. While some staff time was spent developing a report, one early draft of the matter had been rejected several months ago. Because of the enormity of the editing and the fact-checking tasks needed to assure that a report on this topic met the standards of the Subcommittee, no report was issued." This meant that Congressman Dingell had no final shot to fire on the Gallo matter one way or the other. All that time, all that money, all those threats, and all effort added up to what? "No report." Dingell's words then became a hollow echo.

Later, Hadley will try and defend herself as the press now began to question her and her motives. Following the publication of an unflattering article in Nature[235], by reporter Barbara Culliton, Hadley herself writes a letter to the Editor[236] to respond to allegations brought up therein. After she writes, "that proof of intent is not necessary to a finding of misconduct," she asserts, "I always followed PHS Policies and Procedures, which state that subjects of an inquiry or investigation "are provided access to any research data under review…(and) are provided with an opportunity to review and comment on significant investigatory documents." She goes on to write, that it is not correct to say that the OSI's definition of due process, "expressly denies the accused the right to see at first hand all of the evidence against him or her. The only instance of which I am aware in which there was any departure from PHS policy occurred when the OSI did not have possession or control of certain pieces of evidence."

Dr. Popovic disagrees[237]. "*My answer to your question regarding Hadley's claims is that it is simply not true what she claims! As far as I can recall the following most glaring example is the "case of the original version(s) of the manuscript(s)." Ms. Hadley had one early version of my manuscript. She never mentioned it to me or to my counsel (B. Mishkin) and for the very first time I and Ms. Barbara Mishkin saw it during my interview conducted by her and the investigative team. Apparently, she (Hadley) kept the manuscript as "a most valuable secret weapon" to convict me in the misdeeds she accused me of. When I categorically rejected her accusations about "my alleged alterations in the manuscript" Ms. Hadley was so surprised that she simply ignored the statement of Ms. Barbara Mishkin who pointed out that there are other versions of manuscripts as well. Subsequently, Ms. Hadley tried to present the "case with manuscripts" that it was me who withhold the information from her and OSI regarding the existence of the manuscripts. Fortunately, the transcript*

[234]Barbara J. Culliton, Nature Medicine, March 1993.
[235] August, 1991, vol. 352, p. 563
[236] Published in Nature, September 1991, vol. 353, p. 204
[237] In his interview for this book, conducted July 19, 2002

from my interview clearly showed Ms. Barbara Mishkin's statement pointing out the existence of other versions of the manuscript. Here, for the first time, I realized why it was important to have a counsel during my interview particularly when it is conducted by Ms. Hadley and others from OSI."

Dr. Gallo supports that[238]. *"When Popovic was away for a meeting during the time (at Park City), we were preparing the manuscripts for Science in 1984, I asked some others in our group, such as Phil Markham and Zaki Salahuddin, to try and prepare a rough draft. However, they were not close to the work described in the first of our papers (Popovic, et al) but they did their best. I thought this would help time-wise. However, when Popovic returned, he recognized its inadequacies and worked on it from scratch. Somehow Hadley got a copy of that never used draft and just sprung it on Popovic during the recorded interview with him, and with much aggression. I could have easily explained it but no one asked me. The rules required that Popovic be handed this in advance of the interview."*

As for the ORI, after their very public loss, its own spokespeople tried to pin their failure on the "new definition" of scientific fraud circulated by the Appeals Board in order to exonerate; never admitting that they lost their case on the basis of evidence; or its lack thereof (see Appendix 11, p. 323, for more).

The OSI, the ORI, Dingell's Congressional Subcommittee, even journalist John Crewdson, gave it their best shot and enlisted many allies in their quest. Also keep in mind that each of these entities also conducted much more than just one investigation each. Sadly, the controversy clearly overshadowed the all important fact that each and every separate investigation failed to find Gallo guilty of anything that stuck. And what should really drive that point home is this one reminder… Led by Dingell, sparked by Hadley's investigative conduct, and fueled by Crewdson's misguided reporting, each and every investigation, by each and every investigative team WANTED to find Gallo guilty. They were driven to, they were motivated to[239]. Yet they failed…each and every time. What does that say to you? Guilty or not guilty?

On the other hand, what was won…twice? More money for the French from the Gallo patent. Successfully negotiated during the height of the on-going investigations into Gallo's scientific practices. Later in this book is a chapter entitled, The French Bloodbath. After you read it, you will come to understand just what the French Government was willing to do, and who they would sacrifice, for even more money on top of what they were getting from their settlement agreements.

So the question then is this. If Montagnier got his patent accepted first, would he and the French Government have offered NIH a 50-50 sharing of the patent revenue since: (1) the idea of a retrovirus causation of AIDS came from Gallo (2) the technique to grow the T-cells came from Gallo (3) Gallo sent the original IL-2 to Montagnier so he could practice and learn how to grow T-cells (4) Gallo sent reagents for HTLV-1 and HTLV-2 so that Montagnier's new virus candidate could be checked and determined unique (5) Gallo proved through science that Montagnier's virus was in fact the cause of AIDS and finally, (6) Gallo developed the working, effective assay to detect the virus in blood? The answer of course, is obvious.

Still, the underhandedness came at Popovic and Gallo from all sides, and from many people, as has been documented here. But, finally, at long last, Gallo was completely

[238] In his interview for this book, conducted July 18, 2002
[239] Explained later in this book.

exonerated. Yet, that will never truly erase all the damage done to his professional reputation or to his public image (his frank candor lends to that whether we realize it or not). Nor will it ever replace the time, effort, and money he lost in defending himself against his ill-willed and narrow-minded accusers. Gallo was accused wrongly and unjustly, was condemned informally by the press, out of court, and was hurt badly….personally, professionally, financially….all on the preponderance of twisted evidence. Even worse, many in the public worldwide, still think that Gallo is guilty of something; but they themselves don't know for what. It seems that the epileptic palpitations of a disgruntled (nonetheless, powerful) few, will never cease, if just to fan the smoldering embers of doubt. But it will all be forgotten if one prediction comes true. "Gallo is likely to discover a cure for AIDS. And when he does, he is going to be a scientific hero, like Salk or Sabin[240]." To many, he already is.

"If we had lost Gallo from the pressure, and he had seizures at one point, from all this pressure, if we had lost him, we wouldn't have known about the chemokines, we wouldn't know some new things that turned into other things. I think we'd have lost a major force in AIDS. And it's a determent to Crewdson for doing that[241]."

Gallo: *"Let's put it this way – no scientist, perhaps in biomedical history has been so thoroughly evaluated, okay. And we came out scarred but right – scarred because of what they did to us. And some scientists seeing things at a distance were self-righteous and/or jealous, no matter how big, would enjoy the pull down. Not most, not all, but some, including some heavyweights."* In fact, no other scientist has gone through what he has gone through, while still making discoveries to the world that were historically important. His work truly has benefited man, and saved countless lives. That can not be taken away from him: nor should it be forgotten.

Does he then deserve the consideration of a well-earned Nobel Prize for serving humanity so well; at such enormous personal cost? Sadly, no. One prominent scientist who has had those conversations with members of the Nobel Prize Nominating Committee was asked that very question outside the main hall at an International Scientific Meeting; where the author overheard that scientist to say, *"As long as he (Gallo) is committed with Luc (Montagnier), it will never happen. Bob understands that. Luc can not get it."* Innocent of all charges, yet punished still. Remarkable. One fellow immediately asked this scientist[242], *"what about for the HTLVs?"* Meaning of course, if Gallo was being denied a Nobel Prize for his work on AIDS because of the controversy, then why not award him for the discovery of the first (and second) Human Retrovirus? Well…that privileged scientist walked away; ending that discussion, abandoning its debate.

But what about the scandal-free issue of discovering a Human Retrovirus? Is that not worthy of a Nobel in of itself? Let's wait and see. Still, one thing is abundantly clear. "Few AIDS experts -now or then- question the magnitude of Gallo's contributions in paving the way to the discovery of the AIDS virus[243]."

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[240] Quoted from Rita R. Colwell, President of the University of Maryland Biotechnology Institute, appearing in The Once And Future King, by Elaine Richman, The Sciences, November/December 1996, p. 12

[241] Dr. Mark Kaplan, telephone interview on October 14, 2002, 6:19pm PST.

[242] I will not identify this scientist because the conversation was not directed at me, the author. Nor was this scientist aware a book was being written on the Gallo topic. But those words spoken in public matter, and are worth repeating here.

[243] NIH Vindicates Researcher Gallo in AIDS Virus Dispute, by Malcolm Gladwell, The Washington Post, p.A8.

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Friday, Nov. 12, 1993

Contact: Dr. Lyle Bivens
(301) 443-3400

The Office of Research Integrity (ORI) announced today that it is withdrawing its Dec. 29, 1992, legal determination that Dr. Robert C. Gallo had committed scientific misconduct.

ORI is taking this action in light of recent Research Integrity Adjudications Panel decisions, including the related Popovic decision issued on the eve of the Gallo hearing. These decisions established a new definition of scientific misconduct as well as a new and extremely difficult standard for proving misconduct.

The effect of this action is to end an appeal brought by Dr. Gallo and now pending before the panel.

"ORI found that Dr. Gallo misstated the role that the French virus, LAV, played in his work with the AIDS virus. We also found that he failed to identify, in a timely manner, the origin of the cell line used to propagate the virus and that he inappropriately restricted access to the cell line," said Dr. Lyle W. Bivens, director of the Office of Research Integrity.

"After analyzing the panel's Nov. 3 decision, however, it is clear that the panel now applies different standards from those applied by ORI to review findings of 'scientific misconduct,'" Bivens continued.

"The scientific community has a low threshold of tolerance for false statements, and this view is reflected in the regulatory definition of 'scientific misconduct.' ORI maintains that the

- More -

Press release – Dropping the Charges

standards applied by the panel reflect a fundamental disagreement with ORI as to the importance of clarity, accuracy and honesty in science. However, because ORI is bound by the panel's decisions, it will not continue its proceeding against Dr. Gallo. As a practical matter, the panel's recent decisions have made it extraordinarily difficult for ORI to defend its legal determination of scientific misconduct regarding Dr. Gallo."

Under the regulatory definition, scientific misconduct includes "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted in the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data."

In its Popovic decision and others, the panel announced its standard for finding misconduct based on false statements. The panel ruled that ORI must prove deliberate intent to deceive, that a false statement have a material or significant effect on the research conclusions of the paper, and that there be no possibility of honest error.

"Although ORI is not proceeding with the Gallo case, it remains committed to applying the scientific community's standards for integrity, and will vigorously investigate allegations of scientific misconduct," Dr. Bivens said.

Dr. Bivens also noted that HHS is moving quickly to implement new statutory mandates in the misconduct area. These mandates include establishing a Commission on Research Integrity to enhance ORI's ability to address wrongdoing by scientists.

In commenting on the panel's recent decisions, Dr. Bivens stated:

"We believe that ORI's approach to determining scientific misconduct is the correct course of action. We are confident that the new Commission will reinvigorate our efforts to maintain the highest scientific standards and to deal effectively with misconduct. While dismayed by the panel pronouncements, we remain committed to protecting the integrity of Public Health Service research."

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The Research Integrity Adjudications Panel has interim responsibility for hearing appeals in scientific misconduct cases.

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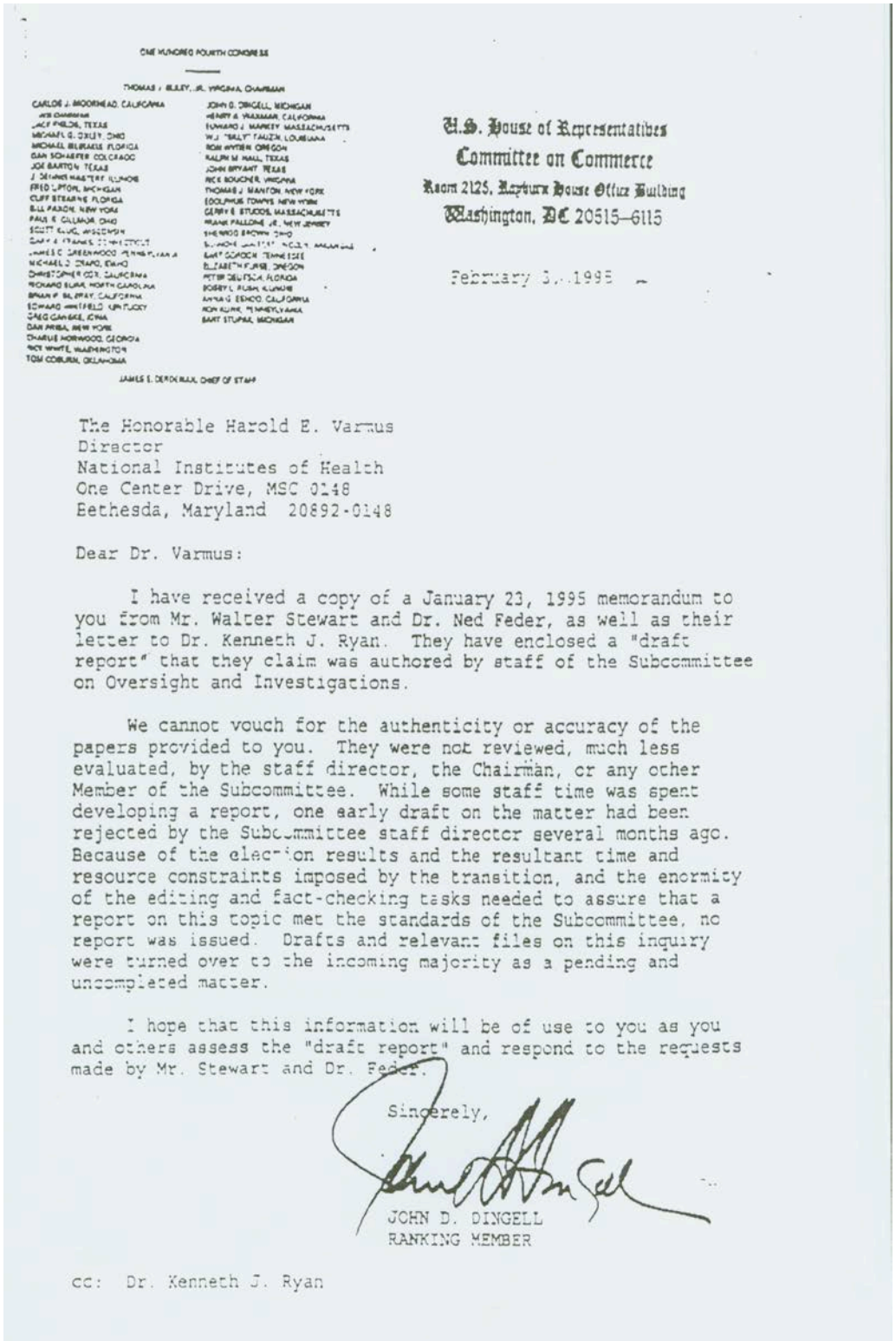

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U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

February 3, 1995

The Honorable Harold E. Varmus
Director
National Institutes of Health
One Center Drive, MSC 0148
Bethesda, Maryland 20892-0148

Dear Dr. Varmus:

I have received a copy of a January 23, 1995 memorandum to you from Mr. Walter Stewart and Dr. Ned Feder, as well as their letter to Dr. Kenneth J. Ryan. They have enclosed a "draft report" that they claim was authored by staff of the Subcommittee on Oversight and Investigations.

We cannot vouch for the authenticity or accuracy of the papers provided to you. They were not reviewed, much less evaluated, by the staff director, the Chairman, or any other Member of the Subcommittee. While some staff time was spent developing a report, one early draft on the matter had been rejected by the Subcommittee staff director several months ago. Because of the election results and the resultant time and resource constraints imposed by the transition, and the enormity of the editing and fact-checking tasks needed to assure that a report on this topic met the standards of the Subcommittee, no report was issued. Drafts and relevant files on this inquiry were turned over to the incoming majority as a pending and uncompleted matter.

I hope that this information will be of use to you as you and others assess the "draft report" and respond to the requests made by Mr. Stewart and Dr. Feder.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

cc: Dr. Kenneth J. Ryan

Dingell's letter distancing himself from "The Dingell Report" by Hadley.

Some of the headlines on the investigation and subsequent exoneration.

23.

THE HISTORY OF A HISTORY

#'s 1-14 verbatim, character for character, no typos…

1) 1970 – 1971: H. Temin's ideas of how RNA tumor viruses (retroviruses) infect cells by a unique mechanism of converting their RNA genome to DNA is proven. This is chiefly achieved with the discovery by Temin and Baltimore of a unique enzyme – called reverse transcriptase (RT) – present in all animal retroviruses.
2) 1970 – 1975: R. Gallo, S. Spiegelman, and some others independently developed techniques for human RT assays. This ultimately provided very sensitive and specific assays for a human retrovirus.
3) 1976: D. Morgan, F. Ruscetti, and R. Gallo discover T-cell growth factor (interleukin-2 or Il-2). This provided the ingredients for the routine and long term growth of human T-cells in vitro for the first time. This discovery eventually proved central to techniques for detection of human retroviruses along with sensitive assays based on using RT as described above.
4) 1978 -1982: Gallo and co-workers isolate and characterize the first human retroviruses HTLV-I and HTLV-II. This provided further technology for culturing human retroviruses.
5) Antibodies to Interferon Alpha (IFNalpha) as a control of mouse retrovirus expression.
6) 1981: M. Gottlieb diagnosed a new disease: AIDS
7) 1982: Centers for Disease Control provides epidemiology suggesting AIDS is a new infectious disease.
8) 1982: R. Gallo propose the hypothesis of a human T-cell tropic retrovirus as the cause of AIDS and begin to discuss data in this respect.
9) F. Barré-Sinoussi, J.C. Chermann, and L. Montagnier identify a new cytopathic retrovirus shown to be different from HTLV-I and HTLV-II in one patient with lymphadenopathy syndrome. They call this virus a human T-lymphotropic virus. Later they called the virus "LAV." For help Gallo provided reagents to HTLV-I and II and Interleukin -2 (T-cell growth factor).
10) September 1983: At the COLD Spring Harbor symposium on Human T-

cell Leukemia/Lymphoma virus, a few other examples of a virus isolated from AIDS patients by Montagnier and co-workers was reported. Its morphology is studied by electron microscope. Its protein composition is studied and its selective affinity for T.4 helper lymphocytes is demonstrated by –J.C. the Pasteur Group. They report the presence of serum antibodies directed against the virus in 60% of patients with lymphadenopathy syndrome but in only 20% of patients with AIDS.
Author's interruption: Although it is crossed out, it continues on to say: Later that month, Montagnier provides some LAV to Gallo, not a cell line, but some virus particles and -noted- that LAV could not be grown in a cell line.
Author's interruption: handwritten in the margin, it reads: Point 10 can be made into 2 or 3 points.

11) Spring (early May) 1984: M. Popovic, R. Gallo, and co-workers report first success in mass production of the virus. i.e., the first permanent cell line (called H-9) infected and producing new retrovirus (they called HTLV-III) providing the first specific reagents to the virus. They also show this virus unequivocally proven for the first time to be the cause of AIDS. They describe a 48 isolates and 90% to 100% positive sera antibodies in blind tests of hundreds of AIDS patients. Combines with the mass virus production this is the first useful blood test in scientific literature for the AIDS virus.
Author's interruption: handwritten in the margin, it reads: Can be made into 2-3 points.

12) July 1984: A combined study of CDC and Pasteur group now describe 41% of AIDS sera are positive for antibodies.

13) 1984 – early 1985: F. Wong-Staal, M. Popovic, B. Hahn, G. Shaw, R. Gallo, and co-workers do molecular gene cloning of the AIDS virus for the first time, discover that it infects the brain, and also that the coat (envelope) is variable (heterogeneity).

14) 1985: S. Wayne-Hobson and co-workers of the Pasteur Institute, and independently L. Ratner, F. Wong-Staal, R. Gallo, and co-workers, and independently Genentech, Inc. investigators, sequence the whole genome of the AIDS virus.

If you're asking what are these fourteen points…well, they are the fourteen points that Chermann and Gallo sat down to write together in April 1985. The very agreement Chermann denies writing, was ordered not to sign, and the one Gallo was asked not to publish (for Chermann's sake). In conducting research for this book I was able to get a copy of this elusive two page document and, between the type and the handwritten notes by both men, I have essentially reproduced it here for you. Why? Because two "official" histories have been published since. The first, The Chronology Of AIDS Research (no single author listed, rather a joint statement from Gallo and Montagnier which as itself states, "constitutes part of the agreement between the U.S. and French AIDS research groups"), was published on April 2, 1987[244]. The second, A History of HIV Discovery (by Luc Montagnier) and The Early Years of HIV/AIDS (by Robert C. Gallo), were published

[244] Nature, vol. 326, pages 435-436.

on November 29, 2002[245]. Each "officially" agreed to by Gallo and Montagnier.

Aren't you curious as to how they compare? Let's do that then. The unpublished 1985 agreement will be our "master original" if you will. Let's see if the one history published in 1987, and the two histories published jointly in 2002 differ from that "original," shall we?

Point 1: From the 1987 chronology: "Following Temin's hypothesis that RNA tumor viruses replicate via a provirus DNA intermediate, Temin and Mitzutani (1970), and independently Baltimore (1970), discover reverse transcriptase." Conclusion: **It agrees**.

From Gallo in 2002: "Howard Temin had proposed that retroviruses replicate through an integrated DNA intermediate, a notion supported by his discovery with David Baltimore of a retroviral reverse transcriptase (RT)." Conclusion: **It agrees**.

From Montagnier in 2002: There is no mention of Temin, Baltimore, or on the discovery of reverse transcriptase. Conclusion: **Point omitted**.

Point 2: From the 1987 chronology: "Spiegelman (1970), Gallo (1971, 1972), Gerwin et al. (1972) and others independently develop useful sensitive specific assays for reverse transcriptase of retroviruses." Conclusion: **It agrees**.

From Gallo in 2002: "We developed sensitive assays to detect RT in order to search for retroviruses at low levels in cell supernatants, membrane preparations, and long term cultures." Conclusion: **It agrees**.

From Montagnier in 2002: "Francoise Sinoussi measured reverse transcriptase (RT) activity (a retroviral enzyme) in the culture supernatants." Conclusion: **Modified, but it agrees**.

Point 3: From the 1987 chronology: "Morgan, Ruscetti, and Gallo (1976) discover T-cell growth factor, or interleukin-2 (IL-2), necessary for long term in vitro cultivation of human T cells." Conclusion: **It agrees**.

From Gallo in 2002: "Next, with Doris Morgan, our group discovered interleukin-2 (IL-2), which we called T cell growth (mitogenic) factor." Conclusion: **Modified, but it agrees**.

From Montagnier in 2002: "We used the new T cell growth factor (now called interleukin-2) discovered in Robert Gallo's laboratory to make short-term T lymphocyte cultures from cancer patients." Conclusion: **It agrees**.

Point 4: From the 1987 chronology: "Gallo, Poiesz, and co-workers (1980) isolate and (1981) characterize the first human retrovirus, called human T-cell leukemia virus type I (HTLV-1)." Conclusion: **It agrees**.

From Gallo in 2002: "This enabled my colleagues and I together with my postdoctoral fellow Bernard Poiesz to isolate the first human retrovirus, human T cell leukemia virus type I (HTLV-1), in 1979 from a patient with T cell malignancy." Conclusion: **It agrees**.

From Montagnier in 2002: "The only retroviruses then known were the human T cell leukemia viruses, HTLV-1 and HTLV-2, identified by Gallo's group." Conclusion: **It agrees**.

Point 5: From the 1987 chronology: **Omitted**.

From Gallo in 2002: **Omitted**.

From Montagnier in 2002: **Omitted**.

Conclusion: **Point Omitted**.

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[245] Science, vol. 298, pages 1727-1730.

Point 6: From the 1987 chronology: "Gottlieb and co-workers (1982), Friedman-Kein and co-workers (1981), Siegel and co-workers (1981), Masur and co-workers (1981) and Mildvan and co-workers (1982) independently diagnose a new disease, AIDS, in groups of young homosexual men." Conclusion: **It agrees**.

From Gallo in 2002: "I first heard about AIDS in 1981 from newspaper reports but more informatively from lectures given by Jim Curran of the CDC, who challenged the audience, asking "where are the virologists?" Conclusion: **Differs from the unpublished**.

From Montagnier in 2002: "It was at this time (1982) that I first heard about the "gay disease." Conclusion: **Differs from the unpublished** (but keep in mind, Chermann co-wrote the unpublished history, this now represents Montagnier's views).

Point 7: From the 1987 chronology: "Epidemiological evidence suggesting that AIDS is a new infectious disease is developed by the Centers for Disease Control (1982)." Conclusion: **It agrees**.

From Gallo in 2002: There is no mention of epidemiological evidence developed by the CDC. Conclusion: **Point omitted**.

From Montagnier in 2002: There is no mention of epidemiological evidence developed by the CDC. Conclusion: **Point omitted**.

Point 8: From the 1987 chronology: "February 1983. At the Cold Spring Harbor Workshop on AIDS, Gallo proposes that AIDS is probably caused by a retrovirus, presumably a variant of HTLV-I or II." Conclusion: **It agrees**.

From Gallo in 2002: "…this led us to propose that AIDS might be caused by a new retrovirus of the HTLV family." Conclusion: **It agrees**.

From Montagnier in 2002: "There were only a few patients with this disease in France, but Gallo's idea that a retrovirus was the cause had already crossed the Atlantic." Conclusion: **It agrees**.

Point 9: From the 1987 chronology: "May 1983. Barré-Sinoussi, Chermann, Montagnier and co-workers publish: (1) the isolation and identification of a non-transforming retrovirus (later called lymphadenopathy-associated virus (LAV)), different from HTLV-1 and HTLV-II, in cultures of T lymphocytes derived from a patient with lymphadenopathy syndrome…" Conclusion: **It agrees**.

From Gallo in 2002: "they told me of their first positive result: the culturing of a virus from the peripheral blood cells of a patient with lymphadenopathy. They were able to identify the virus as a new human retrovirus, but were unable to characterize it in detail." Conclusion: **Modified, but it agrees**.

From Montagnier in 2002: "The virus was new, as was the disease…As I told Robert Gallo, I was convinced that we were dealing with a virus quite different from the HTLV family." Conclusion: **Modified, but it agrees**.

Point 10: From the 1987 chronology: "(September 1983, at the Cold Spring Harbor meeting…) Montagnier and co-workers (1984) report: (1) the identification of LAV-like viruses from 5 patients with lymphadenopathy and 3 patients with AIDS; (2) the selective affinity of LAV for CD4 (T4) helper lymphocytes; (3) the presence of antibodies (enzyme-linked immuno-sorbent assay (ELISA) against the main LAV antigens in patients with lymphadenopathy-associated syndrome (LAS) (63%) and AIDS (20%)…" Conclusion: **It agrees**.

From Gallo in 2002: There is no mention of other French isolates or statistical data on such. Conclusion: **Point omitted**.

From Montagnier in 2002: “We observed a high frequency of antibodies against the virus in lymphadenopathy patients, and noted favored tropism of this virus for CD4+ T lymphocytes. Our results were still controversial,…” Conclusion: **Modified, but it agrees**.
Point 11: From the 1987 chronology: “Gallo’s group (1984) reports: (1) mass and continuous production in a clone of a permanent cell line (H9) of HTLV-III from two AIDS patients…” and later, “The use of anti-p24 hyperimmune sera proves that the 48 isolates belong to the same kind of virus.” Conclusion: **It agrees**.

From Gallo in 2002: “In these papers, we described isolates of the new retrovirus, methods for its continuous production, analyses of its proteins, and evidence that it was the cause of AIDS.” Conclusion: **It agrees**.

From Montagnier in 2002: “In the spring of 1984, Gallo published more convincing evidence that HIV causes AIDS, a finding that was confirmed by Jay Levy’s group.” Conclusion: **Watered down, but it agrees**.
Point 12: From the 1987 chronology: “July 1984. Kalyanaraman, Montagnier, Francis and co-workers (1984) report the detection of anti-p25 (LAV) antibodies in 51 of 125 (41%) of AIDS patients.” Conclusion: **It agrees**.

From Gallo in 2002: There is no mention of the joint French/CDC study. Conclusion: **Point omitted**.

From Montagnier in 2002: There is no mention of the joint French/CDC study. Conclusion: **Point omitted**.
Point 13: From the 1987 chronology: “Shaw, Gallo and co-workers (1985) discover the presence of virus in the brain.” and “Wong-Staal, Shaw, Gallo and co-workers (1984) discover genomic heterogeneity of HTLV-III.” Conclusion: **It agrees**.

From Gallo in 2002: “The HIV-1 genome was sequenced, HIV antigenic variation was discovered, the virus was found in the brain of AIDS patients, genomic sequence variation was found in viral populations from the same patient,…” Conclusion: **It agrees**.

From Montagnier in 2002: “In 1985 came the cloning and sequencing of the HIV genome with identification of new open reading frames specific for lentiviruses.” Conclusion: **Partial acknowledgement but, it agrees**.
Point 14: From the 1987 chronology: “January 1985. The nucleotide sequence is of the AIDS virus genome is established independently at the Pasteur Institute (1985), at the NCI/NIH (1985), at Genentech, Inc. (1985) and at Chiron (1985) revealing similarity of the various isolates.” Conclusion: **It agrees**.

From Gallo in 2002: “The HIV-1 genome was sequenced…” Conclusion: **Watered down but, it agrees**.

From Montagnier in 2002: “In 1985 came the cloning and sequencing of the HIV genome with identification of new open reading frames specific for lentiviruses.” Conclusion: **Again, partial acknowledgement but, it agrees**.

What is now the implication of this comparison? Essentially without the fluff, the 1985 agreement is -without a doubt- the architect for the other subsequent two. Its same points are agreed 2, and again, 17 years later. What’s missing from the French side? Specific acknowledgement of discoveries made outside Gallo’s lab (notably the discovery and role of reverse transcriptase by Temin and Baltimore). While the American side of omissions left out any mention of other French isolates. But in 2002, both histories omit Points #7 & #12, both agreeing that the CDC studies with the French were not significant enough for continued inclusion. This means from the original Chermann/Gallo history, both

sides agreed in 1987 and again in 2002 on eleven of the fourteen points; all of them major, significant points! Just the two original points regarding the CDC have been unanimously tossed aside to correctly show no real influence on the course of AIDS history; as was Point #5 regarding Interferon Alpha[246]. But in regards to the contributions from Gallo's lab, and from Montagnier's lab, they are all -then and now- in agreement to varying degrees.

If that is the case, then one needs ask, after Gallo and Chermann got together in cooperation, why did his superiors at the Institut Pasteur prevent Chermann from formalizing the agreement of 1985? Easy. The lawsuit. How could the French allow an official published document to exist that agrees on key issues, when they were fighting to dispute so many? It couldn't happen. It wouldn't happen. Now, of course, the 1987 and the 2002 agreements/histories have more detail and chronicle other events, but it doesn't change the fact that every single key issue regarding events in both labs is still agreed to today; just as they were in 1985.

But what if Chermann had signed that original historical account? And what if Gallo did publish it? What might have been different because that two page document "officially" existed? That is simple to understand. The truth of the history was deflected for a time; put on hold. The French Government and the Institut Pasteur only wanted to sign such a document at their "right" time, just not the honest time. They needed to win their lawsuit(s) and take advantage of a window that had been opened for them by LAV-BRU. And the money pot from Gallo's blood test patent was big enough to allow for some partners.

It illustrates perfectly how this whole thing was about opportunity. When the scandal was created, and allegations flung, everyone that could, jumped right in on it. At the wide open end of this funnel were the French lawyers, the French Government, the Institut Pasteur, people from the CDC, dubious people from inside the NIH, a U.S. Congressman, mute U.S. officials never aiding their employee, a flotsam of scientists from competing labs, a few journalists, all throwing in their personally motivated ingredients. And the narrow end of that funnel emptied itself right smack into Gallo's lap.

[246] This was used in the original 1985 history as nothing more than an extra reference. It is irrelevant to the isolation of any human retrovirus. The idea behind it is that IFNalpha production by some cells in the culture has the potential to suppress virus production. Therefore, the use of antibodies to IFNalpha, which would inhibit the activity of IFNalpha, might be useful in augmenting virus production, thus becoming useful for the detection of a difficult to find human retrovirus. However, this methodology never saw fruition, was never needed, and certainly not implemented by Gallo, his co-workers, or anyone else…ever. Its omission in all subsequent histories is then proper and absolutely correct.

24.
WHEN COURAGE DEFINES AN EPIDEMIC

Too much has happened to leave out other notables in the history of AIDS. As a goal, this book wants to paint a complete picture of the AIDS story from all sides. Absolutely, others must be mentioned when we talk about the history of AIDS in the United States. To not talk about them, makes them a little more forgotten. So for a moment, let's go outside the bubble of Gallo, the French, even the many discoveries made, and let's view AIDS in a social timeline of poignant stories that shaped for many of us, the dire reality of steps we had to take as a people in order to understand the peril this epidemic has put us all in. And we will start with the worst of them all.

In 1986, William F. Buckley Jr. called upon for people infected with AIDS to get themselves tattooed on their forearms and buttocks in order to protect others from becoming infected. Public health officials were less hysterical however in their response; advising to avoid infection by wearing a condom during sex and by not sharing needles. With the message drilled in peoples' minds, that AIDS equals death, an overwhelming number did take the advice. Avoiding death by AIDS, and the stigma attached to it at the time, was the motivating factor for many.

But how did it get to that? What happened in the past when AIDS was first brought to the consciousness of the masses? And what later happened that affected our future?

Well, in those very early days, AIDS was known as the "gay plague." Nothing more than an unexplained ailment predominately affecting gay men; notably in New York and in San Francisco. When public health officials finally became alerted to this potential new epidemic in the spring of 1981, it began one of the century's greatest medical safaris. What is it? And how can we stop it?

Sandra Ford was a drug technician for the Centers for Disease Control (CDC). In April 1981, she wrote a memo after observing unusual drug requests by doctors treating gay men suffering with immune problems. One doctor was caring for a gay man in his 20's with pneumonia, and asked for a rare drug Ford was in charge of. A drug which either cured patients in a single ten day treatment, or they died. But two weeks later that doctor called to ask for a refill. Which was quite extraordinary; nobody ever asked for a refill. And yet this doctor added he had more patients who also needed the drug. That's when Sandra Ford wrote her memo. A single parent with two little girls, Ford began storing pillows and blankets in her desk, so that her girls might sleep while she packaged the many doses of drugs for these new patients. Many times filling orders till midnight and starting again at 5:00 a.m. Years later someone hung a napkin outside her office door: It was a sign that

read: "In this room in the spring of 1981, the epidemic known as AIDS was first reported." That napkin remained on Sandra Ford's door for years.

In June 1981, Michael Gottlieb, an immunologist at the UCLA Medical School, co-wrote the very first article about the new illness. In the cases he cited, all his patients were homosexuals. When the New England Journal of Medicine told him it would take at least three months to get an article published, he called a colleague, and wrote a draft of the article for a Centers for Disease Control newsletter. One June 5th, the very date his article was first published, the phone began ringing from doctors everywhere who also had similar cases. Now ideas were setting in, whatever this is, it's spreading everywhere…and spreading fast.

In January 1982, Dr. Larry Mass, who had been raising funds to fight the new "gay plague," along with five friends, founded Gay Men's Health Crisis. An organization that by its name, connected the disease with a specific people. While the name inspired homosexuals, it also helped define a target for straight society to pin blame on.

In April 1982, a CDC sociologist named Bill Darrow, interviewed Geatan Dugas, a French-Canadian flight attendant who had been linked in sexual contact with dozens of the earliest AIDS cases. Most everyone remembered this man as he was extremely handsome, muscular, well-dressed, with an attractive French accent. Simply put, he stood out. As Darrow spoke, the man became upset when it was suggested he should abstain from sex until doctors could find out how the illness was caused, and transmitted from person to person. The flight attendant scoffed, "My doctor says I have cancer, and there's no evidence cancer can be sexually transmitted." Then, in a burst of character revelation added, "Besides, if someone gave it to me, why shouldn't I give it to others?" It was later discovered this self-absorbed man had sex partners numbering in the thousands over his lifetime. His method was simple enough. He'd fly anywhere his job would take him, and frequent the gay clubs and bathhouses in those cities seeking new sexual encounters. Also during this time, in an effort to chart the progression of this disease, patients were being referred to by their city and their case number; such as LA1, LA2, NY1, and NY2. Darrow designated the flight attendant Patient O, for "Out of Country." But his colleagues took it to mean Patient Zero.

Dr. James Curran, head of the CDC Task Force studying the disease, attended a meeting in July 1982, where the new epidemic finally received an official name; even though many physicians were already calling it GRID, for "Gay Related Immune Deficiency." However, by then there had been a plethora of new case reports involving intravenous drug users, and in women who were sex partners of men with AIDS. Now that it had spread outside the gay community, a broader name was needed. The CDC Task Force was then known as the Kaposi Sarcoma and Opportunistic Infection Task Force. But that was too awkward; something more descriptive was needed. Accurately, the syndrome was marked by immune deficiency, and what sets this disease apart from other diseases, was the fact that it was acquired, not congenital. Thus the name "Acquired Immune Deficiency Syndrome" came to be. It was shortened to the acronym AIDS, which is how the Government likes to do things.

In December 1982, Dr. James Oleske and colleagues published a paper describing how the disease began showing up in more and more children. Many of which had drug addicts and prostitutes as parents. He wrote the paper in 1981 when he had eight cases of children with an immune disorder. One of the children had died, her mother was also dead

and six months later he met up with the IV drug user father who needed some blood drawn. As Dr. Oleske drew the man's blood, it became obvious to him that he was now dealing with a transmissible disease that was killing men, women, and children.

In December 1982, the CDC confirmed the first documented case in which AIDS was transmitted via a blood transfusion. The fact that the disease began appearing in children and transfusion recipients became a major turning point in terms of public perception. Up until then it was thought, believed, and even hoped for, as an exclusively gay epidemic. So the everyday person never really dwelled on it. But soon nobody could avoid its implications. That's when the first major news stories finally appeared. But where were they that year and half before?

In May 1983, the notion and introduction to the concept of "safe sex" came alive with a booklet entitled, How To Have Safe Sex In An Epidemic. Written by Dr. Jeffrey Sonnabend, a New York physician, and two of his patients (Michael Callens and Richard Berkowitz), this booklet spelled out for its readers that it appeared quite apparent most exposures occurred through the exchange of bodily fluids. This at a time when HIV had not yet been discovered, so these authors were only dealing with theories…which later proved correct. Except for one. Sonnabend pushed the notion that excess production of Interferon[247] Alpha was the cause of AIDS (and he continued his claim long after HIV had surfaced on the scientific frontier). Still, they knew this syndrome was likely a transmittable disease and thus the booklet became a sort of, "how to have sex and live to tell about it" manual. Its publication gave immediate rise to the use of the condom[248] while marking the end of what once was believed to be sexually liberating times.

From the onset, it seemed (or was hoped) that AIDS was a gender based disease where only males could be infected. And people, men especially, took some comfort in believing that their wives, mothers, and daughters would stay safe. Until May 19, 1983, when The New England Journal Of Medicine reported that research showed that AIDS could be transmitted from male to female. With that report, everything shattered. Why? Because men and women have other names too: boys and girls.

By 1984, scientists had identified the virus which caused AIDS, but no effective treatments were yet offered so people were frightened into panic. The only real advancement, that meant anything to the masses, was that the HIV blood test had been created. While it saved countless people with no disease, it defined those with disease as infected; marked. There was nothing for them beyond the death sentence that came with a positive reading. And social lines were drawn. Those without HIV stayed on their side of life, never crossing it even for a show of kindness. Thus, for many in the early era, the blood test became a double edge sword.

In December 1984, the first of many identifiable faces came to the forefront, humanizing the disease for all, helping to break it free of its associations with just homosexuals. At the time when this boy was diagnosed, he was a teenager and a hemophiliac. His name was Ryan White. He was a courageous and optimistic boy who shined through his affliction. For the next four and half years of his life, he spoke out

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[247] Of course, over-production of Interferon is likely a part of pathogenesis (disease mechanism), but says nothing about the primary cause.

[248] Astonishingly, a advocate group calling itself the Freedom Of Information Campaign Committee On Aids, publicly released charges on March 22, 1992, that claimed, "…that the promotion of the use of condoms actively encourages promiscuity and rapidly accelerates the spread of the AIDS virus."

against AIDS-related discrimination. His confidence never wavered, even telling his mother, "Mom, they're working so hard, by the time I get really sick there will be a cure." Ryan White died of AIDS and it affected the entire nation. It wasn't until 1990 when Congress enacted the Ryan White Comprehensive AIDS Resources Emergency (or CARE) Act; which provided much needed federal funds for community based care. Not long after, funding was suspended until 2000, when Congress reauthorized the C.A.R.E. Act a second time.

Scientists began touting that they learned more about AIDS and HIV during the period 1981 to 1985 than they ever learned about hepatitis in decades of study. Yet that was little consolation to a world that only wanted to hear anything with the word "cure" in it. Lacking that, the next best word was "treatment." So the late 1980s saw the introduction of AZT, as explosive growth rates of new cases were being reported worldwide, causing people to band together with concerned social activism.

Actress Elizabeth Taylor hosted the first Hollywood AIDS fundraiser in September 1985. She was asked to use her influence and celebrity status to get people just to come and participate. Concerned friends however advised her not to do it. In fact, Taylor later said she never heard so many "No's" in all her life over this one subject. With just a few months until the benefit, the world was abuzz over learning that fellow acting icon Rock Hudson had AIDS[249]. Everyone reversed their positions, especially the social elite who realized that if Rock Hudson could get it, they could too. But just as they cared about Hudson's condition, the entire country waited to see what would happen to Linda Evans. She, an actress on the popular television show "Dynasty" had shared an on-screen, very ballyhooed, mouth to mouth kiss with Hudson only weeks before he had revealed his disease to anyone. As Hudson's disease progressed through its final stages, the country waited and wanted to know…was a kiss enough to kill you? Happily, Linda Evans never did develop disease from her kiss. A kiss that proved to the world, not all contact with HIV positive people, is deadly contact.

