December 2, 1989

To Joanne Belk

The Honorable John D. Dingell Chairman, Subcommittee on Oversight and Investigations Committee on Energy and Commerce House of Representatives Washington, D.C. 20515

Dear Mr. Dingell:

This is in response to your letter of December 5 concerning the article on human immunodeficiency virus (HIV) written by Mr. John Crewdson and published in the November 19, 1989, <u>Chicago Tribune</u>. My comments are organized in two parts, corresponding to your Question 1 and Questions 2 and 3, respectively.

What is NIH's mechanism for dealing with possible misconduct among intramural scientists?

Response: When the NIH encounters an allegation or suspicion suggesting possible misconduct associated with research in its intramural laboratories or clinics, the first step is an inquiry conducted by the scientific director of the pertinent institute after consultation with the NIH Deputy Director for Intramural Research (DDIR) and the Director, Office of Scientific Integrity (OSI). The objective is to amass a body of facts sufficient to determine whether or not the matter warrants a full investigation. The institute scientific director employs whatever resources he/she determines to be required and keeps the NIH Deputy Director for Intramural Research (DDIR) fully informed. Upon completion of the inquiry, the institute scientific director prepares a written report to the DDIR presenting findings and recommendations. The DDIR consults with the Director of the Office of Scientific Integrity (OSI) before making a determination.

If the inquiry shows the concerns to lack foundation, the DDIR communicates this conclusion to the appropriate parties and takes whatever other steps are necessary to bring the matter to a close. If, on the other hand, the inquiry establishes the need for an investigation, the DDIR and the Director, OSI, develop a plan for the investigation. The investigation generally involves the participation of a panel of subject matter experts drawn from other NIH components and other research institutions. Every effort is made to avoid involving in the investigation individuals who lack - or might be perceived to lack - objectivity with regard to the pertinent individuals and/or issues. The report of the investigation is shared with the Director, NIH, and the Director of the pertinent institute. The Director, NIH, then submits

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his/her findings and recommendations to the Assistant Secretary for Health through the Office of Scientific Integrity Review. The final decision on the disposition of the case rests with the Assistant Secretary for Health.

Throughout the inquiry and investigation phases, the DDIR and the Director, OSI, keep the Director, NIH, apprised of progress and any major difficultites being encountered. If at any time during these processes NIH staff encounter information that suggests the possibility of criminal wrong-doing, the matter is reported promptly to the Office of the Inspector General of the Department of Health and Human Services. Also, the DDIR and Director, OSI routinely seek the counsel and services of the NIH Legal Advisor and the NIH Division of Management Survey and Review as necessary.

These procedures are an updated version of those first adopted officially in 1985. The core ideas from 1985 have proved efficacious in practice and have been integrated with the role and responsibilities of the Office of Scientific Integrity and the Office of Scientific Integrity Review, which, as you know, were created earlier this year. The relevant guidance documents now are being modified as appropriate to be fully consistent with the new organizational and functional arrangements.

2 & 3. Has NIH been aware of the evidence published in this recent account the <u>Chicago Tribune</u>? Has NIH investigated any of these allegations? If so, please specify which allegations were investigated, the findings of those investigations, the factual basis for the findings, and copies of any reports.

What allegations and concerns raised in the article, if any, have not been investigated? If they have not been investigated, does NIH plan to conduct an investigation of these allegations? If so, what office and persons at NIH will be involved in performing the inquiry, and what procedures will be used? When will the inquiry start and what is the estimated time for completion?

Response: The issues raised in the article by Mr. Crewdson now are being examined in accord with the procedures described above. The preliminary analysis by the National Cancer Institute (NCI) indicates that the article presents no new information and, in fact, in many places is inaccurate, incomplete, or otherwise seriously misleading. Once the NCI analysis is complete, the DDIR and the Acting Director, OSI, will review the findings and supporting documentation and, in consultation with me, determine the next steps. Be assured that the DDIR and the OSI are prepared to undertake whatever fact-finding and investigative steps are necessary over and beyond those of the National Cancer Institute to ensure a proper response to the serious charges inherent in Mr. Crewdson's account, including contacting individuals and institutions outside the NIH.

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I will be pleased to report to you further once we have completed the inquiry phase and determined what further steps are necessary.

Sincerely yours,

William F. Raub, Ph.D. Acting Director

bcc: Dr. Mason Dr. Bivens

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