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United States  
General Accounting Office  
Washington, D.C. 20548

Office of Special Investigations

B-261378

July 5, 1995

The Honorable William S. Cohen  
United States Senate

The Honorable Charles E. Grassley  
United States Senate

This letter responds to your request at our February 22, 1995, briefing that we report on our investigation of circumstances surrounding the reassignments of Dr. Ned Feder and Mr. Walter Stewart, within the Department of Health and Human Services (HHS). As agreed with your office, we had focused our efforts on determining the actions of HHS officials, including Secretary Donna Shalala, with respect to the reassignments and whether the reassignments could have occurred in reprisal for public statements by Dr. Feder or Mr. Stewart. You had also asked us to review the University of Wisconsin-Madison's handling, including its inquiry and subsequent investigation, of charges of scientific misconduct against Drs. Hector DeLuca and Heinrich Schnoes, professors at the university.

In summary, our investigation found no evidence that the HHS reassignments had been handled in an improper manner. Further, we found no evidence that Secretary Shalala or any HHS employee pressured staff of the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), to reassign Dr. Feder and Mr. Stewart. We also found nothing to suggest that the reassignments were in reprisal for statements made by Dr. Feder or Mr. Stewart. Concerning the scientific misconduct matter, we found no evidence that the university's inquiry and investigation lacked thoroughness or objectivity.

REASSIGNMENTS OF DR. FEDER AND MR. STEWART

On April 9, 1993, NIH notified Dr. Feder and Mr. Stewart that they were being reassigned. Dr. Feder was to be reassigned as Medical Officer (Research), Review Branch, Division of Extramural Activities, NIDDK; and Mr. Stewart was to be reassigned as Research Chemist, Biophysical Chemistry Section, Division of Intramural Research, NIDDK. At the time of the notification, Dr. Feder and Mr. Stewart were assigned to and were the only employees in the

Biophysical Histology Section at NIH. Dr. Feder and Mr. Stewart had been involved with scientific misconduct issues, including investigations of individual cases of possible scientific misconduct for the previous 10 years. At times, questions had been raised by their superiors concerning the percentage of time that Dr. Feder and Mr. Stewart devoted to investigating scientific misconduct. Although 75 percent of their time should have been devoted to work in the Biophysical Histology Section, according to their supervisor, they had spent 100 percent of their time investigating scientific misconduct issues for over 2 years preceding their reassignment.

In July 1992, NIH's Associate Director for Administration directed that NIH employees not be assigned or perform any tasks as part of their official duties related to investigation of scientific misconduct, since NIH no longer had primary responsibility for investigating such allegations.<sup>1</sup> NIDDK developed a plan to reassign Dr. Feder and Mr. Stewart to NIDDK positions that did not involve scientific misconduct. NIDDK also considered moving them to the Office of Research Integrity (ORI). However, the reassignments were delayed because of the pending presidential elections and the future appointment of a Director of ORI with whom they would consult about the possible reassignments. The reassignment to ORI never occurred because neither the new ORI director nor Dr. Feder and Mr. Stewart found this alternative acceptable.

On February 12, 1993, Dr. Feder and Mr. Stewart, although scientists, wrote to a historian concerning possible plagiarism in biographies that the historian had written on Abraham Lincoln, William Faulkner, and Martin Luther King, Jr. The historian and the press subsequently asked about the appropriateness and legality of NIH employees, supplies, and equipment being involved in this type of activity. In addition, according to an NIH official, informal inquiries with the HHS Office of General Counsel confirmed that it was unlikely that NIH had the authority to conduct an investigation of a historian. According to Dr. Feder's and Mr. Stewart's supervisor, this placed NIH in a position of either condoning their actions or taking steps to ensure the situation was not repeated. Thus, NIH proceeded with the reassignments. Dr. Feder and

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<sup>1</sup>In June 1992, the Office of Research Integrity, placed under the Office of the Assistant Secretary for Health, was made responsible for investigating allegations of scientific misconduct. Prior to that time, NIH's Office of Scientific Integrity had had this responsibility.