In October 1985, Rock Hudson died of AIDS. He was the first major celebrity, known the world over to die of the disease. His passing made both the public and the Government see this disease as something important to them and their lives.

San Francisco Mayor, Dianne Feinstein, in December 1985, recommended the closing of the city's gay bathhouses. The gay community viewed it as a denial of their lifestyle, refusing the notion that these bathhouses were a point of transmission. But in fact they were a gateway for the out of control spread of the disease that absolutely needed to be shut down.

In1986, health care was lacking, even in compassion. As more patients were admitted, nurses still didn't want to draw blood or take temperatures. Food service personnel did not want to enter the rooms, so they left food trays out in the hallway. Housekeeping was too afraid to touch the bed sheets, let alone change them. The partners of these patients had to take on all these roles, quietly, in order to afford their loved ones some measure of dignity. Also, in those days, when the end came, funeral homes preferred

[249] To be absolutely sure, Hudson's sera was tested by Sarngadharan, after a phone call from the actor's personal physician, Dr. Mike Gottlieb. The samples were labelled Gottlieb 1, 2, 3, 4, etc. When Sarngadharan reported the samples tested anti-HIV positive, Gottlieb said on the phone, *"Sarang, you know of course, that they are not actually my sera! All I can tell you, is that he is a big name actor, still kissing leading ladies. He currently is travelling in Europe. You will see big headlines in the news when he dies in the near future."*

cremation rather than a casket funeral, so as to avoid touching or dealing with the body of someone with AIDS.

The Broom Closet Opportunity came in October 1986, when U.S. Surgeon General C. Everett Koop had released the Government's first comprehensive report on AIDS. Koop had, up till then, only spoken with President Reagan, once, privately about AIDS. They were visiting the National Institutes of Health, and were walking down a hallway when suddenly; some Secret Service agents grabbed them and threw them in a broom closet because of a bomb threat. There, in a room as big as a phone booth, squeezed together with mops, Koop looked at the President eyeball to eyeball and said, "I have to tell you about AIDS. It's a disease we have to face - it will never go away by itself. The people around you continue to think that people who have AIDS deserve what they got. But we're fighting a disease, not the people who have it." Before Reagan could utter anything in response, the Secret Service pulled them out of that broom closet. Koop always regretted not having more time to change the President's attitude on the disease.

In 1987, the United States of America added HIV as a, "dangerous contagious disease" to its immigration exclusion list. America was closing its doors to those outside the county with the disease. Tragically, most were coming into America for medical aid in the one country that promised the most hope.

Creator Cleve Jones and fellow activists displayed the AIDS Quilt Project for the first time in October 1987. Jones made the first panel for the quilt in the spring of 1987, in her backyard, to honor her best friend, Marvin Feldman. Her patch was made from an old sheet spattered with spray paint. Jones believed a quilt to be the perfect symbol to attach to AIDS, as it denotes traditional, middle-class family values. When the quilt was first displayed it had 1,927 panels. Today it has more than 50,000.

Drug users were being hit with infections at an alarming rate. Controversy followed when the Government decided to help people who couldn't help themselves. Why? Intravenous drug users weren't just homeless pan-handlers. They were college students, doctors, wives, business men, white, black, Jewish, Christians…the point is, the need to satisfy their addictions were urgent, and common sense took a backseat to the overpowering need to get high. So 1988 saw the very first comprehensive needle exchange program created in the United States. The common man hated that. They felt spending money on addicts, giving them the needles to use for illegal injections, was going too far and condoning drug use. Making it okay. Everyday society preferred that money go to research instead.

Alison Gertz, a 22-year-old New Yorker, had been sick in the summer of 1988. She was tested for everything except AIDS. Because nobody believed a heterosexual woman, who was not a drug user, could ever get it. But in September 1988, Gertz was in fact diagnosed with AIDS. She had contracted it through a one time sexual encounter with a good friend. When The New York Times did a story on AIDS six months later, about gays and drug users, totally neglecting to mention that women too were at risk, Gertz called the reporter. Soon afterwards, the reporter did a follow-up piece on Gertz that was called, The Girl Next Door Gets AIDS. When the piece was published, the phone began ringing with calls from parents all over the country. And they all were saying, "I thought my daughter was the only one." Gertz died in 1992.

In July 1990, the CDC found that Florida college student Kimberly Bergalis had become infected with HIV from her dentist when she had a molar extracted in 1987. Health

officials at first denied the possibility of infection in that manner. But Bergalis kept demanding to look more at the dentist, who himself, later died of AIDS. Eventually the CDC supported her conclusion. Her persistence made the health care profession more responsible, and new guidelines for patient care to be written, and enacted, across the board.

In professional basketball, Los Angeles Lakers guard Magic Johnson announced in November 1991, that he was infected with HIV. A specialist was brought in to answer questions for the press conference. Johnson made the distinction that he did not have AIDS, rather he just had the HIV virus. The conference then became a forum which was televised across the country and people watching become educated, noting there is a difference between having HIV, and having AIDS.

At the 1991 Tony Awards, actor Jeremy Irons was the first to wear a Red Ribbon. Frank Moore II (a Manhattan painter) was instrumental in beginning the red ribbon campaign which has since become an international symbol of AIDS awareness. Moore died of AIDS-related illness in 2002, at the age of 48.

In August 1992, AIDS activist (and HIV positive herself) Mary Fisher addressed the Republican National Convention. The room and the nation went completely silent while she spoke. AIDS was at last in a political arena, on a national forum.

Also in 1992, tennis great Arthur Ashe[250], revealed he had AIDS from blood given to him during his 1983 heart surgery. Ashe devoted himself to AIDS awareness and was a tireless crusader. On February 6, 1993, Gallo's home state of Connecticut, organized an educational program, with a question and answer session. Ashe and Gallo were both invited[251] but Ashe was too sick to attend. Not letting down the Black community, Ash had videotaped his speech which was then delivered to the conference. A man came and said, "Arthur wanted everybody to have this and he's not feeling so well." After the tape had been played for the audience, and the questioning session had begun, a man emerged from behind the curtain and whispered something to Mary Fisher, whose face visibly changed and she began to cry. She had just learned that while his videotape had been playing for them all, Arthur Ashe himself had just died.

In June 1994, MTV cast a 22-year-old gay man with AIDS, on its show, "The Real World." His name was Pedro Zamora. For a generation of youth, Zamora became the first person they "knew" to have AIDS. It painted a picture of pride and responsibility as Zamora kept his commitment to AIDS education, even in light of his diminishing health. Six months after he completed filming for that season, Pedro Zamora passed, as the youth of America saw the tragedy and the seriousness of the AIDS situation. When his death became a nationwide news item, those who didn't before, got to know Zamora for themselves via television reruns. Even then-President Clinton made a statement of condolence for the nation, on Zamora's behalf.

Zamora's death was especially poignant because in that same year, it became a fact that AIDS was the leading cause of death for Americans between the ages of 25-44.

The mid-1990s brought a life-changing breakthrough. Namely, the development of protease inhibitors which, when used in combination with the other existing AIDS drugs, helped reduce virus loads to undetectable levels in some patients. For many, this new AIDS

[250] He was the first African-American to win the U.S. Championship (1968) and Wimbledon (1975).
[251] As were playwright and ACT UP founder, Larry Kramer and Mary Fisher, founder of The Mary Fisher Clinical AIDS Research and Education (CARE) Fund.

"cocktail" brought with it, a pardon to their death sentence. The gay community heard this, and was relieved. AIDS went from "once upon a time you were certain to die," to "now there's a good chance you won't." Conversely, other patients were overpowered by the treatment's toxicity. Treatment went in excess of seventy pills daily, and costs exceeded thirty thousand dollars a year[252].

In January 1996, activist Rebecca Denison became one of the first HIV-positive women to talk publicly about her decision to become pregnant, after delivering twins. Stating she deliberated for five years, that the risk of transmitting HIV to a baby was only one of the many factors she considered. During her pregnancy there were moments when she knew her girls would be okay. The first test results came in five days after the girls were born. They were negative then, and they're negative today.

By 1997, there was a shift in the public's perception, that AIDS and HIV were becoming less of a crisis because of the new medications. But the fact was, all those medications did was stop the manifestations of skin lesions, they stopped one from looking as though they were wasting away. So people without cosmetic reminders to the contrary, talked themselves into believing AIDS was fading from public view. Charities soon saw a decline of more than 20% in their fundraising efforts.

In January 1999, the San Francisco Health Department reported increases of instances of unsafe sex by gay men. The number was once much lower with the message that safe sex equals life, but after the protease inhibitors, that number became more like 50%. Thanks to the drugs, people were no longer looking at certain death. Thus, attitudes about unsafe sex changed.

Los Alamos National Laboratory researcher Bette Korber presented the latest findings on the origins of HIV to an academic conference in September 2000. Working with mathematicians and physicists, she developed an evolutionary model that suggested the version of HIV that caused the epidemic originated around 1930. This theory has been reinforced by another study[253] completed in 2003. In their paper, the authors of this study show that the genetic patterns of a number of SIV-epz[254] strains are of the same variety which have spread into the human population and started the HIV-1 epidemic. It is likely that chimpanzees in West Central Africa ate infected monkey meat, thereby contaminating themselves. It is theorized that after a succession of cross-species transmissions[255] and recombination events, SIV entered the human population around or before the 1930's.

In fact, AIDS is still spreading to this day. As of the writing of this book (2006), it is conservatively (yes, conservatively) estimated that worldwide, there are fifteen thousand new cases of AIDS infection a day. That means every minute, somewhere in the world, 10 new people are becoming infected with this disease. One every 6 seconds. Think about that. How many people healthy now, will not be by the time you finish reading this book? It is a fantastically staggering infection rate given that we know, and are educated, about this disease. Yet, those are the numbers. Fifteen thousand new cases a day, every day. In America alone, 1 in 700 is infected. Of those, an estimated 300,000 don't know they have it.

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[252] And these costs are only rising. Example: On Thursday, March 13, 2003, the FDA approved the first of a new class of AIDS drugs called fusion inhibitors. The drug, known as Fuzeon, works by blocking the AIDS virus from invading white blood cells (the primary targets of HIV) and costs consumers $20,000 a year.

[253] Hybrid Origin Of SIV In Chimpanzees, Elizabeth Balles et al., Science, vol. 300 June 13, 2003, p. 1713.

[254] or Simian Immunodeficiency Virus.

[255] The most likely scenario being chimps ate monkey meat, African hunters later ate chimp meat.

In 2002, the rate of new infections in United States was still the same as it was in 1997. In 2000, eight cents of every federal dollar spent on HIV/AIDS in the United States went towards prevention. From June 5, 1981 (the anniversary date of AIDS) when doctors reported a new and deadly disease found in five gay men in Los Angeles, to twenty-three million dead as of 2002. With another 45 million now infected, AIDS has become a horror on our world. 66% of these cases reside in Africa, 22% in Asia, and 12% in the rest of the world. And it gets grimmer…the worldwide death toll in 2003 reached 8,000 a day from the disease. That number did increase in following years.

In connection with AIDS treatment, Gallo and several members of his lab (Fiorenza Cocchi, Paolo Lusso, and close collaborator Anthony DeVico), searched for, discovered, and identified the first three natural inhibitors of the AIDS virus. Namely a subset of regulatory molecules known as chemo-attractant cytokines (or chemokines). The particular inhibitors, which Gallo calls HIV suppressive factors (or HIV-SF for short), appear to keep HIV out of lymphocytes. This discovery was promoted by the observation of another scientist (Dr. J. Levy) that unidentified cellular antiviral factors circulating in the blood are able to naturally inhibit HIV infection. Within months following the Gallo group's breakthrough, Ed Berger and his team at NIH discovered that HIV needed two receptors to enter cells: the specific CD4 receptor (already known) and a second, which turned out to be a receptor on the cell surface whose normal function is to bind and be stimulated by certain chemokines (a chemokine receptor). Chemokines, therefore, act by blocking HIV's port of entry into the cell, i.e. by attaching to, and causing internalization, of the chemokine receptor needed by HIV.

This finding was immediately recognized as a major development in the field. It was, in fact, reported just as Gallo was leaving NIH (after 30 years of employment) in 1996 to form the new Institute of Human Virology (see Chapter 30), together with other scientists from NIH, and with Dr. Bob Redfield from the Walter Reed Medical Institute. A full scientific account of Gallo's discovery was published in Science, Dec.1995. In fact, Science reported in an Editorial[256] that, this new discovery by Gallo and his co-workers, together with the development of the protease inhibitors by the pharmaceutical industry, were the two most important breakthroughs of the year in all of science! After that, many pharmaceutical companies began banking on the idea that blocking the chemokine receptors would ultimately become one major new drug targeting strategy of future therapeutics against AIDS.

At this time several outstanding scientists (most notably the independent works of Drs. John Moore and Dan Littman and their co-workers in New York) pursued this area of research with outstanding results. One of which, was finding that 1% of the Caucasian population are born without the key HIV receptors, specifically the chemokine receptor called CCR5. In the absence of CCR5 such people are virtually un-infectable by HIV!

But the facts remain simple and harsh. In 2003, there was an unprecedented high of 5 million new infections with over 3 million deaths. Two and a half million children under the age of 15 were also identified as infected. What was AIDS in 2003? The number one cause of death in Africa and the fourth leading cause of death worldwide[257].

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[256] Science, December 20, 1996, vol. 274.

[257] World AIDS Deaths, Infections At New Highs, by Patricia Reaney, Reuters, November 25, 2003.

In fact, it is now the worst in all of recorded history. Yet our search for a cure goes on while more are dying every day from the disease, or from the very drugs intended to treat it.

25.

PROFILE: THE YOKE ON GALLO'S SHOULDERS

"Let's be fair, Mr. Crewdson – just for once. For example, look at the September 22, 1983 presentation at CSH (Cold Spring Harbor) published in 1984 by Montagnier. Read his conclusion, i.e., by late 1983 he states the cause of AIDS could be LAV, HTLV-I, HTLV-II, something new, etc. For the 1000th time: Science grows by pieces just like a jigsaw puzzle – piece by piece. Sometimes a piece fits. Later you learn it is not always the best fit. In May 1983, the period you quote and far later: amyl nitrate, sperm, no cause, antigen overload, fungi, CMV, adenovirus, EBV, God's wrath, syphilis, African swine fever (by your co-worker Mr. Ortleb), were all proposed as the cause of AIDS. Did anyone come closer[258]?"

It has been said that people either admire Gallo or despise him…love him or hate him. And there is no in-between. But then, there are those few who belong to an extreme class all their own; who seem enslaved by an uncontrollable obsession to discredit Gallo of his many achievements. Case in point, John Crewdson, an investigative reporter with the Chicago Tribune. After 15 years, Crewdson returned with a poisonous pen in a book filled with vengeance, resurrecting the same old charges (now over 16 years old, as of 2003) against Gallo, despite the fact that they have all been thoroughly investigated and formally dismissed. He writes of unending wrong-doing against an overwhelming record of exonerating evidence for Gallo. But what purpose can possibly be served by the resurrection of a case settled well over ten years prior?

Crewdson has been doggedly pursuing Gallo for more than a decade following (assumed) leads of (circumstantial) evidence to (alleged) wrong-doings. It is notable that in all that time, and for so many articles, Crewdson has never met Gallo, the subject of his journalistic endeavors. As one of the investigative reporters in the Watergate affair, Crewdson was probably influenced by the political corruption standard, and applied it with unparalleled stubbornness and brutality in Gallo's situation. So the question remains: how many times can one take the same case to court and lose?

Crewdson both directly and indirectly accuses Gallo of, no more and no less, fabricating and falsifying evidence to appropriate the discoveries of others, to mislead the scientific community, and to deceive the public at large into believing Gallo's own propaganda for money and glory. Crewdson uses a wealth of details, impossible for the

[258] Replies to Crewdson Queries, written response by Dr. Gallo to question #161 of a 189 question Questionnaire submitted through the Freedom of Information Act, January 6, 1989, pages 46 & 47.

non-expert to follow (let alone evaluate) to give his truly fictional story a sense of respectability, reliability, authenticity, and authority. Gallo: *"What he does is detail to establish authority and authenticity to make the critics be afraid, and then he selectively leaves out stuff."* Yet, the evidence presented is systematically misrepresented, is in places grossly inaccurate and, in general, deviates substantially from the factual record. "Still, the book's bias is profound and unmistakable, and bias is the antithesis of science[259]." It is based mostly on half-truths and half-lies, which distort the facts and discredit Gallo again, to both his scientific peers and the lay public. In fact, the book attempts a character assassination of Gallo in cold blood with appalling persistence. And it all starts with the title: Science Fictions: A Scientific Mystery, a Massive Cover-up and the Dark Legacy of Robert Gallo[260] (Little, Brown & Co., 2002).

The book contains a phenomenal amount of both technical and non-technical information (some accurate, some less accurate, and some downright false), which implied that science advisors, expert insiders (not all of them truthful), and science writers contributed to his effort over extended periods. Who, then, has been paying the bills for Crewdson's efforts and why?

Before we get to the rehash of the same old accusations, however, a number of points are in order.

Point 1 – Crewdson ignores the evidence and judgments that led to Gallo's exoneration. He himself provides no proof for his allegations, but builds a provocative circumstantial case against Gallo by examining, and subjectively interpreting events with painstaking detail.

Point 2 – Gallo, is no doubt, a definitive figure in 20th century virology. One has only to consider his unparalleled life-long, high scientific citation rating (overall, some 60,000, with almost 37,000 of those in just six years, from 1984-1990). One does not get such a phenomenal number of citations for doing nothing (as Crewdson would have you believe). His dominant role in blood cell biology and tumor cell biology, his command of respect among renowned peers, and his attraction of an international scientific crowd to his yearly lab meetings, are all one needs consider to agree with that statement.

Point 3 – Like virtually all senior scientists that work within a large group, Gallo has not been a bench researcher since the mid-1970s. Gallo is a research manager. The question now is what are the skills and traits of an effective research manager. An effective research manager, like all other managers, gets things done through people by defining purpose and by implementing behavior to achieve purpose. He hires and trains promising research scientists, sets research goals, plans the research activity, organizes the research resources, assigns research tasks, directs the research work, and controls the research effort. He makes breakthroughs, therefore, not by actual hands-on doings, but by exercising leadership; by staying on top of things and by motivating people. Anything

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[259] Double Jeopardy For Gallo, by Martin Delaney, Science, vol. 296, May 31, 2002, page 1616

[260] Book reviews varied from negative (e.g., Lots of Peanut Shells, But No Elephants, by Jaap Goudsmit, Nature, vol. 415, March 14, 2002, p. 125); also Double Jeopardy For Gallo, by Martin Delaney, Science, vol. 296, May 31, 2002, p. 1615, to indifferent, even supportive (The Scientific Method, by Cheryl Clark, San Diego Union Tribune, February 10, 2002). These last by scientifically uninformed reporters betting on the author's reputation, and protests have been voiced against these (Gallo Attacks Are Unfair And Self-Serving, by Drs. Warner C. Greene and Michael B.A. Oldstone, The San Diego Union Tribune, March 19, 2002, p. 6).

else would be akin to criticizing an orchestral conductor who also composed music for (but does not himself play) the flute.

Point 4 – Just who has Crewdson interviewed about Gallo? It turns out, that most of these people are well known Gallo "haters," some of which are grossly biased against him and were willing/wanting to talk. Most have only met Gallo, "*in one or two meetings, or not at all.*" That according to Gallo. Conversely, almost all Gallo sympathizers declined to be interviewed by Crewdson because of a strong belief in the scientific community that his objective was to discredit Gallo by all means and at all cost. Others, who agreed to be interviewed, said later that Crewdson was so committed on "getting Gallo[261]" that occasionally he would appear to resort to unethical practices if individuals were unwilling to talk to him. In one instance, for example, he threatened Dr. Daniel Zagury, who said: *"Okay, you're going to get it as bad as Gallo. If this is your attitude, then I will not just write about Gallo, I will write about Gallo and you."* Which he did. Zagury further recalls, *"My interview with Crewdson, arranged by Claudine Escoffier-Lambiotte of Le Monde, was one of the worst hours of my life."* In another instance he threatened Mark Kaplan (a clinician scientist at North Shore University Hospital in Long Island and also Cornell University) that he would disclose confidential information about a patient, if Kaplan continued to avoid talking to him about Gallo. Kaplan: *"It seemed so peculiar that someone would be going to these extents to get information. He seemed to me, terrorizing Dr. Gallo for reasons I couldn't understand."* Kaplan did not grant an interview and Crewdson carried out his threat. Kaplan was both shocked and outraged at the reporter's willingness to breach the confidentiality afforded all research subjects. In his letter to James Squire, Editor of the Chicago Tribune, Kaplan wrote (10/18/1988), "The only one who breached our patient's confidentiality was Crewdson."

No wonder the comments these others made, upon which conclusions were drawn in Crewdson's book, weigh heavily on the negative side. But there is another, most important reason too. Martin Delaney, Head of Project Inform explains: *"So many of the quotes in the book, you know, the nasty comments that he (Crewdson) digs out, took place or came from that era when Crewdson first wrote his 50,000 word essay which made Gallo look like a monster. And had he asked me at the time, I probably would have made one of those quotes. But he makes it sound like these are the standing opinions of those people when in fact almost everybody's opinion in the scientific community, changed with the information, what was it, in '91?, when they discovered about the (French) contamination. When the independent, outside (unbiased), 5 labs went out and could see that not only Gallo's lab, but in London with Robin Weiss, and Montagnier's own lab, they had all been contaminated by the same, original sample. What would those people have said had they been re-interviewed again with that new information? Cuz you know, he's getting the opinions from 1986 and 1987, making it sound like they're the opinions of people today; when in fact most people's opinion in the scientific community changed dramatically with that other data. So it's a misrepresentation of what so many of those people actually believe to this day."* Author's Note – That is exactly why in this book you are now reading, all the quotes taken from my interviews are all in italics. So there will no mistaking what was said then, and what is being said now.

[261] At NIH, An Unprecedented Ethics Investigation: New Questions Involving Scientist Robert Gallo and Discovery of HIV Being Probed, by Malcolm Gladwell, The Washington Post, August 17, 1990, p. A8

Point 5 – In science, it makes no difference what one believes, proposes, and/or claims to be true [This apple is a special apple]. Conversely, it makes a lot of difference what one demonstrates or proves to peers to be true; based on hard facts and on what one publishes in the peer-reviewed open literature [It is special and let me show you both why and how it is so special]. This means that an uncharacterized structural species (macromolecule, virus, whatever) remains undefined until characterized. Similarly, an obscure functional process remains undefined until described [An apple falls on your head and it means something, but you don't know what]. Consequently, reviewers prevent one from publishing until there are significant findings to show, and has proven those findings are real by unshakable evidence.

Credit does not belong to those that verbalize an unproved idea first. Credit belongs only to those discoverers who prove that their discovery is solid and convinces others that it is so. As DeVita once said to Gallo, quoting Sir William Osler, "credit belongs to the man who proves a discovery to the scientific world." Research is a competitive race and the first one to score in the eyes of his peers triumphs, as science moves from truth to guesswork and from guesswork back to truth in unending cycles. The peer-reviewed professional literature is then the single most credible record of scientific progress to which one must always refer, if one seeks historical truth.

Point 6 – The cause of AIDS was not discovered in the same manner one discovers a lost tribe, i.e. by running into it and studying it. Important discoveries on AIDS were made in discrete stages, by different scientists, working in different labs around the globe, each contributing critical pieces to the overall veiled puzzle. Specifically, in regards to AIDS, after clinicians initially found T-cells were involved…

- ✓ The first stage then was to establish what one should be looking for as the most likely cause of AIDS. Gallo and Essex from Harvard proposed the idea of a new retrovirus, presumably a member of the HTLV family, as the most probable cause of AIDS. This hypothesis was based on a rational, well founded base. That…

(a) the disease involves CD4 T cells and so do the only other known human retroviruses, the HTLVs;

(b) AIDS causes immune impairment and so do the HTLV viruses (albeit minimally) and;

(c) At the time, AIDS was suspected of being transmitted by blood, by sex, and theorized from mother to infant (by all body fluids) as are the HTLV viruses themselves likewise transmitted.

- ✓ The second stage was to hunt for signs of a retrovirus in the blood of AIDS patients

(a) Curran of the CDC had fundamental epidemiology (i.e., who was at risk) giving hints of an infectious agent.

(b) Gallo helped in supplying the biochemical assay tools to hunt for evidence of reverse transcriptase activity, indicating the presence of a retrovirus. Critical to this approach was cultivating human blood T-cells at least temporarily (a few weeks) to verify presence of some virus. This was done with Interleukin-2 (the protein discovered by Gallo's team in 1976) and with the basic protocol first used by the Gallo team for attempts at retrovirus isolation. Indeed Gallo sent that protocol to Dr. Chermann; Dr. Montagnier's co-worker in the early to mid 1980s.

- ✓ The third stage was to detect the retrovirus following confirmation of reverse transcriptase activity, to isolate it, and then characterize it. But Montagnier was first to detect what looked like a new retrovirus, possibly the cause of AIDS.
- ✓ The fourth stage then, was to confirm whether or not the new French virus was related to other known human retroviruses or was a contaminant animal retrovirus. Gallo supplied the biochemical differential assays but, Montagnier was first to insist that the French retrovirus was a new, human-associated species.
- ✓ The fifth stage was to characterize the new virus both biochemically and genetically; both Gallo and Montagnier contributed to this task.
- ✓ The sixth stage was to conduct wide scale sero-epidemiological studies to prove or disprove that the new retrovirus was the cause of AIDS. To conduct these studies, however, one needed the following stages:
  - sub-stage I: To grow the retrovirus in a permanent cell line. Gallo's group was first in achieving this goal having found the optimum cell line and grew the virus on a massive scale;
  - sub-stage II: To develop a working blood test using viral components grown in quantity and in a reproducible manner. Gallo was again first in achieving this next goal, namely the ELISA screen assay and the Western Blot confirmation assay; in combination.

Having achieved both those sub-stage goals, Gallo was also first to conduct wide scale sero-epidemiological studies, was first to prove that the new retrovirus was the cause of AIDS, and was first to establish his AIDS blood test as the gold standard of clinical serology used for protecting the world's blood supply. That two stage test, the ELISA screen assay along with the Western Blot is now in its third generation of refinement, but little has changed from the original. It is still the standard used the world over. Yet, not appreciating (or, not wanting to) the preciseness of the second, confirmatory stage, Crewdson writes about the testing system that, "…false positives are unnecessarily costly, wasting blood and depriving the system of donors…[262]" Even CDC epidemiologist Don Francis, when asked why use the Western Blot, he replied, "I don't know…it was probably the most expensive, difficult thing with a new technology out there, to be honest. It's okay[263]." When the long-awaited, 20-minute HIV test (known as OraQuick) was given FDA approval on Friday, June 27, 2003, the makers themselves, "…caution that a positive result is considered preliminary; another test (the Western Blot) is needed to confirm the result[264]." In fact, every single one of these rapid HIV tests by other companies, all call upon the Western Blot as their final, definitive stage of testing. None of the best minds in the world have come up with a better test in these last two decades; or more cost effective - if you can put a dollar value on any human life. Yet a reporter, an epidemiologist, and yes, even some Frenchmen will tell you different. Go figure.

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[262] Early AIDS Blood Tests OkD Despite Problems, Chicago Tribune, December 30, 1991, p.1

[263] Donald P. Francis, M.D., "Epidemiologist, Centers for Disease Control: Defining AIDS and Isolating the Human Immunodeficiency Virus (HIV)", an oral history conducted on December 22, 1993 by Sally Smith Hughes, Ph.D., in The AIDS Epidemic in San Francisco: The Medical Response, 1981-1984, Volume IV, Regional Oral History Office, the Bancroft Library, University of California, Berkeley, 1997.

[264] 20-Minute HIV Test Becomes Available in L.A., by Steve Hymon, Los Angeles Times, June 28, 2003, p. B3.

Point 7 - None of the above described research stages could have been accomplished when they were without Dr. Gallo.

- ✓ First, Gallo demonstrated the existence of human retroviruses at a time when the scientific community was rejecting the very notion of their existence. What then should one have been looking for as the most likely cause of AIDS if Gallo was not around to suggest a retrovirus at work?
- ✓ Secondly, Gallo had the most sensitive reverse transcriptase assays (for detecting virus in cells and tissues) and the only retroviral DNA probes in the world capable of detecting and differentiating viral species. How else would the French have detected the presence of retroviruses and recognized their individual differences?
- ✓ Thirdly, Gallo had efficient growth factors for the production of viruses in continuous cultures. How else would one have obtained massive amounts of viruses for complete biomolecular, biochemical, and immunological characterization for proving causality through large scale serological screening? Or, for developing an efficient blood test through large scale separation of viral proteins?

Point 8 - Why would anyone engage in acts that invite suspicion and can be proven fraudulent? It really makes no sense at all. Why would Gallo want to steal intentionally somebody else's virus and claim it as his own when he had numerous virus isolates of his own and, therefore, was not dependant upon the French virus to develop his blood test? In 1990, when the Washington Post wanted to ask Crewdson that very question for an article[265] which was being written but, he, "declined to be interviewed." That same article reported, "Other scientists say Crewdson's reporting has serious gaps that biased his conclusions against Gallo."

Logic dictates that an alleged fraud would be discovered in time, especially if one signs a receipt for the goods he is later accused of stealing. Therefore, prudence dictates against it. One can accuse Gallo of many things, such as aggressiveness, impulsiveness, and the like. One can not, however, accuse Gallo of stupidity and it takes a very stupid man to steal somebody else's virus, knowing only too well that the theft could not remain hidden forever. And even though numerous other groups had exactly the same contamination including Montagnier, no one else was ever suspected (nor should they have been) of doing it deliberately.

So, with all the above points in mind, let us now list and address the repeated accusations of an obsessed reporter on a wild goose chase. Specific allegations are listed in the next chapter.

[265] At NIH, An Unprecedented Ethics Investigation: New Questions Involving Scientist Robert Gallo and Discovery of HIV Being Probed, by Malcolm Gladwell, The Washington Post, August 17, 1990, p. A8

July 27, 1988

Mr. James D. Squires
Editor in Chief
Chicago Tribune
435 N. Michigan Avenue
Chicago, Illinois 60611

Dear Mr. Squires:

On 7/18/88, in the evening, I received a telephone call at my home from a Mr. John Crewdson, who stated that he was a reporter on your staff, asking me to discuss with him a certain letter to Nature on which I am a co-author. When I told him that I would be unable to meet with him, he said that I had better, because he was in possession of certain facts proving that misstatements had been made in the letter to Nature and that he intends to make them public. He mentioned that it involved the first publication of electron micrographs of the AIDS virus. He tried to pressure me for about 20 minutes to meet with him, but I told him that I could not.

In my opinion, Mr. Crewdson's attitude was abusive, and threatening during his phone call to me. I strongly object to such treatment. Harrassing scientists by digging up disputes which have long since resolved is, in my opinion, a disservice to the public in that it greatly hampers the search for a solution to the AIDS epidemic. This kind of journalism is unworthy of a reputable newspaper like the Chicago Tribune.

Sincerely yours,

Bernhard Kramarsky

Bernhard Kramarsky, D. Sc.

Silver Spring, MD 20901

le/BK

cc: Dr. T. Truffelli, ENI, Guilford
Dr. R.C. Gallo, NCI, NIH

One of the many letters of complaints against Crewdson citing his “talk-to-me-or-else” tactics. Even from those only remotely associated with the Franco-American dispute.

26.
DISMANTLING DOUBT WITH FACTS, FACTS, FACTS

Throughout this independent investigation logical conclusions were drawn from the facts and the information at hand. And the facts are…

Gallo did not misappropriate any credit from the French,
Gallo never claimed that HTLV-1 was the cause of AIDS,
Gallo did not misappropriate the French virus,
Gallo did not restrict the distribution of reagents to other labs, or that,
Gallo did not fail in his responsibilities as a lab chief,

Thoroughness dictates that we scrutinize the following summary break-down of specific, implied accusations. primarily made by Crewdson, (seemingly) on behalf of French interests, and the list of pertinent facts known about each.

- **Allegation: The initial discovery of the HTLV-1 virus was made by Hinuma in Japan.**

Incorrect - this in itself is an outrageous falsification by Crewdson, which perhaps only one fringe scientist (specifically A. Karpas) in the world would agree with. The original discovery was made and published first by Gallo and his group (see page 17, "The Discovery of the First Human Retrovirus" and page 22, "Unveiling the Epidemiology of the Leukemia Viruses"). In a way, the Gallo group deserves more credit for this discovery because unlike Japan, where the disease was endemic, in the United States, it was sporadic at best. Yet they were still able to isolate it. Gallo: *"If I were in Japan, I think we would have discovered this 10 years earlier. No one in Japan would ever make the claim that the Japanese discovered the virus first. Publication dates are what counts. We're (meaning, the Gallo group) more than a year ahead of them. The whole world knows that, the whole scientific community knows that, certainly Hinuma knows that."* Moreover, Gallo gave many Japanese scientists the reagents to look for the virus, but himself never received any viruses from Japan. Further, his group published a full year before Hinuma, with another four papers already to his name before the Japanese group. This is evidenced further when noted Japanese scientists such as Dr. Maruyama publicly used the term HTLV. Only after Gallo's trouble with Montagnier began, was when Hinuma tried to confuse the situation (and he did cause a great deal of confusion by not clarifying the facts) by saying perhaps Gallo had taken the Japanese virus ATLV. All Japanese scientists today agree, and none disagree, on the scientific history of HTLV-1.

- **Allegation: The epidemiology of HTLV-1 was established by Hinuma in Japan.**

Incorrect - the epidemiology of the disease was first established by Takatsuki in Japan; Gallo and the late Prof. Ito of Kyoto had already linked HTLV-1 to ATL (Adult T-Cell Leukemia) in Japan and had already presented their findings in March 1981, which were also published soon thereafter (see "Unveiling the Epidemiology of the Leukemia Viruses" on page 22).

- **Allegation: The link between HTLV-1 and the leukemia it causes was established by Miyoshi and Hinuma in Japan.**

Incorrect - this link was established by Gallo, and collaborators (see page 17, "The Discovery of the First Human Retrovirus" and page 22, "Unveiling the Epidemiology of the Leukemia Viruses"). Miyoshi alone did not have both the virus and the reagents at the time to show causality.

- **Allegation: The discovery of the T-cell growth factor was made by Morgan in Gallo's lab.**

True - Morgan, a Gallo post doctoral fellow, worked on the project.
Untrue - she was not on her own; Gallo had assigned her to the project and supervised her work and was the senior author of the three papers (see page 16, "The Discovery of Interleukin-2"). All senior scientists have post-docs working on a problem. Hands-on experience is how they learn. Lastly, as a point of fact, Gallo and his colleagues had named the discovery "T-Cell Growth Factor." But most people began calling it Interleukin-2 or IL-2 instead; so its original name got brushed aside and lost to mostly scattered recollections.

- **Allegation: The discovery of HTLV-1 was made by a Post Doc and co -worker in Gallo's lab**[266]**.**

True - two scientists (Poiesz and Ruscetti) contributed to the project.
Untrue - they did not work alone. In fact, they worked along with others in Gallo's lab while Gallo himself made the assignments and supervised the entire multidisciplinary effort (see page 17, "The Discovery of the First Human Retrovirus"). Gallo set up the conditions in which they worked during the prior 10 years (1970-1980) including all materials they used to make the observations. Keep in mind that discovering a Human Retrovirus was Gallo's primary goal for nine years.

- **Allegation: Poiesz and Ruscetti worked on the HTLV-1 discovery project on their own and in secret because Gallo was no longer interested in human retroviruses after the contamination fiasco.**

Untrue - Gallo, in fact, accelerated the pace of the entire research program in an all out lab-wide effort to find the first human retrovirus (again, page 17, "The Discovery of the First Human Retrovirus").

- **Accusation: Gallo fired Ruscetti because of his HTLV-1 discovery.**

Untrue - Ruscetti left Gallo's lab by choice because there were no positions available, and no requested positions were granted for promotion to section chief, per his (Ruscetti's) request[267].

- **Allegation: The discovery of HTLV-2 was made by Kalyanaraman in Gallo's lab.**

Untrue - Gallo predicted the presence of a new HTLV related retrovirus in suspect cells, assigned Kalyanaraman to a part of the task, supervised the progression of the work, wrote

[266] Crewdson first credits the discovery of the virus to Hinuma, and then, re-credits it to the two Gallo scientists; also note that Poiesz was another Gallo post doctoral fellow.
[267] Gallo acknowledges out of literally hundreds of associates and post-docs over 30 years at NIH, Ruscetti was/is a particularly, *"dissatisfied, angry man"* when it comes to him.

much of the paper, and published the results offering Kalyanaraman first authorship, although several others in the lab contributed almost equally to the effort (see page 23, "The Discovery of the Second Human Retrovirus"). Markham: *"Of course he (Gallo) wasn't in there with gloves on."*

- **Allegation: Arthur Levine, chief of NCI's Pediatrics Branch, and Don Francis, an epidemiologist with the CDC, first suggested in late 1982 that AIDS was caused by a retrovirus.**

Untrue - according to Max Essex (who was Francis' Professor at Harvard), Francis had never even heard of human retroviruses until much later. In fact, the suggestion was first made by Gallo and Essex and described in Medical World News in the summer of 1982; a fact ironically (intentionally?) unmentioned by Crewdson. Francis and others at the CDC later claimed HTLV-2 as the cause of AIDS in a pre-print they sent around in early 1984, which they quickly retracted. Again, this goes unmentioned by Crewdson. As for Levine, a June 4, 1984 letter from him to Gallo, regarding a Toronto Cancer Meeting says it all: "I've been informed that you graciously mentioned my name in your talk. It means a great deal to me that you publicly noted our discussion about AIDS and the possibility of HTLV early in 1982. Your acknowledgement was unexpected, but very welcome indeed." Even though Gallo respected Levine's view, he had already (with Essex) come to this opinion; as his notebook records prove.

- **Allegation: The discovery of the AIDS virus was made by Barre -Sinoussi, Montagnier, and Chermann at the Institut Pasteur.**

True - the French scientists were first to detect a new retrovirus. In fact, Gallo has admitted this, then and now. And there is no better proof of that except when it comes from someone not on Gallo's side. Namely, Don Francis; who recorded in bold quotes, these words from Gallo himself: "They first identified the virus[268]." It should also be clarified that all the French work on this was done almost exclusively by Chermann and Barré-Sinoussi in collaboration with French teams outside the Institut Pasteur; with some involvement from Montagnier. This is true of both the original discovery of the virus, and even more so during the development of the French blood test.

Untrue - that they could claim their find to be the AIDS virus, given that they had not characterized the virus and had not proven disease causality (those are both Gallo's achievements). Back in 1983, the French did not have the tools to prove that the new virus was the cause of AIDS.

- **Allegation: Klatzmann at the Institut Pasteur was…**

first to show that the AIDS virus infects and kills T-4 cells **(True),**
first to identify the CD-4 receptor[269] as the portal of the AIDS virus to the T-4 cell **(True)** and the first to establish a highly productive clone of the CEM cell line for the commercial growth of the AIDS virus. **Untrue -** the French were not able to grow their own virus until much later. It was Popovic in Gallo's lab who was the first to grow their virus. Indeed, if it were true that the French did this at such an early time, their scandal (see Chapter 28 for the full story) for not using a blood test until almost one year after most developed nations had

[268] From Don Francis' handwritten notes recording highlights of a phone call with Gallo; June 6, 1984.
[269] The information you are about to read has never been revealed before. Robin Weiss called Gallo about the discovery of the CD-4 receptor. Weiss knew Popovic had an ongoing paper with the same conclusion, namely that CD-4 was one of the receptors used by HIV to enter the cell. A truly important result that was assured to be heralded as critical. Weiss called Gallo asking, "*to hold off publishing because Robin had so little while Mika and I had so many published contributions already in the field."* So Gallo agreed to do this for him.

theirs in place, would be completely without merit and irrational. But, it is not.

- **Accusation: The French AIDS blood test was developed, and tested, first…**

True - the French were first to report preliminary Elisa tests, but their results were very poor; **…and proved superior to Gallo's test. Untrue** - per their own published admission, the French could not achieve better than a 37.5% detection rate in 1984 (up from 20% a bit earlier), while Gallo was already achieving with his, better than 95% detection.

Plus, if the French had a superior test, why would they wait to introduce it in France half a year after the introduction of the American test in the U.S. market? "This delay ended up claiming lives!" as was reported in, "AIDS Scandal Indicts French Government," published in Nature, September 19, 1991.

- **Accusation: Alleged misappropriation of scientific credit rightfully belonging to the French for being the first to discover the cause of AIDS.**

According to the record, the French got the idea from Gallo to look for a retrovirus as the cause of AIDS. This was publicly admitted in September 1984 at a virus meeting in Leriche, Italy, by Dr. J.C. Chermann of the Institut Pasteur. Gallo transferred to the French know-how and reagents to help them enter the field of retrovirology. More specifically, between January and March 1983 the French asked and received from Gallo: (a) advise on how to keep their own tissue cultures growing; (b) a protocol on how to grow retroviruses in human umbilical cord T-cells; (c) reagents to distinguish their viral particles from HTLV-1 and HTLV-2;and (d) HTLV-1 samples. Moreover, in May 1984, Gallo transferred and left with the French: (a) his highly efficient H9 cell line producing the HTLV-3B virus; and (b) protein samples of the same virus.

