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A PROPOSAL FOR A WORKSHOP TO CONSIDER STRUCTURAL AND PROCEDURAL
CHANGES IN THE NIH OFFICE OF SCIENTIFIC INTEGRITY

The Present Crisis

There cannot be many American biomedical scientists so hermetically sealed in the ivory tower as to be oblivious of the public furor about science fraud and sharp fiscal practice. The waning respect for the scientist as a person of the highest integrity threatens the future of our calling. The citizen-taxpayers and their elected legislative representatives are likely to become ever-more restive about continuing to provide the generous financial support to which scientists have become accustomed in the last forty years.

There seems to be general agreement among biomedical scientists that something needs to be done. But there is no general agreement regarding just what that something is. It is widely held that scientists have to educate the public and disabuse it of the misconceptions stirred up by the sensationalist media. But how?

Some believe that it is enough to point out that most biomedical researchers are honest. But so, presumably, are most savings-and-loan executives and television evangelists: A few bad apples are enough to create public distrust. Others argue that science is self-regulating and that truth will out in the end. But in some cases, that end may be long in coming. Many believe that even grave scientific misconduct can best be handled, colleague-to-colleague, at the local institutional level, rather than by federal inquisitors resorting to forensic procedures and scientifically ignorant attorneys.

In the best of all possible worlds, this laissez-faire approach might work, but it is improbable that it can do so in the actual situation. In fact, it is amazing how little oversight has previously been given to the scientific integrity of biomedical researchers supported by federal funds. But it is obvious that autonomous self-regulation at the local level is not going to be allowed to continue. Thus, the question to be faced by the biomedical community is not so much whether there will be governmental oversight as what kind of oversight it will be, and how much of it is going to be exercised by scientists and how much by lawyers and administrators without scientific qualifications.

The Office of Scientific Integrity (OSI)

Since March, 1989, there has existed a governmental entity charged with oversight of the scientific integrity of biomedical

researchers whose work is supported by funds provided by the Public Health Service (PHS). This is the Office of Scientific Integrity (OSI) in the Office of the Director of the National Institutes of Health (NIH). Since the beginning of its operations, more than 250 cases of alleged or suspected misconduct in any of the 2400 institutions subject to oversight by OSI have been brought to its attention. Most of these cases were found to require no action on the part of OSI, and in about 80% of those cases which did form the subject of an inquiry or investigation by OSI, no evidence of misconduct was found.

The relatively few instances in which OSI did find grounds for a charge of misconduct included some -as yet unresolved - cases involving well-known and highly regarded scientists. These cases aroused such a storm of protest against OSI, and an attendant loss of confidence in its operations among members of the biomedical community that the future of OSI has been placed in jeopardy. Whether justified or not, these protests seem to have merely confirmed the public in its perception of a self-serving biomedical community, whose conduct and expenditure of public funds is in dire need of external oversight. There can be little doubt that if OSI is disbanded as a result of such criticism, it will be replaced by some oversight agency outside of NIH and hence even less accessible to biomedical scientists than OSI.

It is proposed, therefore, to hold one or more workshops in the early winter of 1991-92 dedicated to developing proposals to restructure OSI so that it will inspire confidence in both the biomedical community and the general public. The objective is to insure that a responsible OSI, rather than some agency outside of NIH (for instance one mandated by Congress in the Department of Justice), retains oversight over scientific misconduct by holders of PHS research grants.

Present Structure and Function of OSI

[The following description of the present structure and function of OSI is adapted from an article by J.V. Hallum and S.W. Hadley, *ASM News*, 56 (12), 647-51, 1990]. OSI was assigned three major functions related to scientific misconduct (a category which includes, but is not restricted to scientific fraud):

I. Overseeing implementation of all policies and procedures related to matters of possible scientific misconduct.

II. Overseeing investigations carried out by institutions applying for or receiving PHS funds into alleged or suspected scientific misconduct by members of their faculty or staff.

