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**U.S. House of Representatives**  
**Subcommittee on Oversight and Investigations**  
**of the**  
**Committee on Energy and Commerce**  
**Washington, DC 20515-6116**

AND P.F. STUNTZ, STAFF DIRECTOR/CHIEF COUNSEL  
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November 24, 1992

**VIA FACSIMILE**

The Honorable Bernadine P. Healy, M.D.  
 Director  
 National Institutes of Health  
 Bethesda, Maryland 20892

Dear Dr. Healy:

The Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce has received the National Institutes of Health (NIH) November 10, 1992 response to my September 16 letter requesting copies of documents in furtherance of the Subcommittee's ongoing investigation of possible agency misconduct and obstruction of justice associated with the HIV blood test patent dispute. I appreciate receiving the documents accompanying the NIH letter of reply; however, I have very serious concerns about the NIH response, which despite the Subcommittee's numerous requests -- both written and oral -- is still not complete, and which belatedly provides important items that should have been provided many months ago, in response to the Subcommittee's original request. Reasonable cooperation by the NIH would have facilitated completion of the Subcommittee's investigation long ago. Now it is amply apparent that the investigation will have to continue into the new year.

In fact, Dr. Healy, the record of the NIH's actions with regard to the Subcommittee's requests shows a clear pattern of obstructionism and attempted deception that has seriously hindered the Subcommittee's investigation:

1. On January 15, 1992, I wrote to you requesting copies of the Office of Scientific Integrity (OSI) files on the investigation of Drs. Robert Gallo and Mikulas Popovic, co-inventors of the HIV blood test. The NIH responses, provided over the signature of Dr. Jules Hallum, the then-Director of OSI, dragged out over several months. Worse yet, even when the response was said by the NIH to be complete, we found that there were a number of missing documents, as well as a number of documents that were illegible and, therefore, useless. I requested the missing documents in a follow-up letter to you, dated May 27, 1992.

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In late June, several weeks after the requested production date, some of the missing documents were provided, together with a letter signed by Dr. Hallum. However, several key documents sought by the Subcommittee were still not provided. A variety of excuses was proffered by Dr. Hallum as to why the documents could not be provided; none of these excuses had any validity whatsoever with respect to a request from the United States Congress.

This required another follow-up letter from me to you, dated August 19, 1992. Finally, in mid-October 1992, nine months after the initial request, all documents responsive to the January 15 request purportedly were provided, with an accompanying letter signed by Dr. J. Michael McGinnis, the newly-appointed Acting Director of the Office of Research Integrity. The Subcommittee is reviewing these documents to determine if, in fact, all relevant documents have been provided at long last.

2. While the Subcommittee awaited a response to its January 15 request, we received reliable information that documents from the Gallo/Popovic investigation files were being shredded at OSI. I immediately wrote to you about this matter on February 19, 1992. Six weeks later, the NIH produced a report about the shredding incident, and provided it to the Subcommittee over the signature of NIH Associate Director John Mahoney. The report admitted that documents -- original documents -- had been shredded. But the report asserted that "[t]he standard practice in OSI is to shred duplicate materials."

The NIH report on the shredding incident also asserted, with no substantiating evidence, that "... the only materials, other than bad xerox copies of the materials being prepared for the Subcommittee, that were shredded that relate to the Gallo investigation" were pages from Dr. Jules Hallum's notebooks that "... were intended to be kept only until the transcripts [verbatim interview transcripts] were prepared."

These assertions are patently fallacious. The presence of numerous duplicates in the Gallo files, and in other case files provided to the Subcommittee, demonstrates that there is no "standard practice" of shredding duplicates at OSI. Moreover, the existence of a verbatim transcript did not invariably lead to the destruction of interview notes, as proved by the provision of some Hallum notebook pages recording interviews for which a verbatim transcript exists. Thus, the destruction of interview notes clearly was selective, and does not reflect a uniform policy.

Furthermore, the shredded documents were not "duplicates" of other documents in the OSI files. Handwritten notes are in no way "duplicates" of verbatim transcripts -- "duplicate" being a term that denotes identical items such as photocopies, as opposed to successive renditions of the same event or successive versions of the same document.