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Mr. Stewart obtained counsel and attempted to negotiate alternative reassignments. However, they could not reach a mutually agreeable alternative; and in September 1993, NIH directed them to report to their new assignments.

UNIVERSITY OF WISCONSIN-MADISON'S SCIENTIFIC MISCONDUCT INVESTIGATION

In 1985, Research in Medicine and Chemistry (RIMAC), a pharmaceutical research firm, filed a lawsuit against the Wisconsin Alumni Research Foundation (WARF), challenging the validity of patents held by WARF originating from the work of Drs. Hector DeLuca and Heinrich Schnoes, professors at the University of Wisconsin-Madison. Mr. Stewart served as a consultant on a pro bono basis for RIMAC from February to April 1987. In an affidavit on the matter, Mr. Stewart alleged scientific misconduct on the part of Drs. DeLuca and Schnoes. In April 1987, after learning of Mr. Stewart's allegations, Drs. DeLuca and Schnoes reported the allegations to the university's Dean of the School of Medicine.

On January 6, 1988, after the RIMAC litigation had been settled, Dr. Howard Rasmussen, Professor of Medicine, Yale University School of Medicine, wrote the University of Madison-Wisconsin's then Chancellor Shalala. Dr. Rasmussen, who had also been involved as an expert in the RIMAC litigation, advised her that allegations of scientific misconduct by professors DeLuca and Schnoes had been disclosed during the litigation. The university's Vice Chancellor for Academic Affairs subsequently selected a committee of three professors, one each from the fields of chemistry, biochemistry, and medicine. These professors, connected with other universities, formed an "inquiry committee." In April 1988, the university convened the committee and directed it to determine the facts in the matter and decide whether the allegations warranted further investigation.

Committee members told us that they used Mr. Stewart's affidavit to focus on five issues. After conducting its inquiry during the summer of 1988, the committee concluded that further investigation was warranted on two issues.

For the investigative phase, Chancellor Shalala requested retired Senior Federal Judge John Reynolds to chair an investigative hearing. Judge Reynolds told us that, consistent with Wisconsin law,<sup>2</sup> a hearing preceded by full

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<sup>2</sup>Wis. Stat. Ann. ch. 227 (West 1994).

discovery was held. He said the hearing was appropriate because the charges of scientific misconduct could have potentially damaged the reputations of the two scientists and would, if substantiated by the investigative committee, have adversely affected their careers, prestige, and opportunities for receiving grants. Under Wisconsin law, the investigative committee used the standard of "clear and convincing evidence" to determine whether a finding of scientific misconduct was warranted.

The investigative committee also included a biochemistry professor and a chemistry professor from other universities. The fourth committee member was a Professor Emeritus of the university whose scientific specialty was microbiology. The university employed a local law firm to represent it. Drs. DeLuca and Schnoes were each represented by counsel.

After a 4-day hearing starting in October 1989, the investigative committee concluded that scientific misconduct had not occurred. Our review of hearing transcripts and documents and our interviews of committee members; attorneys; and Dr. Robert Hesse, a RIMAC scientist who testified as an expert witness, found no evidence that the hearing was unfair or biased.

#### METHODOLOGY

We interviewed each person involved in the reassignment process and reviewed their calendars and working files on the reassignments when they were available. We also reviewed Secretary Shalala's internal and external correspondence and her calendar for January through June 1993, the period beginning with her confirmation until several months after the reassignments.

Further, we interviewed University of Wisconsin-Madison officials, including the Vice Chancellor for Legal and Executive Affairs. We also interviewed each member of the university's inquiry committee and its investigative committee, as well as the attorneys for the university in the investigative hearing. We reviewed the depositions and exhibits available to each committee, including the deposition provided by Mr. Stewart. We interviewed Dr. Feder, Mr. Stewart, and RIMAC's expert witness in its litigation against WARF. We reviewed copies of relevant scientific notebooks and files maintained by ORI. We also interviewed a former ORI official.