III. Conducting, when necessary, inquiries into, or investigations of alleged, or suspected scientific misconduct by investigators applying for or supported by PHS funds.

The oversight and investigative authority of OSI is not restricted to NIH but is PHS-wide, for both intra- and extramural research. In addition, OSI was assigned a fourth function:

IV. Participation in, and direction of, preventive and educational measures to encourage the responsible conduct of research.

The present *modus operandi* of OSI in cases of alleged or suspected scientific misconduct in extramural, PHS-supported research is as follows:

Grantee institutions are required to notify OSI when, after an initial inquiry or fact-finding phase, a formal investigation will be undertaken. OSI monitors the investigation for thoroughness, fairness, objectivity, and timeliness. Upon conclusion of the investigation, OSI receives a full report on the institution's investigation citing the evidence, findings, conclusions, and sanctions imposed, if any. OSI reviews the report and decides whether the findings of the investigation are fair and consistent with the evidence. If misconduct is confirmed and OSI agrees, the report is forwarded, together with any additional sanctions imposed by OSI, to the appropriate agency director, who then sends it to the Office of Scientific Integrity Review (OSIR) in the Office of the Assistant Secretary for Health (ASH) for review. If OSIR approves of the report and recommendations made by OSI, the report is forwarded to the ASH for final review and disposition of the case.

If OSI does not accept the findings of an institutional investigation, it can ask that the institution reopen the investigation or it can open its own inquiry or investigation. OSI can also open its own inquiry or investigation in response to allegations of misconduct made directly to it.

The process by which OSI conducts its inquiries and investigations differs significantly from that by which attorneys gather evidence to decide whether prosecution of an accused is warranted, and, if it is, prepare their cases for trial before the court. OSI refers to its investigative procedure as a "scientific dialogue". The features of OSI's scientific dialogue that set it apart from a normal forensic investigation include the following:

1. A final report of an OSI investigation that finds misconduct and recommends imposition of penalties is not intended to prevail in adversary proceedings before a tribunal but to muster approval of a reviewing official, namely the ASH.

2. To protect the rights of the person accused of misconduct in the absence of adversary proceedings before a tribunal, the scientific dialogue provides for the participation of the

respondent in the investigation. The respondent is kept informed of the progress of the investigation, can introduce evidence or suggest witnesses at any stage, and if OSI uses a panel of expert scientific advisers in its investigation, can suggest scientists to serve on that panel. The respondent (who can be accompanied by counsel) is interviewed, and a full transcript of the interview is sent to the interviewee for correction, commentary, introduction of new evidence or other material, and for refutation or rebuttal of previous evidence. However, the scientific dialogue does not provide the respondent with the opportunity to confront or cross-examine witnesses on whose testimony the findings of the final report may depend. When OSI prepares a draft report containing findings of misconduct, a copy of that report is sent to the respondent for correction, commentary, or rebuttal of evidence. This response may lead to substantial changes in the report. In any case, it is appended to the final report sent to higher authorities for review.

Some Topics for Discussion at the Workshop

1. Identification of the causes for an apparent lack of confidence of the biomedical community in OSI. This discussion would have to avoid any attempt to judge the guilt or innocence of the parties involved in the unresolved, complex cases currently before OSI.
2. Examination of the frequently expressed - but seemingly incoherent - demand by biomedical scientists for the provision of due process to persons accused of scientific misconduct in the absence of adversary proceedings and significant participation by lawyers.
3. Does the OSI investigative "scientific dialogue" actually afford "due process"?
4. Can procedures be devised that would protect whistleblowers from retribution while affording the accused the opportunity to cross-examine witnesses?
5. Would it be desirable to have the final OSI report submitted to a tribunal for adjudication, where due process is observed, in keeping with the American understanding as practiced in our court system, rather than to administrative review?
6. Creation of an Advisory Board to OSI, whose members comprise distinguished persons representative of a broad spectrum of interests and expertise, ranging from the biological and physical sciences, through the social sciences, to the legal profession, politics and industry.

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