Moreover, the Subcommittee's review to date indicates that the NIH report's characterization of the notebooks is seriously incomplete. Review of the verbatim transcripts shows that they contain no "off-the-record" comments, nor comments by the investigative team before or after the interviews. The Subcommittee has reason to believe that such comments may well have been recorded in the notebooks. Moreover, the few Hallum notebook pages that have been provided to the Subcommittee contain a variety of entries in addition to interview notes, e.g., vitally important notes of data reviews. The shredding of some of Dr. Hallum's notebooks means that the information in these notebooks is irretrievably lost. The shredding of these notebooks, well after OSI's receipt of the Subcommittee's document request, is at best, a very serious mistake. At worst, it is a potential obstruction of the Subcommittee's investigation.

Finally, the plainly inadequate nature of the NIH's "report" on this incident can only raise further questions about the propriety of the NIH's conduct -- particularly when juxtaposed with the curious diligence the NIH showed in its efforts to search out and destroy the person or persons suspected of having blown the whistle on the shredding incident.

3. On February 26, 1992, I wrote to you requesting that you provide to the Subcommittee "for the time period January 1, 1984 to December 31, 1987, copies of all (NIH) records and documents pertaining to Dr. Gallo's HIV blood test and patent and the related cell line patents, as well as the French/American patent dispute." In my letter, I particularly cited Drs. Robert Gallo and Peter Fischinger, Mr. Robert Lanman, and the Offices of the Directors, the NIH, and the National Cancer Institute (NCI), as sources from which documents were sought.

Upon reviewing the NIH response to my February 26 request, we identified several significant gaps in the NIH document production, notably in the following areas: Office of the Director, NIH; Office of the Director, NCI; Dr. Robert Gallo; and Mr. Robert Lanman. On July 1, 1992, I wrote you about these gaps in the NIH document production, noting, in particular, the complete absence of any documents from the files of Dr. Gallo or

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Mr. Lanman. The NIH response to my letter, stated, with respect to these areas, that "...no additional documents have been located pursuant to your concerns."

4. Meanwhile, the Subcommittee was informed by Mr. William Bundren, formerly of the law firm of Roberts & Bundren, outside patent counsel for the Department of Health and Human Services (HHS), that he had returned the firm's original NIH patent files to the NIH, in May-June 1988. Included in these files were the files on Dr. Gallo's AIDS-related patents. In my July 1, 1992 letter, I requested copies of these documents, which clearly fall within the ambit of the Subcommittee's original February 26, 1992 request, and thus, should have been provided in the initial NIH response.

The NIH response to this request, accompanied by a letter signed by NIH Associate Director, Dr. Jay Moskowitz, included none of the documents specifically sought in my letter. The NIH response included Roberts & Bundren documents from the NIH files, not previously provided to the Subcommittee, but it did not include any of the law firm's original files.

5. Because of the NIH's failure to be responsive to my July 1 letter, it was necessary to write you yet again. In an August 19, 1992 letter, I informed you that the Roberts & Bundren documents provided by the NIH, while within the ambit of the Subcommittee's February 26 request, were "not the documents referenced in my July 1 request." Once again, I made it clear that the Subcommittee was seeking the "complete 'original Gallo file,' which Mr. William J. Bundren has stated he returned to the NIH 'about May or June, 1988.'"

6. In my August 19 letter, I also noted I found it puzzling that neither Mr. Lanman nor Dr. Gallo had any documents responsive to the Subcommittee's request. I specified that "the Subcommittee's request includes documents under the control of either Mr. Lanman or Dr. Gallo or under the control of any of their staff, as well as any documents these individuals may have attempted to 'privatize' by taking them home or transferring them to third parties such as Dr. Gallo's personal attorney." I asked that the NIH make a further search for any responsive documents and I requested that "[i]f Mr. Lanman and/or Dr. Gallo represent that no such documents exist," that the NIH provide to the Subcommittee "a signed statement from either or both of these individuals attesting that the documents sought by the Subcommittee do not exist."

7. In the last week of September 1992, the Subcommittee received the NIH response to my August 19 letter. Again, the letter accompanying the NIH response was signed by Dr. Moskowitz.

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In this response, the Subcommittee was informed, at long last, that the NIH acknowledges the existence of the original Roberts & Bundren files, but is unable to locate them.

