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July 21, 1992

NOT FOR PUBLICATION

Mr. Leonard Downie, Jr.
Executive Editor
The Washington Post
1150 15th Street, N.W.
Washington, D.C. 20071

Dear Mr. Downie:

Thank you for your letter of July 7 in response to my letter to you of July 2, 1992. We greatly appreciate your taking the time to look into The Washington Post's coverage of the dispute between the Pasteur Institute and Dr. Gallo. Again, if the Post plans an editorial on this subject, I would ask that we be permitted to present Pasteur's side of the story to the editorial writers.

We do not doubt that the Post strives to employ reporting methods of the highest standard and that your reporters work hard to be accurate and fair. Nevertheless, we feel compelled to bring to your attention a number of aspects of the stories appearing on page A3 of the July 10, 1992 edition, and on page A21 of the July 17, 1992 edition of the Post (attached hereto), including several indisputably false statements. The following is a representative sampling of such statements:

July 10, 1992 Story

1. The second sentence in the last paragraph of the first column states that "[e]arlier this year, a report from NIH's Office of Scientific Integrity cleared [Gallo] of major misconduct or fraud in his role in the discovery of the AIDS virus."

This assertion gives readers the impression that the report represents the official position in this matter. This is false.

The report does not represent the official U.S. position on the issue. It was transmitted by NIH to James O. Mason, Assistant Secretary for Health, for "ACTION," and was specifically labeled "LIMITED OFFICIAL USE ONLY" on each page. Still further, the transmittal letter accompanying the report (authored by Bernadine Healy of NIH) stated unequivocally that "[u]nder the established procedures the Assistant Secretary for Health must make the final determinations regarding scientific misconduct in the intramural programs of the NIH." Dr. Mason has yet to adopt or reject the recommendations of the report.

Contrary to the assertion in your story that Dr. Gallo was cleared by the report, the report recommends that Gallo be held fully responsible for inaccuracies appearing in publications bearing his name and the names of his associates. The report described such inaccuracies as "rang[ing] from editorial mistakes to knowing misrepresentations."[1] Specifically, "[t]he investigative team believed that Dr. Gallo should be held directly responsible for discrepancies [, contained in the 1984 Science paper, numbered] 17-19 [listed on pages 111 through 113 of the report]. In addition, he breached his overall responsibility as head of the LTCB and senior author to ensure the accuracy of the paper."

Nowhere mentioned in the Post's story are the statements of Dr. Frederic M. Richards, the chairman of the panel of scientists appointed by NIH to consult with the OSI investigators. In a separate document,[2] Dr. Richards stated that Dr. Gallo's behavior "constitutes intellectual recklessness of a high degree -- in essence, intellectual appropriation of the French viral isolate." (Emphasis in original.) Dr. Richards further explained that "[t]he Gallo lab 'went to school' with the French virus, yet they later failed to mention the fact that they had propagated the French virus and stated . . . that the French virus had never been transmitted to a permanent cell line." (Emphasis in original.)

2. The second full paragraph in the second column quotes Dr. Robert Redfield as stating that "[i]t is absolutely a matter of public record that Gallo's lab -- and really Gallo's lab alone -- is responsible for the development and implementation of this test in what was an unprecedented period of time."

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1. See page 115 of the OSI report.

2. This document, entitled "Response to the Charge to the Consultants to the Director of the National Institutes of Health Concerning the Investigation of Drs. Gallo and Popovic," was sent to Bernadine Healy with a cover letter dated February 19, 1992.

While we assume that the story accurately quotes Dr. Redfield, we were surprised to see that his statements were chosen for this story. Dr. Redfield is an AIDS researcher at the Walter Reed Army Institute of Research, as the story reports, but also happens to be one of Dr. Gallo's collaborators and active supporters. In fact, Gallo nominated Redfield for a seat on the Scientific Advisory Committee of the World AIDS Foundation.[3] Your story could have obtained an independent scientist's view or could have presented both the Gallo/Redfield view and the Pasteur Institute view.

Moreover, the quoted remarks of Dr. Redfield are inaccurate. The Pasteur Institute performed its first ELISA in Paris on July 10, 1983, while the first ELISA performed in Gallo's laboratory was not done until January 6, 1984 -- and this test was done with the virus discovered by Pasteur's scientists. Montagnier published the first description of the ELISA procedures in April, 1984, in The Lancet.

3. The last paragraph in the second column of the story states that "[i]n 1985, the patent on the Gallo lab test was granted, several months before the Pasteur group received its patent."

This statement is false. Pasteur Institute filed its U.S. patent application for its test in December, 1983. The Gallo application was filed in April, 1984. Gallo received his patent in May, 1985. Pasteur Institute did not receive its patent "several months" later, but in fact did not receive its patent until more than two years later -- and not until after the 1987 Settlement Agreement was entered.