According to the record, Gallo intervened and reversed a decision by Science which rejected publication of the initial French paper reporting the detection of a new retrovirus, first announced at a meeting in November 1983. He did so because he felt that the French were on the right track, even though both he and the French felt the results were preliminary. Moreover, Gallo was asked by the French themselves to write (and he did so) the abstract of the paper prior to publication[270]. Through these actions and through explicit words and deeds, both then and later, Gallo acknowledged all along that the French had indeed discovered a new retrovirus.

Is this kind of supportive behavior indicative at all of one seeking to misappropriate credit from the French? Or does it show Gallo seeking to help the French get credit? Even twenty years later Gallo would acknowledge this all over again (citing, The Early Years of HIV/AIDS[271] by Dr. Robert C. Gallo): "Thus, the paper by the Montagnier/Chermann group is unequivocally the first reported true isolation of HIV from a patient with lymphadenopathy. However, the cause of AIDS was still unknown," at the time.

- **Accusation: Insisting mistakenly the HTLV virus as the cause of AIDS.**

It is reasonable to first ask, what would one conclude in those times of total ignorance, when the Gallo team was detecting the wrong virus (HTLV-1) in 35% of doubly infected AIDS patients, while Montagnier, searching for the right virus (LAV), was detecting it in only 20% of AIDS patients? At the time, who would have ever suspected a high percentage of double infectivity (HTLV plus HIV)?

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[270] Then, and today, any paper missing an abstract makes it incomplete and would have been returned to Montagnier, thus delaying its publication in any scientific journal.

[271] Science, November 29, 2002, vol. 298, page 1729.

Even so, according to the record, Gallo never suggested that HTLV-1 or HTLV-2 were or could be the cause of AIDS. By late May 1983, Gallo already had solid proof that the suspected AIDS virus was indeed new. In a letter to Science, Gallo presented his evidence that AIDS was not caused by a virus significantly close to HTLV-1 and HTLV-2. Nonetheless, he named the new virus HTLV-3. By September 1983, the Gallo group amassed enough evidence to preclude, not only HTLV-1, but also any variant or mutant, as the cause of AIDS.

On August 4, 1983, Gallo outlined his thoughts on the possible cause of AIDS in a letter to the Director of the National Cancer Institute, NIH. Unfortunately, these Gallo thoughts, expressed even earlier in public, were misinterpreted by many people to mean that one of the known HTLV viruses was the cause of AIDS. Furthermore, by naming his new virus HTLV-3 he made matters worse and, as expected, that led to a lot of disorder. In a letter to Gallo (3/4/85), Montagnier points this out rather bluntly: "in renaming this virus HTLV, you have induced a lot of confusion amongst unaware people." Gallo himself had to intervene in writing on different occasions to correct this misconception and reduce the confusion, but unfortunately, this met with little success.

In a letter to Dr. J. Curran of the CDC, dated June 3, 1983, Gallo clarifies: "I have read some of your comments concerning HTLV. It is obvious that neither we nor anyone else claims to have proven that a member of the HTLV family causes AIDS. This is clearly stated in my papers. I hope in the future you will point this out."

At the NCI-AIDS Advisory Group Meeting on July 18, 1983, Gallo had this statement put on record: "Dr. Gallo urged caution in coming to the conclusion that HTLV was the certain causative agent (for AIDS)….."

Also, in a letter to Prof. F. Deinhardt in Germany, dated Sept. 27, 1983, and in a similar letter to Prof. H. Hausen (also in Germany), dated Sept. 28, 1983, Gallo repeats: "After a recent trip to Europe I have become concerned that some people are under the impression that I believe AIDS is caused by HTLV. I am writing to you because of your central position in viral oncology in Europe, and I hope you will help me dispel this impression when it comes up."

In a letter to Prof. J. Levy in the U.S., dated Feb 9, 1984, Gallo reaffirms: "I never said that HTLV caused AIDS. From the beginning I have said we are testing the idea that a human T-lymphotropic retrovirus is involved…"

In July of 1985, Gallo again, openly relates to this theory as wrong; "…since the nucleic acid sequence has become known[272], it is clearly much more different than we or the Pasteur group knew or even suspected before…Moreover, I bet you would be surprised to know that the only published claims that LAV or HTLV-III is closely related to HTLV-I or HTLV-II come from the Pasteur group and CDC which are quoted from their papers (Science, July 1984)…we all recognize now that they are only distantly related to HTLV-I and II[273]."

- **Accusation: Gallo's insistence that HTLV-1 was the cause of AIDS, delayed progress in the field by more than a year.**

Untrue - Gallo was always referring to an HTLV-1 like virus and, progress in isolating, characterizing, and proving causality never did stop, rather continued at speeds unparalleled in the history of medical science.

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[272] Gallo is referring to the results of the two unpublished papers discussed back on page 97.

[273] Quoting a letter Gallo wrote to Doctor C. Escoffier-Lambiotte of Le Monde magazine, July 1, 1985.

True - it is almost unanimously agreed upon by the all the top AIDS researchers that progress in AIDS prevention and therapeutics has been delayed. That we are, in fact, five years behind where we ought to be because of the loss of time caused by the unending hindrances of Crewdson and his FOIA requests, plus the time spent defending charges in all those scientific inquires brought on by the Dingell gang. Truth be told, the one, lone scientist that keeps this from being a unanimous charge, believes that we are just three years behind where we ought to be in AIDS prevention and therapeutics. Still…what will come in these three or five years that would already be, had it not been for a Franco-American fiasco that still never goes away?

- **Allegation: Gallo does not give credit to his collaborators.**

Untrue - in his own book (Virus Hunting - AIDS, Cancer, & The Human Retrovirus – A Story Of Scientific Discovery), for example, Gallo gives all his people full credit. But is there a chief scientist who does not get help and hands-on support from post-doctoral researchers and technicians? Moreover, Gallo always gives first and prime authorship freely to deserving collaborators and 99% of his colleagues attest to that. In fact, one reviewer in New York said Gallo's book read like Tolstoy's War and Peace, because it had so many names (of people acknowledged).

- **Allegation: Betsie-Reed Connole, not Gallo, made the breakthrough of cultivating the AIDS virus in cell lines.**

True - Reed Connole, a technician (in Gallo' lab) working under Dr. Popovic, actually "mothered" four virus producing cell lines, including the HTLV-3RF virus, while Popovic cultivated the HTLV-3MN virus in cell lines.

- **Accusation: Gallo never had 48 distinct isolates of the AIDS virus.**

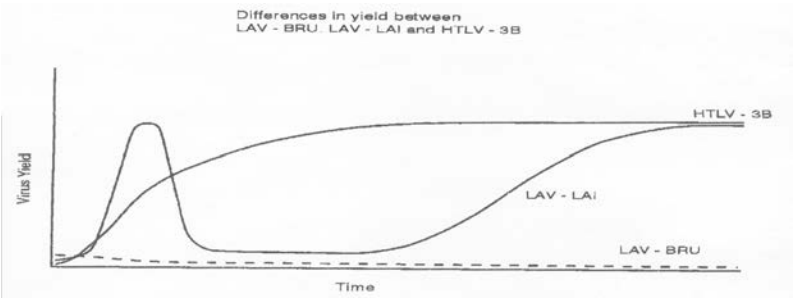
Untrue - Gallo did have 48 patient infected specimens by April 1984 and later many more; this fact was not only published in one of the Science papers in May 1984, but was also well documented by independent virologists during the inquiry. Markham: *"When it was actually investigated, tested, there was no question (that in fact Gallo had the isolates his lab claimed)."* Moreover, in a memorandum to the Department of Health and Human Services, Dr. Bernadine Healy, then the Director of the NIH, also acknowledged Gallo's documentation of different HIV isolates from multiple individual patients. The title of Gallo's paper carefully states 48 detections and/or isolates. He defined "isolate" as at least temporary growth of the virus over days in culture. This was achieved with over half of those 48, which were cultured (had detections) in just one day. This also brings up another item that needs to be clarified once and for all. Fact: Gallo had viral isolates starting in November and December 1982. But why was this never mentioned in the many ensuing articles? Simple. There were no reagents to HTLV-3/LAV at that time because the virus could not be mass produced by anyone then. Plus, two articles were published on the subject.

- **Accusation: Gallo renamed the LAV French virus HTLV-3B, which he then claimed as his own.**

Untrue - Gallo did not know and could not have known that HTLV-3B was an LAV accidental contaminant, until the genetic maps of both were published. That being true and since the technology was in place to make such mapping possible, how could any learned scientist ever think such a wrong would NOT be revealed sooner or later? In fact, HTLV-3B proved dissimilar to LAV-BRU, but identical to LAV-LAI. It is now known, and this is key, that LAV-LAI (which accidentally contaminated LAV-BRU back in France those

samples sent to Gallo by Montagnier) also contaminated the Gallo cultures. Crewdson just ignores this key information.

Moreover, the production curves of LAV-BRU, LAV-LAI, and HTLV-3 (shown in the chart that follows), during that time, are so different that no one could have guessed then, that two of the three viruses would prove almost genetically identical. Furthermore, the Gallo group was first to describe variations among different isolates of the AIDS virus, proving that the Gallo group already possessed several variants and did not need the French virus to produce his blood test. As for the name HTLV-3, quite simply, it means the third T-lymphotropic human retrovirus (which is a rather neutral name given its relationship to AIDS). In fact, scientists in both Gallo's and Montagnier's labs co-authored two papers (refer back to page 97) on the comparative properties of the LAV virus, the HTLV-3B virus, and several HTLV-3 variants[274]. Where did they come from, if not from Gallo? Unfortunately, Montagnier did not authorize their publication. Lastly, Science (February 22, 2002, p.1442) reported, "Montagnier himself says he does not believe theft occurred."



Comparing yields between: LAV-BRU, LAV-LAI, AND HTLV-3B

With regards to the preceding chart, one logically asks, if HTLV-3B and LAV-LAI are now known to be one and the same, why are their production curves so different? Essentially, you are seeing two stages of the same virus at different time intervals. LAI represents the virus being introduced into a cell line, while 3B represents the end results; a permanent cell line of the same (past the initial burst) now producing. In reality, from start to finish, they are a match.

Does this mean that the Gallo group knew it had the French virus based on the meaning of the chart? No. Keep in mind, that to achieve the genesis of the 3B permanent cell line, Dr. Popovic made the pool from the culture fluids of ten patients. So the amount of virus he had in that pool was very, very small. Meaning that when you look at the culture, the cell count, and the RT activity from those early stages of the pool, they would be inescapably and significantly different from what you would see in a culture supernatant that contains concentrated virus. To clarify, supernatants are not patient samples. They are a super-enhanced virus source. Logically then, when you try to infect a cell line with LAI supernatant, you see a bigger burst then when infecting with only short-term culture supernatant (albeit pooled and concentrated) containing limited amounts of the same virus (3B). Thus no yields could ever match between LAI as a supernatant sample, and the

[274] Comparative Immunological Properties of LAV and HTLV-3, J.C. Chermann, F. Barre -Sinoussi, F. Rey, and L. Montagnier in France -and- M.J. Sarngadharan, M. Popovic, F. Veronesi de Marzo and R.C. Gallo in the U.S. Also, Different Isolates of HTLV-3 and Lymphadenopathy Associated Virus (LAV) are Genetic Variants of the Same Virus, F. Wong-Staal, B. Hahn, G. Shaw, M. Popovic and R.C. Gallo in the U.S. -and- S. Wain-Hobson, F. Barre -Sinoussi, J.C. Chermann, L. Montagnier, and M. Allison in France.

budding 3B rising to dominate Popovic's pool. Hence, no red flag. Besides that, yield charts are not a test on which you would base a comparative study between any two isolates[275]. A proper yield comparison can only be made by a fresh infection of target cells (like H9) using a supernatant source of HTLV-3B, a supernatant source of LAV-BRU, and a supernatant source of the contaminant LAV-LAI.

- **Accusation: Alleged misappropriation of scientific credit rightfully belonging to the French for being the first to develop an effective AIDS blood test; and to prove causation.**

Untrue - Although the French had indeed discovered a new retrovirus, they had not proven causation. Even today, the French scientists have repeatedly acknowledged this. Yes, the new French retrovirus was later shown to be the cause of AIDS. Proof of causation, however, required availability of a reliable AIDS blood test and meaningful wide scale serological results, both unattainable at the time. Prerequisite to such availability too, was the establishment of a process capable of producing large quantities of the AIDS virus (required to mass produce an AIDS blood test), which could only be achieved by infecting successfully (with the suspect virus) an accommodating cell line.

According to the record, in December 1983, Gallo's group was successful in infecting a particular cell line, designated HUT 78, with a particular Gallo isolate, designated HTLV-3RF and in continuously producing the virus. By mid 1984, the French still had problems growing their AIDS virus in quantity.

Also according to the record, by March 1984, Gallo's group was successful in developing an AIDS blood test with 88% reliability against the CDC reference blind blood panel. Within weeks, following this success, the Gallo group produced a refined blood test system with 100% reliability. This system consisted of a skewed ELISA detection AIDS blood test (to preclude false negatives) and a confirmatory Western Blot assay (to retest for false positives). Armed with this blood test system, Gallo conducted wide scale serological testing of the general population, confirmed in parallel experiments the presence of the AIDS virus in the blood of patients that had tested positive, and firmly established the link between virus and disease. The results were submitted to Science on March 10, 1984, and published on May 4 of the same year. The French had no comparable data at the time. Hence, Gallo was first to develop a reliable AIDS blood test system and first to prove causality.

In Montagnier's own distorted, but confirming words (A History Of HIV Discovery[276], by Luc Montagnier): "New evidence that this strange retrovirus (LAV) was the cause of AIDS came from our team in the fall of 1983 and the winter of 1984. We observed high frequency of antibodies against the virus, in lymphadenopathy patients and noted the favored tropism of this virus for $CD4^+$ T lymphocytes. Our results were still controversial, however, and we had difficulty in obtaining the funding needed to better characterize the virus and to develop a blood test. The tide only turned in France when Robert Gallo and his group in the United States made a similar discovery. In the spring of 1984, Gallo published more convincing evidence that HIV causes AIDS..."

- **Accusation: Alleged misappropriation of the French virus.**

[275] You would rather extract the protein and make an immunological comparison and also by analyzing the DNA for nucleic acid similarities.

[276] Science, November 29, 2002, vol. 298, page 1728.

According to the record, one of the Gallo viruses, designated HTLV-3B, which he used to develop the AIDS blood test, proved identical to the French virus, designated LAV. This identity was verified during the last quarter of 1984 by independent scientists and Gallo himself (i.e. some six months following the development of the Gallo AIDS blood test during the first quarter of 1984). Samples of the French LAV virus had been sent to Gallo from the Pasteur Institute on two different occasions; in July 1983 and again in September 1983. This transfer of the French virus across the Atlantic, coupled with the identity of HTLV-3B and LAV, prompted many into believing that Gallo had misappropriated the French virus to develop his own AIDS blood test. But did he? He obviously had the means and the opportunity to do so, but he definitely had no motive. In fact, he was strongly motivated not to do so for several reasons.

According to the record, between October 1982 and December 1983, the Gallo group had analyzed forty-two samples of AIDS and lymphadenopathy patients, as published in one of the May 4, 1984 Science papers (independently verified by Government investigators). Thirty-two of these samples were found positive to HTLV-3. In a letter to I. Munro, Editor of Lancet, on March 5, 1984, Gallo also reported: "We have many (over 40) isolates of human T-lymphotropic retroviruses…which differ significantly from our original HTLV isolates…(These) were obtained over the past two years from AIDS and lymphadenopathy patients and are presently being characterized in detail. Moreover (and confidentially), we have very exciting patient serological data results with these viruses…They may be related to what the French group have described in one paper last May in Science, but unfortunately their virus has never been characterized nor transmitted permanently to a recipient target cell…Therefore, no one has been able to work with their particles…" This then shows, Gallo had numerous isolates of his own and definitely had no use of the French virus to develop his AIDS blood test.

According to the record, all attempts by the Gallo group to transmit the French LAV virus into permanent cell lines remained unsuccessful. The same experience was shared by the French. This negative finding is still true to this day. Hence, Gallo could not, would not have chosen the resisting growth French virus for his own AIDS blood test, simply because the LAV virus could not be massed produced.

According to the record, Gallo and Montagnier had both agreed that it had become essential, at their then stage of collaboration, to explore the relatedness of HTLV-3 and LAV. The following exchange of letters between the two parties is illuminating:

Montagnier to Gallo March 5, 1984: "I learned from Jean-Claude Chermann that you have made isolates morphologically similar to LAV. This is good news for all of us, and I share with you the feeling that it is time to make closer the collaboration between our laboratories. To begin with, I would like to suggest two things: 1) Exchange of material - it is important to investigate the relatedness of proteins of your isolates to LAV p 25…, 2) Exchange of information…"

Gallo to Montagnier July 3, 1984: "We have sent Sarngadharan (Sarang) to you to compare the proteins of LAV and HTLV-III using our hyperimmune sera to HTLV-III. As you know there is substantial cross-reactions as anticipated…As we both agreed by telephone on a few occasions it would now be nice and perhaps essential to compare the molecularly cloned genes of HTLV-III and LAV. We have several isolates of HTLV-III which are cloned, and…we are waiting for you to make a decision as to when you will send someone from your lab to us with your clones of LAV for comparison

(clone to clone) as the final experiments before we publish something together."

Would this have been agreed to if one of the parties was guilty of misconduct and had something to hide? Gallo had of course nothing to hide; he was just simply unaware of the identity of the two viruses until months later, following the development of his AIDS blood test.

According to the record, Gallo had considered two isolates, designated HTLV-3B and HTLV-3RF, as his final candidates for use in the production of his AIDS blood test. Among the two candidates, HTLV-3B was selected for production. In a memo to Gallo on November 28, 1984, his co-worker Dr. M. Popovic explains the reasons for that choice: "…I wish to explain the reasons why this (HTLV-3RF), one of the first well documented and carefully followed isolates…obtained and propagated in HT cells…, has not yet been selected for large scale production and distribution as a prototype of HTLV-3 … The HTLV-3RF…is the most divergent type HTLV-3 isolate compared to HTLV-3B, -3MN, etc (other Gallo isolates)… (However), because of the (initial) lack of EM evidence we decided to pursue the isolate(s) obtained from pooled culture fluids known as HTLV-3B… Because of the enormous requests and pressures from other laboratories to provide HTLV-3, we disseminated H9/HTLV-3B into laboratories all around the world before all control assays were completed…"

By then, Gallo had also made his own decision to use -3B for large-scale production because of its lack of a Haitian origin, that it was possibly a divergent isolate from the mainstream AIDS viruses, and, also, because HTLV-3B was further along in the production process than HTLV-3RF. Would Gallo have chosen HTLV-3B over HTLV-3RF had he known that HTLV-3B was identical to LAV, a fact which sooner or later would have become known? Would Gallo have chosen HTLV-3B over HTLV-3RF, if he had misappropriated the French virus, knowing only too well that the mere dissemination of HTLV-3B to labs around the world would have opened the door for comparison studies between the two viruses, and actually did?

Example: M. Martin (Chief LMM, NIAID) had the following statement put on record on November 9, 1984: "While attending a workshop sponsored by NIAID in Hamilton Montana (Nov. 1-3, 1984), I became aware that HTLV-III and LAV proviral DNAs have virtually identical restriction endonuclease cleavage maps. In a presentation by Dr. Murray Gardner (University of California, Davis), a Southern Blot was shown that indicated LAV and HTLV-III viral DNAs were indistinguishable following digestion with four different restriction enzymes."

How then, did the French LAV virus find its way into the Gallo AIDS blood test? The Popovic memo on the selection decision, points out that HTLV-3B was obtained "from pooled culture fluids." This pooled culture contained many Gallo isolates plus the French LAV-LAI contaminant (which was not intentional), in an attempt to permanently infect a recipient cell line by increasing the collective shear bulk of transmitted viruses, because each of them was available only in minute quantities. LAV in the past had resisted all attempts to infect recipient cells at both sides of the Atlantic and, therefore, was not expected to surface as the dominant isolate, but miraculously did. This LAV dominance was not known or even suspected at the time because the July 1983 virus sample sent to Gallo by the French was supposedly LAV-BRU, an isolate of verified resistance to cultivation. So what caused it then? Well, we know now that the September 1983 virus sample sent to Gallo was actually a mixture of two viruses due to an accidental

contamination of LAV-BRU by LAV-LAI at the French lab. Neither the French nor Gallo were aware of this happenstance at the time. Consequently, the identity of HTLV-3B and the French virus was established by comparing HTLV-3B, not with LAV-BRU, but with LAV-LAI. Meanwhile, both the French and Americans were under the impression that HTLV-3B was being compared to LAV-BRU. So no one had a clue! In fact, in a short article published in Nature in February 1991, Gallo was first to report that the genetic sequences of HTLV-3B and LAV-BRU (still in his freezer from the July 1983 shipment) were surprisingly dissimilar. Montagnier admitted soon thereafter the occurrence of the contamination in his own lab, in a short article published in Science in May 1991. The same admission was also repeated some ten years later (A History Of HIV Discovery[277], by Luc Montagnier): "…although we discovered later that the LAI virus had contaminated our BRU culture (Science 252, 961-965, 1991). At least six laboratories received that LAI sample (under the name BRU) from our group and experienced the same contamination. We think that the LAI virus readily contaminated the BRU culture because it associates with a mycoplasma species, Mycoplasma pirum, usually present in T cell lines. This physical association makes a fraction of the LAI virus highly infectious, and, in fact, this fraction can be neutralized with antibodies against M. pirum. As mycoplasmas are common contaminants of cultured cells, an infectious pseudotype virus (LAI associated with M. pirum) may have caused several contaminations between 1983 and 1984 in different laboratories."

If the accidental contamination of the French virus had not occurred in the French lab, then LAV would have remained LAV-BRU. LAV-LAI would not have found its way into Gallo's lab, no French virus would have surfaced in Gallo's AIDS blood test (since LAV-BRU was and is still not amenable to cultivation), and no Franco-American dispute over patent rights would have ever occurred. But the jesters of chance wanted things to play out differently. And Gallo suffered for it.

Be that as it may, on November 2, 1990, Dr. W. Raub (Acting Director of the NIH) sent to J. Onek (Gallo's lawyer) an official letter attesting to the following: "The National Institutes of Health inquiry disclosed no evidence that Dr. Gallo misappropriated LAV; neither does the focus of the investigation as presently formulated include possible misappropriation…."

- **Accusation: Alleged restriction of availability of reagents to requesting scientists from other labs.**

In a memo to Dr. R.H. Adamson, Director DCE, NCI, dated September 17, 1987, Dr V. DeVita (Director NCI), brought forth the issue of alleged restrictions in the supply of materials, and thereby ordered some fact finding. In it, he writes that Dr. H. Temin, as incoming Chairman of the NCAB Subcommittee on AIDS, "informed us that the general impression in the community is that Dr. Gallo restricts availability of reagents to collaborators. He indicated, and we agreed, that is undoubtedly an exaggeration…Nonetheless, the perception is as much a problem, as the reality…It seems to me that it would be appropriate to ask some members of your Board of Scientific Councilors to conduct a review of the distribution of reagents from Dr. Gallo's laboratories as well as contractors that collaborate with Dr. Gallo…I believe this review will be useful to Dr. Gallo." Fact: In 1984 alone Gallo's lab made his H9 cell line available to 45 different laboratories in 17 different countries.

[277] Science, November 29, 2002, vol. 298, page 1728.

True- there have been instances when requests took slower than usual to process and when requests for live AIDS virus were denied, in accordance with NIH transfer regulations. Gallo: *"Well if there are 20,000 people dying in the sea and you're in a boat, do you take this one before that one? Obviously you can not satisfy everyone at exactly the same moment. You make choices. Just as obviously, you send it to your colleagues who know how to handle dangerous viruses. Well, it is also obvious that the people in the field are my friends. So I was confident they knew what they were doing. Look, first I had to be sure that they have a qualified lab to handle HIV. It's a new field opening up and as you said earlier, we didn't know at the time how dangerous the cultures could be. And first, early on, I didn't even have approval from NIH to send the reagents out because the patent was trying to bring in the big companies*[278]*. The patent was trying to bring in the big companies so that the world could be tested. You don't want every little lab saying "I'm going to make this blood test" and the big companies say "screw this." You had to give some license. Select some. And finally, they say I made restrictions. Those are the restrictions which were made by the National Cancer Institute of the NIH. And the people I talk to today say they those restrictions were very liberal compared to the restrictions made by some Universities."*
True - there have also been complaints by investigators "believing" they were not served properly. There has only been one single instance where Gallo did not respond properly; and that was in the case of Mal Martin and his request for the HT cell line on May 14, 1984.

On that, Gallo says, *"In that instance regarding Dr. Martin I was wrong and I regret it. I did not know Mal Martin on a personal level, nor did I know a great deal of his work. But I had heard how he mistreated a student and two post-docs of mine (Steve Josephs and Genoveffa Franchini) at a meeting in Cold Spring Harbor*[279]*, but that is no excuse for me."* When asked, were they treated badly because of their association to him, Gallo replies, *"Well, that was the implication."* Genoveffa Franchini herself adds: *"Yeah, yeah. (The reason for it was my association with Gallo), nothing more than that. He was particularly unkind and attacking us. You know, after Bob (Gallo) left, I had a different occasion to interact with (Mal) Martin, and things went very well. Very professional. No problems."* Gallo too says he has come to respect Martin's science and sees him now as a colleague; and believes that one misunderstanding generated the poor relations. Regardless of all that, it was in fact, Richard Adamson, the Divisional Director at the NCI, (Gallo's superior) who was the one who prepared those release forms and created the criteria under which reagents would be sent out. Not Gallo. Everybody recognized that AIDS was a new bio-hazardous material. Gallo: *"it couldn't just be sent out to any one who wanted to research it for the simple fact that you can not send it to hundreds of scientists at the same moment."*

- **<u>Accusation:</u> Gallo labeled a microscopy picture of LAV as HTLV-3, plus altered the report of a collaborating microscopist by re-describing an LAV sample, negative for retrovirus, while, in fact, it was positive. All this a scheme to misappropriate the LAV virus for himself.**

[278] This illustrates how the U.S. Government was pulling many strings behind the scenes, and when push came to shove, they left Gallo to fend for himself. But he couldn't even do that because they made him sign that "gag order" against making public comments.
[279] This particular meeting was before HIV, even before Montagnier presented on what would become LAV. So as you can see, Gallo was getting friction from other scientists well before the AIDS scandal. Presumably because he proved so many wrong with his discovery of HTLV-1.

Untrue - the factual record, verified by U.S. Government lawyers, proved that the microscopy picture sent for publication was selected and labeled by the microscopist, not Gallo (who was blamed for this mistake). Popovic had sent a sample of a LAV culture testing positive for the virus, to the EM lab for imaging[280]. Popovic adds: *"When, a problem emerged with EM pictures having LAV instead of HTLV-III, that composite picture published in Science, Zaki tried to put the blame on me, (even) though the pictures were prepared by him, Zaki Salahuddin, in collaboration with Dr. Gonda (of Frederick, NCI). Fortunately, when the composite EM picture was made by Zaki and Gonda, I was at that time in Park City, Utah on the meeting. Thus, Zaki had to drop the accusation regarding my participation of preparing the EM pictures with LAV instead of the HTLV-III. Dr. Fischinger (Assistant Director to Dr. DeVita, NCI Director) made the investigation of the LAV pictures and I was cleared. Isn't it interesting that Zaki Salahuddin was not investigated by Dr. Hadley and (the) OSI?"*

Duplicate copies of the microscopy report were also found in Gallo's lab files and in the files of the Department of Health & Human Services (DHHS). No altered report ever came from or, was found in, Gallo's lab. So that EM picture published with the Gallo Science paper, selected by the microscopist (not Gallo), was wrong[281]. The caption below the image in question refers to HTLV-3, when in fact it is an EM image of LAV.

It is VERY important to note here that no one, not even Gallo, catches this error. That is…no one in science catches it because electron microscopic pictures of various HIVS are essentially identical. But in the legal field, the New York based French lawyers do. Which begs the question, how? No scientists anywhere in the world saw it, yet a specific team of lawyers do? One consideration is that they had people working for them within the NIH, immortalizing a gaff that could be -and was- used against Gallo, as proof of intentional wrong-doing later. On this matter, Gallo says, *"Robert Charrow was the lawyer for the Government most intimately involved. He told me that, "we know the altered report did not come from your laboratory because there are duplicates of the material from your laboratory and office." I asked, from where could it have come? His reply was that it could only have happened on the way from the Frederick facility to the lawyers, or in the lawyers' office."* Whatever the truth is, one fact remains. To this day, no one is clear just how the French legal team knew that the image was incorrect to begin with. Popovic elaborates on the improbable: *"Look, if you get 30 pictures combined…particles from those 30 where you have a total of about 1,000 virus particles from which is picked up (meaning, photographed). How the hell do lawyers, bench lawyers, could get that (from) one picture? That (one) picture where one particle was cut out from that paper. How the hell do they (know from a single particle picture, that was LAV)?"* Even Science reported, "The mistake came to light recently after a meeting between Gonda and Swire[282]."

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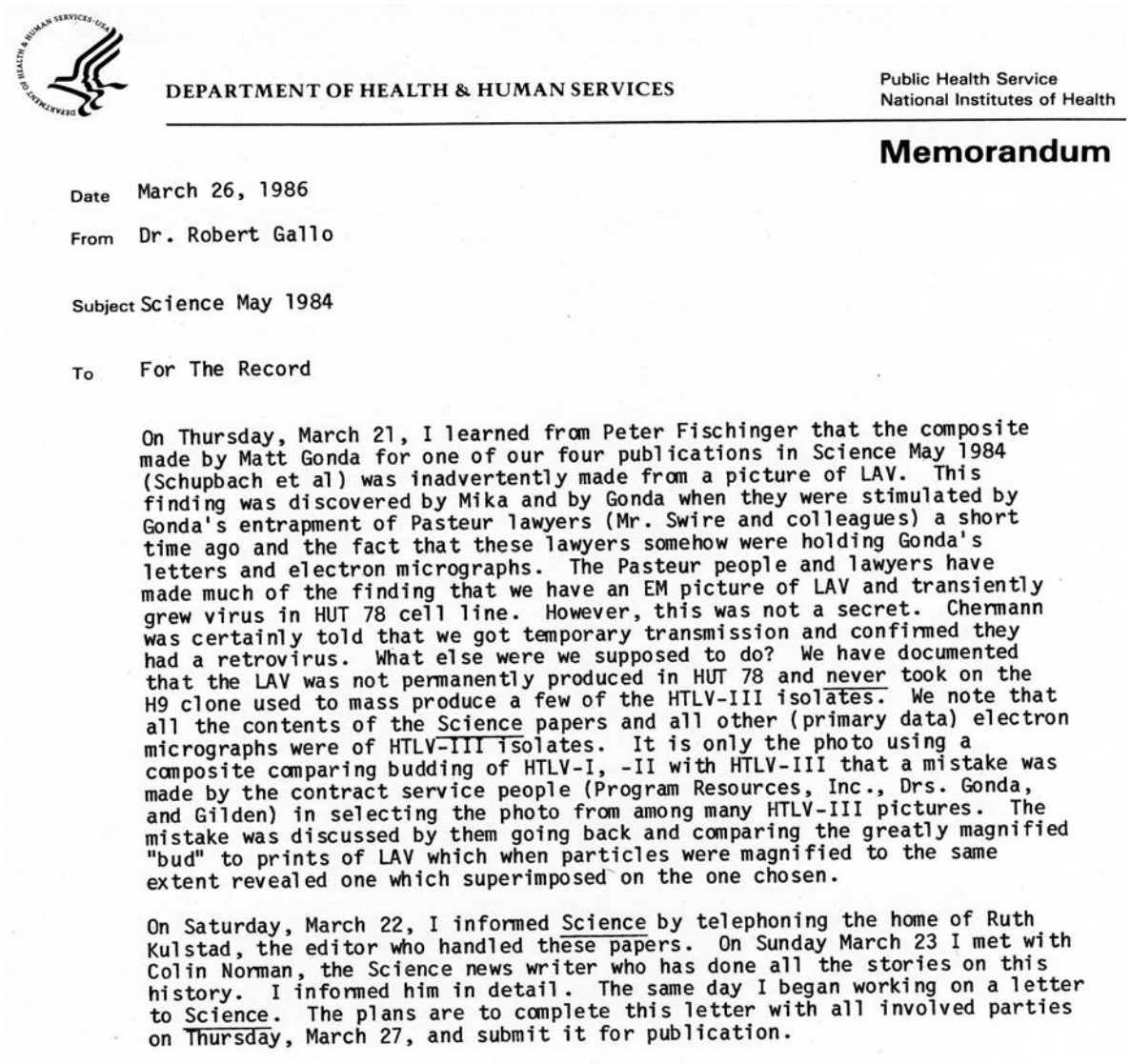
[280] See the accompanying letter signed by Popovic, page 241.

[281] Proof of this comes from a Letter Of Correction, To The Editor of Science, Entitled: HTLV-III Legend Correction, written by both microscopists Raymond Gilden and Matthew Gonda. It reads, "We recently re-examined the electron micrographs used in our publication in Science (4 May 1984) and discovered that in the composite micrograph of Schüpbach et al.(1, figure 4) the panel labelled HTLV-III was inadvertently composed of photographs of a HUT-78 culture transiently infected with a sample of LAV-1 provided by L. Montagnier's laboratory. One appeared in Gallo et al.; others were used in Popovic et al. and Shaw et al…Thus, this correction relates only to the choice of photographs used in the one communication and not the content of that paper or any of the other papers." Letter published Science, vol. 232, April 18, 1986, p. 664.

[282] A New Twist In AIDS Patent Fight, by Colin Norman, April 18, 1986, vol. 232, p. 309.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date March 26, 1986

From Dr. Robert Gallo

Subject Science May 1984

To For The Record

On Thursday, March 21, I learned from Peter Fischinger that the composite made by Matt Gonda for one of our four publications in Science May 1984 (Schupbach et al) was inadvertently made from a picture of LAV. This finding was discovered by Mika and by Gonda when they were stimulated by Gonda's entrapment of Pasteur lawyers (Mr. Swire and colleagues) a short time ago and the fact that these lawyers somehow were holding Gonda's letters and electron micrographs. The Pasteur people and lawyers have made much of the finding that we have an EM picture of LAV and transiently grew virus in HUT 78 cell line. However, this was not a secret. Chermann was certainly told that we got temporary transmission and confirmed they had a retrovirus. What else were we supposed to do? We have documented that the LAV was not permanently produced in HUT 78 and never took on the H9 clone used to mass produce a few of the HTLV-III isolates. We note that all the contents of the Science papers and all other (primary data) electron micrographs were of HTLV-III isolates. It is only the photo using a composite comparing budding of HTLV-I, -II with HTLV-III that a mistake was made by the contract service people (Program Resources, Inc., Drs. Gonda, and Gilden) in selecting the photo from among many HTLV-III pictures. The mistake was discussed by them going back and comparing the greatly magnified "bud" to prints of LAV which when particles were magnified to the same extent revealed one which superimposed on the one chosen.

On Saturday, March 22, I informed Science by telephoning the home of Ruth Kulstad, the editor who handled these papers. On Sunday March 23 I met with Colin Norman, the Science news writer who has done all the stories on this history. I informed him in detail. The same day I began working on a letter to Science. The plans are to complete this letter with all involved parties on Thursday, March 27, and submit it for publication.

The entrapment referred to in that letter stems from a summer of 1984 incident in which Swire (an attorney for the French) lied to Gonda about who he really was. Swire had represented himself as a company delegate seeking scientific advice; then proceeded to ask Gonda loaded questions designed to label him a liar.

- **<u>Accusation:</u> Gallo renamed the Gazdar HUT-78 cell line, in which the AIDS virus grows, to H-9, then claiming personal credit.**

True - H-9 is a clone of HUT-78; and was indeed developed by Gazdar, partly in collaboration with Gallo's lab.

Untrue - Popovic, not Gallo, named H-9, a clone of HUT-78; and justifiably so since H-9 is not HUT-78, but a sub-class of this cell line, which does require separate identification.

- **<u>Accusation</u>: Gallo falsified events, dates, and data to hide the truth about everything he has allegedly done wrong.**

Untrue - despite desperate attempts by prosecutors to prove wrong-doing, all such accusations were proven unfounded.

- **<u>Accusation</u>: Gallo made changes in manuscripts between submission and publication to twist the truth according to his needs.**

Untrue - all such accusations contradict the factual record, only updates are allowed. And updates were made on occasion which is perfectly allowable in normal scientific practice.

- **<u>Accusation</u>: Gallo knowingly lied in his patent claim.**

Untrue - Gallo stated in one of the claims that there was no reason to believe that the French and American viruses were the same although they would be of the same type. In fact, prior to sequencing there could be no way to know that the two viruses were almost genetically identical.

- **<u>Accusation</u>: Gallo was accused of perjury and obstruction of justice.**

Untrue - he never was accused; investigated yes. Even the Justice Department, after being approached by Congressman Dingell to look into that matter, refused to prosecute Gallo in the face of contradictory evidence.

- **<u>Allegation</u>: Gallo allowed co-workers to keep sloppy research records and commit financial fraud.**

Untrue - Gallo did not allow any of this ever.

True - that in two rare instances, however, misdoings and wrong-doings did take place without Gallo's knowledge. In one instance, materials developed in Gallo's lab were diverted to a private company for sale by a technician, Zaki Salahuddin[283]. Not coincidentally, that private company happened to be co-owned by Salahuddin's wife. Regarding Salahuddin, Gallo says only, *"This was bad, and when I learned of it and questioned him, he point blank lied in my face."* In the second, there was misappropriation of funds by one official in Gallo's lab, Prem Sarin. On this Gallo says, *"Prem Sarin consulted while he collaborated, which was not allowed[284]. Then was pressured by my accusers to testify against me, in which case the charges against him would be dropped, or he would go to jail – his answer was, "I guess I go to jail." However, he did open a door to Dingell. Zaki, on the other hand, apparently collaborated with Crewdson, while at the same time opening the door wider to my investigation by Dingell – all because of his own financial wrong doing."* It was Zaki Salahuddin who directed Dingell's chief investigator, Peter Stockton, to Prem Sarin in the first place. The same Salahuddin who was openly hostile and jealous of Popovic.

- **<u>Accusation</u>: Gallo provided material and endorsed clinical trials on human subjects, run by collaborator Prof. Daniel Zagury, outside the U.S., in gross violation of both NIH and WHO (World Health Organization) regulations.**

Untrue - Gallo provided material for studies only on baboons prior to clinical trials. Like all other accusations this one too was initiated by Crewdson more than a decade ago and found to be totally without basis. Dr. Zagury, initiator of these vaccine studies, testified that Gallo was never involved in the human studies in France and Zaire. Zagury was further accused by Crewdson, for using volunteers (both adults and children) without their informed consent and for injecting his subjects with live HIV virus (Gallo: *"ridiculous, never done."*) following their inoculation with an experimental vaccine. Crewdson (and the

[283] As a result, Salahuddin resigned on June 2, 1990. Then on September 7, 1990, he pleaded guilty to criminal charges of conflict of interest and accepting unlawful gratuities. On December 20, 1990, he was debarred from future federal employment.

[284] From the March 6, 1991 statement of W.M. Raub before the Dingell Committee. Fact: On January 14, 1991, Gallo already had in place an LTCB policy to "discourage his staff" from such consultations "to avoid even the appearance of conflicts of interest."

Chicago Tribune) headlined these stories as front page news, indicating involvement by Gallo. After showing/proving this to be all untrue, 15 years later, Crewdson puts it again in his book. The fact is that vaccine did not contain live HIV virus, but rather the delivery vehicle was an attenuated vaccinia virus, carrying a few HIV genes (which do not make an HIV infectious virus particle). Indeed the approach is used widely used by European and American pharmaceutical companies in their vaccine approaches. It is in fact, the most common approach with any vaccine. But even if Crewdson was right about Zagury, he wrote two front page stories against Gallo who was not associated with the study. As usual there were no public retractions for those articles. Also, it is never mentioned anywhere, that Dr. Zagury had injected himself with this experimental vaccine first, before giving it to any other human being. An extremely important distinction needs to be pointed out here, which is, although Zagury's trials did not adhere to U.S. policy for such clinical trails, he was a French scientist conducting a study in Africa. By both French and Zairian standards, the trials did in fact follow all the set policies/procedures those two Governments had in place at the time. Add to that, that in June 1988, with over 10 million viewers watching, ABC News Television named Zagury their "Man of The Week" for these same vaccine trials. But because of the accusations, Zagury lost funding for two years. Even French President, Francois Mitterand in October 1991, blocked Zagury from returning and denied any more cooperation from any French scientist into Zaire even though he was found completely innocent and in total compliance with medical ethics and the legal requirements; in both France and Zaire. Eventually Zagury's vaccine would not work because of the hyper-variability of the virus.