I must say I find the alleged "loss" of these documents exceedingly curious, and no mean feat, considering that, according to the NIH's own information, the documents amount to "150-170 files." The loss of such a substantial quantity of original -- and potentially sensitive -- documents, pertaining to an ongoing matter, is itself a great concern, but equally troubling is the NIH's prolonged failure to disclose the documents' existence and loss to the Subcommittee.

8. As for the Lanman and Gallo documents, a substantial quantity was provided at last in response to my August 19 letter. While this was gratifying, it in no way cures the fact that many of the documents fell within the ambit of my original February 26 request and thus should have been provided months earlier.

In this regard, I note that both Mr. Lanman and Dr. Gallo signed statements, included in the September 1992 NIH response, asserting or implying that all responsive documents had been provided to the Subcommittee. Dr. Gallo's statement was particularly noteworthy:

"I really do not know what Mr. Dingell is referring to in terms of documents not received relating to the patent. As far as I recall, or am aware (i.e., to the best of my knowledge), I gave all the original LTCB notebooks to the OSI a long time ago. As far as I am aware, the other documents are listed as having been given to Mr. Dingell. Perhaps there are other documents which the department has, but I do not have any recollection of them."

The fact that such statements were made to the Subcommittee while the person making them continued to possess responsive documents (see below) is deeply troubling.

9. Meanwhile, despite the NIH's repeated claims that it had provided all documents responsive to the Subcommittee's request, we received information concerning the existence of a substantial quantity of documents generated by, or previously in the possession of, Dr. Peter Fischinger, formerly NCI Associate Director and Deputy Director. Incredibly, throughout the many months of repeated requests, these documents were never provided to the Subcommittee. The Subcommittee has learned that certain individuals at the NIH, including Robert Lanman and the NCI's Dr. Thomas Mays, had specific knowledge concerning the existence of these documents, which clearly fall within the ambit of the Subcommittee's February 26 request.

I wrote you about the missing "Fischinger documents" on September 16, 1992, asking that the NIH undertake a specific search for, and provide to the Subcommittee, "all documents irrespective of the date, produced by, or in the files of, Dr. Fischinger relating to Dr. Robert Gallo's AIDS research, Dr. Gallo's AIDS patents, and/or the French/American patent dispute."

10. The NIH response to my September 16 letter, the latest chapter in this matter, is the most troubling of all. Three weeks after the requested date for the response, Dr. Jay Moskowitz wrote that "no additional documents were found that would be responsive to your request." Yet, said Dr. Moskowitz, the NIH desired an additional three weeks "to allow us to thoroughly search all possible resources."

At this point, Mr. Peter Stockton of the Subcommittee staff informed Dr. Moskowitz by telephone of the Subcommittee's strong concerns about the NIH's failure to produce documents known by the Subcommittee to exist. Finally, after more than three additional weeks, accompanied again by a letter signed by Dr. Moskowitz, the NIH provided an additional substantial quantity of documents, most of them appearing to have been generated by or previously in the possession of Dr. Fischinger. Dr. Moskowitz's letter stated that "[t]his submittal should complete NIH's response" to the Subcommittee's request.

I was pleased to receive these documents, although again, I note that they clearly fall within the ambit of the Subcommittee's original request, and thus, should have been provided many months ago. But, incredibly, the documents still do not include certain Fischinger documents known to exist and sought by the Subcommittee. The NIH apparently is still withholding documents.

Moreover, given Dr. Gallo's protestation that he could not even imagine what the Subcommittee meant concerning its document request, I was puzzled to find that most of the documents included in the November 10 NIH response came from Dr. Gallo's Laboratory of Tumor Cell Biology. Among these documents was a vitally important memorandum never previously provided by any NIH, Public Health Service, or Department of Health and Human Services office. Now we learn that this memorandum apparently has been in the files of Dr. Gallo since 1985, the selfsame Dr. Gallo who proclaimed that "I really do not know what Mr. Dingell is referring to...."

I must say, Dr. Healy, that the Subcommittee has been exceedingly patient with the NIH in this matter. I personally have been exceedingly patient. In my August 19 letter, I noted that "...the record of the NIH's response to the Subcommittee's

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requests has not been one of notable cooperation." I told you that "[t]he Subcommittee's investigation has been hindered by the NIH's slow response and, in some instances, its complete failure to respond." I said I trusted that "we can anticipate more active cooperation by the NIH...."