4. In the fourth column, third paragraph, the story states that "Gallo's laboratory . . . managed to get its test to market far more quickly."

Gallo's laboratory had nothing to do with marketing the test. The laboratory gave the virus to the manufacturing companies. These companies then commercialized the test; it was the companies and FDA that determined when marketing could begin.

5. The first full paragraph in the fifth column states that "[t]he test described in the French patent application had only a 20 percent success rate in detecting HIV-infected blood . . . . In other words, their patent did not describe a test that would have been immediately practical for large-scale use in diagnosing HIV infection."

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3. The Scientific Advisory Committee of the World AIDS Foundation consists of 10 members -- five of which were nominated by Dr. Gallo, and five of which were nominated by Dr. Montagnier.

This statement is false and misleading. The sensitivity data for the Pasteur ELISA blood test showed a rapid increase from the initial 20 percent ratio, to 40 percent in October, 1983; to 70-80 percent in December, 1983 through February, 1984; and to nearly 100% in April, 1984. In fact, during February/March, 1984, the Centers for Disease Control performed a direct comparison of the Gallo and Pasteur ELISA blood tests and found that the tests performed equally well, both at a high level of accuracy, in identifying the presence of the AIDS virus.

6. In the last column of the story, the last sentence of the carry-over paragraph states that "[b]ecause the American test has consistently outsold the French version (this year U.S. Royalties will be close to $10 million, while French royalties will [sic] about $ 1 million), the settlement agreement has always resulted in significantly less money for the Pasteur Institute than for the U.S. government."

This statement is wrong. Pursuant to the Settlement Agreement, NIH and Pasteur Institute each retain 20 percent of the royalties each entity collects. Of the remaining 80 percent, which is placed by each institution into a common fund, each institution receives 37.5 percent. Because NIH's contribution to this common fund is significantly greater than that of Pasteur Institute, Pasteur Institute not only receives back all that it has put into the common fund, but also a significant portion of that contributed by NIH.

7. The sixth column, fifth paragraph states: "The recent NIH report said Gallo had many different strains of the virus in his laboratory at the time he developed the blood test, others of which could have been used in the invention."

This is untrue. There is no such statement in the OSI report. To the contrary, the OSI report makes clear that Gallo's own isolates -- which possibly could have been used to create a bloodtest -- were not available until well after the creation of Gallo's blood test. We challenge anyone to substantiate this claim.

<u>July 17, 1992 Story</u>

1. The first sentence of the story refers to "a panel of patent experts." As the story later indicates, this merely refers to a single law firm commissioned by the Department of Health and Human Services ("HHS") to render an opinion on the validity of the Pasteur and Gallo blood test patents.

The reference to "panel" implies that there were multiple, independent, patent experts studying the validity of the patents. This is entirely misleading. There was no "panel" of experts. The "patent experts" referred to consist only of the attorney or attorneys from the one Chicago-based law firm hired by HHS.

2. This story is internally inconsistent. In the first column, second paragraph of the story, it states that Pasteur's scientists "filed for patents on the test simultaneously with the laboratory of National Institutes of Health researcher Robert C. Gallo." In the second column, third and fourth full paragraphs, the story states that the Pasteur Institute filed its U.S. patent in "late 1984," and NIH filed for its patent not "simultaneously," but "[s]everal months later."

The filing dates reported in the story are plainly inaccurate. As we have pointed out above, Pasteur Institute filed its U.S. patent application in December, 1983, not in "late 1984" as the story reports.

3. The story focuses on the report written by the attorneys hired by HHS to determine whether the U.S. should renegotiate the division of royalties. From the story, it appears that the law firm has engaged only in an analysis of the technical validity of the two patents. The issue of whether the division of royalty rates should be renegotiated encompasses far more than this one issue. This decision involves legal, diplomatic and political issues that cannot be ignored, as the Post's story seems to do.

That "Gallo conceded publicly what many -- including the French -- had suspected all along: that in developing his test, he accidentally used a strain of the virus given to him by the French," as the story admits (second column, sixth full paragraph) is, in and of itself, sufficient reason to renegotiate the royalty division. The present royalty arrangement was premised on Gallo's repeated claim -- prior to this admission -- that there were two separate viruses -- his, and Pasteur's. The royalty division was not premised on the validity of Pasteur's patent or Gallo's patent -- the latter of which would not exist if not for Gallo's unauthorized use of Pasteur's virus -- which he falsely claimed to have discovered himself.

Again, we would welcome the opportunity to meet with your editorial writers at their convenience.

Sincerely,

Robert C. Odle, Jr.

Attachments