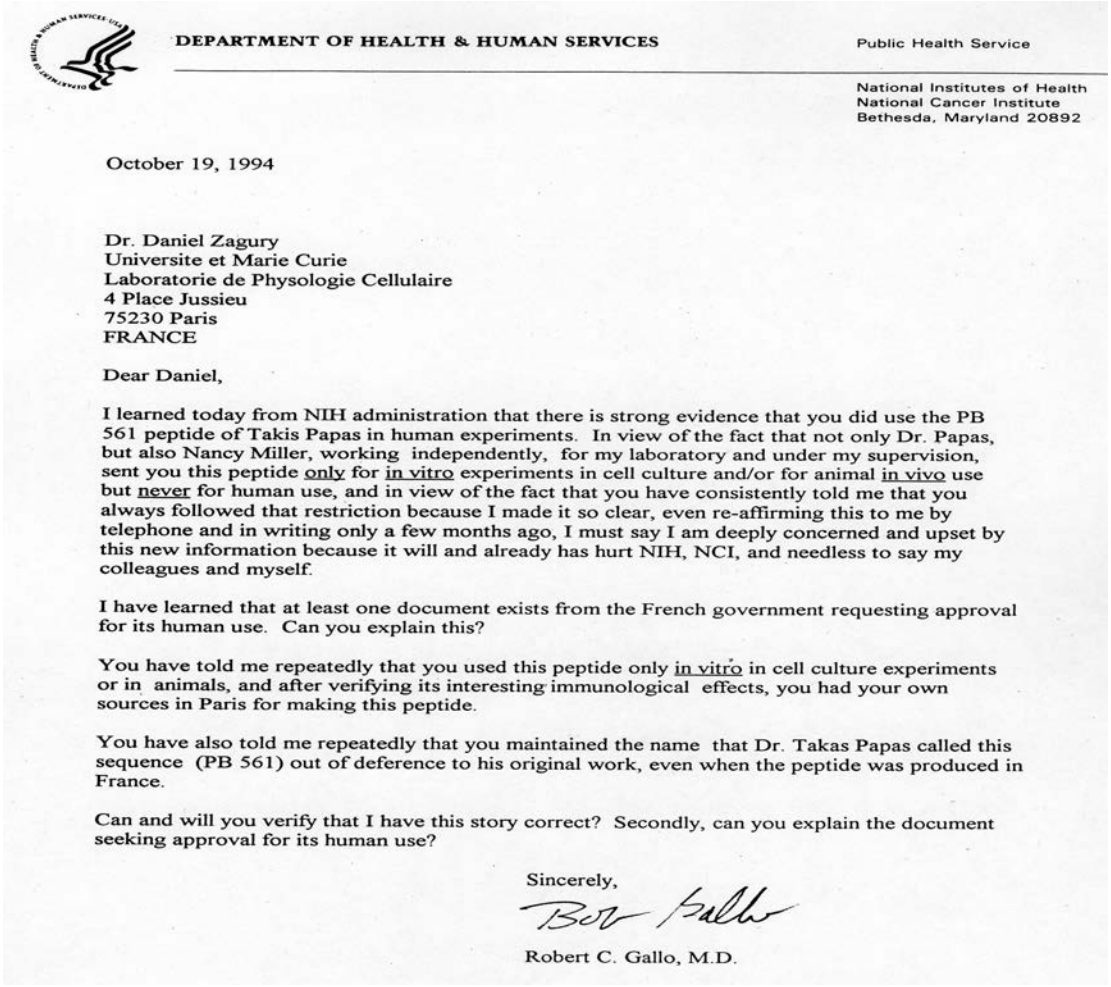
Odd note here. It seems that in search of incriminating evidence in this Gallo-Zagury collaboration:

1) Gallo's house in Bethesda was broken into[285] (through a broken window) and his personal files searched (the Bethesda police were notified),
2) Takis Papas' (a colleague, collaborator, and friend) reported that his lab at the NIH campus in Frederick, Maryland was broken into[286] and sera sent[287] by Zagury for testing were removed from the premises (the NIH police were notified),
3) Gallo's files[288] in his lab at the main NIH campus in Bethesda were broken into[289] and searched; mostly files belonging to Nancy Miller which related to the inquiry and the Gallo records (the NIH police were notified),
4) Guy de Thé's offices at Mount Parnass in Paris were broken into and searched – de Thé was the custodian of funds received from European sources for Gallo to distribute to European scientists for training African doctors. The office was ransacked and files were taken (the French police were notified), and,
5) Daniel Zagury's office, lab, and collaborators offices, at St. Antoine Hospital in Paris were broken into and searched (hospital authorities were notified). Records

[285] The break-in happened on the night of Gallo's Annual Lab Meeting Banquet. Which suggests someone knew exactly when Gallo would be gone from his home for some time.
[286] This happened soon after Papas had been threatened by Crewdson, *"I'll destroy you Pappas if you don't give me that stuff on Gallo."*
[287] What was in that sera? Antibodies in which you could tell if they were likely to be humans inoculated with this material.
[288] This despite the fact Gallo had made all his files and records available. In fact, the Pasteur lawyers in New York came down one day and simply took everything. And Gallo didn't care – he said, "Fine."
[289] Files kept in the corridor were all locked. Somebody had sawed through those locks – all of them.

relating to the collaboration between Zagury and Gallo with patient population[290] were all that was taken.

No resolution by any police in any of the preceeding cases was ever reached. But what makes all this so odd, is that by curious coincidence, whenever and wherever these break-ins occurred, Crewdson was in town at the time. By the way, nothing stolen was ever important enough to mysteriously surface again and hurt Gallo.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

October 19, 1994

Dr. Daniel Zagury
Universite et Marie Curie
Laboratorie de Physologie Cellulaire
4 Place Jussieu
75230 Paris
FRANCE

Dear Daniel,

I learned today from NIH administration that there is strong evidence that you did use the PB 561 peptide of Takis Papas in human experiments. In view of the fact that not only Dr. Papas, but also Nancy Miller, working independently, for my laboratory and under my supervision, sent you this peptide only for in vitro experiments in cell culture and/or for animal in vivo use but never for human use, and in view of the fact that you have consistently told me that you always followed that restriction because I made it so clear, even re-affirming this to me by telephone and in writing only a few months ago, I must say I am deeply concerned and upset by this new information because it will and already has hurt NIH, NCI, and needless to say my colleagues and myself.

I have learned that at least one document exists from the French government requesting approval for its human use. Can you explain this?

You have told me repeatedly that you used this peptide only in vitro in cell culture experiments or in animals, and after verifying its interesting immunological effects, you had your own sources in Paris for making this peptide.

You have also told me repeatedly that you maintained the name that Dr. Takas Papas called this sequence (PB 561) out of deference to his original work, even when the peptide was produced in France.

Can and will you verify that I have this story correct? Secondly, can you explain the document seeking approval for its human use?

Sincerely,

Bob Gallo

Robert C. Gallo, M.D.

When the allegations began, Gallo acted. Does this confidential correspondence read as though Gallo had any prior knowledge as to what Zagury was alleged to have been doing?

[290] Which Gallo was not involved with.

- **<u>Accusation</u>: Gallo misled the public into believing that he had the cure of Kaposi sarcoma.**

Untrue - Gallo helped unravel the pathogenesis of the disease and suggested a line of clinical research that might lead to possible benefit.

- **<u>Accusation</u>: Gallo claimed the discovery of natural suppressor factors (chemokines) of AIDS, actually discovered by Jay Levy, and also claimed for himself the discovery of the chemokines' mechanism of action, actually discovered by Ed Berger.**

Untrue - Gallo: *"If you can find anywhere where I said any of that, I will eat the paper."* Levy found evidence of inhibition but never identified its cause or source. Gallo completely acknowledged Levy's contribution when his group published their paper on identifying the first naturally occurring HIV suppressors. It is true that following Gallo's paper, Berger did later identify the chemokine receptor as the second receptor of HIV (that provides a mechanism for disease infection) on the surface of target cells. But of course, the previous discovery by Gallo, helped Berger make his. However, Gallo and his group were clearly first to identify the natural inhibitors of HIV, namely some of the molecules known as chemokines.

- **<u>Allegation</u>: Gallo became an embarrassment to the NIH and was asked to leave.**

Untrue - both the Director of NIH, Dr. Bernadine Healy, and the Director of the NCI, Dr. Sam Broder, remained highly supportive and never asked Gallo to leave. Gallo: *"Was Sam scared? More than anybody I ever saw. Was he depressed? Yeah. Were we friends? Yeah. Would he have preferred that I enriched myself and found a big professorship somewhere and did well and got away from this thing? Yes. For his sake, for my sake. But did he every say, "I am going to fire you, or that you must leave." No, never. But I will say this - in view of the horrible pressures from Dingell's staff and the gross, constant distortions of Crewdson, I would not have blamed him if he had."*

Gallo left the NCI, on his own, in late 1995 after completing exactly 30 years of public service, and 3 whole years after all charges against him were dropped to form his own Institute of Human Virology. It is something he has, *"dreamed of doing since the AIDS epidemic began. But because of the difficulties caused by Crewdson…"* Gallo intelligently waited until he was exonerated of all accusations before negotiating with any university. In fact, the only difficulties before that (up until August 29, 1994) came from the Hadley-Stockton pressure which had succeeded in reducing funding in Gallo's lab by 20-30%.

- **<u>Accusation</u>: Alleged failure in responsibilities as lab chief.**

In a memo to J. Diggs, Deputy Director for Extramural Research, NIH, dated February 18, 1992, J. Hallum, Director of OSI, NIH, brings attention to several administrative findings of the OSI investigative team concerning Gallo's activities: "These activities in themselves did not constitute scientific misconduct…However, the investigative team believed that Dr. Gallo's conduct had on numerous respects fallen well short of the conduct expected of a responsible senior scientist and laboratory chief…Serious problems…were traceable in substantial measure to Dr. Gallo's hands-off approach to management of his laboratory…Dr Gallo failed in his responsibilities…(and) he thereby fostered conditions which provided the opportunity for the creation of falsified/fabricated data and falsified scientific reports."

On February 25, 1992, E. Korn, Scientific Director, NHLBI, NIH, sent a memo to B. Healy, Director of the NIH, criticizing harshly Gallo's administrative practices: "As

head of the Laboratory, Gallo must assume responsibility for the way it operates…Specifically, in essentially all 20 of the issues examined (grouped in 16 allegations) Gallo failed in his responsibilities as the head of the Laboratory. The evidence in the OSI report, taken together with past incidents, leads me to believe that Dr. Gallo has failed to fulfill his responsibilities of scientific leadership. Dr. Gallo's scientific accomplishments are many and notable but these accomplishments neither justify nor excuse his failings...If Dr. Popovic is to be found guilty of misconduct, so should Dr. Gallo. Irrespective of whether misconduct is found,…I recommend that you remove Dr. Gallo from his position as chief of the Laboratory…"

It is really sad to read these words. How did Gallo presumably fail in his responsibilities of scientific leadership? By leading his research team from success to success? By accumulating more scientific AIDS related citations[291] than any other person dead or alive? By opening the field of Human Retrovirology? By discovering the cause of AIDS? By developing a reliable AIDS blood test system? By protecting the world's blood supply and saving countless lives? Failings? Did Gallo ever fail in his responsibilities during the many investigations against him? Not according to the final verdict. Did Gallo undermine the French and American research efforts on AIDS? Did Gallo inflict damage on the scientific enterprise? Of course not. His accusers did that by bringing a parade of unjustified charges! Gallo was the bull's-eye victim of an inter-institutional clash keenly focused on money! Thus. any substantial consequences from that clash should be attributed to greed and not to fictional scientific misconduct.

- **<u>Accusation</u>: The NIH (meaning Dr. Bernadine Healy, Director of the NIH) and the USDHHS (meaning the Appeals Board of the Department) were instrumental in a massive cover-up of the truth in the Gallo case to protect U.S. interests against the French.**

Untrue - Gallo conceded in the open scientific literature that, due to an accidental contamination in his lab, his HTLV-3B virus was actually the French LAV-LAI virus. So what was the purpose of a cover-up if this vital information for the French was already publicly disclosed? Was the purpose of the cover-up then intended to protect Gallo from an embarrassing guilty verdict? Or was the cover-up hypothesis just wishful thinking of those who wanted Gallo convicted, but lost out again and again?

Just what was really covered-up? The fact that Gallo had numerous isolates (as confirmed by the OSI)? That several of them could have been used to manufacture a commercial version of the blood test before the French? The fact that Gallo did the sero-epidemiological study first and proved HIV to be the cause of AIDS (confirmed by the publication record)? Or, that Gallo's blood test protected the world's blood supply and saved countless lives? Yes, yes, yes, and yes. Those are exactly what the Gallo accusers really wanted to cover up; all the Gallo achievements.

As you have just read, the list of suspected wrong-doings is varied, rather long, and seemingly over every single accomplishment the Gallo group ever made. With so many allegations, that are so wide-ranging in their scope, isn't it odd that no evidence was ever found to support a single one of these charges? One must ponder for oneself what that means, and what it proves. With regards to all these points, allegations, whatever they might be called, two words should be stamped down in light all this research:

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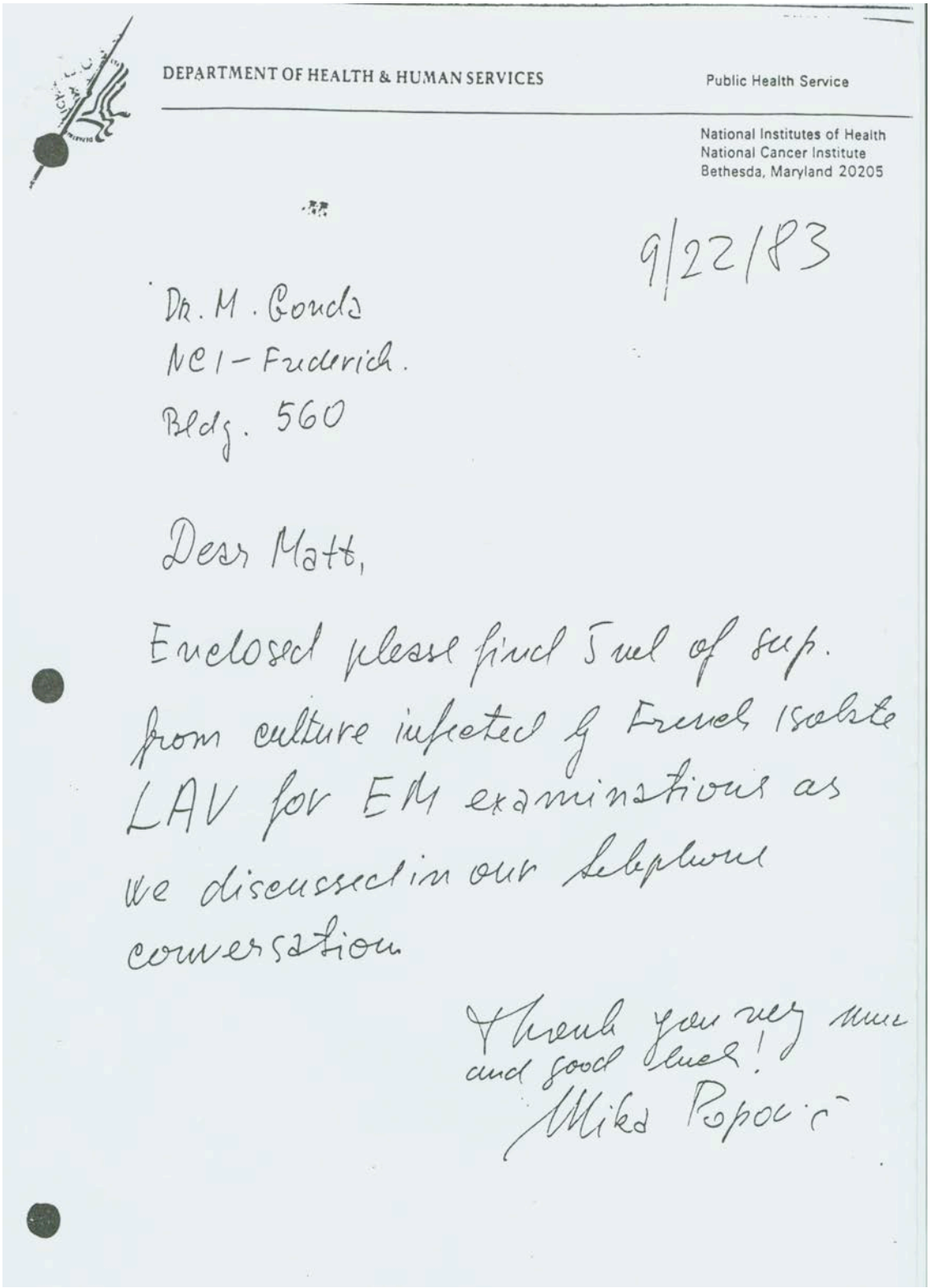
[291] On September 25, 2003, Gallo was named the 6th "Citation Superstar" in overall citations according to the Thomson ISI list for all disciplines. The official count for Gallo was 930 papers, with 61,303 citations.

Case Closed



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20205

9/22/83

Dr. M. Gonda
NCI – Frederich.
Bldg. 560

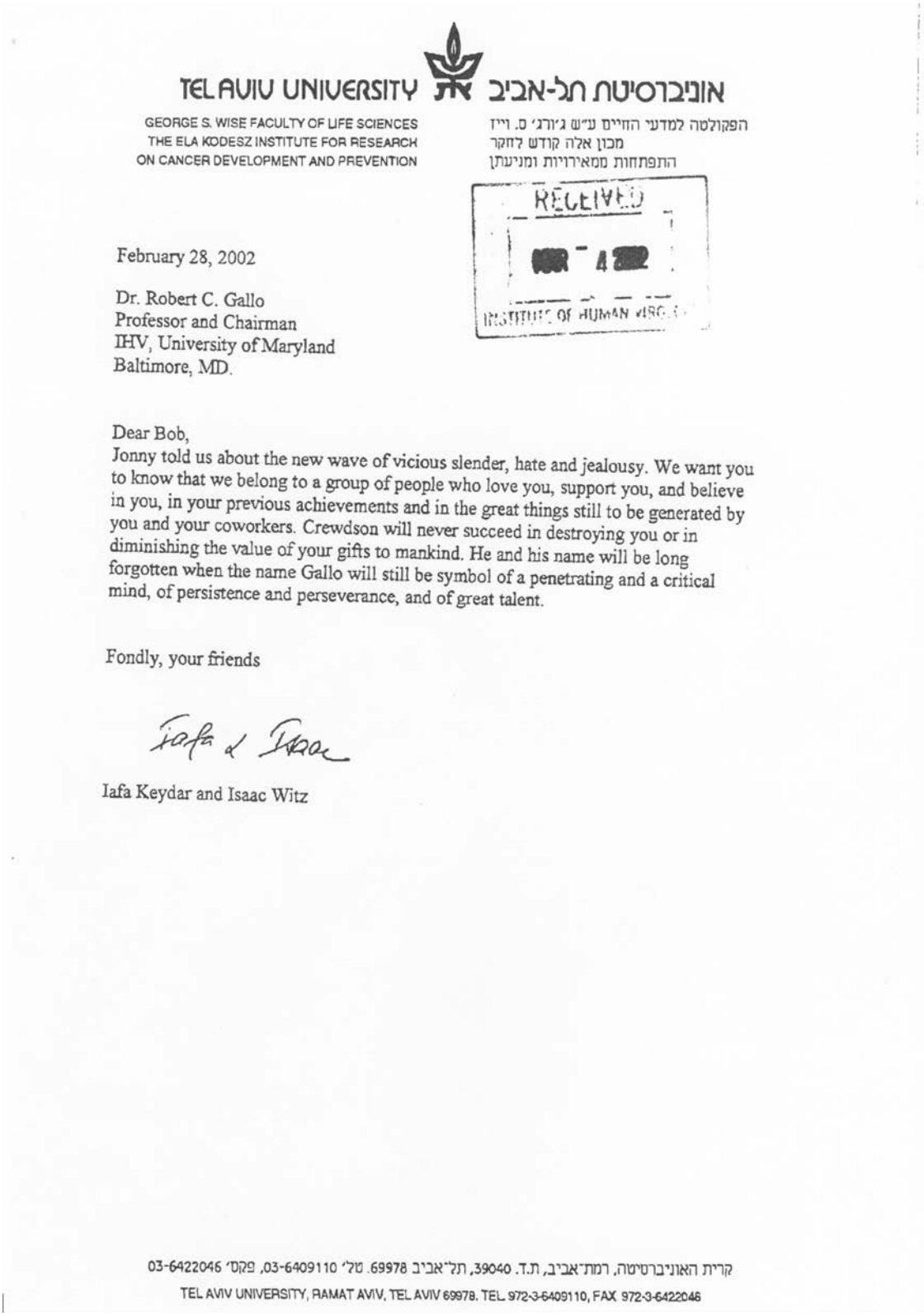
Dear Matt,

Enclosed please find 5 vel of sup. from culture infected g French isolate LAV for EM examinations as we discussed in our telephone conversation.

Thank you very much and good luck!

Mike Popovic

Letter from Popovic to Gonda: The virus was labeled “LAV from the French.” Ask yourselves this: if it’s being sent out to be photographed via electron microscopy, how can this virus ever be intentionally stolen? Photographic evidence will then exist.



TEL AVIV UNIVERSITY אוניברסיטת תל-אביב

GEORGE S. WISE FACULTY OF LIFE SCIENCES
THE ELA KODESZ INSTITUTE FOR RESEARCH
ON CANCER DEVELOPMENT AND PREVENTION

הפקולטה למדעי החיים ע"ש ג'ורג' ס. ויז
מכון אלה קודש לחקר
התפתחות ממאירויות ומניעתן

RECEIVED
MAR - 4
INSTITUTE OF HUMAN VIRO

February 28, 2002

Dr. Robert C. Gallo
Professor and Chairman
IHV, University of Maryland
Baltimore, MD.

Dear Bob,
Jonny told us about the new wave of vicious slender, hate and jealousy. We want you to know that we belong to a group of people who love you, support you, and believe in you, in your previous achievements and in the great things still to be generated by you and your coworkers. Crewdson will never succeed in destroying you or in diminishing the value of your gifts to mankind. He and his name will be long forgotten when the name Gallo will still be symbol of a penetrating and a critical mind, of persistence and perseverance, and of great talent.

Fondly, your friends

Iafa & Isaac

Iafa Keydar and Isaac Witz

קרית האוניברסיטה, רמת-אביב, ת.ד. 39040, תל-אביב 69978. טל' 03-6409110, פקס' 03-6422046
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One of the many letters of support after the publication of Science Fictions.

27.
PRIMING A PRESS CONFERENCE

Much has been made about then U.S. Secretary of Health, Margaret Heckler's Press Conference. It made world-wide news when she announced that U.S. scientists had isolated and discovered the cause of AIDS. Some people clapped, others lowered their heads in disbelief, others still, got angry. That press conference affected scientific and international relationships in ways the public never knew about. All they heard was…there's hope. But before those men and women stepped up to that podium, before the press quieted down to hear the announcement that was coming, before people the world over bit their lips watching their television sets, there were external circumstances shaping the words of that day. That's what this chapter is all about.

As Dr. Gallo has been the one targeted, singled out, held responsible for how and why the press conference was called, it is appropriate he should respond in his own words. He has, along with others. And before you read what they have to say, you need to keep in mind this simple fact that people seem to lose sight of. Dr. Gallo, for all his accomplishments, for all his glory, for all his sought after tutelage, was back then just a Government employee. In other words, he still answered to, and had to take direction from his superiors. One name to throw in the backdrop is Terry Scott, a consulting lawyer specializing in patent issues, already hired by the National Institutes of Health. With that said, let's go back, and read about the events that lead to a very pivotal event in scientific history.

Gallo: *"Oh, it was the U.S. press conference. Margaret Heckler, Vince DeVita, James Wyngarden, the NIH Director at the time, the Director of CDC, James Mason, Jim Curran from CDC, all were there. And you know it seems like yesterday. I've been forced to watch it two or three times. No questioning (what) I said. In response to a question. They were using it against me because they were going to try to claim patent fraud because I said in the patent, that I couldn't be sure the viruses were substantially the same. Right? That was based on consultations – the U.S. lawyers told me what to say. The U.S. lawyers are saying, "You couldn't know they were the same type because you hadn't analyzed them." And I said, "That's true, but I suspected." So the statement in the patent that they tried to get me with for (on) patent fraud; (was) because I did not know the viruses were substantially the same. Okay?*

"But in the press conference I'm telling the person not to call the virus HTLV-III only – call it HTLV-III/LAV because it probably is going to come out to be a (similar) virus.

So no matter which way you go you're a bad guy for not mentioning it, or I'm a bad guy because in the patent they didn't think we told the truth. You see."

Author: They had a lot of suggestions at NIH…

Gallo: *"Oh, of course. They wrote it. They wrote my things – I signed it. Yeah, yeah. It's all in writing for the patent. They come to you and you sign it. And I said, "But I did think they were going to be related." He said, "How could you think they were going to be related – you had no analogy from a legal point of view." By the way, that lawyer testified to that. Terry Scott, he testified that that was his advice to me and that was what he told me and that's what I had to follow."*

Author: And he was an NIH attorney?

Gallo: *"No, he was a consultant at NIH. NIH hired him. Consultant lawyer to make patents. That was the formal advice given to me. I'm a lab scientist, you know."*

Author: So other people filled it out (the patent application) and you go up and you sign it?

Gallo: *"He (Terry Scott) said, "How could you think they were going to be highly related if you didn't analyze them? You can't really say that." I said, "I couldn't know. I suspected." He said, thus Gallo had no reason to believe that the substances are the same or identical. I said, "If you put it that way, that's true and I assume the precise legal view.*

"So now the interesting thing is, even if you said they were going to be highly related, we still would have won the patent because they couldn't reduce the test to practice at that time. We beat them on that. Our patent preempts them because their patent has 17-18 percent seropositivity among AIDS patients. Their patent actually states the virus can not be grown! It's right there in their patent.

"As to isolation, I never claimed to be the first – I said that in the press conference. I would challenge any one to find that, even though is heavily insinuated in <u>And The Band Played On</u>, and in Crewdson's writing .Never in my life can you find any book that I said I was the first. I would bet anything. As for the insinuation that we patented the blood test for money, we were told we must patent by the NCI. Sam Broder used to always say to me, "Bob, they may do anything to you but no one on earth is ever going to say you ever did anything for money." Because of Sarin's stuff and Zaki Salahuddin they thought the big fish would be making millions, right. Well, the big fish didn't do anything wrong. And they wasted years investigating me for that. So, they lost with that and now (their implication was) I have to be doing it for riches. Why would I be doing all of this? There was no money to be made. The rules (at that time) were we couldn't make any money. When we did this (made the blood test) Lowell Harmison came to see me with Peter Fischinger telling me to patent. Did I patent HTLV-I? No. Is there a blood test for HTLV-I? Yes. Could I be making money on HTLV-I? Yes. Did I patent IL-2 (Interleukin-2)? No. Is there money to be made for IL-2? You bet. Okay, so how come, all of a sudden, I become the guy who patents to make money? Which is not necessarily a bad thing, and which is done widely in science today anyway, right? But there was never a motive to patent anything in my lab for personal enrichment.

"It happens to be that Peter Fischinger and Lowell Harmison came to see us. Peter Fischinger was an intermediary Government official that was bridging lab science at the NCI to the Director's Office and giving advice to me. From my understanding, Lowell Harmison was a technology transfer person from the HHS which as you know, the NCI and all of NIH reported to; and who was mostly advising me all the time. So, they tell me to

patent. You know what my thoughts were? Patent?! I never even could conceive of a patent. I didn't even know what they were talking about. Because at NIH, previous to that, we had never patented anything. However since the blood test of 1984 NIH scientists now, just like university and industry scientists, are encouraged to patent. So now at NIH they patent everything they had since that blood test.

"I am told that the blood test for HIV makes more money for the U.S. Treasury than all biomedical research patents from the Government and all other biomedical research inventions combined! That's who made money. Who also made money on this were the lawyers in New York, the Pasteur Institute, as well as NIH. Overall, I suppose we're talking about hundreds of millions of dollars. But instead you're talking about my, I won't say stinking hundred thousand, it means a lot. The lawyers laugh at me when I think it's a lot of money. This is mega-millions. So, we did it (signed and filed a patent application). (At that time, yes) we were most certainly told we wouldn't get anything. Then about 2-3 years later, that changed with (President) Reagan.

"If you ask me a direct question – did I know Reagan was going to change the law? No. Did anybody in the world know he was going to change the law? Not to my knowledge. I certainly had to be among NIH's first patents because they didn't believe in patents. Maybe somebody invented a machine or something – I don't know. Then everybody patented …miserable pricks, you know. I mean is it a lie to say that money was made (by me)? Is it a lie to leave out Reagan changing the law? Of course, it's a lie. This was one of the most painful accusations made by Crewdson, in his writing. Making it appear we did our work for patent money and royalties. That is such a lie."

Dr. Robert Redfield comments on the before and after of the press conference: *"Well, they (the Reagan Administration and the authorities at the NIH) didn't fight for him. You know he got set up. If early on he had said, when he had his discovery, and had been allowed to give the speech that he wanted to give, which he was cut off, you know – if you remember that original speech where he acknowledges working with Luc Montagnier, and he couldn't, he wasn't given that opportunity, then people just started attacking him and you know his personality - when he gets attacked (he) is not one to say, "Well listen, let me try to explain everything." His personality when he gets attacked is to, you know…They don't call him Gallo for nothing, you know. He's like a cock in a cockfight.*

"And Bob Gallo's interests weren't served by the Reagan Administration. He was involved with Reagan and the President of France and – it was a big mistake. And in the decision to rewrite those historical documents and have the - they're not co-discoverers of the virus. Every time I hear that I go nuts. They're not co-discoverers. Montagnier detected, was the first to show us there was this new virus and Gallo proved it was the cause of AIDS. They are totally two separate pieces."

Dr. Sarngadharan adds the conditions on how and when the press conference was to get underway: "*Heckler's assistant, his name was Edward Brandt, summoned us all that morning of the conference. We (myself and Gallo) were in a conference room behind his office and we filled out the patent application*[292]*. Then he made us sit there and wait. When the (patent) papers were delivered, received, and accepted by the Patent Office, that's when he called the news conference. I felt something more was going on, I didn't know what. So I left. I didn't even go to the press conference."*

[292] Popovic had earlier signed in the lawyer's office because he was going to be out of Washington that day to attend a conference.

The doors then opened, and amidst beaming spotlights and live-feed television cameras, an announcement was made to the world[293]. The rest as they say is history.

[293] See Appendix 14 (p. 331) for a transcript of the Heckler Press Conference.

28.
THE FRENCH BLOODBATH

Chief Prosecutor, Jean-Francois Burgelin: "Taken as a whole, the health policy of the government of France from April to September 1985 was catastrophic, as far as the struggle against the spread of the AIDS was concerned[294]."

In his book, journalist Crewdson goes a long way to convince his readers that the French blood test for AIDS out-performed the American one, both in the laboratory and on commercial levels. According to him, "the Gallo AIDS test had a crucial defect: compared with the Pasteur AIDS test, it was incorrectly scoring high percentages of blood samples as positive" and again, "compared to the Abbott test the Genetic Systems[295] test was the test of choice."

Yet Genetic Systems did not have a test until much later. And to be clear, the Abbott test is not synonymous with/to the American blood test. There were others that performed with fewer false positives. By making this statement, Crewdson reveals ignorance (as well as extreme bias) on how the AIDS blood test works. It is an inviolate fact that performance-wise, the false positive and the false negative scorings move in opposite directions as one tries to adjust the test according to different optimization criteria. This means, that if one adjusts the test to give higher false positive scorings, he would automatically get less false negative scorings and vice versa. Arguably, then, any responsible blood test provider would choose to minimize (preferably eliminate) the false negative scorings at the expense of the false positive scorings, which will be respectively maximized. By necessity, therefore, AIDS blood testing calls for a two stage system. A screening assay stage (ELISA) and a confirmatory assay stage (Western Blot), which retests all samples scoring positive at the screening stage. "At a meeting in August (1985) to evaluate (several of) the (different blood) tests, Dr. Walter Dowdle, head of the CDC (now head of VaxGen), described their (Abbott's) performance as "just fantastic[296]."

Of course, by its very definition, ideal test performance is one that achieves 100% sensitivity and 100% specificity. Statistically, tests need to approach these numbers for FDA approval. Criteria definitions are: Specificity – ability to score negative all true negatives, and, Sensitivity – ability to score positive all real positive samples.

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[294] French Ex-Premier Acquitted in HIV-Tainted Blood Scandal (Blood Scandals Go Mainstream), by Craig R. Whitney, New York Times, March 10, 1999.
[295] Genetic Systems was licensed by the French to manufacture their test in the U.S.
[296] Blood Supply Called Free of AIDS, by Larry Altman, New York Times, August 1, 1985.

Still, Crewdson was unsatisfied, and has remained so, even when he himself conducted interviews and hears it with his own two ears. In 1991, while pressing Karen Lipton, an attorney with the American Red Cross, she responds to him, "I don't agree that any amount of (AIDS-contaminated) blood got into the system. Do I think it was safer to get a unit of blood from some place that was using a Genetic Systems test versus an Abbott test?" Lipton asked. "No, I don't. Would I have personally gotten a blood transfusion from a Red Cross center that was using an Abbott test rather than Genetic Systems? Yes I would[297]."

According to the record, CDC officials collaborated closely with the French during that 1983-1984 time period, to help them improve their own AIDS blood test. Influenced by this collaboration, CDC officials came to believe and, in fact, were first to announce that the French had discovered the cause of AIDS. In a letter to Curran, Head of the CDC Epidemiology Branch, Don Francis himself wrote, "the French clearly found the cause of AIDS first, and Dr. Gallo clearly tried to upstage them." It appears, however, that Francis and others at the CDC had no clue as to the difference between the notion of detection and, to what the discovery of a new virus entails. That is again evidenced by a letter (dated July 5, 1984) when Francis wrote to Gallo: "Although the CDC has been in virologic pursuit from the very beginning, we did not describe the cause first and the French did."

Even the Justice Department asserted in court that, on the day the Gallo patent application for a blood test was filed, there was no evidence that the French had developed an effective blood test. Still, the French blood test was plagued with problems from the start. In fact, Francis had recruited Kalyanaraman from Gallo's lab and dispatched him to France for that very purpose; thereby forcing technology transfer from Bethesda to Paris. He also repeatedly sent to the French, various CDC blood panels, thereby transferring technology again from the U.S. to France (which the French then used to adjust and refine the accuracy of their test). Subsequently, Francis inappropriately set the acceptance levels (limits) of the ELISA score much too low, without first defining his test optimization criteria and, without having a clue as to the test's trade-off requirements for adjustment. This led him to believe his own propaganda and erroneously conclude that the French test was superior to the American one. Perhaps he ultimately should have heeded Gallo, and remained an epidemiologist.

Yet, there is no question whatsoever that from the very start Gallo's laboratory tests outperformed any Pasteur's laboratory test. At the commercial level, however, superiority is a more complex issue. What must be understood and made clear is that once a laboratory test is released to a licensee, it is true to say that in a sense it is no longer the scientists' responsibility. The licensee gets it and now they become responsible for mass producing it. Following good manufacturing practice, they have to figure out how to manufacture the test correctly, and do so in the millions. When you think about the market share for an HIV test, remember that every blood bank in the world wants it, every clinic in the world wants it, every hospital in the world wants it, and so on down the line. The commercial Abbott test, from the American side, was immediately mass-produced to gigantic industrial scales in response to worldwide demand. Transferring production methodologies of an excellent laboratory sized test to a machine-made, industrial scale test for commercial purpose,

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[297] Early AIDS Blood Tests Okd Despite Problems, by John Crewdson, Chicago Tribune, December 30, 1991, News Section, p.1

expectedly introduces initial problems of efficiency, effectiveness, and reliability. Problems that only hands-on experience can resolve and in fact did so quickly. Conversely, the small scale Genetic Systems (a U.S. company) doing the test for the French, with its initial zero demand for use, was not mass-produced right away and, thus, retained more or less its laboratory character, at least at first. Comparing the commercial Abbott test to the initial in-house Genetic Systems test, is like comparing night and day. And frankly, not fair to the Abbott test which is now in its third generation of refinements; moving from a 94.5% sensitivity and specificity factor to a 99.5%-99.8% sensitivity and specificity factor.

Indisputable proof that the commercial version of the French blood test ran into production problems and was late entering the market place, rests with the fact that French authorities intentionally delayed its initial approval for months until its performance was made satisfactory. One reason, was based on their Science article (see page 71), where they saying they were still unsure as to what exactly was the real cause of AIDS. So if they didn't know what the cause was, how could they then make a definitive test for people to use? How? They did not know what that singular cause of AIDS was. It doesn't make sense that you want to make an AIDS test, but you don't know exactly what you're trying to detect. You can't screen anyone's blood with such broad parameters.

Gallo's take on this is simple and to the point: *"The excuse they use is – they used to say they didn't really know the cause of AIDS. Well thank you, say it publicly. Then what credit should go to France? It's 1985 folks. We claimed in the spring of '84 there is no question as far as the cause of AIDS. So you're going to tell me in 1985 that you don't know the cause of AIDS. Well, that's your incompetence and you deserve no credit, okay. So are you then saying that you acknowledge incompetence and you don't deserve any credit? You simply can't have it both ways. You can not get credit for showing the cause of AIDS in 1984, then deny knowing the cause of AIDS in 1985 in order to excuse your failure to create a blood test for HIV, prior to medical use of that procedure in blood transfusions!"* Add to that, the French test fell behind the American test in the race to develop a marketable product because of their inability to grow the virus in large amounts in continuous culture. Hence, the resulting French bloodbath. They would not and did not use the American test in their own country and that right there is the one real AIDS scandal!

Gallo candidly remarks: *"There wasn't any French test. That's the point. Marc Girard worked at the Pasteur Institute and he worked in their industrial site also. It was his responsibility to move this blood test forward. He told me two weeks ago*[298] *that one of the delays – and it cost them six months – was Montagnier's claim that you could grow the virus in B-JAB*[299]*, a B-lymphocyte cell line. B-lymphocytes are the cells that make antibodies. Well you probably know that you can't infect B cells with HIV. HIV grows in T cells. Of course, all over the world, what is used to grow HIV is exactly what we described; namely CD-4 positive T-cells, immortalized. Nobody does it differently, including the French. Does Crewdson say that? No. He says Montagnier made a breakthrough in*

[298] The week of January 20-26, 2002.

[299] JBB were peripheral blood monocytes from a normal person in the lab, whose initials were JBB. Supposedly, at some point, JBB's B-cells were immortalized to make the cell line FR8; which was the source for the HIV infected B-cell line. FR8 is reported to be in repository somewhere in France, but has shadily vanished from sight and was never, ever given out for either study or verification.

growing the virus in B-JAB. Can others (anyone) grow the virus in B-JAB, even today? No."

A well placed, confidential source in France supports this, adding, *"This B-line, B for Big One, was supposedly producing HIV and was patented by Montagnier himself. Five months later, in October 1984, after a team, including Marc Girard, had wasted much time and lost much hair trying to culture HIV, Montagnier pull(ed) out of his hat the CEM line (a CD-4 positive T-cell line) that Robin Weiss had given him (previously) in May."*

In 1985, French Government officials delayed the approval of the U.S. based Abbott AIDS blood test, so that the French test could be introduced into the domestic market first and capture it. Specifically, the National Health Laboratory of France, acting on instructions from Edmund Hervé, Secretary of State for Health, blocked Abbott's blood test application from February 11, 1985 (date of submission) until July 24, 1985 (date of approval); a period of over five months. Thus, the approval of the Abbott test in France came almost two and a half months after the application expiration date of May 13, 1985, the legal date the French had to respond to the Abbott application by. More than four and a half months after approval of the test in the U.S., which was granted on March 3, 1985. Alternatively, the application for the French test was submitted for French approval, in France, on February 28, 1985 and approved on June 21, 1985, over a month before the Abbott test was also approved.

The gap of almost five months between the application of the Abbott test (early February) and the approval of the French test (late June), or the gap of almost four months between the approval of the Abbott test in the U.S. (early March) and the approval of the French test (late June), left the French people exposed to AIDS, since neither one of the two tests was ever made available during that time period. Tragically, thousands of transfused people were infected with AIDS in that interval, prompting their families to file lawsuits against the French Government and prompting the resignation of Michel Garretta, Director of the National Blood Transfusion Center; who ended up in jail (for that and because he knowingly released AIDS contaminated blood products for use in hospitals). Sadly, these products could have been tested by the Abbott test before being released, but were not. A telex from Travenol (an American laboratory) to the French National Center for Blood Transfusion (CNTS) exists that proves, from 1983 the Americans were the only ones to offer heated blood products that could stop the virus contamination. But France chose to distribute its non-heated blood products until 1986; to rid themselves of their surplus stock. News coverage was heavy over the whole affair, which the media called a major scandal. In an implied admission of guilt, the French Government pledged to pay $4 billion to the victims and their families.

Jacques Leibowitch, a physician with a pivotal role in the early days of French AIDS discoveries, states, *"I will never forget and forgive what happened to the French recipients of blood who were left unprotected. Crewdson spent hours with me. I had nothing to hide. Nothing at all. He asked me to forgive. I can not. Gallo had indeed the best test and it was not used."*

Dr. Gallo remembers: *"I was once hosted by the Head of the Hemophiliac Society in France. He and his entire family, were all infected. They were all infected! He was treating me, hosting me, he was very, very nice to me. And he told me how he got infected, how his family got infected, and how, you know the French – there was no blood test. We*

know - that's public record. I didn't learn anything new. (But) I am sitting there, looking at this guy and his whole family was infected because of what the French Government did."

Fortunately, not everyone waited for France to give its approval. A transfusion center in Bretagne defied the law (that's right – using the Abbott test was illegal in France) and began using the American test in April 1985, to save and preserve the lives of those that needed the center's services.

Now the story goes even deeper still. According to a report in the early 1990s by Michel Lucas, Inspector General of Social Affairs, the trail of misjudgments led all the way back to the office of then Prime Minister, Laurent Fabius. During a key inter-ministerial meeting on blood testing for AIDS, arranged on behalf of the Prime Minister by Francois Gros (Advisor to the Prime Minister), and held on May 9, 1985, instead of deciding to speed up the blood testing process to save thousands of lives at risk, it was decided to wait in order to prevent a U.S. entity (Abbott) from monopolizing the French market. As argued then, the U.S. entity was already licensed in America, was already looking at the French market, was already promoting its products in France, and was already setting prices half that of the French test. Thus, if the French test was not used in the Blood Transfusion Centers first, it was clear there would not be a domestic market for this product and, consequently, no international market either. So, any concern to protect their compatriots from infection was tossed aside, for nothing more than a business plan to make some money and gain some French prestige, while transfusions of untested blood carried on, day after day, patient after patient, all over France.