But, if anything, the NIH has become less, not more, cooperative. And, my patience is nearing an end, for there is a clear pattern of delay, obstructionism, and abuse in the NIH's actions in this matter that is intolerable, and strongly suggests an attempted cover-up is underway.

Nor, it appears, is the Subcommittee the only object of the NIH's obstructionism with respect to Dr. Gallo's AIDS research and patents, for we recently have learned that a virtually identical pattern of events has played out in a federal courtroom in the cases of Burroughs Wellcome Co. v. Barr Laboratories, Inc. and the National Institutes of Health (Nos. 91-41-CIV-4-N and 92-117-CIV-5-H, respectively). We are informed that in this matter the United States District Court recently issued an order compelling the NIH's cooperation with outstanding discovery requests pertaining to Dr. Gallo's AIDS blood test patent, including verification of the accuracy and completeness of submissions.

According to the Court's Memorandum and Order, judicial intervention was necessitated not only by the NIH's persistent failure to meet deadlines (the court had ordered full production by April 15, 1992, but the NIH's production was still incomplete as of October 27, 1992) but also because:

"On numerous occasions, HHS/NIH employees have given conflicting testimony concerning the existence of documents and the location of documents in the files of certain HHS/NIH employees.... HHS/NIH employees would certify that no responsive documents existed in certain files, only to have responsive documents produced from those files at a later date."

Because of the demonstrated unreliability of the NIH's representations concerning its compliance with discovery, the Court found: "Counsel for BW Co. has a legitimate basis for questioning the accuracy and completeness of the HHS/NIH's document production thus far." The Court noted that: "The issue of compliance by the HHS/NIH with BW Co.'s discovery requests has been a recurring theme throughout discovery. It is an old song with too many verses." And the Court added that: "The Court will not allow the HHS/NIH...to participate half-heartedly and thwart the parties' discovery goals."

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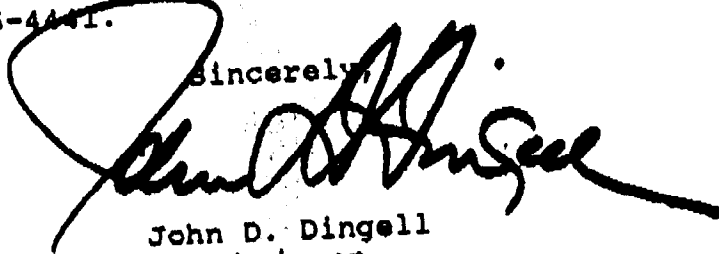
Because of the NIH's poor record in the litigation, the Court included in its order an extraordinary requirement that HHS attorneys meet personally with over a hundred individuals and specifically verify knowledge of the document demands and compliance with them.

The pattern of the NIH's activity recounted in the Court order, is strikingly similar to the NIH's actions vis-a-vis the Subcommittee. Like the United States District Court, we will not tolerate further obstructionism and delay. I intend to send a team of Subcommittee investigators to the NIH in the near future to interview selected NIH employees about this matter, including, but not limited to, Dr. Gallo and Messrs. Lanman and Mays. I ask that you ensure that the Subcommittee interviews are facilitated in every regard.

Dr. Healy, it should be evident to you from this chronology of very troublesome events, that it is essential for you to give this matter your urgent, personal attention. The matter reflects on the integrity of the NIH and on your stewardship as NIH Director. As a starting point, I ask that you respond to this letter by the close of business on Friday, December 4, 1992. Please include in your response a clear-cut statement as to whether you are personally satisfied with the NIH's response to the Subcommittee's requests. If you are not satisfied, please indicate what steps you have taken, or will take, to determine the truth about the documents the Subcommittee seeks, and to ensure that a complete and accurate response to the Subcommittee is promptly provided. In addition, I ask that you inform me how the NIH will respond to the order of the United States District Court discussed above.

The Subcommittee staff will contact your office in the near future to arrange for the interviews necessary to the Subcommittee's investigation. Meanwhile, if you have questions about this letter, you may contact Messrs. Peter D.H. Stockton or Bruce F. Chafin or Ms. Janina A. Jaruzelski of the Subcommittee staff at (202) 225-4441.

Sincerely,



John D. Dingell  
Chairman  
Subcommittee on  
Oversight and Investigations