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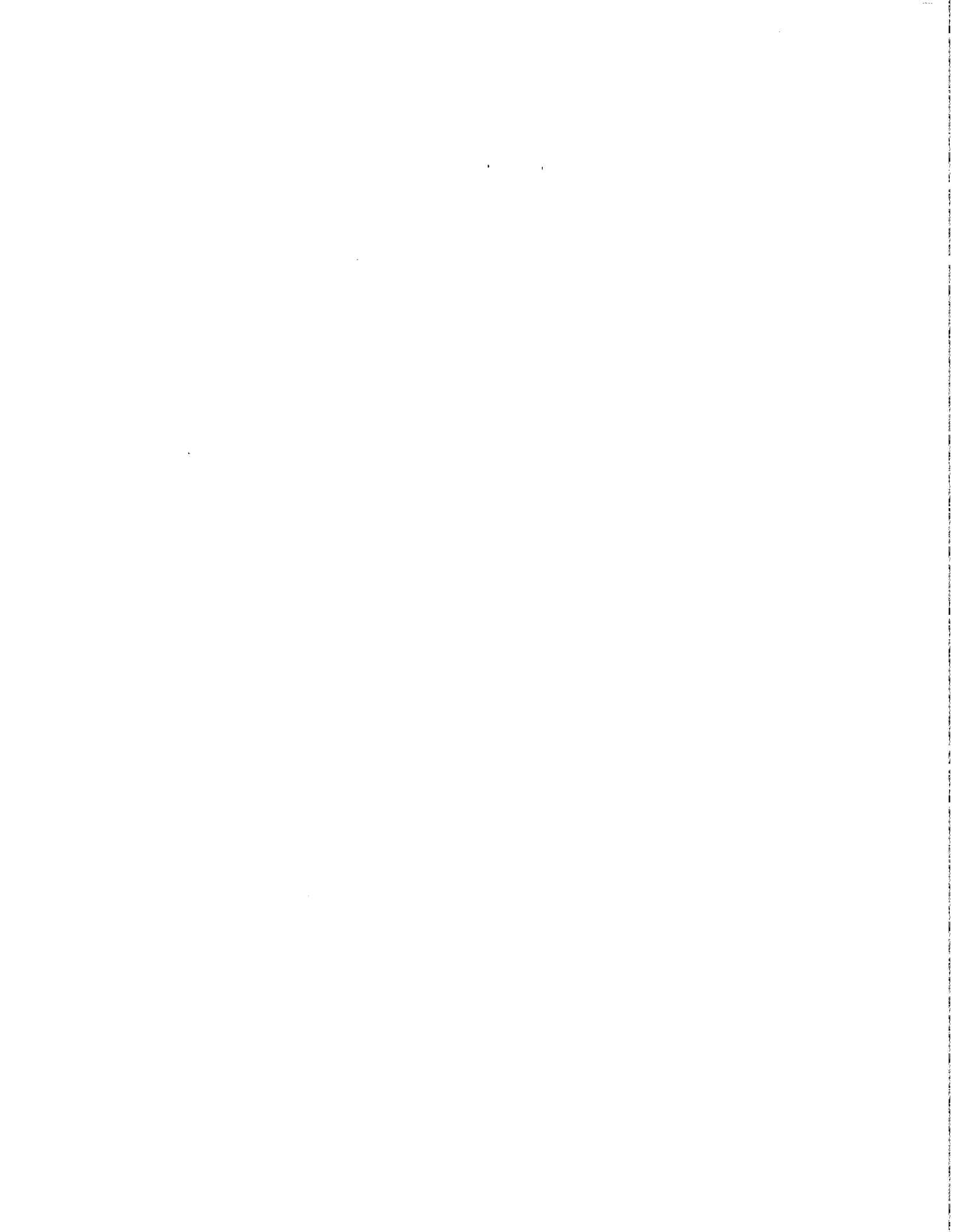
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Should you have any questions concerning our investigation, please contact me or Assistant Director Barney Gomez of my staff at (202) 512-6722.

A handwritten signature in cursive script, appearing to read "Richard C. Stiener".

Richard C. Stiener  
Director

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