Consequently, the approval of the American test was to be withheld for some additional time (until the French test could hit the market first). Time for them to refine their troubled test which at one point reported over 20% false negative readings. The CDC had sent 205 serum samples, which the French used testing Lot No. 6. Ninety-two samples tested positive, but for 21 of these 92, the lots did not give the same results. And to think that all of those deliberations were happening in spite of considerable pressure from the media for assertive action, writing to protect hemophiliacs and other blood recipients at risk.

By May 1985, France had 300 AIDS patients and approximately 300,000 seropositives. The situation was becoming dire, and Government officials knew that. Likewise, they knew tests existed to screen for the disease. Yet they continued collecting unscreened blood to produce blood products; ignoring the fact that just a single seropositive donor was enough to infect everything. And this was the case, more often than not. So collecting blood which was sometimes contaminated, was used to produce blood products that were almost all contaminated. Like adding bad creamer into a pot full of good coffee and pouring that mixture into separate cups.

It has been estimated that between six to seven thousand French Nationals received contaminated blood transfusions in that four month period. In France no less, where from the start they claimed to have a better screening test. Well, if a test isn't working, if it isn't ready for use, how good is a test like that to anyone? No. The French were playing Russian Roulette with their blood. But instead of one bullet whirling in the gun's chamber, there were five. The odds were against the citizens of France, and the people in power at this meeting were the ones who made it so.

Participants to the May 9 meeting, besides Francois Gros, former Director of the Institut Pasteur (1976 – 1981) and Advisor to the Prime Minister, were:

- Denise Paulin, researcher at the Institut Pasteur;
- Michel Ramos, representing the General Secretary of the Government;
- Jean Debeaupuis, representing the Minister for Economy and Finance (who was actually in charge of Hospital Policy);
- Michel Lelong, representing the Minister for Industrial Organization and External Trade;
- Anne-Marie Cailloux, Cabinet Chief of the State Secretary of Family and Senior Citizens, representing the Minister of Social Affairs. She, according to official minutes of that meeting, was opposed to "the reimbursement by health insurance; and of the AIDS screening test because of the importance of the sums involved" (not quite the social security matters she was in charge of); and
- Claude Weisselberg, Advisor to the Minister of Health.

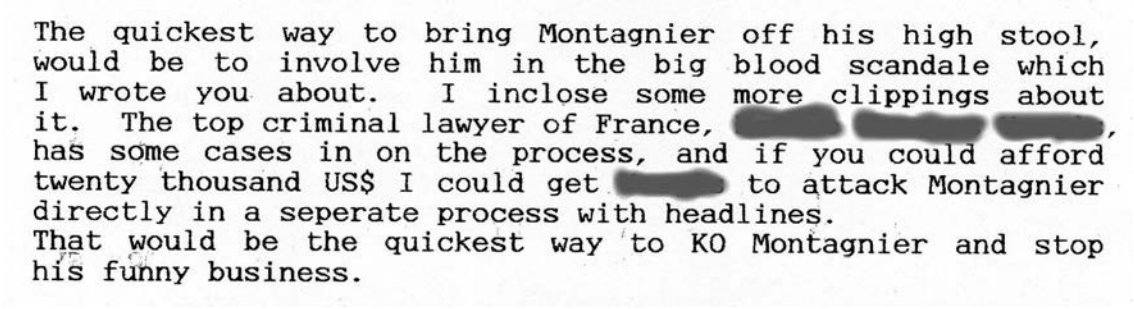
The Lucas report concluded that the participating French health officials at the meeting were guilty of disregard of public safety, if not outright criminal conspiracy. They knew that many blood recipients would be infected by AIDS, but instead gave priority to a potential loss of income, rather than to the health risks. And the French people paid the price for decisions made by these people. This was nothing more than a strategy of favoritism that delayed systematic testing for AIDS using the American-made test, until their own French test was ready. Their own report on the minimum estimates put those likely receiving AIDS contaminated blood because of their premeditated delay, at a rate between 100-200 each month. And that was acceptable to them.

All potential victims were not even notified of their situation until 1992. They had no idea what their own Government caused and allowed to happen to them.

Gallo himself asks, *"If they had a better test why was France the last country in the industrialized world to have a blood test for their own population? Why didn't they apply it in France? If they had the test doing so well, what the hell was wrong with them – why didn't they use it? The answer is obvious. They didn't."*

The facts were submitted to the Minister of Health Bruno Duriew, who expectedly turned it over to the Minister of Justice for possible prosecution. Legal proceedings started and the case kept pending in the French courts. The victims in France however, did not have the luxury of time. There were Ministers and ex-Directors of the Pasteur Institute that faced life imprisonment, who repeatedly had the trials postponed many times. Why did they want to postpone the trial? Because the people who were transfused were almost all dead. Ninety percent were dead by 2003. Given time, there wouldn't be anybody left to press charges. So they delayed, and delayed, and delayed. The French people rightfully became incensed.

During research for this book, a secret memo from France to Gallo was discovered, dated October 22, 1992. Seemingly, the outrage in France had opened up opportunities to essentially "get back" at those who had made American scientists and American science look so immoral for so long; while "honorable" French officials were likely to get away with murder.



The quickest way to bring Montagnier off his high stool, would be to involve him in the big blood scandale which I wrote you about. I inclose some more clippings about it. The top criminal lawyer of France, [redacted], has some cases in on the process, and if you could afford twenty thousand US$ I could get [redacted] to attack Montagnier directly in a seperate process with headlines.
That would be the quickest way to KO Montagnier and stop his funny business.

The identity of the lawyer is not pertinent as it can not be shown he/she had any complicity or foreknowledge of the proposal. Gallo declined the offer by simply ignoring it.

Martin Delaney: *"I didn't really know much about the French blood test scandal until it finally kind of broke in the news. And then it all started to come together what this (the Gallo issue) was about. (It) was about who was or wasn't going to go to jail in France. You know, we also saw Crewdson was making all these trips over to France frequently. And he would stay at the Ritz Hotel, which is like $500 a night. How does a reporter for the Chicago Tribune stay in that class of a hotel? I mean, I doubt that the Tribune would have even paid for him to go over there because he wasn't writing stories about the French blood test scandal. He was just over there. It became pretty obvious that he was feeding information to the French lawyers and to that process. There was some reason for him to be in France, and somebody was paying for it, and it wasn't the Chicago Tribune and it probably wasn't John Crewdson."* That statement becomes very credible since it was learned in 1992 that Crewdson's Chicago Tribune Office in D.C., was in the very same building as the Washington office of the New York lawyers representing the French Government!

Nevertheless, when French Prime Minister Fabius was finally tried in 1998 over the scandal, his line of defense (which was incidentally supported by no less than the public prosecutor trying him!), was that there was no American blood test available. That, if there was one, it was worthless. In other words, he was claiming that the French people were better off without the Abbott test, even if it was available. This in lieu of the documented fact that the minutes of a May 9, 1985 meeting of senior Fabius aides states: "The Prime Minister's Office requests that the Abbott approval be delayed for a period of time."

Obviously, this was an astonishing attempt by the French Government, to give merit to the issue that the case should have been dismissed and tossed out of court. And what significance is there to the public prosecutor supporting the defense claims? It stops the civil cases, and makes them impossible to win. How can you, when the prosecutor you'd hire is in agreement with the defense lawyers? …and says so in public?

Behind the scenes the Pasteur manipulation of events immediately became suspect. The end result was that the Prime Minister was cleared of all charges in a decision that stumped the world. Even the former Secretary of Health, Edmond Hervé, who was found guilty, received a suspended sentence. Why? They argued that he, "had suffered enough during the five year inquiry leading up to the unprecedented trial." All he

could say after his verdict was that he believed that the court did not, "have the courage to convict me really[300]."

Sarngadharan comments on the French attacks regarding the validity and existence of the blood test that he helped create: *"Their attacks were just financial. Based on their documented memo, the only reason they didn't want to do testing was, if they tested with an American test, when they didn't have their own test, then when their test becomes available, it'll be hard to export to other countries. Because people will say, "Hey, you were using the American test in your own country."*

First, the American blood test was inferior. Now, it didn't even exist. What had they been suing America and Gallo over for then? Where were the millions they were collecting royalties on, coming from if the American blood test did not exist?! Clearly, these claims by the French in court to assure acquittals were most certainly false in the face of unquestionable evidence. Fact: France was the last state in Europe to use a blood test to protect its blood supply. Fact: the Abbott test was available in enough quantities for world-wide demand. Besides, what is also ignored (or more likely omitted) is the fact that there were three other tests (derived from the same NIH/Gallo group test) that were out at that time. They were the Dupont Test, the Electro-Nucleonics Test, and the Litton Bionetics Test (later bought by and called Organon-Teknika). Fact: all four tests performed satisfactorily and, in synergy with the Western Blot, provided results that were uncontestable.

Except for the issue of costs, so what if the tests were reporting a small number false positives? All that should have mattered, was that they were not reporting false negatives. Twice positive (or repeat) ELISA blood, is discarded. Now imagine if false negative blood was not. Additionally, the evidence shows that, within six months after the introduction of the commercial blood tests in the American market, the rate of blood contamination dropped to practically zero.

It is now known that back in 1985, the French Press Corps itself was approached by a Pasteur Official to actually keep quiet on the urgent need for a blood test and the damage any delay in getting one would cause; even though out of 200 donors, they knew one was already providing contaminated blood, which they continued using anyway. Well, it is shocking to report that yes, the press complied and kept mum on the whole thing. Unsubstantiated, yet heavily rumored, is that money played a role in this silence.

But these trials had another important significance for the French people. With them, they were testing for the very first time since World War II, whether their Ministers could be held accountable for official crimes. That did not appear to be the case in trail after trial. Even with Michael Garretta (the convicted Director of the National Blood Transfusion Center) admitting in 1994 that everybody in the French Government "knew about it, including me[301]" was not enough.

It is noteworthy, that Crewdson, at great lengths, tried to desperately convince his readers that the French blood test was all along far superior to the American; which of course is untrue. In fact, on this issue he becomes highly emotional and throws away all his convincing sophistication in presenting a seemingly factual story; but it's not. If one had a

[300] French Ex-Premier Acquitted in HIV-Tainted Blood Scandal (Blood Scandals Go Mainstream), by Craig R. Whitney, New York Times, March 10, 1999.

[301] Petition Reopens Wound in French Blood Scandal; Health: Letter seeks pardon for two doctors who were jailed for giving AIDS-tainted products to hemophiliacs, by Scott Kraft, Los Angeles Times, January 22, 1994, Saturday, Home Edition, page A-19.

suspicious mind, one would expect to find the Crewdson book introduced as a defense tool in the French trials. Well, guess what? It was in fact referred to in the final stages of the proceedings. So now, the purpose and motive for publishing it, becomes very evident. To once more discredit Gallo and his accomplishments then, become nothing more than a happy by-product, a means to an end. The "end" was to somehow convince and prove to a French court, that the AIDS blood test (virus, process, and all) was invented and developed by the French[302]; that the AIDS blood test patent rightfully belongs to the French; that the American version of the AIDS blood test was flawed[303], and that the French Government had justifiable grounds to delay the introduction of the Abbott test in the French market. All these "proofs" that Crewdson writes of, are invented and reiterated to help win a non-guilty verdict for the accused French. But again, you only might think that…if you had a suspicious mind. Do you? Read on and decide for yourselves.

On July 4, 2002 (after the French court case entered its fourteenth year), a French appeals court dismissed all charges against thirty defendants; including public health officials, researchers, and doctors, who failed to protect those victims from infection to the AIDS virus. On July 9, 2002, prosecutors announced they would take the case to the final appellate court. It would seem that the guilty parties involved, those who made a conscious decision for an entire country, not to screen blood for disease, even though testing was available, who allowed needless infections (in the thousands) of HIV to occur, would likely go unpunished.

I ask you, how could that be?

Alas, that's exactly what did happen. On Wednesday, June 18, 2003, France's highest court (the Court of Cassation) did in fact throw out all the cases against those thirty defendants who had been charged with poisoning or complicity in poisoning, and, involuntary homicide or injury. The court ruled that "initial contamination" had occurred before the U.S. or French blood tests were ever made available. On the matter of poisoning, the court contended that the defendants - these medical professionals - did not have prior "knowledge of the necessarily deadly character" of the tainted blood products they distributed to the victims. Really? Well, all one needs to point out is simply this; the now infamous French inter-ministerial meeting occurred May 9, 1985; and Dr. Gallo made news around the globe when he published/proved the cause of AIDS (in one of the four landmark papers) on March 4, 1984. Also, why, between those two dates, did Francois Gros himself write on January 14, 1985, "The disease…can also occur in anyone who receives a transfusion…" As early as July 11, 1983, the Research Director of the Institut Mérieux, J. Armand, whose company is "involved in the production of blood derivatives," writes and admits to having, "paid special attention to your (Gallo's) papers."

And yet, none of these defendants had any medical "knowledge of the necessarily deadly character" of tainted blood?!

You be the judge.

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[302] The facts are simple, and the facts Crewdson forgets to mention are, the French had nothing to patent at time they filed their application; their blood test simply did not work. By their own admission they could not pick up more that 18% of the infected, and they could not grow the virus to manufacture the test.

[303] Crewdson simply ignores that screening for AIDS involves de facto, both the ELISA test and the Western Blot assay, as the serological standard.

29.

TAKING CARE OF ONE'S OWN: THE FRENCH WAY

The French way of taking care of their own is most revealing, and adheres to a characteristic feudal mentality. Meaning, if people are of the establishment, or one part of the establishment, then no resources and/or manipulations will be spared to get them off the hook; irrespective of guilt. The most open example of this has been illustrated by the case of the contaminated blood scandal (previous chapter). If people work for the establishment, then rewards and/or punishments are administered on the basis of loyalty, irrespective of accomplishments. We can illustrate this best if we consider how some of the early players in AIDS were handled.

Chermann choose to remain friends with Gallo and his career stagnated. Barre - Sinoussi chose to fully serve the Pasteur's interest and her career advanced. Rozenbaum did too and his career advanced as well. Leibowitch chose to collaborate with Gallo and his career was impeded. Leibowitch expresses his bitterness, *"Not only I never got acknowledged for my accomplishments in AIDS research, but my career was blocked as well. I was not given advancement on the last 18 years and I was never elected to Professorship. In fact, Prof. Seligmann, Director of the Electorate body over my candidacy, and President of the French Universities, told me in no uncertain terms that he would refuse to present my dossier if I were to include my work on AIDS. Thus giving me absolutely no chance to become a Professor."* Indeed, Leibowitch declares, *"I introduced the Gallo notion of a retrovirus as the cause of AIDS in France, first in a seminar on October 1982, to Jean-Paul Levy's[304] group and again two months later in a conference on general hematology and immunodeficiency."*

Gallo too reveals (The Early Years of HIV/AIDS[305]) that: "In February 1983, a clinician (Jacques Leibowitch) arrived from Paris, with cell samples from AIDS patients. One of these samples came from a man (CC) who received blood transfusions in Haiti. My co-worker, Mika Popovic, succeeded in growing $CD4^+$ T cells from the sample. These T cells were highly positive for RT,…The virus from these T cells cross-reacted with antibodies to HTLV core proteins, yet unlike HTLV, it killed target T cells. …With a more detailed molecular analyses of the virus from patient CC, we concluded that HTLV-positive results in samples from 5-10% of AIDS patients were due to a double infection with HTLV and a new human

[304] Levy was a senior virologist in Paris who eventually became head of the French Governmental Agency which funded much of the French AIDS research. A position he held for several years.
[305] Science, November 29, 2002, vol. 298, page 1729.

retrovirus. Moreover, the early 1983 experience with sample CC proved that the new retrovirus could be grown in continuous culture." Something that Montagnier and Chermann believed impossible because, even to this day, their LAV-BRU virus can not be cultured.

Getting back to how the AIDS players were handled in France; Luc Montagnier himself tried to walk the middle road and suffered for that. *"It is common knowledge,"* relates Montagnier, *"that I have not been very happy at the Pasteur. It was alright at the beginning. They used me initially, but later they became afraid that I was getting too much power because of my HIV discoveries. They tried to counter that and did everything to stop me from getting the Nobel Prize. They did not ask that Gallo should be denied the Prize; they only ask that Montagnier be denied. Why would they do that? Why would they try to destroy me?"*

How do other respected scientists feel about Montagnier's efforts (initial and continuing) in the scheme of AIDS research? According to Crewdson[306], Pasteur Institute co-worker, Wain-Hobson, is quoted to have said about Montagnier, "Around here, we say, he stumbled onto the virus, and he's stumbling still." Worse yet, fellow Frenchmen and Nobel Laureates Francois Jacob and Andre Lwoff threatened, "if ever Montagnier were to get the prize (Nobel), they would send their own Nobel Prizes back. Never in the history of the Nobel Prize did a man who did nothing important in his lab, but see one virus, never before did such a scientist get the Nobel Prize for such a little thing." Finally, "When Science surveyed France's hottest AIDS researchers, …missing from the list was Luc Montagnier."

Still damage was done, and what will be revealed now, only a handful of people ever knew before this book was published. A punch in the gut, fast and vicious came at Gallo whose reaction was both surprising and revealing of his underlying character. It began one evening, on the first Sunday of October in 1988, when NIH Director James Wyngarden took Gallo out to dinner. He said, "Tomorrow you're a Nobel Prize winner," and shook his hand. Wyngarden had been told the news directly from Sweden. Gallo's office had likewise been informed two days prior (on Friday) by the Swedish Science News Agency (Gallo was out of the country when the call came). He had been instructed to be awake early Monday morning; and told that he had won the Nobel jointly with Montagnier. But the Nobel Committee changed it all in those final two days before making their public announcement. The author has learned that Francois Jacob had written that letter (cited in the previous paragraph) to the Nobel Committee some two weeks prior, threatening to give back his Prize if Montagnier were to win. It seems that Montagnier tried to become Director at Pasteur while Jacob was President. It was no secret that for whatever reason, Jacob did not like Montagnier. No matter, the letter had the desired effect.

Gallo reflects: *"The people who won the Noble Prize that year were the very people who created drugs that gave my sister another year of life with her leukemia. So there is no way I could be jealous. In fact, strange as it might seem, I felt a certain calm happiness that somewhere, there was a lesson in that."* As fast as you read it, he said it[307]. Gallo, a 65 year old man, was still thinking about his six year old sister, dead for so long a time. And his first frank, spontaneous remarks about losing the Nobel in such a way, meant nothing

[306] Science Fictions: A Scientific Mystery, a Massive Cover-up and the Dark Legacy of Dr. Gallo, John Crewdson, Little Brown & Co., 2002, pages 329, 327, 531.
[307] On July, 25, 2003, 2:16pm EST.

before honoring those whose work helped keep a little girl alive, for a little while longer, back in 1949.

So almost ten hours after he had been congratulated by the NIH Director, and told he'd won, Gallo heard the official announcement that the Nobel for Medicine had been spilt and awarded to Sir James W. Black, Gertrude B. Elion, and George H. Hitchings for their discoveries of important principles for drug treatment.

To Gallo, nobody said a word that day. No one.

Could it be that the present formal collaboration between Gallo and Montagnier is still hurting the former of ever getting the Nobel Prize? I, the author, speculate yes, because of that one conversation I overheard (refer to page 193). But only time will tell if that will become a fact in history.

Lastly, the French Politicians enacted laws in recent years to save themselves from the reporting of future scandals by the press. Courts now actually forbid the journalists to produce documents covered by legal confidentiality that prove the validity and seriousness of the journalist's investigations. Making journalists caught between being accused of libel if they fail to prove their assertions, and of illegally possessing information, if that material which proves their story, is part of an ongoing investigation.

The French bloodbath was and is covered under those guidelines. In 2001, the convict Dr. Michael Garretta (see previous chapter) won a libel suit against a daily paper reporting on the matter.

Additionally, French Senator Pierre Fauchon of the Union for French Democracy (a center-right political party), introduced a law which was passed by the National Assembly on July 10, 2000. This law, widely viewed as legislative amnesty for the defendants in the then on-going trials for the tainted blood scandal, essentially required prosecutors to demonstrate a "characterized error" of a "particular gravity" in order to legally prove anyone guilty of involuntary crimes. This "Fauchon" law had a very effective and obvious role in the blood scandal when you consider the following. There was enough evidence to convict Minister Edmond Hervé in 1999, but the same evidence was insufficient to later convict his counselors (and the other defendants) in 2003.

To be sure, that's taking care of one's own.

30.
THE INSTITUTE OF HUMAN VIROLOGY

Ever since the early days, Gallo feared that AIDS as a deadly epidemic may well be the herald to other serious diseases caused by emerging viruses. Logically then, he proclaimed the study of human viral diseases as a matter of scientific urgency and went on to propose that a major international institute of human virology be created to prepare our defenses against the possibility of a future viral epidemic. Gallo was also convinced that cytokines (biological active molecules, like growth factors) are of crucial importance to health and disease, and must be thoroughly studied within the context of the Institute's scope.

The world was indeed unfortunate that the AIDS epidemic did occur, but at the same time, it was fortunate that the disease occurred when it did. By then, molecular biology, immunology, and animal retrovirology gave a solid technical framework to attack the problem – because of contributions from hundreds of scientists. Also, Gallo had opened the field of Human Retrovirology, and developed the distinctive techniques for the study of human retroviruses in a laboratory setting; which quickly brought this disease into understanding and even partial control. Gallo: *"At the beginning when I was negotiating to leave NIH, I wanted my work and that of my colleagues to be able to go from lab to clinic much more rapidly. I wasn't sure how to do it. And then one fine day I was approached by Bill Blattner from NCI, a lab chief, and he was telling me that he and Redfield were interested in making a move at the same time, and they wanted to know what I'd think about an Institute together- epidemiology, the clinical, and basic research… Because I wanted clinic, I didn't think about epidemiology and public health, but that would be wonderful. At NIH I would have to find somebody to collaborate with who's in the clinic, whose priority might not be mine. When you're an Institute Director, and you got people thinking similar, at least with similar goals, Bob Redfield's goal is to make biological therapy instead of just chemical therapy and to find new ways to treat AIDS patients, and to make it available to the Third World. That's exactly my goal. All of us have a goal of developing a preventive vaccine or to help the world to develop a preventive vaccine. So we're all in it together."*

Gallo's idea regarding the creation of an Institute of Human Virology was at first to combine it within the NIH campus; having the best of Government for political support, the best of University for scientific support, and the best of industry for technological and commercialization support. He also wanted to secure enough funding and enough flexibility for fast-paced progress. In the minds of many this idea seemed too wild to be realized. Yet,

the past NIH director James Wyngarden endorsed it, and the late British tycoon Robert Maxwell volunteered to finance it.

So enamored with Gallo's idea was Robert Maxwell, that in 1988, after the original plan had failed due to last minute glitches, he bought a $15 million biomedical facility about 10 miles north of the NIH campus, hoping that Gallo would use it to establish his Institute of Human Virology (or, IHV). Gallo, however, declined. He judged that Maxwell's facility, as a stand-alone work-place was far removed from all poles of scientific action, and therefore would not do for his purpose. So he made up his mind to search for alternatives such as various university campuses.

Finally, on August 25, 1995, after reviewing eight different offers, and seriously considering six of those, Gallo and his scientific team were lured by the University of Maryland in Baltimore[308]; and by the state Governor, Parris Glendening, whose own brother had died of AIDS. On its campus they finally established their dream of an Institute of Human Virology. The Institute was initially endowed with $12 million in state and city funds for the first three years, and was provided with a magnificent research facility. Fact: From 1983 to 1995, fifty-four (54%) percent of all the patent royalties collected by NIH were derived from Gallo's achievements and that potential income was not ignored by those seeking to woo Gallo.

Yet, how could the IHV open without something to come along and pester even this effort? As it turns out, Dr. Suzanne Hadley, ex-Deputy Director of the OSI, reappeared and lobbied against Gallo's Professorship at the University of Maryland. Fortunately, hers was a rumble of insignificance that went unheard by all (Appendix 12, p. 326).

In February 2002, Gallo and a small team of IHV Department heads went to former U.S. President, Bill Clinton; seeking his efforts to help raise money for an endowment. IHV Chief Operating Officer, Michael Goldrich recalls: *"I said exactly these words to the President; "Bob Gallo is going to be at his best when he thinks, not when he applies for grants. If you can get Bob Gallo back in the lab and just thinking, that's when you're going to get the greatest return on an investment than anybody you've ever made."* It is a statement that holds true for many of Gallo's collaborators and long time colleagues – irrespective of the stigma of the past, and the innuendos of their association with him. By the way, Clinton did not commit at the time, but was willing to be approached once he had finished raising his own endowment for the building of his Presidential Library.

Already, the research spearheaded by Gallo at IHV has attracted considerable international attention from Academia and Industry seeking to participate in strategic alliances. Israel and Maryland have started a biotechnology fellowship at the IHV, to tap into each other's growing talent in the field. In the summer of 2003, the same occurred with Italy. And biotechnology companies have signed licensing rights to commercialize discoveries coming out of IHV research.

Indeed, in its first 6-year history (1996-2002) the IHV came a long way:
- growing from a handful, to a staff of more than 220 people;
- obtained over $25 million per year for research, of which more than $15 million come from sponsorships such as, NIH grants, foundations, and pharmaceutical companies.
- its clinical base has grown from a few hundred AIDS patients, to more than 4,000 patients with viral and infectious diseases (as of January 2004), who are receiving care and support on both an outpatient and inpatient basis;

[308] His appointment at the University as a Professor of Medicine with tenure would begin October 1, 1995.

- awarded 21 patents (as of August 2003) with dozens more pending; and
- made notable basic and clinical research advances in transgenic mice, experimental therapeutics, vaccine designs, and cancer biology.

The IHV consists of five major divisions:

- Basic Science Research
- Animal Model Systems
- Clinical Care and Research
- Vaccine Development
- Epidemiology and Prevention

These five divisions work independently, yet synergistically with each other, to serve the common goal of making research discoveries and bringing those discoveries to the patient as quickly as possible. Obviously, such a goal necessitates additional efforts in product development, which the Institute is attaining, by creating its own Bio-technology company (Maryland BioTherapeutics, Inc., formed last quarter 2003), and by making strategic alliances with large pharmaceutical companies.

An independent review of the Division of Epidemiology and Prevention was completed November 9, 2000. It is an indicative example of the high marks the IHV has earned in all its divisions. In that report they wrote, "The Division has been remarkably successful in a relatively short period of time since the establishment of the Institute in 1995. The track record of major research funding is impressive, including the recently successful application to become an HIV Vaccine Trials Unit (HVTU)…"

In February 2002, Dr. Robert Gallo (Director of the IHV) and Dr. Luc Montagnier (President of the World Foundation for AIDS Research and Prevention[309]), under the auspices of UNESCO (United Nations Educational, Scientific, and Cultural Organization), entered into a formal collaborative partnership to speed along the discovery of AIDS vaccines, as a global endeavor (Appendix 13, p. 328). The Program for International Viral Collaboration will provide the working platform for this joint endeavor. The World Foundation will provide leadership in developing resources to sponsor and fund research activities on a global scale, while the IHV will provide its already developed vaccine concepts, while additionally housing the Laboratory for International Viral Collaboration as a basic support component of this endeavor.

An immediate promising opportunity, developed by IHV scientists (especially Timothy Fouts and Anthony DeVico), is a novel vaccine design that went into clinical trials in 2004. This design generates the broadest HIV immune response seen to date in the laboratory, blocking infection caused by all strains of HIV, by inducing neutralizing antibodies. It is a remarkable achievement to say the least. Gallo himself says[310], "This is like nothing we've seen before. It has neutralized (blocked HIV infection) of almost all the strains we have tested, and we have tested a lot." But the slow pace of vaccine research has proven exasperating. Everybody was working on different areas without collaboration. So Gallo, along with John Evans (an entrepreneur and co-founder of the cable channel C-SPAN), created the Waterford Project. An ambitious plan to link Gallo's Institute with researchers at Harvard, the University of California at San Francisco, and the University of Michigan utilizing Internet 2 broadband

[309] This is a different entity that Montagnier created in France, and should not be confused with the World Aids Foundation that closed after funding from the blood test royalty payments ended in 2002.
[310] Outsmarting AIDS, by Robert Langreth, Forbes Magazine, September 17, 2001, p. 160

technology to share data and results. The goal? To ready the new vaccine for human trials in as little time as possible. Unfortunately, however, the source of funding planned by Evans was to be from the Information Technology Industry, which suffered a decline in stock market value due to world events[311]. This has made fund raising seriously problematic.

This new vaccine concept was conceived many years ago by Anthony DeVico, Ranajit Pal, and Mangalasseril Sarngadharan, who all jointly own the patent rights to the concept. DeVico is a biochemist working presently with Gallo at the IHV. The vaccine research is focused on stimulating the immune system to produce antibodies against specific proteins (antigens) present on the virus surface. An important protein on the surface of the AIDS virus is the so-called gp120 antigen, which could become the target of immune response for vaccine design. Unfortunately, the exposed part of the gp120 antigen on the virus surface, not only differs between different strains of the AIDS virus, but also mutates constantly and rapidly to delay detection by the immune system; thereby escaping assault by antibodies. However, when the gp120 antigen locks onto the CD4 receptor of target cells, in preparation of virus penetration, the normally obscured parts of the gp120 become exposed for about a half-hour to the immune system for attack. These obscured parts of the gp120 antigen hardly mutate and, therefore, are ideal targets of antibody attack if somehow they could be exposed to the immune system over much longer periods of time.

DeVico's concept is to fuse the gp120 antigen to its CD4 receptor so that the obscured parts of the first are permanently exposed for detection. He argues that shots of this fused vaccine preparation would prompt the immune system to produce a flood of antibodies, that would attack viruses, in their exposed gp120 parts, during that crucial half-hour of waiting in preparation of cell penetration. Recent tests of the new vaccine concept in monkeys have confirmed that the immune system produces antibodies and, that the antibodies block infection in laboratory tests from a wide spectrum of virus strains from all over the world. Obviously, the vaccine preparation is designed to be given prophylacticly as a preventative vaccine stopping infection upon exposure. But there is rationale for its use in therapy for patients with frank disease also.

A rival vaccine design is AIDSVAX introduced by VaxGen of Brisbane, California (headed by Don Francis, formerly of the CDC), which was already under large scale efficacy trials world-wide. AIDSVAX is made of purified envelope proteins from the AIDS virus and it was intended to provoke the immune system into making antibodies that would prevent the AIDS virus from infecting cells. Unfortunately, this same vaccine design had been shown ineffective some years ago by the Gallo team (and many other groups) and inadvertently removes patient population from proper vaccine studies. The reason this vaccine design is ineffective is because the particular viral protein (the envelope of the virus, gp120 alone) used in the study to stimulate antibody production, actually produced antibodies effective against only a very restricted range of HIV variants. Gallo reinforced his position by going to record[312] to say, "This is not a vaccine approach that was based on science." It has taken VaxGen and epidemiologist Francis, over two hundred

[311] Most notably the terrorist attack of September 11, 2001, on U.S. soil which has had a lasting effect on the economy.

[312] Caution Urged On Reading AIDS Vaccine Data, by Jonathan Bor, Baltimore Sun, February 25, 2003.

million dollars[313], to prove what the Gallo team (and others) already knew, and published about this vaccine approach. Incidentally, in 2000, the top three administrators of VaxGen (of which Francis is one) each received an eight million dollar bonus. Not for progress with their vaccine. No. These bonuses were for maintaining value of their company stock over a certain level, for a certain period of time.

Gallo comments on the ironic origin of the VaxGen viral envelope protein, gp120, by Francis[314]: *"What is his vaccine? It's the envelope of the virus. What virus? MN isolated in our laboratory by Phil Markham in the beginning of 1984. Put into a permanent cell line by Mika Popovic and Betsy Read-Connole in our lab in February 1984. The genes cloned by Marv Reitz - also, from our lab. The cloned genes sent to Genentech[315] by Marv Reitz as a gift. Genentech expresses it and makes envelope protein. It's in their freezers, they have no use for it, they know it's not going to be a good vaccine. They sold or gave it to Don Francis who raises 220 or 250 million dollars to make this a vaccine. We've already tested it on and off for years – it's worthless. It's an approach that nobody in the world is taking now – it ended by the mid-late '80s. So he made money on it. He's already cashed in stock for millions of dollars."* The gene clones being referenced are of the HIV strain called HIV-MN. This strain of HIV was one of the early strains isolated by the Gallo group from an AIDS patient and was described in one of the four Science papers published in March1984. But the notion promoted heavily by consultant Don Francis in both the book and film versions of And The Band Played On, was that the Gallo group had no isolates of their own in 1983-84. Amazingly, Francis has the audacity to select this particular strain of HIV for the commercial efforts of his company.

If you're not at least 40% effective in the United States, the FDA will not approve any vaccine. Simply because there is evidence behavioral change will start in any population that thinks that they're now protected. And that only makes matters worse. Which brings us back to VaxGen and some new problems that have arisen from their faulty vaccine. There was a substantial increase in the amount of infection in both the vaccinated and the placebo group[316]. The vaccinated group had a little less infection (5.7%) than the placebo (5.8%). Overall, more people were infected than would have been infected anyway because of them believing they were now protected by the vaccine. Since they officially announced on February 24, 2003 a very meager 3.8% effective rate[317] in the overall study group, the FDA will deny the vaccine in the United States. But it will go into Third World countries with disastrous results and lots of money. Keep in mind, most studies have a margin of error, plus or minus 3 to 5 points. So VaxGen's claim of 3.8% almost certainly means zero. In March 2003, a multi-million dollar lawsuit was announced against VaxGen for securities fraud, alleging it allowed "favored" investors to sell stock before it officially

[313] In the summer of 1983, Francis publicly attacked NIH for refusing to fund his vaccine trials and went so far as to compare their refusal with that of the blood banks refusing to acknowledge AIDS in 1983.
[314] Yes. This material was being used by the same Don Francis who in the HBO film, And The Band Played On, lionized himself at Gallo's expense; and also by making the first implication that Gallo did not have his own virus isolates.
[315] Where Francis began working in 1992 after retiring from the CDC.
[316] The placebo group because they thought they were protected.
[317] Yet, alleges a 78% effective rate, based solely on 13 infections, among Black participants in the study. VaxGen defied scientific logic when they proposed that vaccinated Blacks in their study had higher levels of HIV anti-bodies than their White counterparts. Thereby asking us to just forget how high the infection rate is among the Black population world-wide.

announced the failed results of the aforementioned 4 year trial. It remains to be seen if Francis will acknowledge the fact that his fruitless vaccine does more harm than good. Or will he emerge as the crusader of the sick he portrayed himself to be in the movie, And The Band Played On, and admit it's time to move on to something beneficial to those in real need?

One new, notable research venue from the IHV is on the horizon. Gallo gives some details: *"Some peptides from urine of early pregnancy, naturally occurring products have anti-tumor effects and may have some HIV suppressive effect. These peptides can kill many tumor cells by inducing programmed cell death, what we call apoptosis."*

Another immediately promising opportunity, presently explored by IHV scientists, is the use of certain chemokines, discovered by Gallo and his team in 1995, as blocking HIV infection against a whole class of virus strains (back on page 212). In a televised interview with CNN, Gallo was asked what he expects to see happen in the next 20 years in relation to HIV and AIDS. "I expect it to be finished. On the way, getting there, I expect to see better approaches to therapy that aren't so toxic, and I expect us to have solved the problems in the Third World, by making it (drugs) cheaper. I expect that we'll have a preventative vaccine[318]."

But with the advances for those infected with HIV, come the setbacks too. In 2002, the IHV had some bad news for the protease inhibitors. They are great drugs against HIV which the pharmaceutical industry developed but unfortunately, the IHV and other independent clinics, announced that within one year of being on these drugs, 50-70% of the patients become resistant, because the virus travels extensively, establishing new infections, and becoming resistant to the protease. Meaning these multi-drug resistant viruses are resisting various proteases. Coupled with that, the proteases are having toxic effects. Those who took the drugs long ago, who don't have resistance, are getting toxicity after 8 years of therapy. And the toxicity is becoming more serious, the drug resistance more problematic, and therefore, even for the industrial world, new forms of therapy are needed.

What is on the horizon? On July 25, 2003, while driving along the Bethesda Beltway, Gallo shared some of his foreknowledge with me; *"I don't think the variation (mutations) in the virus will prevent us from a preventative vaccine. I think that problem is solvable and I think it has been solved in our Institute already. Although not many will agree, but I know what we have."* This vaccine utilizes the sequences of the first macrophage-tropic virus; a discovery made in Gallo's lab in 1986. Which exemplifies how findings made in the 1980's are still of significance today. There is one structural refinement hurdle yet to clear: their vaccine needs higher, tighter antibodies so they can get more of them into the mucosal membranes, into the vaginal track, into the urethra, and into the rectal canal. On September 9, 2003, the IHV received FDA approval to go forth.

With the world waiting, what will the 2004 Phase 1 Clinical Trials of this vaccine bring?

[318] Interview conducted Tuesday, June 5, 2001, at 1:30 pm EDT.

31.
3 LITTLE QUESTIONS

Many interviews were conducted in order for this book to be written. For some, the trip back in time was not a pleasant one. For others, it was an eager opportunity to clarify things once and for all. But for many, the questions asked of the interviewees, had been asked before. Except for three. Which were always, always the last three questions asked before any interview was concluded. Each was surprised, not expecting the questions at all. But upon thinking about them with some pause, they all had very telling answers to give.

Question 1 – What is the one thing that has been taken away from you because of all this (the scandal)?

Dr. Max Essex: "*We were not saying that it was HTLV-1, (we) were saying it was retrovirus like HTLV-1 and I think we were unfairly painted for that.*"

Dr. Genoveffa Franchini: "*I think that what has been taken away from me, as a person working in that lab, is the sense that you definitely had to work harder to establish your credentials (and) reputation. I definitely felt that. Some people still (to this day) look at me like that. Actually, I think what has been taken from me is I could have had a totally different kind of career. Totally faster. Because what people call a legacy has been tainted on some levels.*"

Dr. Farley Cleghorn: "*So, what does it take away from me? I think what it took away from me was seeing the sapping of the energy of Bob. That's what it did. It really, the unjustness of it, in his opinion, made him less than what he was. And it made a lot of people less than what they were because they were demoralized because they thought they were doing good. That's what it did. And I am thinking about people like Mika, I'm thinking about Marv, I'm thinking about a lot of people who left the lab and went off because after a while people just can't do it anymore.*"

Dr. Phil Markham: "*Peace of mind.*"

Dr. Daniel Zagury: "*Oh they claimed that I – that I killed children, which is unbelievable. They claim that I killed people, which is unbelievable, which is completely stupid because anything I did – in Zaire – was done with – under the French legislation and also the Zairian legislation.*"

Dr. M. Sarngadharan: "*Part of my feeling of accomplishment.*"

Dr. Bernadine Healy: "*My belief in the system and my political innocence.*"

Dr. Robert Gallo: "*What did they take away? Well, they hurt my reputation. They questioned my character. And they took away four years of research effort because we were*

bogged down for four years because of Crewdson's constant harassment for Freedom of Information – the inquiry that he stimulated. So he took away four or five of the best years of my research time in life and the best lab I ever had was hamstrung by it."

Question 2 – What is the one thing no one has been able to take from you?

Dr. Genoveffa Franchini: "*What has not been taken away? You have to be true to the facts of Science. And never sit on a concept too long and move on and think always about the biology. This can not be taken away from me because I learned this and I think it has served me very well. I think that the scientific method Bob has given people in his lab, but also people outside his lab; Bob has created a new area of research in thinking.*"

Dr. William Blattner: "*The truth.*"

Dr. Daniel Zagury: "*Of course, they tried to – to destroy me. And, in fact, they quite succeed but I survived because of my friends, because of my will, and this … , this … they give to me – this shot they did to me had helped me to make a step ahead by working more and more and getting more data.*"

Dr. Luc Montagnier: "*My scientific curiosity.*"

Dr. M. Sarngadharan: "*The scientific evidence and our knowledge of it.*"

Dr. Phil Markham: "*The actual historical facts.*"

Dr. Bernadine Healy: "*My moral integrity and my sense of fairness.*"

Dr. Robert Gallo: "*What didn't they take? Needless to say the contributions showing the virus causes AIDS and the development of the blood test which saved lives no matter how Crewdson tries to misrepresent it.*"

Question 3 – If a magic genie told you, you could ask one question of any one at all, and they would have to give you an honest answer, what would you ask…and to who?

Martin Delaney: "*I'd like to ask John Crewdson, what is this about and what is your connection to the French lawyers and the Dingell Committee?*"

Dr. M. Sarngadharan: "*Why the orchestrated effort to convince people we committed fraud?*"

Dr. Phil Markham: "*What was the motivation behind the accusations?*"

Dr. Genoveffa Franchini: "*I particularly would ask (Simon) Wain-Hobson, tell me exactly what went on at the Pasteur Institut during that time? And when I say that time, I mean during the time of the lawsuits, and they went back and looked at the samples, what did they really know?*"

Dr. Mark Kaplan: "*I guess I would direct it to Mika (Popovic). Because Mika was in the thick of it. And I would say to Mika, "Did you really discover this virus?" And I know the answer. Because I've asked Mika. And he said, "Absolutely." And I believe him.*"

Dr. William Blattner: "*I would ask Crewdson, how much he was paid by the French? Of the French I would ask, "Was this scandal orchestrated to allow you to make more money?*"

Dr. Daniel Zagury: "*I say I don't want to have anything with Crewdson. Crewdson is a liar. Crewdson made so – I mean so, so big lies toward me – I mean liar of the first degree.*"

Dr. Bernadine Healy: "*Why did Dingell never study the case himself to come to a fair and honest determination and, what reasons, political or otherwise, did he instead go after prominent scalps for nothing?*"

Dr. Robert Gallo: "*I guess I would ask all of them, Dingell, the French, Crewdson, I guess I would ask do they really think that we truly did anything wrong? I mean I'm curious what they thought. Did they really believe we did something wrong? I know the answer, they don't. They had contaminations themselves. So I don't know what to say. For the French*

lawyers I'd ask if the money made a qualitative difference in their lives. And I'd ask all of them if they truly do sleep well. Do they truly know what they've done? Do they really understand what they've done? Do they understand the measure of cruelty? Do they understand the measure of harm to AIDS research? And do they understand that they created the whole phenomena all for their own greed?
"The thing you didn't ask me was if I had to do it over again, what would I have done differently. I wish I insisted that the French be at the press conference – that would be number one. Second, I wish I would have taken more control of my own destiny. I wish I was the master of my own destiny more instead of blindly following with what I was counseled to do by various people. But I was a Government employee and who knows what I could really do. Third, I know I held onto the concept that the retrovirus causing AIDS (HIV) must be reasonably, closely related to the other retroviruses we had previously discovered, for some 4-6 months longer than I should have. I thought this just had to be true. I was overconfident. However, unlike the picture painted by some, this in no way hurt progress in the field. I wish I was more objective about the relationships with HTLV-I and –II because when I was younger I was always demanding to see what the data showed – no prejudice. But I thought it was so obvious that it had to … I was too cocky."

32.
MOTIVE, MEANS, & OPPORTUNITY - EXAMINED

It is safe to say, that whenever something shameless happens to another, the act has an origin, a motive if you will. That motive creates a means for the act and sometimes even facilitates the opportunity for such to occur. In police work, examining those three elements are the foundation upon which all investigations must be based, and the right questions asked.

This story is centered on two research groups and one all-around lethal virus; from those who worked on it and studied it, to those that have it inside them and have died from it. But in the end, the egos and prestige of two Governments went to war. Money, the single driving factor. A windfall of hundreds of million of dollars, annually, was the prize. There was profit to be made in global suffering. And when the French got a slice, they created an opportunity to help themselves to a second, even bigger slice of that money pie. Only in the declining years of the patent, were true mistakes revealed. The key component, the French had a contaminant in their lab first. That's what started and ended this whole thing. One virus hiding in another. Opportunity.

Anyone who has followed this story, and studied it in any measure, has seen the fury of relentless accusations and blame throwing as a tornado of incensed headlines. Yet, this critical bit of news, that the French were the singular cause of Gallo's contamination, that their microscopic contaminant somehow made its way all the way to the American blood test designed to save the world, blew as if it were nothing more than an apologetic breeze that carried with it an attitude of, "oh well, sorry." It was the same with the French trials; their outcome a certainty of innocence, despite the needless deaths of so many blameless people. Is no one accountable for that? Still, in light of any of this, the accusations have remained a shadow over many of these American scientists. It is a smudge on both their characters and their accomplishments. It all comes down to who you want to believe.

You the reader, are obviously interested in the subject, and have been able to follow the story, its players, and its many layers. From the fair representation of facts, documents cited, interview conversations shared, your final, inescapable opinion on this matter should come on its own, without any drive-thru rhetoric to guide you. As the end of this book approaches, arrive at your own opinion about a team of people whose accomplishments benefit us to this day, whose discoveries have come regardless of the many opposing forces creating a scandal like no other. And, who are continuing their efforts to this day in spite of, and sometimes because of, what they endured.

Of course then, we must peek into the motives, means, and opportunity of this story's key players to make the picture infinitely clearer. Before we do, consider these words asked by Dr. Chermann[319], "A crime always has a motive: what was it? I prefer to close this discussion by asking this question: who profited from the crime?"

The Institut Pasteur

Motive: 1) Money. They wanted (and got) as big a share as they could get of the royalties from the American blood test. In spite of saying they had for themselves, a better, more effective blood test, they never delivered on that promise. 2) Money again. Remember, for every penny the Institute makes on its own by selling product, the French Government would match it with grant money (and the sale of the American blood test, to which they became attached, falls under that umbrella as part of the settlement). 3) They also sought tangible, historical recognition of their contribution with respect to AIDS research.

Opportunity: 1) The issuance of patent rights to the American research team first, despite the fact the French could not grow their virus, or demonstrate a working blood test. 2) Releasing their virus to the Gallo team. 3) The many, many Crewdson articles and the many, many investigations by the OSI, the ORI, and Dingell's Congressional Sub-Committee claiming Gallo stole the French virus in order to make his own test. All of which never ended with a guilty verdict that withstood any and all scrutiny.

Means: 1) Legal action taken. 2) Public opinion bending, Governmental embarrassment created, through non-stop mobilization of the news agencies and the press.

The French Government

Motive: 1) A new, abundant source of national income. 2) Later, it became - to protect their own during the trials over the blood scandal. 3) Save face.

Opportunity: 1) Again, the issuance of patent rights to the American research team first, despite the fact the French could not grow their virus, or demonstrate a blood test. 2) Last Crewdson book discrediting the American blood test and its inventors/manufacturers. 3) Boosting the image of the French blood test.

Means: 1) Using Crewdson's book as an authoritative, defense tool.

The French Government Lawyers

Motive: 1) The money made from all the legal fees and compensation for achieving a favorable settlement not once, but twice.

Opportunity:1) The Franco-American dispute over allegations of the theft of a viral isolate. 2) The many, many Crewdson articles and the many, many investigations by the OSI, the ORI, and Dingell's Congressional Sub-Committee. 3) Their clients having given the Americans the LAV isolate; concealing a contamination by LAV-LAI. 4) Gag orders suppressing American Government scientists to properly defend themselves and rebuke the accusations.

Means: 1) Lawsuits resulting in settlements based on the limited knowledge of contaminant origin at the time.

United States Congressman John Dingell (and in particular, some of his staff)

Motive: 1) Power. 2) Prestige. 3) Reelection.

Opportunity: 1) The original Crewdson article.

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[319] The closing sentences from the Preface, French Edition of Gallo's book, Virus Hunting - AIDS, Cancer, & The Human Retrovirus – A Story Of Scientific Discovery, written by J.C. Chermann, August 13, 1991.

Means: 1) Using Congressional authority to secure name-making, news-worthy guilty verdicts.

Dr. Suzanne Hadley

Motive: 1) Making a name for herself. 2) Getting in good with a U.S. Congressman to be included under his umbrella of power. 3) Getting power from her association with same. 4) Restoring her name after unsuccessfully trying to bring about the downfall of other scientists[320].

Opportunity: 1) Assigned to the Gallo case without proper credentials to get her there. 2) Kept investigation going against Gallo, even when that was no longer her task. 3) Denying those she investigated due process and putting the burden of innocence on them.

Means: 1) Using her authority, power, and association with Congressman Dingell to secure name-making, news-worthy guilty verdicts.

Dr. Donald Francis

Motive: 1) Getting even for ridicule and being looked down upon. 2) Preoccupied with credit as evidenced by his own portrayal as consultant to the movie And The Band Played On, regarding supposed role in Ebola, other viral diseases, as well as HIV. 3) He was promised a Director's role in the newly planned retrovirus center, within the CDC, if he could convince his superiors of leadership ability.

Opportunity: 1) The HBO Movie which was filled with scientific and historical inaccuracies, which lifted his own self-image, while it simultaneously, and very publicly, squashed the reputations of others. 2) Court hearing which afforded him a forum to put his perception of scientific events (that he really never truly was a part of) into public record.

Means: 1) Being the movie's guiding voice allowed him to create very negative images of specific people and specific events. 2) Being an expert witness allowed him to again, create very negative images of specific people and specific events.

Journalist John Crewdson

Motive: 1) To explode a story that would grant him authority as the hero who uncovered a controversy. Which, with it, would bring him the following: 2) Power, 3) Prestige, 4) Money.

Opportunity: 1) Making the Franco-American dispute come alive in the first place. 2) Making alliances with both Dingell and the French.

Means: 1) Bending public opinion through negative reporting and innuendo alone.

Dr. Luc Montagnier

Motive: 1) Prestige. 2) Fame. As long as the Franco-American dispute continued, and escalated, his name kept rising from anonymity.

Opportunity: The Franco-American dispute. Since the French Government, along with the Institut Pasteur, used his discovery to achieve their ends, it only stands to reason that he would likewise be included to some measure of the reward.

Means: 1) Finding the HIV strain from patient BRU. 2) His lab being responsible for a contamination that Gallo was accused of. 3) His isolate making its way into HTLV-3B, which was ultimately used in the development of the American blood test. 4) Not really taking the steps to clear up the contamination issue until forced to by other studies – but by then, settlement agreements had already been reached.

Dr. Robert Gallo

Motive: 1) Prestige (which he already had with the HTLVs). 2) Fame. By stealing

[320] Kevles D.J., The Baltimore Case – A Trial of Politics, Sciences and Character, W.W. Norton & Co., 2000.

the French virus (despite having his own isolates).

Opportunity: 1) Had the French materials in his possession (even though the isolate in question was, and still, is a non-producer).

Means: 1) Deliberate misappropriation (which would have been found out in time – just as the French contamination was).

Sheer luck, the opportunity to begin this blight of a scandal, came in the form of an isolate named LAV-BRU. What Montagnier's group caught their first time out viral fishing, was that isolate. The right isolate. And we do acknowledge that[321]. But they were lucky in two ways. That virus could have been anything, it just happened to be the right one. And the work from another laboratory told them so. Secondly, they were also very lucky that patient -BRU was not doubly infected with HTLV-1 or -2. Some of Gallo's isolates were, and look what happened to him. Eventually, the -BRU culture was infected with –LAI virus, however nothing near as bad happened to French because of that; did it? Fact: Montagnier's second isolate was doubly infected. As Montagnier has said to Gallo, "Quirks of fate. If that happened to me first, I don't where I would have been." Certainly history would be different.

The patent issue is over now as is the money. The World Aids Foundation closed with a ceremonial banquet held at the Institut Pasteur just as the Second International AIDS Society Conference on HIV was to get underway (Monday, July 14, 2003) in Paris. The guests of honor at the banquet were both Gallo and Montagnier. With a half-cocked smile of amusement, shaking his head in disbelief, Gallo recounts on the foibles of time, especially now that the patent money has stopped for all: *"They (the French) were hugging me, lots of smiles, why now? Who knows. It was a love-in."* Even past Pasteur Director Raymond Dedonder, who was there, *"at the worst period of time for me before M. Schwartz became Director. Dedonder was quite rough with me. Though socially, always friendly. This time Dedonder came over to me; was laughing, was play boxing with me: this is a guy who was now smiling, put his arms out to me and said, "You will never change, but I love you for it." That was a change for the better and I have to admit I'm happier with that change."*

In fact, not only were the French friendly, but they also seeking partnerships in future business endeavors. Gallo explains: *"When NIH and Pasteur made the agreement, NIH gave to Pasteur access to some of our other patents on HIV which might be awarded in the future[322]; like the second generation blood test with recombinant proteins and nucleic acid probes, But they gave it to them with the condition that they could elect to pursue things with them (NIH) if they thought it was interesting."* At the Pasteur banquet Gallo was approached, *"Great Virus-Hunter, let us talk to you." They wanted help with records. And I said, "Sure." Isn't life full of ironies?"*

Isn't it though?

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[321] Gallo does too.

[322] To clarify, a company named Charon has been involved in a patent debate (dispute) over the 2nd generation blood test. Both NIH and the Pasteur have joined forces to fight Charon's claim.

33.
THE UNASKED QUESTION

Sometimes, in stories that are so complex, one forgets the basics. I, the author, fell into that trap myself. With intricacies unending, it was easy to get lured into the many layers this investigation revealed to me. There came a point when I lost sight of the original goal; which is what precipitated this original controversy? What was it before all those layers, before all the players lined up for a turn at history? You the reader, after so many pages, may likewise have forgotten it. Did Dr. Robert Gallo steal/misappropriate the French virus LAV-BRU? That's the core question right there. When you hunt for a motive, you ask many questions to see things from all sides. In police work, that approach is when logic brings focus. Especially when you list the facts that are known qualities of the item allegedly pilfered. What facts that were true in 1982 are still true today? This then resulted in asking the most important question of all; which has never before been asked. Not by the ORI, the OSI, the NIH, not the lawyers, not by Governments, reporters, movies, other books, news agencies, not even by Gallo himself. Not till now. Admittedly, it took me nearly two years to see it myself! So take a breath and think hard about this. History asks, was the French isolate, LAV-BRU (pure and uncontaminated) misappropriated? We finally then must ask the unasked…

Why would anybody steal a virus KNOWN to be IMPOSSIBLE to cultivate?

What could be done with it?

And while you ponder that, solve this too. If I write, "The French were first to find the cause of AIDS," what does that mean? Did they find the cause of AIDS? Sure they did; but by default. They isolated a suspect, undefined virus which happened to be the right one. Could they prove it was the cause of AIDS? No. They could not and did not.

If I write, "Gallo's lab was first to find the cause of AIDS," what does that mean? Did they find the cause of AIDS? They sure did. With scientific proof of the causation process. Were they first to isolate, even by default, the causative virus? No. They were not.

So who is right to stake claim? Well, there is simply no answer to that question, is there? It's rather a simple sentence but monumentally confusing too. Reporters had a field day dissecting that simple sentence. Each side claiming to be first, their supporters debate their views with conviction. But which is the right interpretation? It's almost like asking which came first; the chicken or the egg? As you decide for yourselves, can you remain objective enough to see the fury the two sides created by debating that claim? See how their interpretation was the only logical one grounded in truth? It is a debate that continues even to this day. Adding to the confusion is the fact that newspaper headlines are never long in

length. Examples: “French Find Cause of AIDS” vs. “NIH Scientists Discover Cause of AIDS.” Such a quarrel had never happened before in science and each side was fervidly entrenched. Because being recognized as the first seriously matters in science.

To that one sentence, there is no unanimous consensus in the scientific community as to what it actually means. So, who did discover the cause of AIDS?

34.
CONCLUSIONS

The biggest pin to pop Crewdson's work, happily, is from the least likely person of all. "As a living actor of AIDS research since the early days, I regret to say that this is not a book I would recommend for anyone interested in medical history[323]." That published statement comes from none other than Dr. Luc Montagnier himself; who continues in that same letter to cite the "many mistakes and fallacious statements" within Crewdson's book. Martin Delaney, reflecting on his long acquaintance with Luc Montagnier, had this to offer, *"He's (Montagnier) has had every opportunity to tell me what a monster Gallo is, and he never, he never saw the story the way Crewdson and company saw the story."*

It is unbelievable that Crewdson wants his readers to believe that Gallo, among the most gifted research minds in the last quarter of the 20th century, is a fake and a fraud, without a single significant achievement of his own. That is fiction, pure and simple. Fact: according to a Institute for Scientific Information report, "he (Gallo) is one of the three most influential biomedical scientist in the world for the past fifty years." So then, who on earth (literally) solved the AIDS problem? Are we to forget that Gallo was inducted into the National Inventor's Hall of Fame on February 11, 2004 for "identifying the cause and detection[324]" of AIDS and developing "a laboratory test to detect HIV?" But, then again, this is not Crewdson's concern at all. His only concern and, in fact, his goal in life, as expressed by two separate sources[325], is to "put an end to Gallo's and co-workers' activities…"

In particular, two separate, independent book reviews of Crewdson's work ended in words that caught my (the author's) attention. The first said, "A full, accurate, and fair accounting can only come from a writer who has nothing riding on the outcome, someone whose own reputation and judgment are not entwined with the story[326]." This book aspires to that goal. The other review ended with, "If the

[323] This comment published March 6, 2002, New York Times, as a part of a written response to a review of Science Fictions by John Horgan, New York Times Book Review, March 3, 2002, p. 9.
[324] Official Press Release. Incidentally, Montagnier was also inducted only for the distinction of "his 1983 discovery of" HIV.
[325] Who wish to remain anonymous. But the author, came into these personal letters from a third party source.
[326] Double Jeopardy For Gallo, by Martin Delaney, Science, May 31, 2002, vol. 296, p. 1616.

Gallo camp has a rebuttal, let's hear it[327]." I would clarify and answer that particular reviewer by saying; the Gallo camp does not have a rebuttal. The truth does!

In the final analysis, Gallo is not guilty of any of the fictional accusations brought by Crewdson, Dingell, or Hadley. He is guilty, however, of all together different charges. He is guilty of being fiercely competitive, highly emotional, unconventional, unpredictable, ambitious, and controversial. Yet, his accomplishments and discoveries are all real, all scientific fact, regardless of those traits. But are not those the traits of many first rate investigative scientists? And if medical research is to advance, the gifted, the non-conformists, and "the Mozarts (of science) must be allowed to flourish[328]," as Dr. Bernadine Healy has stated. Finally, Gallo is guilty of helping the French publish their first paper on AIDS and, of giving them the reagents they needed to pursue their work on AIDS, at the expense of his own peace of mind.

Gallo himself has this to add about the whole twenty year affair. *"If there is only one guilt, one shame, and one stupidity in the entire AIDS story, it's that in April 1984, when our blood test became available, neither me, neither the Secretary of Health, neither the Director of the NIH, neither the Director of the NCI, neither the Director of the CDC, neither the Director of the FDA, neither the press (including Crewdson), ever thought of hiring extra technicians in the lab to identify contaminated blood. But at the time, with all that was going on against me, I couldn't think straight."*

Meaning…in 1984, Gallo had an experimental lab version of the blood test that worked perfectly. And no one ever thought of using that test, in his lab, by extra technicians, to test at least the blood products regularly infused into hemophiliac patients and the many others who also received infected blood. Testing of highly suspicious blood could and should have been preformed instead of waiting until the Abbott test was commercialized later, in January 1985. Gallo notes that even though they couldn't handle thousands and thousands of samples, they could have done many hundreds – particularly from hemophiliacs who received pooled blood from thousands of human sources. But the laboratory version of the blood test was never FDA approved during that time; not until Abbott introduced a commercial version of the same. Still, why would it matter if it wasn't FDA approved, given that it had the capacity to save lives? People, as we all know, were dying. Despite that regret, in reality there would have been no hope to challenge the FDA rule that approval must come before commercialization. That is a regulatory requirement. Continuing, Gallo adds, *"Why didn't we think of this? Why did I, and my group, and others assume it was being done somewhere since we made the virus, cells, and test system available? Sure it would have been impossible for our lab to test everyone in the world, but we could have done something. Even if it was just the samples given to hemophiliacs."*

It is impossible to measure how many people are still alive with AIDS today, because of Dr. Gallo. And how many healthy people have remained AIDS free, again, because of accomplishments by the same man. The tally of that number is immeasurable, and grows daily, all over the entire world.

"As for Crewdson," Marshall Goldeberg writes[329] in a commentary, "there is a rule among medical educators that you can use any doctor in a teaching program, if only as a horrible example. I'd imagine that the same rule applies equally well to those that teach journalism."

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[327] Gallo Revisited, by Daniel S. Greenberg, New Scientist, April 6, 2002, vol. 174, p. 48.
[328] Healy Ready To Take On NIH, Nature, March 21, 1991, vol. 350 page 178.
[329] The Philadelphia Inquirer, Saturday, April 25, 1992, page A9.

According to Dr. Howard Streicher (Gallo's former Administrative Assistant): *"Gallo is unique. He sets his mind on overpowering objectives and then seeks instant results with unparalleled tenacity, speed, and creativity. He is not afraid to explore unconventional ideas, to swim upstream or to cut against the grain. He seeks and finds new paths to follow and new places to go where people have never gone before. Yet, some individuals find all these traits objectionable, simply because they are just plain envious. Others go even further. They want him destroyed, out of science, and even in jail for money, power, glory, revenge, or resentment. People have made reputations by keeping away from Gallo and by opposing and fighting him. Conversely, people have also made reputations by remaining close to Gallo and by keeping good working relationships with him.*

"The repeat cases against Gallo missed the point entirely. The point is that the world had a life-saving blood test thanks to Gallo and there was nothing fraudulent about it. Moreover, the case was also blown unnecessarily out of proportions, for it turned into a witch-hunt after an irrelevant target, verifying that there is still darkness in man and evil in the world."

Multiple interests were, in fact, aligned in this witch-hunt, passionately seeking to obliterate Gallo. These interests did not necessarily unite in a conspiracy, although suspect alliances were formed.

- The Pasteur Institute turned against him and indeed, Gallo was warned by the head of the Pasteur Institute that unless the French participate in the sharing of the royalties of the American AIDS blood test, there would be an ugly, legal dispute during which the patent holders would be badly hurt. And they were.
- Genetic Systems Inc., for money and their share of the international blood test market. Logically, since Genetic Systems Inc., was licensed by the French to produce and market their blood test in the U.S., by necessity it represented their interests. Thus, in June 1984, Genetic Systems VP, G. Todaro approached R. Gilden (of Program Resources, Inc.) about collaborating to show "Gallo has Montagnier's virus." This happened before any analytical comparative data became available on LAV-1 vs. HTLV-3B. Why? According to Gallo, Todaro had told him it was not in his best interest that the "arrogant U.S. Government" selected only 5 companies (to produce its blood test) and that he will have "many enemies" as a consequence. Moreover, on July 3, 1985 and again on July 17, 1985, Genetic Systems Inc. had its lawyer, Mr. Bert Rowland, approach the legal Department of DHHS to inform *"that there is conclusive evidence that the French are the first inventors of the subject invention (the AIDS blood test) and that an Interference should have been declared while the patent…was still pending."*
- The law firm and the public relations firm in New York, representing the French, in alliance with Dingell. Moreover, in a privileged communication to Gallo, Prof. Ashley Haase, University of Minnesota, with access to inside information, confided that *"the lawyers handling the French case over the patent dispute were unhappy because of inadequate compensation out of the American settlement; so they put together a plan to reopen the case with the help of Congressman Dingell."*
- Crewdson in alliance with Congressman Dingell and allegedly (likely) with the French too (he could have been hired by the lawyers in New York to support French interests). Regarding Crewdson's involvement with Congressman Dingell, David Hamilton, a Wall Street correspondent in Japan and former Science writer, disclosed to Gallo at a

luncheon meeting: *"Crewdson is in close co-operation with Congressman Dingell's office to nail you…(Crewdson) is getting sensitive information in advance on you, and is being given loaded questions to ask."* When asked how he knew this, Hamilton confessed he had worked on Dingell's staff prior to getting into science. In view of this disclosure and in view of Charrow's and Haase's statements above, is it not reasonable to ponder whether or not the original 52,000 word article by Crewdson was perhaps…prompted by Dingell?

- Congressman Dingell in alliance with the lawyers in New York (registered agents of the French Government and defenders of the Pasteur Institute interests) and in alliance with selected press correspondents, in violation of the Privacy Act. It is a fact that Congressman Dingell solicited the help of the New York lawyers to nail Gallo when members of the Office of Research Integrity (ORI), indirectly under him, visited these lawyers. It is also a fact that the New York lawyers representing the French were at the same time representing the General Motors Foundation whose President was Congressman Dingell's wife. It is Gallo's contention that the New York lawyers approached Congressman Dingell's wife and, through her, influenced her husband to help them build a case against him.
- The "Dingell staff investigators" lead by Peter Stockton in alliance with the lawyers in New York, representing the French, and of course with Congressman Dingell (continuation of employment was predicated upon convictions). They spared no dubious effort, no questionable method, no witness intimidation or threat tactic, countless due process violations, and no expense to the taxpayer to collect, even snatch and twist evidence from both domestic and foreign sources, just to nail Gallo. In the words of Dr. Bernadine Healy, the then Director of NIH: *"Dingell's staff behaved like absolute thugs, cursing, intimidating and threatening. They were scrappy, brutal and vicious."* Also, according to Dr. Brian Kimes, former Acting Director of OSI: *"Dingell's staff was totally unethical, leaking confidential information to journalists, just to hurt people still under investigation."*
- Dr. Suzanne Hadley (Gallo's chief prosecutor at the NIH's Office of Scientific Integrity) in alliance with Dingell and, through Dingell, with the French. According to Dr. Brian Kimes (Hadley's boss at OSI): *"Hadley knew only too well that Dingell and his staff were unethical, denying elemental protection of the accused, and going after the accused publicly. Therefore, she did not herself care about fairness, objectivity, due process, or confidentiality."* One should also keep in mind that other than being a Dingell mole, Hadley was not a bench scientist and understood no bench science at all. There also exists documented evidence that Hadley was working secretly with the New York lawyers, representing the French. In fact, *"she was being briefed directly, in writing, by the lawyers to help her with the case."* This explosively important information was relayed to the author in February 2002, and again in July 2003, by two distinctly separate, well placed sources at NIH, who, for the time being choose to remain anonymous.
- Don Francis with anyone for revenge. Those who gave him a forum were HBO for the anti-Gallo HBO movie, <u>And the Band Played On</u>, and the patent hearing against Gallo where he appeared as an expert witness for the prosecution. According to Kalyanaraman, *"Francis became resentful of Gallo, feeling that he was being always looked down on by him, and feeling that he was refused to be treated as an equal.*

Unable, in turn, to get anywhere with Gallo, he was driven to Montagnier's camp, expectedly increasing the friction of an already strained relationship." He was also in alliance with Genetic Systems and the French by supporting the French research effort, committing CDC resources for that cause, and collaborated with the French, the accusers, and the media in the case against Gallo.

Gallo adds: *"Of all the people in the whole damn thing, I think he, Francis, is the worst. I think Crewdson and Hadley are likely, simply ill. And Dingell and some on his staff are just what everybody knows them to be; rough and a bully. And the New York lawyers for the French Government, they were simply greedy. Without much concern as to who and how they hurt."*

After everything else, and the investigations were all done, Francis wrote to Gallo (letter not dated, but on DHHS letterhead); "Unfortunately I realize a number of my comments concerning the work leading to the discovery of HTLV-III/LAV, including those made while an employee of the Center for Disease Control, those to Randy Shilts for his book And The Band Played On, others at a recent meeting of Health and Hospital Administrators in Atlanta, those to Mr. Crewdson of the Chicago Tribune, and again more recently some to Mr. Blow of Regardie are incorrect and were made without full knowledge on my part…I wish to apologize for the tone of my remarks in the past. They have done you, your colleagues, and the international scientific collaboration against AIDS an unwarranted disservice."

- A few independent scientists, extremely resentful of Gallo. Like Dr. Abraham Karpas[330] who apparently was in collaboration with Crewdson to hurt Gallo; as he was a chief source of information quoted throughout the Crewdson's book. In fact, Crewdson himself states in his book (page 624), that Karpas is an "indefatigable critic of Gallo's research on HLTV-1 and AIDS," and that is Karpas's only claim to glory. So it is no wonder that Gallo reveals, *"Karpas would like to believe, and us to believe, that he himself discovers viruses. It is an honor to be slandered by a man of his character since he did that before to most of his compatriot virologists; especially those who are among the most well known and most respected."*

These alliances, although not necessarily all co-ordinated together, but simply working at the same time, for the same purpose (get Gallo), proved that lynching without cause is still practised in our day. But lynching or not, the scientific record will always stand as an obstacle unmovable, and will always speak for itself.

So, just how did Gallo ever survive all the repeated attacks seeking his demise? He was tough, smart, and sometimes volatile; bewildering his accusers because of his unpredictable nature. Standing with resilient tenacity and stamina, while enduring all they put him through. Most importantly, he had truth on his side; which held up every single time it was investigated (formally or informally). Plus, he had a lot of good people around him (co-workers, who kept things going for him in the lab, outside fellow scientists, and personal friends), all unquestionably supportive both in front -and behind- the scenes, who

[330] Gallo met Karpas twice in his life. Gallo was jokingly told by scientists in England, *"Thank God he is now after you."* When Gallo asked for an explanation he was told by the late leading Herpes virologist, Dr. Peter Wildie, that Karpas *"fanatically goes after leading virologists."* The list includes, Wildie, Tony Epstein (of Epstein Barr virus fame (which is the cause of infectious mononucleosis and some cancers), Robin Weiss (England's leading virologist), and William Jarett (the Scottish discoverer of the cat leukemia virus); just to mention some of the prominent few.

really helped him in his hours of need and stress. Most importantly, however, it was the character strength of Dr. Bernadine Healy, the NIH Director, who *"managed to keep my integrity and fairness in discharging my responsibilities,"* that saved Gallo from burning in the witch-hunters' fire.

Of course there are the lawyers who defended him battle after battle. *"If not for the lawyers (Bob Charrow and Joe Onek) we*[331] *would all be dead,"* admitted Gallo. But as Gallo puts it: *"I already won. I live, I have an Institute, I've made discoveries since then, I'm successful, and I know my work has helped human beings. I wonder what are the long lasting achievements of the two Johns, Dingell and Crewdson?"*

Dr. Bernadine Healy, former Director of NIH, adds: *"it is beyond belief that Dingell, Crewdson, and others, all after Gallo's head, were unable, worst yet, unwilling to focus on two realities. First, on the importance of the Gallo and Popovic work in saving lives, and secondly, on the negative impact to public health that a potential discontinuance of federal funds to them would have had."*

Now that, "all the sound and fury" is gone, Gallo must be recognized as an exceptional researcher who will appropriately take his deserved place in the history of science.

Remember…the future of medical research is rapidly coming to benefit us all. Spearheaded by remarkable scientists making remarkable discoveries. Don't wait for it; rather watch for it; and trust in its success…against any odds.

Here's to the fight then. That this, our blackest plague may one day be put away forever into the records of remembrance, its threat nothing more than a memory of the terrible blight which it created for so many all over our world.

Until then…

THANK YOU

[331] By "we," Gallo means, himself, his group, and those locked in Dingell's sights such as David Baltimore, Bernie Fischer, and all the other innocent victims.

APPENDIX 1
CITATION SUPERSTARS

CITATION SUPERSTARS

THE 100 MOST CITED SCIENTISTS DURING THE PERIOD 1981-1988

RANK	NAME	FIELD	CITATIONS
1	Gallo RC	Cell Biology/Virology	23,232
2	Schlossman SF	Immunology	15,528
3	Vale WW	Neuroendocrinology	14,027
4	Hood LE	Molecular Biology	12,708
5	Messing J	Molecular Biology	12,438
6	Nishizuka Y	Cell Biology	11,513
7	Rivier J	Endocrinology	11,297
8	Fauci AS	Immunology	10,617
9	Reinherz EL	Immunology	10,603
10	Bloom SR	Gastroenterology	10,450
11	Berridge MJ	Cell Biology/Biochem.	10,146
12	Irvine RF	Cell Biology/Biochem.	9,527
13	Bishop JM*	Virology	9,011
14	Brown MS*	Biochemistry	8,886
15	Chambon P	Molecular Biology	8,744
16	Weber K	Biochemistry	8,630
17	Franke WW	Cell Biology	8,363
18	Witten E	Theoretical Physics	8,098
19	Seeburg PH	Neurobiology	8,017
20	Strominger JL	Virology	8,009
21	Thomas ED	Oncology	7,875
22	Hokfelt T	Neuropharmacology	7,819
23	Wong-Staal F	Virology	7,772
24	Dinarello CA	Immunology	7,742
25	Sarngadharan MG	Virology	7,656
26	Snyder SH	Pharmacology	7,594
27	Baltimore D*	Virology	7,574
28	Polak JM	Histology	7,488
29	Leder P	Molecular Biology	7,366
30	Goldstein JL*	Genetics	7,025
31	Lefkowitz RJ	Pharmacology	6,993
32	Lundberg JM	Physiology	6,959
33	Weinberg RA	Molecular Biology	6,920
34	Gossard AC	Physics	6,892
35	Pastan IH	Biochemistry	6,858
36	Waldmann TA	Immunology	6,799
37	Maniatis T	Molecular Biology	6,758
38	Kappler JW	Immunology	6,608
39	Ling N	Biochemistry	6,599
40	Austen KF	Immunology	6,536
41	Marrack P	Immunology	6,462
42	Hunter T	Molecular Biology	6,377
43	Storb R	Immunology	6,307
44	Vieira J	Molecular Biology	6,301
45	Collen D	Hematology	6,277
46	Popovic M	Virology/Cell Biol.	6,166
47	Ruoslahti E	Molecular Biology	6,127
48	Varmus HE*	Virology	6,124
49	Herberman RB	Oncology	6,039
50	Sharp PA	Molecular Biology	5,943
51	Aaronson SA	Oncology	5,876
52	Goeddel DV	Neuroscience	5,854
53	Genest J	Biochemistry	5,831
54	Tsien RY	Physiology	5,785
55	Evans RM	Molecular Biology	5,761
56	Sporn MB	Biochemistry/Oncology	5,752
57	Gilman AG	Pharmacology	5,735
58	Paul WE	Immunology	5,678
59	Cuatrecasas P	Biochemistry	5,593
60	Tonegawa S*	Immunology	5,540
61	Croce CM	Genetics	5,513
62	Cantin M	Medicine	5,429
63	Crystal RG	Biochem./Internal Med.	5,377
64	Springer TA	Cell Biology	5,348
65	Smith KA	Microbiology	5,317
66	Cohen P	Biochemistry	5,262
67	Martin GR	Pharmacology	5,237
68	Kaufman L	Medical Mycology	5,234
69	Fiers W	Molecular Biology	5,226
70	Daly JW	Pharmacology	5,223
71	Rich A	Molecular Biology	5,214
72	Greene WC	Oncology	5,206
73	Corey EJ	Organic Chemistry	5,189
74	Hsu S-M	Pathology/Mol. Biol.	5,183
75	Morley JE	Endocrinology	5,165
76	Verma IM	Molecular Biology	5,155
77	Gillis S	Immunology	5,144
78	Greengard P	Cell Biology	5,071
79	Scolnick EM	Virology	5,054
80	Janossy G	Hematology	5,014
81	Wüthrich K	Molecular Biology	5,003
82	Rosenberg SA	Surgery/Oncology	5,000+ (est
83	Timpl R	Biochemistry/Immunol.	4,971
84	Swanson LW	Neuroendocrinology	4,921
85	Ellis J	Physics	4,896
86	Tjian R	Molecular Biology	4,873
87	Masur H	Medicine	4,870
88	Koprowski H	Microbiology	4,868
89	Robb RJ	Molecular Immunology	4,749
90	Rutter WJ	Molecular Biology	4,711
91	Kahn CR	Endocrinology	4,699
92	Doolittle RF	Biochemistry	4,676
93	Unanue ER	Immunology	4,673
94	Nanopoulos DV	Physics	4,638
95	Spiess J	Biochemistry	4,633
96	Nadler LM	Tumor Immunology	4,609
97	Gale RP	Oncology/Hematology	4,609
98	Laragh JH	Cardiology	4,601
99	Klein J	Genetics	4,592
100	Edelman GM*	Immunology	4,566

This list of the 100 most cited scientists is based on citations throughout 1981-88 to papers written during that same period. The counts are taken from the Philadelphia-based Institute for Scientific Information's *Science Citation Index*. An asterisk indicates a Nobel Prize winner.

The preponderance of life scientists listed as opposed to those in the physical sciences is in part a reflection of the number of researchers working in the different areas. There are considerably more publishing investigators in the life sciences than in physics, chemistry, geology, and so forth. As a result, high-impact papers in the life sciences generally have a higher citation rate than their counterparts in the physical sciences. Combined with higher productivity, this leads to more "citation superstars." *The Scientist* will continue its list of 1981-88's most cited researchers in future issues.

** According to The Scientist's estimate, the papers of Steven A. Rosenberg, chief of surgery at the National Cancer Institute, have accumulated at least 5,000 citations during the period 1981-88. A precise figure is unobtainable because citations to the papers of Saul A. Rosenberg, a Stanford University oncologist, are intertwined with those of Steven A. Rosenberg in the data examined by *The Scientist*.

APPENDIX 2
HIV DETECTIONS

History of HIV-I Detection and Isolation at Laboratory of Tumor Cell Biology, NCI 1982

May	August	October	December
• 3 New AIDS Samples in Culture	• 1 New AIDS Sample in Culture	• 5 New AIDS Samples in Culture	• 2 Cultured Samples Found to Be Low RT+ HTLV-I p19 and p24 Negative
• 2/33 AIDS DNA Samples Found to Be + for HTLV-I	• Med. World News. Gallo Predicts a Retrovirus as the Cause of AIDS		

History of HIV-I Detection and Isolation at Laboratory of Tumor Cell Biology, NCI 1983

February

- 23 New AIDS Samples in Culture
- 2 Cultured Samples Found to Be Low RT + and HTLV-I p19 and p24 Negative
- CC in Culture

April

- 3 New AIDS Samples in Culture

May

- 11 New AIDS Samples in Culture
- Aberrant Virus Particles Seen in EM of CC

June

- 19 New AIDS Samples in Culture
- 3 Samples RT + and HTLV-I p19 and p24 Negative

July

- 11 New AIDS Samples in Culture
- 3 Samples RT + and HTLV-I p19 and p24 Negative
- First LAV Sample Received and Used to Infect Fresh PBL

August

- 9 New AIDS Samples in Culture
- 2 Samples RT + and HTLV-I p19 and p24 Negative

September

- 29 New AIDS Samples in Culture
- 5 Samples RT + and HTLV-I p19 and p24 Negative
- LAV Sample (MKT and JBB) Received (9/22)
- SN in Culture (9/15)
- Cold Spring Harbor Meeting

October

- 19 New AIDS Samples in Culture
- 4 Samples RT + and HTLV-I p19 and p24 Negative
- LAV in Culture (Hut 78 and Ti 74)

November

- 6 New AIDS Samples in Culture
- RF in Culture (11/15)
- IIIB, RF and LAV in Cell Lines
- Cloning of H4/H9 from HT (Hut 78)
- WT, LS, BK and MOV in Culture (11/15)

December

- 21 New AIDS Samples in Culture
- MOV Inoculated in Rabbits

History of HIV-I Detection and Isolation at Laboratory of Tumor Cell Biology, NCI 1984

January

- 23 New AIDS Samples in Culture
- LAV Culture Terminated (1/15)
- JS in Culture
- EM of RF

February

- 39 New AIDS Samples in Culture
- 12 Samples RT + and HTLV-I p19 and p24 Negative
- MN in Culture
- MOV Rabbit Antisera Used for IFA (2/24)
- LAV(JBB) in Culture. Did Not Grow and Terminated

March

- 8 New AIDS Samples in Culture
- 4 Samples RT + and HTLV-I p19 and p24 Negative
- RF, EM +
- Meeting with Jim Curran at La Miche

April

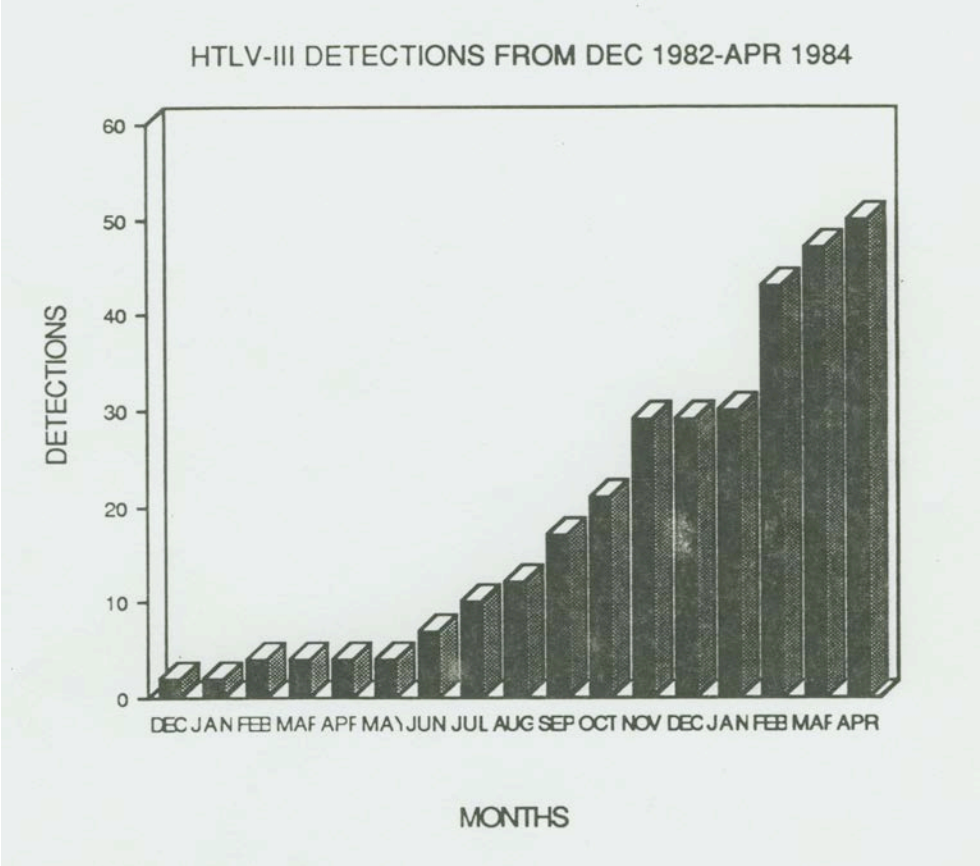
- 3 New AIDS Samples in Culture
- 3 Samples RT + and HTLV-I p19 and p24 Negative
- Gallo Lecture at Pasteur Institute
- IIIB Production at FCRF, NCI
- Blood Test Patent Filed (4/23)
- Secy. Heckler's Press Conference

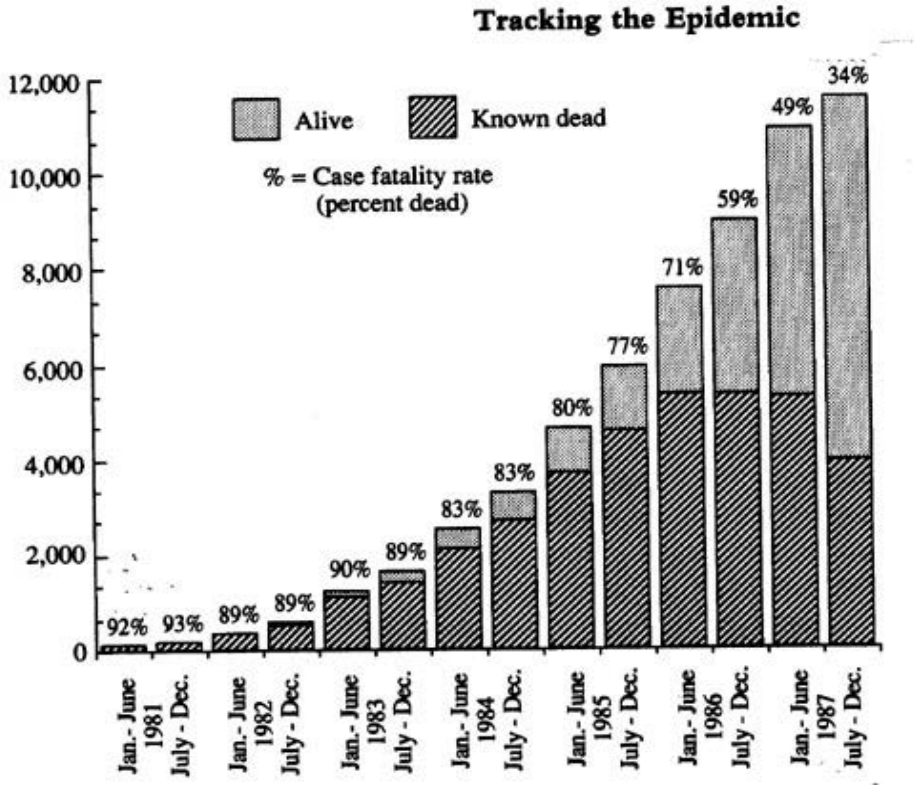
May

- IIIB Culture Taken to Montagnier by Sarngadharan
- Montagnier Tells Sarngadharan That There is No gp41 in LAV
- 4 Papers on HIV-I (IIIB) Published in Science

June

- At Denver, Colorado Meeting, Gallo and Montagnier Announce That IIIB and LAV are the Same


HTLV-III DETECTIONS FROM DEC 1982-APR 1984
DETECTIONS
60
50
40
30
20
10
0
DEC JAN FEB MAF APF MAY JUN JUL AUG SEP OCT NOV DEC JAN FEB MAF APR
MONTHS

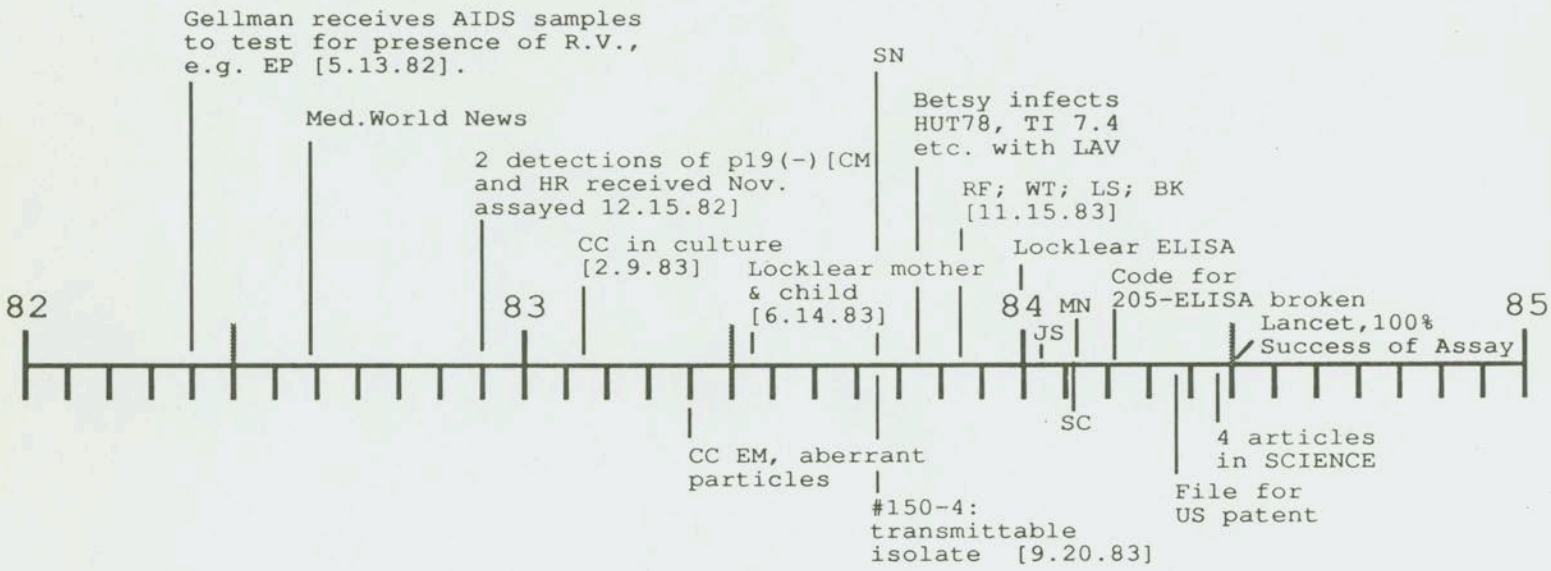

Tracking the Epidemic
Alive
Known dead
% = Case fatality rate
(percent dead)
12,000
10,000
8,000
6,000
4,000
2,000
0
92%
93%
89%
89%
90%
89%
83%
83%
80%
77%
71%
59%
49%
34%
Jan.- June 1981
July - Dec.
Jan.- June 1982
July - Dec.
Jan.- June 1983
July - Dec.
Jan.- June 1984
July - Dec.
Jan.- June 1985
July - Dec.
Jan.- June 1986
July - Dec.
Jan.- June 1987
July - Dec.

APPENDIX 3

CHARTING EVENTS LEADING TO GALLO & FRENCH PATENT APPLICATIONS

Key Events Towards Gallo Patent

(not including HTLV-IIIB or MOV)*.



Gallo Patent : 10 claims, all concered with a method.

The antigen is <u>not</u> claimed.

Preferred embodiment is ELISA using H9 derived antigen as a reliable constant source.

HTLV-III is not to be equated with HTLV-IIIB, the latter is just a specific case of the former generic term.

By the time the patent is filed, more than 5 separate, independently cultured isolates exist (besides HTLV-IIIB or MOV). These are all suitable as antigen in the claimed assay (all were found IFA + with either Bru or ET serum).

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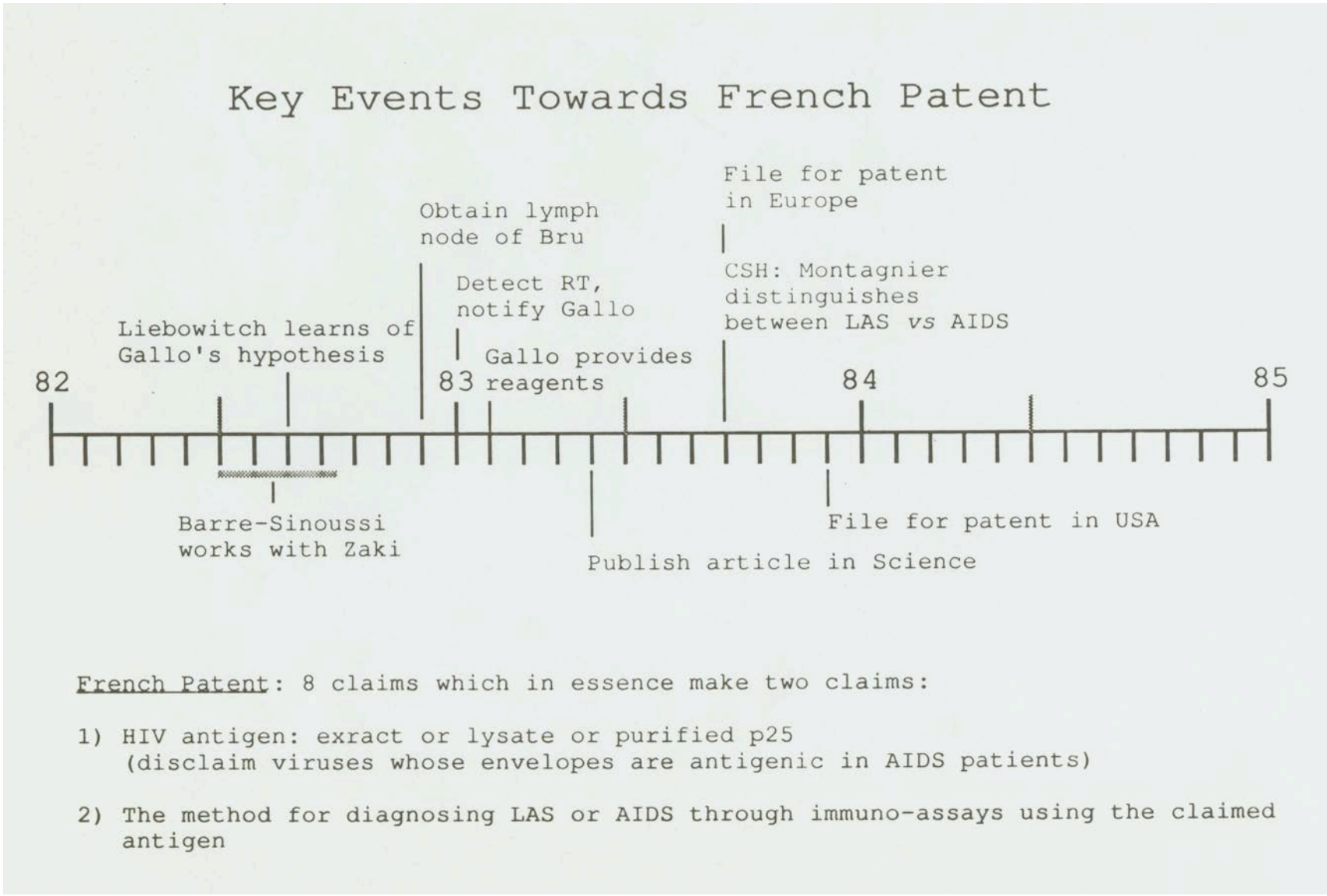
* is not a complete list of data or detections


Key Events Towards French Patent
File for patent in Europe
Obtain lymph node of Bru
CSH: Montagnier distinguishes between LAS vs AIDS
Detect RT, notify Gallo
Liebowitch learns of Gallo's hypothesis
Gallo provides reagents
82
83
84
85
Barre-Sinoussi works with Zaki
File for patent in USA
Publish article in Science
French Patent: 8 claims which in essence make two claims:
1) HIV antigen: exract or lysate or purified p25
(disclaim viruses whose envelopes are antigenic in AIDS patients)
2) The method for diagnosing LAS or AIDS through immuno-assays using the claimed antigen

APPENDIX 4

NATURE ARTICLE

Vol. 326, April 2, 1987

NATURE VOL. 326 2 APRIL 1987 COMMENTARY 435

The chronology of AIDS research

This statement from Gallo amd Montagnier constitutes part of the agreement between the US and French AIDS research groups.

We set out a brief chronological history of some critical published facts, in the period up to May 1985, on the discovery and demonstration of AIDS as a retroviral disease.

Retroviruses

1970–73. Following Temin's hypothesis that RNA tumour viruses replicate via a provirus DNA intermediate, Temin and Mitzutani (1970)[1], and independently Baltimore (1970)[2], discover reverse transcriptase. Later, the existence and integration of infectious proviral DNA is demonstrated by Hill and Hillova (1971)[3] and confirmed by Montagnier and Vigier (1972)[4], Svoboda and co-workers (1973)[5], and others. Spiegelman (1970)[6], Gallo (1971, 1972)[7,8], Gerwin *et al.* (1972)[9] and others independently develop useful sensitive specific assays for reverse transcriptase of retroviruses.

1976. Morgan, Ruscetti and Gallo (1976)[10] discover T-cell growth factor, or interleukin-2 (IL-2), necessary for long-term *in vitro* cultivation of human T cells.

1979. Barre-Sinoussi, Montagnier, Lidereau, Sisman, Wood and Chermann (1979)[11] show that antibody against alpha interferon allows significant increase in mouse retrovirus production by infected cells.

Human retroviruses

1980–82. Gallo, Poiesz and co-workers (1980) isolate[12] and (1981) characterize[13] the first human retrovirus, called human T-cell leukaemia virus type I (HTLV-I). Hinuma *et al.* (1981)[14] identify C-type virus in a cell line isolated by Miyoshi from a patient with adult T-cell leukaemia (ATL) and detect antibodies against antigen-bearing cells in patients with ATL. Yoshida and co-workers (1982)[15] isolate and characterize adult T-cell leukaemia virus (ATLV) and demonstrate clonal integration of ATLV proviral DNA in leukaemic cells of patients. In a cooperative study, Gallo and co-workers together with Miyoshi and co-workers (1982)[16] show ATLV to be identicial with HTLV-I. In collaborative studies, Catovsky, Blattner, Gallo and co-workers (1982)[17,18] show HTLV-I to be a contributing actiological factor in T-cell leukaemia in the Caribbean region. Gallo and co-workers (1982)[19] isolate a second type of retrovirus, HTLV-II, from a cell line obtained from a patient with hairy-cell leukaemia.

AIDS

1981. Gottlieb and co-workers (1982)[20], Friedman-Kien and co-workers (1981)[21], Siegel and co-workers (1981)[22], Masur and co-workers (1981)[23] and Mildvan and co-workers (1982)[24] independently diagnose a new disease, AIDS, in groups of young homosexual men.

1982. Epidemiological evidence suggesting that AIDS is a new infectious disease is developed by the Centers for Disease Control (1982)[25].

February 1983. At the Cold Spring Harbor Workshop on AIDS, Gallo proposes that AIDS is probably caused by a retrovirus, presumably a variant of HTLV-I or II.

May 1983. Barre-Sinoussi, Chermann, Montagnier and co-workers (1983)[26] publish: (1) the isolation and identification of a non-transforming retrovirus (later called lymphadenopathy-associated virus (LAV)), different from HTLV-I and HTLV-II, in cultures of T lymphocytes derived from a patient with lymphadenopathy syndrome; (2) the continuous passage of the virus by its transient growth in cultures of T lymphocytes of normal blood donors; (3) the identification of a major protein associated with this virus, p25, not immunologically cross-reactive with the p24 of HTLV-I; and (4) the detection by immunoprecipitation of antibodies against this protein in two patients.

Essex and co-workers (1983)[27] detect antibodies cross-reactive with HTLV-I membrane protein in 25–30% of AIDS patients.

Gelman and co-workers (Gallo's group) (1983)[28] find evidence for presence of the viral genome of HTLV-I or an HTLV-I variant in 2 of 33 AIDS patients.

September 1983. At the Cold Spring Harbor meeting on human T-cell leukaemia–lymphoma viruses:

Montagnier and co-workers (1984)[29] report: (1) the identification of LAV-like viruses from 5 patients with lymphadenopathy and 3 patients with AIDS (homosexual, haemophiliac, Haitian); (2) the selective affinity of LAV for CD4 (T4) helper lymphocytes; (3) the presence of antibodies (enzyme-linked immunosorbent assay, ELISA) against the main LAV antigens in patients with lymphadenopathy-associated syndrome (LAS) (63%) and AIDS (20%); (4) that LAV is morphologically similar to equine infectious anaemia virus (EIAV) and different from HTLVs; and (5) the antigenic cross-reactivity between core proteins of EIAV and LAV (virus isolates from LAS patients are called LAV, and from AIDS patients are called IDAV).

Gallo and co-workers (1984)[30] report the presence of HTLV-I antibodies in 10% of AIDS patients and isolates of HTLV-I or HTLV-II or variants of it in fewer than 10% of such cases.

March–April 1984. Montagnier *et al.* (1984)[31] by using more sera of horses infected with EIAV confirm cross-reactivity of the core proteins of LAV with that of EIAV and identify a second viral protein, p18. Vilmer, Chermann, Montagnier and co-workers (1984)[32] confirm previous isolation of an LAV-like virus from one haemophiliac and isolate another one

This history is by no means exhaustive. It outlines the main contributions of the two central parties and of some other groups to the determination of the causative agent of AIDS (acquired immune deficiency syndrome). This is not to diminish the important contribution made in this field (either independently or in collaboration with us) by other laboratories and clinicians distributed worldwide.

Both sides wish it to be known that from the beginning there has been a spirit of scientific cooperation and a free exchange of ideas, biological materials and personnel between Dr Gallo's and Dr Montagnier's laboratories. This spirit has never ceased despite the legal problems and will be the basis of a renewed mutual cooperation in the future.

The parties also believe that some clarification is needed regarding their position on nomenclature. Various generic names have been given to the AIDS virus. Dr Gallo and his collaborations named it HTLV-III in their May 1984 publications according to a recommendation made in September 1983 at the Cold Spring Harbor meeting on HTLVs by a group of ten European, Japanese and American retrovirologists. They suggested that names of human retroviruses discovered in the future related to but distinct from human T-leukaemia virus be named sequentially, numbered HTLV-III, IV, and so on.

Dr Montagnier and his collaborations first reported in May 1983 the identification of a novel human retrovirus not closely related to HTLV-I and II and in public meetings from September 1983 and subsequently in publications from 1984, they named this virus LAV for lymphadenopathy-associated virus because the first patient from which it was isolated had lymphadenopathy syndrome.

The US Department of Health and Human Services officially assumed a double generic name HTLV-III/LAV in recognition of the contributions of both sides.

When the genome structure of the AIDS virus was determined in 1985, the results showed some major differences in the organization of the genetic information from HTLV-I and II. This prompted another and more formal nomenclature committee to suggest a simpler and new generic name as the virus belonged to an entirely new class of human retroviruses. Their suggestion was to use the generic term HIV — human immunodeficiency virus. They also suggested maintaining specific strain names ($LAV\text{-}I_{BRU}$, $LAV\text{-}I_{LAI}$, $HTLV\text{-}III_{B}$ $HTLV\text{-}III_{RF}$, ARV1...) in the interest of continuity and appreciation of the biological differences of the strains. Both groups agree with this recommendation.

from his asymptomatic brother.

May 1984. Gallo's group (1984)[33,36] reports: (1) mass and continuous production in a clone of a permanent cell line (H9) of HTLV-III from two AIDS patients and four additional isolates (SN, BK, CS, WT) also infectious for another clone (H4) derived from the same parental cell line (Popovic, Sarngadharan, Gallo and co-workers[33]).

(2) 48 virus isolations, that is, 18 of 21 patients with pre-AIDS, 3 of 4 clinically normal mothers of juveniles with AIDS, 26 of 72 juveniles and adults with AIDS, 1 of 22 healthy male homosexuals, and 0 of 115 heterosexual subjects (Gallo, Salahuddin, Popovic and colleagues[34]). The use of anti-p24 hyperimmune sera proves that the 48 isolates belong to the same kind of virus;

(3) The introduction of the Western blot technique for clinical detection of antibodies in 88% of 48 patients with AIDS, 79% of 14 homosexuals with pre-AIDS and less than 1% of hundreds of heterosexuals. A gp41 is identified as a major viral antigen (Sarngadharan, Popovic, Gallo and co-workers[35]). Later, it is demonstrated by Veronese, Sarngadharan and Gallo to be the HTLV-III viral transmembrane component of the envelope[63].

(4) Partial characterization of the immunologically reactive proteins by the Western blot technique. (Schupbach, Sarngadharan, Popovic, Gallo and co-workers[36]).

June 1984. Safai, Gallo, Popovic and Sarngadharan report 34 of 34 (100%) of AIDS patients positive for HTLV-III antibodies, 16 of 19 (84%)of LAS patients and 0 of 14 (0%) of controls (1984)[37]

Brun-Vezinet, Barre-Sinoussi, Montagnier, Chermann and co-workers (1984)[38] publish detection of antibodies against LAV proteins by ELISA in 74.5% of the patients presenting with lymphadenopathy syndrome, 37.5% of patients with frank AIDS, 18% of healthy homosexuals, 1% of blood donors.

July 1984. Kalyanaraman, Montagnier, Francis and co-workers (1984)[40] report the detection of anti-p25 (LAV) antibodies in 51 of 125 (41%) of AIDS patients, 81 of 113 (72%) of LAS patients, and 0 of 70 of healthy individuals; Montagnier and co-workers (1984)[41] report the growth of LAV in continuous B-cell lines, most of them transformed by Epstein–Barr virus.

Klatzmann, Gluckman, Chermann, Montagnier and co-workers (1984)[42] publish: (1) the selective isolation of LAV from $CD4^+$ ($T4^+$) lymphocytes of a healthy carrier of the virus; (2) the inhibition of CD4 cell growth at the same time of *in vitro* virus production; (3) the simultaneous disappearance of the CD4 antigen at the surface of the infected CD4 lymphocytes.

August 1984. A third group, Levy *et al.*, (1984)[43] isolate virus antigenically and structurally related to LAV from San Francisco AIDS patients.

September 1984. Cheinsong-Popov, Weiss and collaborators publish identical prevalence of antibodies against antigens of HTLV-III grown in H9 line and of LAV-1 grown in CEM line in UK patients with AIDS or at risk of AIDS (1984)[44].

Goedert, Gallo and co-workers (1984)[45] report that in a cohort of homosexual men at risk of AIDS, 53% were antibody-positive for HTLV-III. In HTLV-III antibody positive subjects, AIDS developed at 6.9% per year.

October 1984. Brun-Vezinet, Montagnier, Piot, Quinn and co-workers (1984)[46] publish the presence of antibody against LAV in 35 of 37 Zaïrean patients with AIDS.

Zagury, Gallo and co-workers (1984)[47] isolate HTLV-III from cells cultured from semen of two patients with AIDS.

November 1984. Hahn, Gallo and co-workers (1984)[48] report the molecular cloning of HTLV-III virus.

Kitchen, Allan, Essex and co-workers (1984)[49], (1985)[50] identify the viral external glycoprotein gp120, a finding confirmed by Montagnier and co-workers (1985)[51].

December 1984. Alizon, Barre-Sinoussi, Wain-Hobson, Montagnier and co-workers (1984)[52] report the molecular cloning of LAV-1.

Wong-Staal, Shaw, Gallo and co-workers (1984)[53] discover genomic heterogeneity of HTLV-III.

Dagleish, Weiss and co-workers (1984)[54] and independently Klatzmann, Gluckman, Montagnier and co-workers (1984)[55] show the CD4 molecule is involved in the receptor to the virus.

Popovic, Read-Connole and Gallo (1984)[56] publish a series of CD4-positive human neoplastic cell lines susceptible to and permissive for HTLV-III, including HUT78, Molt3 and CEM cell lines.

January 1985. The nucleotide sequence of the AIDS virus genome is established independently at the Pasteur Institute (1985)[57], at the NCI/NIH (1985)[58], at Genentech, Inc. (1985)[59] and at Chiron (1985)[60], revealing the similarity of the various isolates.

Sodroski, Wong-Staal, Gallo, Haseltine and co-workers (1985)[61] demonstrate transactivation of transcription in HTLV-III infected cells.

Shaw, Gallo and co-workers (1985)[62] discover the presence of virus in the brain.

March 1985. Redfield, Gallo and co-workers (1985)[64] describe heterosexual transmission of HTLV-III. □

We wish to acknowledge with gratitude the generous help of many of our colleagues in the preparation of this history. We cannot individually thank them all here, but would like to offer special thanks to Dr Jonas Salk for his help and guidance in completing this project.

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APPENDIX 5

CHICAGO TRIBUNE

January 19, 1995

Chicago Tribune
January 19, 1995

No conspiracy in HIV controversy

CLEVELAND—In his final spasm as outgoing chairman of the Energy and Commerce Committee, Rep. John Dingell (D-Mich.) heaved another package of fabrications and distortions. These latest accusations arrived in an allegedly unauthorized, "leaked," secret draft report on a three-year investigation of a controversy surrounding the 1984 discovery of the AIDS virus (HIV) reported by the Tribune Jan. 1.

One hopes this marks the end of Dingell's deluded notions of a multi-administration conspiracy to protect Dr. Robert Gallo, one of the discoverers of HIV who also developed the blood test for HIV. At enormous taxpayer expense, Dingell has pursued Gallo and attacked anyone who has refused to join in his crusade.

The former chairman first accused me, as then-director of the National Institutes of Health, of "replacing" an employee of the NIH's Office of Scientific Integrity (OSI) who wrote a report that was "sharply critical of Dr. Gallo."

This employee was never replaced. On the contrary, before I arrived at the NIH, she requested and was given a new job in an unrelated department. She was also given leave at that time to complete her work on the Gallo case. I did ask her to revise the amateurish and poorly written report for style and structure, but when she complained that revision would change the meaning, I withdrew my request immediately. I subsequently accepted the employee's report which ironically, though critical of some of his actions, had always exonerated Dr. Gallo of misconduct.

Second, the former chairman contends that I "bypassed" the "conclusions" of an advisory committee in accepting the OSI report that exonerated Dr. Gallo. In fact, I was presented with several non-binding recommendations of advisory groups, all of which advised acceptance of the report except one. The one contrary recommendation came from a committee that refused to consider evidence or testimony from the accused.

I easily could have ignored all other findings in favor of the advice from the one flawed advisory committee. Instead, I made an independent judgment that, after careful review, seemed to me to be correct.

My unwillingness to be a pawn in the former chairman's smear campaign prompted further false accusations. An example is the third charge in his report, his invention of a conversation in which I told him that I felt I had to "save Bob [Gallo]." I never made such a preposterous statement.

As the head of an agency that was a frequent target of Dingell's witch-hunts, I saw first-hand the abuse of power by a long-time committee chairman and his staff acting as secret police, prosecutor, judge and jury under the old House rules. Americans would be shocked to learn of the clandestine tape recordings, document theft, threats, foul-mouthed verbal rantings and abusive closed-chamber interrogations of the former chairman and his staff of over 100.

Immune from the Freedom of Information Act and the laws against libel and slander, Dingell and his staff operated in virtual secrecy, withholding any documents that displayed its methods of operation or contradicted its fabricated story line. This gave them *carte blanche* to make reckless and unsupported statements about people or institutions.

Let the actions of Dingell and his bloated staff be a memorial to what went wrong with Congress after 40 years of single-party rule.

Bernadine Healy
Staff, Cleveland Clinic Foundation
Former director, National Institutes of Health

APPENDIX 6

FROM THE WHITE HOUSE:
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
DECEMBER 6, 2000

FEDERAL POLICY ON RESEARCH MISCONDUCT[332[1]]

I. Research[333[2]] Misconduct Defined

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- *Fabrication* is making up data or results and recording or reporting them.
- *Falsification* is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.[3]
- *Plagiarism* is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.

II. Findings of Research Misconduct

A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community; and
- The misconduct be committed intentionally, or knowingly, or recklessly; and
- The allegation be proven by a preponderance of evidence.

III. Responsibilities of Federal Agencies and Research Institutions[4]

Agencies and research institutions are partners who share responsibility for the research process. Federal agencies have ultimate oversight authority for Federally funded research, but research institutions bear primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution.

- Agency Policies and Procedures. Agency policies and procedures with regard to intramural as well as extramural programs must conform to the policy described in this document.
- Agency Referral to Research Institution. In most cases, agencies will rely on the researcher's home institution to make the initial response to allegations of research misconduct. Agencies will usually refer allegations of research misconduct made directly to them to the appropriate research institution. However, at any time, the Federal agency may proceed with its own inquiry or investigation. Circumstances in which agencies may elect not to defer to the research institution include, but are not limited to, the following: the agency determines the institution is not prepared to handle the allegation in a manner consistent with this policy; agency involvement is needed to protect the public interest, including public health and safety; the allegation involves an entity of sufficiently small size (or an individual) that it cannot reasonably conduct the investigation itself.
- Multiple Phases of the Response to an Allegation of Research Misconduct. A response to an allegation of research misconduct will usually consist of several phases, including: (1) an inquiry – the

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[332[1]] No rights, privileges, benefits or obligations are created or abridged by issuance of this policy alone. The creation or abridgment of rights, privileges, benefits or obligations, if any, shall occur only upon implementation of this policy by the Federal agencies.

[333[2]] Research, as used herein, includes all basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals.

[3] The research record is the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

[4] The term "research institutions" is defined to include all organizations using Federal funds for research, including, for example, colleges and universities, intramural Federal research laboratories, Federally funded research and development centers, national user facilities, industrial laboratories, or other research institutes. Independent researchers and small research institutions are covered by this policy.

assessment of whether the allegation has substance and if an investigation is warranted; (2) an investigation – the formal development of a factual record, and the examination of that record leading to dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate remedies; (3) adjudication – during which recommendations are reviewed and appropriate corrective actions determined.

- Agency Follow-up to Institutional Action. After reviewing the record of the investigation, the institution's recommendations to the institution's adjudicating official, and any corrective actions taken by the research institution, the agency will take additional oversight or investigative steps if necessary. Upon completion of its review, the agency will take appropriate administrative action in accordance with applicable laws, regulations, or policies. When the agency has made a final determination, it will notify the subject of the allegation of the outcome and inform the institution regarding its disposition of the case. The agency finding of research misconduct and agency administrative actions can be appealed pursuant to the agency's applicable procedures.
- Separation of Phases. Adjudication is separated organizationally from inquiry and investigation. Likewise, appeals are separated organizationally from inquiry and investigation.
- Institutional Notification of the Agency. Research institutions will notify the funding agency (or agencies in some cases) of an allegation of research misconduct if (1) the allegation involves Federally funded research (or an application for Federal funding) and meets the Federal definition of research misconduct given above, and (2) if the institution's inquiry into the allegation determines there is sufficient evidence to proceed to an investigation. When an investigation is complete, the research institution will forward to the agency a copy of the evidentiary record, the investigative report, recommendations made to the institution's adjudicating official, and the subject's written response to the recommendations (if any). When a research institution completes the adjudication phase, it will forward the adjudicating official's decision and notify the agency of any corrective actions taken or planned.
- Other Reasons to Notify the Agency. At any time during an inquiry or investigation, the institution will immediately notify the Federal agency if public health or safety is at risk; if agency resources or interests are threatened; if research activities should be suspended; if there is reasonable indication of possible violations of civil or criminal law; if Federal action is required to protect the interests of those involved in the investigation; if the research institution believes the inquiry or investigation may be made public prematurely so that appropriate steps can be taken to safeguard evidence and protect the rights of those involved; or if the research community or public should be informed.
- When More Than One Agency is Involved. A lead agency should be designated to coordinate responses to allegations of research misconduct when more than one agency is involved in funding activities relevant to the allegation. Each agency may implement administrative actions in accordance with applicable laws, regulations, policies, or contractual procedures.

IV. Guidelines for Fair and Timely Procedures

The following guidelines are provided to assist agencies and research institutions in developing fair and timely procedures for responding to allegations of research misconduct. They are designed to provide safeguards for subjects of allegations as well as for informants. Fair and timely procedures include the following:

- Safeguards for Informants. Safeguards for informants give individuals the confidence that they can bring allegations of research misconduct made in good faith to the attention of appropriate authorities or serve as informants to an inquiry or an investigation without suffering retribution. Safeguards include protection against retaliation for informants who make good faith allegations, fair and objective procedures for the examination and resolution of allegations of research misconduct, and diligence in protecting the positions and reputations of those persons who make allegations of research misconduct in good faith.
- Safeguards for Subjects of Allegations. Safeguards for subjects give individuals the confidence that their rights are protected and that the mere filing of an allegation of research misconduct against them will not bring their research to a halt or be the basis for other disciplinary or adverse action absent other compelling reasons. Other safeguards include timely written notification of subjects regarding substantive allegations made against them; a description of all such allegations; reasonable access to the data and other evidence supporting the allegations; and the opportunity to respond to allegations, the supporting evidence and the proposed findings of research misconduct (if any).

- Objectivity and Expertise. The selection of individuals to review allegations and conduct investigations who have appropriate expertise and have no unresolved conflicts of interests help to ensure fairness throughout all phases of the process.
- Timeliness. Reasonable time limits for the conduct of the inquiry, investigation, adjudication, and appeal phases (if any), with allowances for extensions where appropriate, provide confidence that the process will be well managed.
- Confidentiality During the Inquiry, Investigation, and Decision-Making Processes. To the extent possible consistent with a fair and thorough investigation and as allowed by law, knowledge about the identity of subjects and informants is limited to those who need to know. Records maintained by the agency during the course of responding to an allegation of research misconduct are exempt from disclosure under the Freedom of Information Act to the extent permitted by law and regulation.

V. Agency Administrative Actions

- Seriousness of the Misconduct. In deciding what administrative actions are appropriate, the agency should consider the seriousness of the misconduct, including, but not limited to, the degree to which the misconduct was knowing, intentional, or reckless; was an isolated event or part of a pattern; or had significant impact on the research record, research subjects, other researchers, institutions, or the public welfare.
- Possible Administrative Actions. Administrative actions available include, but are not limited to, appropriate steps to correct the research record; letters of reprimand; the imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of an award; suspension or termination of an active award; or suspension and debarment in accordance with applicable government-wide rules on suspension and debarment. In the event of suspension or debarment, the information is made publicly available through the List of Parties Excluded from Federal Procurement and Nonprocurement Programs maintained by the U.S. General Services Administration. With respect to administrative actions imposed upon government employees, the agencies must comply with all relevant federal personnel policies and laws.
- In Case of Criminal or Civil Fraud Violations. If the funding agency believes that criminal or civil fraud violations may have occurred, the agency shall promptly refer the matter to the Department of Justice, the Inspector General for the agency, or other appropriate investigative body.

VI. Roles of Other Organizations

This Federal policy does not limit the authority of research institutions, or other entities, to promulgate additional research misconduct policies or guidelines or more specific ethical guidance.

APPENDIX 7

THE GAG ORDER: SILENCE BY PAPER

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute

Memorandum

Date February 14, 1992

From Associate Director for Biological Carcinogenesis
Division of Cancer Etiology

Subject Implementation of the July 9, 1991 Memorandum from Drs. Healy and Broder to Dr. Robert C. Gallo

To Dr. Samuel Broder, Director, NCI, NIH

The following is a list of steps that have been taken as of February 14, 1992 to implement the 14 points of the memorandum of July 9, 1991 from Drs. Healy and Broder to Dr. Gallo.

Point #1. **Dr. Gallo should familiarize himself with the regulations.**

Dr. Gallo has asserted that he has familiarized himself with the regulations. Furthermore, in my interactions with him since the memorandum was issued, I have not observed any lack of knowledge of the regulations applicable to his duties as laboratory chief.

Point #2. **Terminate all professional or consultative outside activities, with or without compensation.**

Dr. Gallo has been told that any professional or consultative outside work activities must be ended. He has told us in writing that he has resigned from Novacell, Savin Biomedica, and from adjunct professorships at Cornell and Rutgers.

The following requests for outside activities have been denied:

World Laboratory
Swedish Agency for Research
in Developing Countries (SAREC).

(Dr. Gallo was also informed in a memorandum from Dr. Stonehill that the following additional outside activity approvals were canceled until a new form 520 was filed:

Farma-Biagini S.P.A.
Council for Cancer Research
Foundation for Biomedical
Research
L.I.F.E.
The Wistar Institute

Dr. Gallo submitted copies of his letters of resignation to these.)

The following requests for outside activities were approved:

Medical Science Advisory Committee
of the U.S. Information Agency
One-day workshop at Institute
of Medicine on July 26, 1991
Brookings Institution Seminar, December 3-5, 1991
Basic Books (related to his previously
published book)
Adjunct Professor, Johns Hopkins University
Adjunct Professor, George Washington University

The following outside activity was conducted by Dr. Gallo without having requested clearance:

Ceremony at Whitman Walker Clinic, around
December 19, 1991, as reported in The
Washington Post.

Point #3. **Obtain advance written permission for publication of any manuscript.**

The following requests for publication clearance were denied:

Letter to Science (about the failure of articles to reference his virus strains); denied November 18, 1991.
Letter to Time (in response to their comments about him); denied September 27, 1991.

Numerous scientific manuscripts were approved for clearance.

The following manuscripts were submitted for publication by Dr. Gallo without requesting clearance:

Two papers in Science, in press as of January 1992.

Point #4. **Obtain advance written permission for interviews with the media.**

Permission for the following interviews was denied:

Interview	Date of Interview
Santé Magazine	September 17, 1991
Fox Morning News	November 22, 1991
Gina Collatta, New York Times	November 26, 1991
BBC documentary	February 14, 1992

Permission for the following interviews was approved:

Interview	Date of Interview
USA Today	September 17, 1991
M. Gladweller, Washington Post	November 8, 1991
Mr. Hiller, Gannett News	November 13, 1991
Susan James, Genetic Engineering News	December 17, 1991
R. Yogeshwar, German TV-WDR (Cologne)	January 8 or 9, 1992

On two other occasions, Dr. Gallo inadvertently gave telephone interviews without clearance. In one case (Journal of NIH Research, interview of July 31, 1991) he informed us of it; in the other, he confirmed it upon inquiry (Paul Rayburn, Associated Press, October 29, 1991).

Point #5. **Obtain advance written permission to make any speech.**

Dr. Gallo has requested permission for speeches. However, most of these were also requests for travel funded by non-government sources, so they are discussed below.

Point #6. **Sign all documents needing laboratory chief signature or initials.**

I told Dr. Gallo (verbally and in writing) that the request that he sign all documents as laboratory chief applies to all documents with a line for the LTCB laboratory chief signature. These could not be signed by an acting laboratory chief in his absence. Dr. Gallo appears to have complied fully with this request.

Point #7. **Refrain from travel paid for by sources other than the United States government.**

The following requests for travel funded by non-government sources were denied:

Destination	Approximate Dates of Travel
Atlanta	February 2-4, 1992
University of Virginia	1992
Calgary and Vancouver, Canada	February 18-23, 1992
Israel	March 21-28, 1992
University of Maryland	April 21-22, 1992
University of South Florida	May 30 - June 1, 1992
Nagoya, Japan	June 3, 1992
Berlin, Germany	June 13, 1992
San Marino, Italy	1992

In addition, an attempt has been made to discourage Dr. Gallo from spending too much time away from the laboratory even on official travel funded by the U.S. government. The following trip of this type was denied:

Destination	Dates of Travel
Mexico City, Mexico	October 13, 1991

Point #8. **Obtain written approval for any collaboration with scientists outside the United States.**

A large number of requests for approval were submitted for foreign collaborations that are already in progress. Dr. Gallo is aware that all new foreign collaborations are to be submitted for clearance before they begin.

Point #9. **Ensure that shipping of biological substances, etc., meet all DHHS, PHS, NIH, and NCI regulations.**

Dr. Gallo was informed that all shipping must meet regulations and a signed Materials Transfer Agreement (MTA) must be on file for each shipment.

Point #10. **Suspend and resubmit for approval any membership in foreign organizations.**

Dr. Gallo requested approval of service in two foreign organizations, SAREC and the World Laboratory. Both were denied (see Point #2, above).

Points #11, 12, 13.
Review of primary data leading to any publication on which he is a co-author; maintain adequate laboratory notebooks; cooperate with periodic audits of laboratory notebooks.

Dr. Gallo asserts, and members of his laboratory confirm, that he has formally looked through many of the notebooks since July 9, 1991.

I informed Dr. Gallo that he will be expected to review all primary data of all non-tenured employees who report to him. In addition, he is responsible for reviewing primary data of any paper of which he is a co-author, including collaborative studies and studies conducted by other tenured employees of LTCB.

The first audit was held October 4, 1991. The second audit is scheduled for February 21, 1992.

At the October audit, the notebooks were found to be generally adequate with some exceptions. After the audit, Dr. Gallo was given a copy of the results of the audit and was informed in writing:

> You must make greater efforts to ensure that the notebooks in LTCB are complete. I was told by your scientists that you have looked through some of their notebooks recently. This current audit suggests that you must make a stronger effort to monitor the notebooks and to ensure that your senior scientists do so. Adequate laboratory notebooks must be maintained for each manuscript.
>
> Both Dr. Adamson and I feel strongly that your laboratory notebooks should be in such good condition that they will be above criticism. Your notebooks, because of your prominence and visibility, should meet the expectations of the public perception of what a good scientist's notebooks should be, even when that perception is more strict than what is common practice in many laboratories.
>
> Please inform all of your senior investigators that data that are stored on gel radiographs or computer tapes must be identified in the written notebooks, and the gel number/computer file number and the location where it is stored must be stated. This is particularly true for data that subsequently appear in publications.

Point #14. **Submit a written report of steps being taken to comply.**

Dr. Gallo submitted such a report on July 16, 1991.

Edward Tabor, M.D.

APPENDIX 8
ADDRESSING THE COMMITTEE

April 8, 1990

Gallo’s Opening Statement

Before the Committee

Preamble

I am confident that this review body will learn that my co-workers and I have been wrongly treated, that there has been no wrongdoing in my laboratory, that there has been substantial misrepresentation in select press, and we hope that these evaluations will be able to help us rectify these misconceptions. We are justifiably proud of our work. The instigation of this inquiry came out of an article by a reporter who had implied though not clearly claimed some kind of wrong doing in my laboratory during a very critical period of our work. The allegation or implication really boils down to one old issue: a deliberate use of a Institut Pasteur isolate called LAV for the U.S. blood test. But the implication is untrue. Moreover, as I understand the situation, the U.S.-French agreement was made with this possibility already considered in 1987 and with full understanding of the many contributions of both groups, including our group obtaining several, not one, HIV-1 isolates. Moreover, most of these questions were already addressed in the first public disclosure of our findings (see Secretary Heckler's press release).

Despite the fact that the U.S.-French agreement included disavowing of any wrongdoing by either side and dismissal of all pending litigation, it is surprising that damage to our reputations continues by virtue of "anonymous" distribution of one reporters' work to scientists all over the world. Just prior to the U.S.-French agreement identical bad publicity was stimulated by the litigation, e.g., publications in the New Scientist. Now Mr. Crewdson has resurrected these lines of attack but adding that this is a conspiracy at the government level.

One particular allegation that has been most distressing to me is his allegation of "the lost year," i.e., that I personally caused a year to be lost in the fight against AIDS. It is difficult for me to understand this charge when it was our success with the blood test and evidence for causation that led to the controversy. Even by March 1984 the Montagnier group had not convinced the scientific community. It was no one's fault that they did not. Although not well known, in many instances we went out of our way to help them. For instance:

(1) the very idea to search for a retrovirus cause of AIDS that started as Pasteur scientists in the field came from us. The lineage can even be traced in Crewdson's article: Gallo → Leibowitch → Klatzman → Montagnier → Chermann → Barre-Sinoussi;

(2) some important reagents for their first work came from me and my colleagues and this was acknowledged in their 1983 paper;

(3) one of their key technicians (now a Ph.D.), Ms. Ann Laurent, trained in my laboratory the year (1982) before the Pasteur group entered this field and Francoise Barre-Sinoussi, the first author of the Montagnier 1983 paper, spent 6 weeks with me in tissue culture technology;

(4) the very approach - the very assays to detect and transiently grow LAV were identical to those developed by us years earlier for the discovery and isolation of HTLV-1, including the use of cord blood human T cells and interleukin-2, and in this respect J. C. Chermann, Montagnier's co-worker, told me I gave him the protocol by telephone when they were losing LAV early in their 1983 work;

(5) the work on LAV after the May 1983 paper was published was supposed to be collaborative with us, but in July 1983 Dr. Montagnier told us he changed his mind. It had to be a1l done in France;

(6) I asked Essex to delay publication of his paper, as we did ours, to wait for Dr. Montagnier's 1983 paper;

(7) immediately before publication I went to Paris to tell them of our results; and

(8) immediately after publication of our papers in May 1984, my colleague Sarngadharan went to Paris, brought one of our cell lines producing HIV-1, and to compare our isolates to LAV.

It seems to me that lost in all of this is the perspective of the efforts, work, and achievements that have really brought progress. I would like to mention a few of these points here.

(1) My group was the first to systematically handle samples from AIDS patients (1982) (as many as 50 samples in a day). This was at a time when no one knew how infectious the causative agent might be. Literally, our lives were risked daily. Often I was reminded that as cancer researchers, we had no obligation to get into this problem, and we were crazy to do so. Our facilities, far from optimum, were overwhelmed at a time when most academic institutions had forbidden AIDS samples to enter their facilities. It was only after our development of systems for handling of this agent, our convincing results that the new virus was the cause, and our characterization of the virus that most institutions opened their doors to HIV research.
(2) Our contributions to this field include: the idea of a retrovirus cause; the technology to grow T cells; the first permanent cell line culture and mass production of HIV; the first reagents (specific antisera and molecular clones); the first peer reviewed convincing data that this virus is the cause of AIDS; the first workable blood test used all over the world which saved many thousands of lives and which significantly diminished the epidemic; the majority of HIV-1 isolates today and earlier used all over the world; the discovery of virus variation (heterogeneity); the discovery of virus in brain, saliva, plasma, and semen; the discovery that macrophage not only T4 cells are targets of the virus, and that microglial cells are the major targets in the brain; the development of the first infectious molecular clones of HIV; the discovery that HIV kills T4 cells after HIV is induced to be expressed by T cell activation; much of the early molecular biology studies and early epidemiology; the discovery (with Haseltine) of the transactivation phenomenon; the development of the systems for the AZT early studies by Broder; the first evidence of mother-child transmission and of heterosexual transmission (with collaborators); the first development of a laboratory system for the study of Kaposi sarcoma which is just beginning to lead to some promising results for therapy of this cancer; by far the major source of reagents for AIDS research to scientists all over the world; and the laboratory that has trained the most scientists for work on human retroviruses.
(3) We should keep in mind the status of this field at the time of our May 1984 publication. The 1983 Science paper of Barre-Sinoussi et al. described their only isolate in 1983. Some additional detections, probably of the same virus, were described in oral presentations by

Montagnier late in 1983 and early 1984. At the time of our reports the classification of the AIDS virus was not clear, first (in 1983) called type-C, later type-D, and only a lenti-retrovirus by 1985. Its immunological relationship to the HTLVs was also not clear. Furthermore, the seroepidemiology was far from certain and far from a causal link of this virus and AIDS. Our work turned a guessing game into a science. As late as March 1984 there were rampant speculations on the cause of AIDS, most very far from the notion of a retrovirus cause of AIDS, even including an NIH announcement of a fungus cause of AIDS in February 1984. The publication of our May 1984 papers dramatically changed the state of the field. These were the first papers to be published in peer reviewed journals from the time of the one 1983 paper.

Finally, I want to add a few points pertinent to our current process. These are events which are six to seven years old. Also, of course, the records are not my own personal records but those of my colleagues, including technical staff, some of whom are no longer with me. Nonetheless, I will do my best to openly discuss all points.

Also, I want the committee to know that for different reasons I have been through some of this before with the Pasteur agreement (1987 and earlier). All our notebooks, letters, and documents were available and scrutinized by Institut Pasteur scientists, administrators, lawyers, public relations people, and their consulting scientists during the litigation because of the Freedom of Information act. However, none of theirs was available to us. Evaluation of these matters in the past led to our agreement in which it was frankly stated in writing that there was no wrong doing. This agreement was between respective presidents, governments, scientific institutions, lawyers, and scientists.

As a government scientist of 25 years duration, I find myself a very vulnerable target for attacks, many of which seem to be directed at government officials, most of whom are no longer in office. Moreover, I have no access to lawyers or public relations firms, etcetera, without personal sacrifice. In the midst of financial interests, patent debates and intrigues, legal aspects, political and national pride, media phenomena, and other forces that I do not understand - I can only state that the integrity and value of our scientific work has stood the test of time. I hope that at the end of

these inquiries I will never again have to lose time from my scientific work to go through this process. My colleagues and I would like to return as soon as possible to our much unfinished work on human retroviruses.

APPENDIX 9
HEALY WARNS OF MEN LIKE DINGELL

The Dangers of Trial by Dingell

by Bernadine Healy, MD

Columbus, Ohio - In 1991, shortly after becoming director of the National Institutes of Health, I was summoned to Capitol Hill by the staff of Representative John Dingell, the powerful Democratic chairman of the House Energy and Commerce Committee. The panel's Oversight and Investigations subcommittee, which he also led, wanted to discuss draft reports being prepared by the fraud office at N.I.H. on two high-profile scientific misconduct investigations.

In one, Dr. Thereza Imanishi-Kari, an immunologist, was accused of fabricating data to support a 1986 article in the journal "Cell." Her research had been conducted in collaboration with David Baltimore, a Nobel Prize Winner who vehemently defended the findings. In the other, Robert Gallo, and Mikulas Popovic of the N.I.H., were accused of falsifying data in a study of the virus that causes AIDS.

Becoming director in the midst of the mess, I received a crash course on how basic, constitutional principles can be violated. At the meeting, I was taken aback by the Dingell staffers' childish behavior, which seemed calculated to put me on notice that these inquiries were really their investigations -- even though the Office of Scientific Integrity, a unit of N.I.H., was officially conducting them.

The staffers demeaned the N.I.H. leaders (we were lap dogs, not scientific watchdogs, they said), and they gloated about having taken down two of the biggest names in science -- Dr. Baltimore and Dr. Gallo. I reminded them that neither scientist had been found guilty and that the report accusing Dr. Imanishi-Kari of fraud was a leaked preliminary draft that she had neither seen nor had a chance to rebut at N.I.H. What about due process?

The staffers made it clear that they thought she was guilty, so who cared about the rest? Meanwhile, the National Institutes of Health was to bow to the subcommittee's staff, and I was instructed "to repent" for criticizing the conduct of these inquiries inside and outside N.I.H.

The final guilty verdicts on these cases were issued a few years later by the renamed Office of Research Integrity, which had moved to N.I.H.'s parent, the Department of Health and Human Services.

Last week, the department's appeals board reversed this office's finding against Dr. Imanishi-Kari and completely exonerated her. The board also vindicated Dr. Baltimore,

who in 1991 was forced to resign as president of Rockefeller University because of the controversy.

These exonerations followed others the appeals board had issued since 1993. It found that Dr. Popovic had not committed misconduct, as the fraud office charged, and it withdrew the case against Dr. Gallo, Dr. Ramesh Sharma, a biochemist accused of falsifying data, was also exonerated. All of these cases were of special interest to the Dingell subcommittee.

It would be a mistake to see these acquittals as isolated decisions. Taken together, they expose how unbridled political power, career opportunism and plain cowardice hijacked a process initially created by scientists to insure research integrity.

What happened? In 1991, Mr. Dingell, as head of Energy and Commerce and its investigative subcommittee, had amassed a reputation as the most powerful man in Washington (it all ended when the 1994 elections swept a Republican majority into the House). He used all these cases to burnish his image as a crusader against fraud in science. His subcommittee had broad subpoena authority and virtually unchecked power to investigate, prosecute and judge its targets. For example, the panel used its muscle to derail an open hearing on Dr. Gallo by the National Cancer Advisory Board, which operates under the aegis of N.I.H.

At the same time, Congress, exempt from the Privacy Act and similar laws, allowed Mr. Dingell's staff to have unrestrained and privileged access to irrelevant material (including medical information in personnel records of one accused scientist). And the Constitution's speech and debate clause -- intended to give immunity to legislators speaking on the floor of Congress -- was used liberally, and was extended to protect staffers who leaked confidential and often distorted excerpts of documents to favored reporters. This was material inaccessible to the accused scientists and uncooperative journalists.

There were other critical players in the so-called fraud-busting campaign: a cadre of N.I.H. employees outside of the official fraud office who essentially became self-appointed investigators for the Dingell panel. Incredibly, they also invoked the speech and debate clause when their activities came to light -- actions like taking confidential records out of N.I.H. offices; leaking privileged materials from scientists' files; misleading supervisors about the full scope of their activities and making unauthorized use of N.I.H. resources.

My staff saw the contents of a computer used exclusively by one of these employees. It contained drafts of demanding letters from Mr. Dingell to me -- and to the Secretary and an Assistant Secretary of Health and Human Services -- about the inquiry, as well as a near-complete draft of what was to be the subcommittee's report on Dr. Gallo. As if all this were taken from "The Wizard of Oz," an N.I.H. bureaucrat appeared to be host-writing the intimidating words of the mighty Congressional chairman.

All this, plus the lack of due process in its proceedings, drastically compromised the workings of the Office of Research Integrity. The subversion of due process was aided by many prominent scientists who seized the chance to wound their competition. Outside experts used in the fraud office's investigation of the accused scientists met behind closed doors, unrestrained by judicial rules of evidence and order or the rigor of the scientific method. Before a verdict was in, one Nobel winner came to see me to say that Dr. Baltimore should be kicked out of the National Academy of Sciences and stripped of his Nobel Prize.

The prevailing response to the unfair system of justice melted out by Mr. Dingell and the Office of Research Integrity was appeasement: kneel, apologize, grovel and, if need be, collude. For daring to question the independence and impartiality of this bizarre system, I was subjected to heavy fire by the subcommittee.

How do we make sure that such abuses of power never happen again? One effort to correct the highly polluted process has been successful. At the insistence of some of us at N.I.H., the appeals board at Health and Human Services was set up in 1992, so that scientists can learn of charges against them, see the evidence, confront their accusers and defend themselves in an open hearing before a panel trained in judicial procedure. And Congress is dismantling the Energy and Commerce Committee's sweeping investigatory power structure.

About a half century ago, Supreme Court Justice Robert Jackson wrote that "the most odious of all oppressions are those which mask as justice." This sentiment must resonate with the scientists who faced destruction. We must see that this sad story is never repeated.

APPENDIX 10
MARTIN DELANEY LETTER

Mr. John Madigan
Publisher, Chicago Tribune
435 N. Michigan Avenue
Chicago, IL 60611

November 8, 1993

Dear Mr. Madigan,

In August of 1990, I wrote to you expressing my concern about tactics employed by Chicago Tribune writer John Crewdson in his career-consuming assault on AIDS research Robert Gallo. At the time, it was difficult to complain about anything more than the tactics and odd behavior of the reporter, since multiple investigations were launched in response to his articles. Pending the outcome of those investigations, substantive issues would also became fair targets of discussion. In light of recent events, particularly the striking rebuttal of these allegations the first time they were ever assessed under rules of law in the Popovic acquittal, and in light of other recent activities by the reporter, I wish to once again put a number of matters before your personal attention. I do so because I have come to believe that no at the Tribune truly understands or even follows these issues except through the eyes of this single reporter. As a matter of your own integrity as a journalist and publisher, I think it is critically important that you widen your view.

I never received a response to my last letter, but I respectfully urge you to respond to this one. A careful reading of the facts makes it highly likely now that this matter and the federal investigations will not end in a manner supportive of the allegations raised by the Tribune. Moreover, the legal opinions rendered in the Popovic acquittal make it clear that these allegations have been unfounded, perhaps even unprincipled, from the beginning. As I said at the end of my last letter, when the dust settles, it is my intention to hold the Tribune accountable for the actions of its reporter in this matter of national importance. We have begun accounting the costs incurred, to the individuals, to the reputation of science, to the tax payers, and to people with AIDS.

I raise these issues knowing full well that it will likely lead to new personal recriminations against me by your reporter, as occurred the last time (see Appendix A for a description of Mr. Crewdson's effort to destroy my own credibility after my initial defense of Dr. Gallo).

I have enclosed here a copy of the judge's complete ruling in the Popovic case, and I urge you to either read it yourself or have it read by someone at the Tribune who is more concerned with the paper's interests than Mr. Crewdson's. My suspicion is that no one other than Mr. Crewdson has read this document, and therefore no one is likely to challenge his interpretation of it. Surely even you must admit that Mr. Crewdson is not a disinterested party to these events, virtually all of which have been triggered by his articles. By no stretch of the imagination can he be considered an objective outside party reporting the story. His own credibility, as much as that of Drs. Popovic and Gallo, are virtually on trial here.

From that perspective, I was astonished that the Tribune permitted publication of his article last week on the acquittal of Dr. Popovic. Virtually every other news source which has written on this has seen it as a stinging rebuttal of the government's case against Dr. Popovic. This was the first time in the history of these allegations that (1) any witness, other than the accused, was asked to testify under oath; (2) that Popovic and his attorney were permitted to confront and cross-examine those making accusations; (3) that the rules of law and the rules of evidence were applied to the proceedings; (4) that a truly disinterested outside party was asked to objectively evaluate the accusations and evidence. Because you perhaps only saw Mr. Crewdson's version of the story, you may have missed the fundamental conclusions drawn by the court:

- Not only did the evidence fail to support a claim of intentional wrong-doing or malicious self-serving error, but it failed to find any evidence of error at all in the paper under question.
- All accusations were rejected, without qualification.
- New accusations which were improperly and unfairly raised by the government were also dismissed, even though the judge had no obligation to hear them at all.
- Some of the government's key witnesses, such as Dr. Mal Martin, were singled out by the court as highly biased and unobjective because of their own personal disputes with Dr. Gallo.
- The so-called "blue ribbon" Richards panel was found not to have taken its positions based on an independent assessment of the evidence in the case, but solely on the views and perspectives presented to it the Office of Research Integrity.
- The government was on several occasions itself found to be misstating, misrepresenting, and improperly paraphrasing the evidence or statements of witnesses and Dr. Popovic.
- The government's accusation that there existed a pattern of self-serving misrepresentation of data was found to be false and to consist only of a pattern of scientific misunderstanding on the part of the government investigators.
- The government and its advisors were frequently shown to misunderstand, misstate, and misrepresent the scientific issues at question; the sole scientist the government witness who was qualified in matters of retrovirology was found, on the whole, to support Dr. Popovics' view of events rather than the governments.

The bottom line here is that a great injustice has been done to Dr. Popovic. This man, who is viewed by many as a unique artisan in retrovirology, became literally unemployable for the last 1 years, at a time when the world greatly needed his skills in the fight against AIDS. It is difficult, if not impossible to measure what has been lost. The court went out of its way to acknowledge the tremendous importance of his contributions and the contributions of the Laboratory of Tumor Cell Biology in the discovery of the cause of AIDS and to decry how he has been treated.

Since the case against Popovic was considered by previous panels to be stronger than the case against Dr. Gallo himself, the outcome seems highly predictive of what to expect in Dr. Gallo's own appeal. The matters in the Popovic case have been seen as the heart of the accusations against Gallo. In light of these findings, the government immediately sought a delay in Dr. Gallo's appeal hearing, which was scheduled to begin on Monday 11/ 8. An initial ruling by the court has already ruled out many of the tactics proposed by the government, and severely limited the scope of the hearing. Government prosecutors had sought to reopen all matters and all allegations against Gallo, even though these had already been rejected by both previous investigative panels. The court's ruling has restricted the Gallo appeal to discussions of the sole charge of misconduct issued against him, which amounts to the interpretation of a single ambiguous sentence in a singe scientific publication.

This outcome amounts to a resounding rejection of the allegations of Mr. Crewdson as little more than hearsay, bias, and misunderstanding of the scientific issues. The court did not flinch from noting that this entire process was based on the accusations raised in "a 1989 newspaper article."

So what did Mr. Crewdson report to Tribune readers the day after this historic ruling? He wrote an article which claims that a federal courts actions will make it impossible for the government to prosecute science fraud. Such a conclusion is so biased, and so self-serving, as to be breathtaking. It is amazing that the

Tribune would permit its publication. On the contrary, what the court did was make it impossible for the government to accuse and find scientists guilty of fraud and misconduct unless the evidence actually supported such a finding. It said that people could not be accused and found guilty based on hearsay, based on unintentional error, based on accusations of biased witnesses testifying in the press without oath, based on misunderstand of scientific matters, or in short based on hyperbolic and one-sided newspaper reporting. If that is the judge's decision - and it clearly is - then we should applaud this reaffirmation of the American system of justice and celebrate that this nightmare of trial by media has finally come to an end.

For the record, I would like to know who else, if anyone, at the Tribune had read the complete text of the court's ruling before permitting publication of Mr. Crewdson's review of it. I would like to know how far in the institution this style of journalism has spread. Perhaps not since Nazi Germany and pre-1990 Pravda have journalists been permitted by publishers to so severely distort the facts.

I believe that an objective assessment of Mr. Crewdson's behavior, if tested by the standards applied to scientists, would result in a charge of journalist fraud and misconduct. In repeated instances, constituting a broad pattern of self-serving misrepresentation, Mr. Crewdson has selectively amplified statements which support his hypothesis, misstated facts and misconstrued events in a manner which support his hypotheses, and suppressed all evidence which fails to support his hypotheses. If equivalent actions were to be taken by the scientists he is so anxious to condemn, would surely result in an unambiguous finding of fraud and misconduct. Before which investigative panel shall I bring forward my charges against a journalist?

I ask the Tribune to describe to me what standards of conduct it employs in such matters. Does it contest that Mr. Crewdson has selectively reported "facts" in these matters? Can it show me where and how he willingly has put forth a balanced view which reported also those views and facts which failed to support his hypotheses? Or does it simply admit that he has, for the last 4 years, been engaged in a highly personalized witch hunt rather than journalism? Silly me, I thought that the role of the journalist was to seek and report the facts, not use the press as one's personal bully pulpit.

For further evidence of the journalistic distortions coming from Mr. Crewdson, I have also enclosed my own review (Appendix B) of his recent article about a French vaccine.

I look forward to hearing from you.

Sincerely,

Martin Delaney

Appendix A: The Attack on Martin Delaney

Approximately one year ago, I learned from several sources that Mr. Crewdson was now "investigating" me, making calls to many people working in our field. This didn't particularly concern me, because as he no doubt discovered, I had nothing to hide. His investigations led nowhere, I assume, because he never was able to publish against me in the Tribune. Around this time my work in AIDS had been described positively in a book written by another acclaimed journalist, Jonathan Kwitney (*Acceptable Risks*, Poseidon Press). Mr. Crewdson took this an opportunity to attempt to publicly and professionally discredit me. He wrote a lengthy piece in the Washington Journalism Review, accusing me of misappropriating funds at my foundation and claiming that I was being removed from office and duty. He used these claims to discredit Kwitney's book and to suggest that it was published "just in time," before the posse was about to circle and capture me for gross misdeeds. It was indeed insulting to be vilified in a prestigious journal, especially since not a word of what he said was remotely true. Kwitney was later given a brief opportunity to respond and did so. Today, I am as much or more both in charge and publicly respected at my foundation, Project Inform, and my work continues unabated. There never were any charges of misappropriation, nor was any action either contemplated or taken against me by anyone. Crewdson's fantasy about me apparently originated in a complaint by fired employee which surfaced in the local press. The ex-exployee was angry about the priority placed internally on funding the department in which he worked and was essentially complaining that grant funds had not been allocated to the project he desired. To him, this constituted misappropriation. No grantor ever made such an accusation, nor did my own board of directors, nor anyone else. This was a sorry, personal matter which arose at a time of compression at Project Inform, when staff size was being reduced.

I learned a great deal from this experience. It told me that Mr. Crewdson, without checking for facts with anyone, would willfully repeat his own misunderstood interpretation of angry hearsay in a major national journal. This confirmed a great deal which I had suspected about his journalistic ethics and practices, about which I have previously complained to you. Furthermore, it demonstrated that he knew no boundaries of ethics, honesty, or integrity when it came to seeking to harm Dr. Gallo. The only reason I had become a target of his, as had Zagury and Popovic before me, was that I had dared to defend Dr. Gallo and attempted to have his side of this story heard. I will just write this off as a personal lesson in dealing with Mr. Crewdson, and expect to weather some form of similar attack after I once again raise my voice.

Appendix B - The Zagury Article

A second recent incident which further causes me to write is the article he published approximately one month ago concerning a lab worker involved in Dr. Daniel Zagury's vaccine research in France. The gist of the article was that a lab worker had been injected with the vaccine, at his own desecrate request, yet still came down with AIDS when he later suffered a laboratory exposure to the virus. Mr. Crewdson used this incident to make several claims:

1. that the vaccine didn't work
2. that an identical vaccine, implicitly connected to Gallo and Zagury, was about to be tested on tens of thousands of US citizens
3. that the vaccine in question was a product of Dr. Gallo, repeatedly referring to it as the "Gallo-Zagury" vaccine
4. that the experience of the lab worker had been hidden from scientific reviewers to cover up the failure of the vaccine
5. that Gallo and Zagury had publicly and falsely claimed that the vaccine was effective in prevent AIDS
6. that innocent, risk free children had been harmed by the vaccine
7. that human trials had taken place without proper approvals
8. that the NIH was seeking to patent the vaccine in Gallo's name but removed it when the trouble came to light.

Quite an amazing story. The problem is that there is hardly a single sentence in the article which was true. But because the Tribune has come to so completely rely on Mr. Crewdson's versions of events, perhaps due to the scientific complexities involved, it was printed without a single fact being checked. What this article demonstrated, perhaps more clearly than in any of the previous ones, that Mr. Crewdson hopelessly misunderstands the scientific issues about which he is writing. This is particularly sad, since he has virtually made a career in recent years of as a scientific poseur, sufficiently managing the lingo to convince his editors, and the lay public, that he knows what he is talking about.

Had the facts been checked by anyone with legitimate scientific knowledge, you would have discovered:

(1. the vaccine didn't work): no vaccine on the planet works uniformly in all circumstances. The ability of a vaccine to protect against the common forms of exposure may or may not confer protection against other forms of exposure. Few vaccines work from a single injection. Most importantly, no one ever claimed that this vaccine - or any AIDS vaccine yet tested - has effectively protected a human against infection. At this stage, all vaccine development is target toward information gathering - learning a step at time what will be needed to produce an effective preventative agent. As of today, no one, including Gallo and Zagury, have suggested that we even understand the correlates of protection, let alone that an effective compound exists. I know from personal experience that Gallo is, and has been for several years, pessimistic about the chances for developing an effective vaccine. Thus, Crewdson's first point is both false and makes no sense. Presenting a more factual description of the purpose and state of current vaccine testing, however, would not have supported his hypothesis, so this alternate approach was apparently chosen.

(2. an identical vaccine is about to be foisted upon the American public): The article references, I assume, the controversial GP160 -based product of a Connecticut company called MicroGeneSys. Crewdson may

have read that the company's lobbyists secure a $20 million appropriation from Congress to perform widescale testing of the product. Several points of gross error are involved here. (a) Zagury's vaccine is not based on GP160; (b) it bears no relationship to that vaccine; (c) neither Gallo nor Zagury have any connection to the GP160 product; (d) the tests of the GP160 product in discussion are intended for use in people already infected with the AIDS virus, not as a preventative vaccine; (e) no specific preventative vaccine, from any source, has been selected by anyone, inside or outside the US government, for widescale testing, and all discussions of long-range planning for vaccine tests make it clear that any such initial test would be done primarily for learnings sake, not because anyone believes an effective vaccine yet exists. So what is Crewdson talking about here? since he is evidently so knowledgeable about the state of vaccine research in the United States and around the world, one can only assume that he deliberately misstated this point, perhaps to better support his hypothesis.

(3. the product was a joint effort of Gallo and Zagury - the "Gallo-Zagury" vaccine); Mr. Crewdson repeated that phrase almost endlessly in the article, perhaps assuming that because repetition in the past eventually led the public to consider his statement as facts. No more so than before does this reflect the truth. Gallo's entire relationship to the Zagury vaccine is that his laboratory supplied a reagent (a lab chemical) to Zagury which played role in laboratory testing. The supply of that reagent was done under clear and unambiguous conditions that it was not to be used in human testing. Mr. Crewdson devotes a single, buried sentence to this most critical fact. Gallo is linked to this by Crewdson because his name appears in the middle of along list of names of authorship in article published by Zagury. He conveniently fails to mention that other NIH people were also on the list, at the same level of priority, and for essentially similar contributions. To suggest that this makes the product the "Gallo-Zagury" vaccine is a great misstatement to your readers, as well as to everyone else involved.

(4. the failure of the vaccine in the lab worker was covered up in the published article): Mr. Crewdson had in his possession clear information which showed that the lab worker himself insisted, as was his right, that his experience be kept out of the article. More importantly, the lab worker was never a part of the protocol or test involved. His experience is thus irrelevant to any publication and I believe every journal editor would agree with that. To include his experience in the article would be akin to blending the experience of individual patients who sometimes receive an experimental drug on a "compassionate basis" into the results of patients who receive the drug in a controlled clinical protocol. To do so is simply bad science. Many desecrate patients are sometimes granted access to an experimental agent outside of a structured protocol. When the results of the protocol study are reported, those experiences are correctly deleted because they are virtually uninterpretable, whether negative or positive. Thus, the lab worker's experience did not belong in the article. Moreover, they were consciously excluded at his own request - which Mr. Crewdson knew and choose not to report - obviously because it did not support his hypothesis.

(5. Gallo and Zagury claimed the vaccine worked); There is simply no evidence to support this accusation, as a reading of the published articles and public statements will readily confirm. One possible explanation of Mr. Crewdson's allegation is that perhaps he doesn't understand the nomenclature of clinical research. The only claims made in any articles or public statements about this vaccine (or any other AIDS vaccine to date) is that the product may have produced some form of immunogenic activity, as measured by a variety of possible lab markers. This the proper way of stating results. It is possible that writer inexperienced in such matters might misinterpret such a statement as to mean that the vaccine "worked" in the sense understood by the lay public - that it prevented disease. But certainly no scientist, nor most science writers, would make such a mistake. And certainly no review board of any peer-reviewed journal would make such a misunderstanding, and obviously, none did. No one, other than Mr. Crewdson, flagged statements of immunologic activity as overstatements of a vaccine's efficacy. Thus, we can either attribute this to a lack of knowledge on Mr. Crewdson's part, or perhaps to a malicious effort to smear the targets of his investigation. The unfortunate thing is that the lay public may be unable to make such distinctions. They rely instead upon the integrity of publishers to be certain they are not mislead.

APPENDIX 11
LETTER FROM PROJECT INFORM

PROJECT inform

Date: November 12, 1993
San Francisco Project Inform

Contacts: Martin Delaney 415-332-0184
Brenda Lein 415-558-8669

Press Statement: Government Drops Charges Against AIDS Researcher Robert Gallo

In a tersely worded statement released today, the Office of Research Integrity of the Department of Health and Human Services withdrew its charges against AIDS research Dr. Robert Gallo. The decision was reached in light of an Appeals Board ruling this week in a related case against Gallo associate Dr. Mikulas Popovic, who had also been charged with misconduct. In the Popovic case, the Appeals Board ruled that it found no evidence of either intentional or unintentional error in the paper published by Popovic. The ruling in the Popovic case was cited by all parties as the reason for withdrawing the accusations against Gallo, as it demonstrated how the legal process viewed the evidence in these matters.

"This decision should end a long and painful saga of AIDS research which has cost the taxpayers millions of dollars and diverted an enormous amount of time and energy away from the fight against AIDS." said Project Inform Founding Director Martin Delaney. *"The Appeals Board ruling makes it abundantly clear that the Popovic acquittal was not due to any mere technicality, but to that fact that it found no substance to any of the allegations, which instead rested on misreading of the language of the paper, misinterpretation of scientific issues, and misrepresentation of the facts."* Earlier in the week, the astonished Appeals Board asked *"How could it happen that such a massive effort* (the multi-year, comprehensive investigation) *produced no substantial evidence of its premise?"* How indeed, we ask?

The involvement of the Appeals Board was the first time in the history of these allegations that *(1) any witness, other than the accused, was asked to testify under oath; (2) that the accused and his attorney were permitted to confront and cross-examine those making the accusations; (3) that the rules of law and the rules of evidence were applied to the proceedings; (4) that a truly disinterested outside party was asked to objectively evaluate the accusations and evidence.* In this perfectly appropriate environment, the government's case - in effect, the case mounted by Chicago Tribune writer John Crewdson - crumbled like adobe in an earthquake. Since the government's case against Gallo was in many ways based upon a similar quality of evidence, the Popovic acquittal signaled the government that its' Gallo case would likewise fall.

"I am perplexed, however." Mr. Delaney of Project Inform said, *"that ORI spokespeople are attempting to save face by suggesting the failure of their case is due to some 'new definition' of scientific fraud promulgated by the Appeals Board. That is completely untrue, as even a casual reading of the Appeals Board ruling will demonstrate. The ruling explicitly shows that it tested these cases against the existing, 1989 HHS definition of misconduct. These people have clearly lost their case on the basis of the evidence, yet are now pretending otherwise. This is shameful, and typical of the low-rent tactics which have been employed in this matter since the beginning."*

Project Inform believes that these matters were fully settled between the French and American researchers several years ago and that this ultimately failed effort to prosecute these two important scientists has unnecessarily damaged the cause of AIDS research, as well as the public's trust in science. Project Inform urges those who would believe otherwise, or who give credence to ORI's face-saving gesture, to simply read the text of the Appeal Panel ruling. We found it to be easily clearest, least ambiguous, and most accurate statement yet in the entire duration of these proceedings.

Project Inform applauds this decision and fully expects Drs. Popovic and Gallo to renew their efforts in the fight against AIDS. *"What matters most,"* said Brenda Lein of Project Inform, *"is that the these two important scientists can now finally devote their full time and energy to solving the truly important questions of AIDS research. It makes no sense whatever to waste scarce resources like Drs. Popovic and Gallo when there remains so much work to be done. Let's hope this is truly the end of this debate and that we can all move forward to find solutions to the problem of AIDS."*

Project Inform, one of the nation's best known non-profit AIDS Treatment Information and Advocacy bureaus, supplies treatment information services nationwide. It is also the sponsor of a prestigious Think Tank on Immune Reconstitution, and a co-sponsor of the Future Directions in AIDS Research process, a diversely based national effort to reinvigorate the federal AIDS research programs.

APPENDIX 12
HADLEY TRIES AGAIN

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September 18, 1995

1026:lwp
30836.012

VIA FEDERAL EXPRESS

Edmund Tramont, M.D.
Professor and Director
Medical Biotechnology Center
618 W. Lombard Street, 2nd Floor
Baltimore, MD 21201

Dear Dr. Tramont:

It is my understanding that Dr. Suzanne Hadley has recently been lobbying the legislature concerning Dr. Robert Gallo's professorship at the University of Maryland. I thought therefore that you should have a copy of the attached decision by the U.S. Department of Health and Human Services Departmental Appeals Board in the case of Dr. Mika Popovic, a case prosecuted by Dr. Hadley when she was at the Office of Scientific Integrity. The Board concluded (page 1) that "after all the sound and fury," there was not even "a residue of palpable wrongdoing" by Dr. Popovic.

Since leaving the Office of Scientific Integrity, Dr. Hadley has continued her attacks on innocent scientists. And she continues to be all sound and fury, without the slightest judgment or wisdom.

If you would like further information about Dr. Hadley's role in the cases of Dr. Popovic and Dr. Gallo, please let me know.

Sincerely,

Joseph Onek

Joseph Onek
Counsel for Dr. Robert Gallo

APPENDIX 13

AFTER 20 YEARS: A HISTORIC AGREEMENT

Agreement for the Establishment of a Program for International Viral Collaboration

Background: Since the discovery of HIV-1 by Professors Luc Montagnier and Robert C. Gallo, an unrelenting epidemic of increasingly diverse subtypes of infection has swept across all continents, but disproportionately impacted countries with limited medical infrastructure, especially the countries in sub-Saharan Africa. The co-discoverers of the virus propose to join efforts in an international collaboration through the **World Foundation for AIDS Research and Prevention under the auspices of UNESCO** to foster the accelerated development of preventive vaccines and therapies that are effective, affordable and well tolerated for all people.

The **Program for International Viral Collaboration** is the platform for this joint research endeavor. This Program will facilitate the translation of basic discovery to benefit those areas hardest hit by the epidemic. The Program will build upon prior links of these scientists to the Ivory Coast Cameroon and Nigeria to build an international partnership that will engage in a broad portfolio of basic, therapeutic, prevention and education activities. Attention will also be paid to activities in other countries significantly affected by the epidemic, such as Honduras in Central America.

An innovative component of the Program is the **Laboratory for International Viral Collaboration.** This basic research "wet" laboratory will be housed at the Institute of Human Virology in Baltimore. Under the co-directorship of these pioneering scientists, basic research studies will target projects aimed at catalyzing rapid translation of vaccine and therapy research concepts through animal safety testing into human trials first in the US and Europe and shortly to the international partnership sites. Other scientific projects will be carried out in collaboration with the University "Tor Vergata" in Rome, and with other appropriate institutions able to catalyze new competences and synergies.

Mission Statement: In the face of the most devastating infectious disease epidemic of all time, HIV/AIDS, to foster research discovery that benefits mankind through international partnership, and promotes transfer of knowledge and preventive program.

Structure: The World Foundation for AIDS Research and Prevention is the major agent for organizing and implementing the Program for International Viral Collaboration. This research structure is designed to create the basis for future novel partnerships between "north" and "south" countries where common purpose translates leadership, discovery, knowledge, and capacity development to the goals of preventing HIV infection and disease and makes treatment accessible to all. To achieve this goal the Program will develop safe, affordable and effective preventative vaccines and microbicides, along with sustainable therapies that limit the virus by harnessing biologic approaches such as vaccine therapy and biologically derived approaches that limit toxicity and sustain long-term survival of men, women and children infected with the virus.

Implementation: The **World Foundation for AIDS Research and Prevention,** in close cooperation with the Institute of Human Virology, will provide leadership in developing resources to sponsor and fund an international research network involving a basic research laboratory at the Institute of Human Virology in Baltimore and clinical and prevention research sites in Nigeria and Ivory Coast in West Africa, Cameroon in Central Africa and Honduras in Central America. Professors Gallo and Montagnier will co-direct the research at the laboratory site in the United States and coordinate links to the international sites in Africa. Professor Montagnier will be named as an adjunct professor at the Institute of Human Virology. Staffing of the Laboratory at the IHV site will include a mid- to high-level basic scientist, 2 post-doctoral scientists, 2 laboratory technicians and a scientist coordinator who will facilitate implementation of the research projects co-developed by Professors Montagnier and Gallo. Funding for this laboratory will be developed under the auspices of the Program for International Viral Collaboration.

The Program will develop funding support for the Ivory Coast, Nigeria, Cameroon and Honduras sites and will include funding for epidemiologists to support cohort development, behavioral scientists to facilitate prevention activities, and clinical staff to provide training in treatment and vaccine research. By building capacity for research and prevention implementation among local staff on site and providing training opportunities for scientists in the principles of basic research, a true partnership for change can be developed.

Site implementation at the international sites will be funded to support local investigators and clinical and laboratory staff at each locale responsible for implementing research studies ranging from cohort studies to pathogenesis to clinical trials research. By targeting sites in a region of Africa experiencing a major epidemic of a shared recombinant virus sub-type (A/G in Nigeria and Ivory Coast) and multiple types in Cameroon in locales where Professors Montagnier and Gallo have longstanding relationships, the World Foundation Program for International Viral Collaboration will provide an optimal platform for interfacing basic and translational research in a balanced international partnership.

In witness whereof, the parties do hereby execute this agreement effective as of February 13, 2002.

Robert C. Gallo, M.D.

For the Institute of
Human Virology

Luc Montagnier, M.D.

For the World Foundation
for AIDS Research and Prevention

APPENDIX 14

TRANSCRIPT: HECKLER NEWS CONFERENCE MONDAY. APRIL 23, 1984

STATEMENT BY SECRETARY HECKLER

April 23, 1984

On June 14th of last year -- about ten months ago -- I traveled to Denver to tell the United States Conference of Mayors that I had made the conquest of AIDS the federal government's number-one health priority.

I told the Mayors and the American people that this awesome medical problem was "a disease with two names." One was "AIDS," Acquired Immune Deficiency Syndrome. The other was "Fear."

In the intervening months, public education and public understanding have substantially reduced the incidence of fear. The panic which, for a time, began to spread through American cities has quieted.

Today I am proud to announce that the arrow of funds, medical personnel, research and experimentation which the Department of Health and Human Services and its allies around the world have aimed and fired at the disease AIDS has hit the target.

Only two or three rings away from the bulls-eye.

Here are the specifics:

First -- the probable cause of AIDS has been found -- a variant of a known human cancer virus, called HTLV-III.

Second -- not only has the agent been identified, but a new process has been developed to mass produce this virus. This discovery is equally crucial because it enables us, for the first time, to characterize the agent in detail and to understand its behavior.

Third -- With discovery of both the virus and this new process, we now have a blood test for AIDS which we hope can be widely available within about six months. We have applied for the patent on this process today.

With the blood test, we can now identify AIDS victims with essentially 100 percent certainty. Thus, we should be able to ensure that blood for transfusion is free from AIDS. We should be able to prevent transfusion-related AIDS cases, as well as those which might appear in hemophiliacs.

We will also be able to promptly and easily diagnose people who may have been infected by the virus, and perhaps develop ways to prevent the full syndrome from occurring.

Finally -- we also believe that the new process will enable us to develop a vaccine to prevent AIDS. We hope to have such a vaccine ready for testing in about two years.

The credit for these discoveries belongs to many people. Under the leadership of the Public Health Service, many scientists, both inside and outside the government and around the world, have given their time, their dedication, their genius to solving this puzzle.

In particular, credit should go to Dr. Robert Gallo, chief of the NCI Laboratory of Tumor Cell Biology, who directed the research that produced this discovery; to Dr. Edward Brandt, the Assistant Secretary for Health, who has led the PHS-wide effort; to Dr. Vincent DeVita, Director of the National Cancer Institute; and to Drs. James Mason and James Curran of the Centers for Disease Control.

And as is so often the case in scientific pursuit, other discoveries have occurred in different laboratories -- even in different parts of the world -- which will ultimately contribute to the goal we all seek: the conquest of AIDS. I especially want to cite the efforts of the Pasteur Institute in France, which has in part been working in collaboration with the National Cancer Institute. They have previously identified a virus which they have linked to AIDS patients, and within the next few weeks we will know with certainty whether that virus is the same one identified through the NCI's work. We believe it will prove to be the same.

I also want to clear up any misunderstandings about these discoveries which have resulted from news reports published before the full import of NCI's work had been shared. That work is described in the four articles in "Science" magazine which are being released today.

The NCI work provides the proof we need that the cause of AIDS has been found. It does this because it goes beyond the simple identification of a particular virus. The special value of the NCI work is that it has developed the process to mass reproduce the virus. Without that ability, we could not be sure of the characteristics of the virus in question -- in short, whether it truly demonstrated the behavior which was a plausible cause of AIDS. Furthermore, without that process, we could not move ahead to the all-important advances in diagnosis, prevention and ultimately treatment.

That is why today's announcement, embodied in the articles by Dr. Gallo's team, are so crucial.

Today's discovery represents the triumph of science over a dreaded disease. Those who have disparaged this scientific search -- those who have said we weren't doing enough -- have not understood how sound, solid, significant medical research proceeds.

From the first day that AIDS was identified in 1981, HHS scientists and their medical allies have never stopped searching for the answers to the AIDS mystery.

Without a day of procrastination, the resources of the Public Health Service have been effectively mobilized. Since 1981, a total of $75 million has been spent toward understanding and overcoming this disease.

For the next fiscal year, the President has requested an additional $54 million to pursue this effort. The work of the National Institutes of Health, the Centers for Disease Control and the Food and Drug Administration inspired by the progress made to date will keep the research and investigation throttle on the floor.

There will be no pause in bringing the full benefits of today's discovery to the victims of AIDS and those at risk:

-- We must quickly take steps to mass produce the material necessary for the blood test -- that work is underway;

-- We must accellerate our efforts to produce a vaccine to prevent AIDS, as well as developing other interventions to halt development of AIDS;

-- And we must, without surcease, continue the hunt for effective therapy for those already afflicted by this disease.

All of these tasks will be pursued with the same zeal, brilliance and tenacity which have brought discovery of the virus HTLV-III.

Today we add another miracle to the long honor roll of American medicine and science. Yet another terrible disease is about to yield to patience, persistence and outright genius.

To Dr. Gallo and all his colleagues and allies in and outside the Department of Health and Human Services who have given so many hours of caring and hard work to make possible today's achievement and the achievements that still lie ahead, I offer the thanks and gratitude of the American people.