ORI NEWSLETTER

Volume 2, No. 4, Office of Research Integrity, U.S. Public Health Service, September 1994.

SCIENTIFIC MISCONDUCT CHARGES AND FALSE CLAIMS ACT SUIT SETTLED

On July 22, 1994, the Office of Research Integrity (ORI) settled scientific misconduct charges against John L. Ninnemann, Ph.D., formerly of the University of Utah and the University of California, San Diego, that will result in his retraction or correction of several articles related to immunosuppression.

In a related agreement, the Department of Justice, Ninnemann and the two universities also agreed to a $1,575,000 settlement repaying grants made by the National Institutes of Health (NIH) for the research. This is the first settlement ever made for alleged scientific misconduct under the False Claims Act.

Although Dr. Ninnemann has not admitted guilt to ORI's allegations that he falsified and misrepresented scientific experiments in grant applications and publications in the 1970s and 1980s, he has agreed to:

1. Be excluded from eligibility for all federal grants, contracts and cooperative agreements for three years.

2. Be excluded from serving on any Public Health Service advisory committees, boards or peer review committees for three years.

3. Submit letters of retraction for five scientific articles.

4. Submit letters of correction for four additional scientific articles.

The Department of Justice separately settled a False Claims Act action against Dr. Ninnemann, the University of Utah and the University of California, San Diego, for $1,575,000. The suit was originally filed by J. Thomas Condie, Ninnemann's former laboratory assistant, under the qui tam provisions of the False Claims Act which permits citizens to initiate a suit on behalf of the government. The suit was based on the scientific misconduct charges settled by ORI and on numerous alleged false statements in several NIH grant applications and progress reports submitted during the 1980s. As part of the settlement agreements, the University of California and the University of Utah agreed to establish programs to prevent future scientific misconduct and to correct deficiencies identified in their institutional policies and procedures for addressing scientific misconduct. Mr. Condie will receive $311,000 plus an additional $255,000 to cover his legal fees.

Dr. Philip R. Lee, HHS Assistant Secretary for Health and

Director of the Public Health Service, said that "this use of the False Claims Act should send a signal to grantee institutions as well as to researchers themselves that they are responsible for the accurate reporting of research in grant applications and reports."

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ORI ADDRESSES MORE ISSUES RAISED BY INSTITUTIONS

This article continues the discussion begun in the September 1993 ORI Newsletter of important issues which have arisen in the course of inquiries and investigations conducted by extramural institutions. The following responses represent ORI's position with respect to PHS scientific misconduct issues and are not necessarily applicable to independent determinations regarding an institution's own professional norms.

DATE Whistleblowers - good faith or good motive - The question of what constitutes a good faith allegation continues to cause concern and confusion among institutions. Under the regulations, institutions must protect the rights and reputations of all parties involved, including individuals who report perceived misconduct in good faith [42 C.F.R. REWRITE 50.103(d)(13)]. A "good faith" allegation means that the whistleblower honestly believed that the allegation was true. Thus, an allegation may be made in good faith even if after investigation the allegation is not proven to be true, or even if the allegation was made for personal reasons. Therefore, if the allegation is made in good faith, under the assurance program the whistleblower may not be retaliated against for making the allegation. Institutions and researchers must guard against the initial reaction of blaming the whistleblower and firing or ostracizing the individual.

DATE Who owns research data and how long must it be kept - Research data generated under PHS funding generally is owned by the grantee institution, not the principal investigator or the researcher producing the data. The institution is the grantee and assumes legal and financial accountability for the awarded funds [See 42 C.F.R. REWRITE REWRITE 50.102 and 52.2(e)]. Therefore, a grantee institution has not only the right, but the obligation to require a researcher to produce accurate supporting data not only for funded programs but also for grant applications. Additionally, grant regulations require an institution to retain records for specific lengths of time and to provide records on request to support a grant project [45 C.F.R. Part 74, Subpart D]. Some institutions have also developed specific internal procedures defining the types of research records that must be kept, their form, and the length of time they must be retained. In conjunction with the regulations, policies such as these help to protect both institutions and responsible researchers in the event of an allegation of scientific misconduct.

DATE Institutional versus PHS standards - Scientific misconduct
under the PHS standards must meet certain legal requirements which may be greater, lesser, or different from an institution's own internal standards. Therefore, an institution in the course of an investigation may find conduct to be actionable under its standards, although the action does not meet the PHS definition of scientific misconduct. Also, if ORI reaches a determination that a particular action does not fall within the definition of PHS scientific misconduct (as opposed to whether the action actually occurred), this finding does not have any bearing on the institution's internal finding or any administrative actions it imposes.

DATE Credentials and publications - The falsification or fabrication of a researcher's credentials and publication list in an application for PHS funds can result in a finding of scientific misconduct. [See Case Summaries on page 3 in this issue.] A review of credentials and publications during the peer review process may be critical to determining if an individual is capable of performing the proposed research.

One institution discovered that due to the lag time in reviewing grant applications, some researchers were inaccurately noting publications as "submitted," "accepted," or "in press." Another institution found that researchers were inserting "anticipatory research" with the hope that actual research would confirm the results before the application went through the review process. These institutions immediately advised all their researchers that such practices were not acceptable.

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Case Summaries

MISCONDUCT FINDINGS RESULT IN VOLUNTARY EXCLUSIONS

Mark S. Chagnon, Sc.D., Molecular BioQuest, Inc. ORI found that Mark S. Chagnon, Sc.D., had engaged in scientific misconduct by misrepresenting his academic credentials in five research grant applications submitted to the National Institutes of Health. ORI found that Dr. Chagnon falsely claimed to have completed undergraduate and graduate studies in chemistry at the Massachusetts Institute of Technology (MIT), Lowell University (Lowell Institute of Technology), and Northeastern University. ORI also concluded that Dr. Chagnon falsely claimed to have earned an M.S. degree in organic chemistry from MIT. ORI's investigation found that Dr. Chagnon was never enrolled as an undergraduate or graduate student at MIT. Because it found that Dr. Chagnon does not possess a degree from any officially recognized institution of higher learning, ORI also concluded that a separate claim that he had conducted graduate studies also constitutes falsification. Although he neither admits nor denies the ORI finding of scientific misconduct, Dr. Chagnon has agreed to a Voluntary Exclusion and Settlement Agreement under which he

will not apply for Federal grant or contract funds and will not serve on PHS advisory committees, boards, or peer review groups for a three-year period beginning June 28, 1994.

Mr. Pantelis Constantoulakis, Advanced BioScience Laboratories, Inc. An investigation conducted by Advanced BioScience Laboratories (ABL) found that Mr. Constantoulakis had committed scientific misconduct by falsifying and fabricating data in biomedical research supported by a contract with the National Cancer Institute and by misrepresenting his academic credentials for purposes of his employment under the contract. Mr. Constantoulakis was at that time an employee of ABL at the Frederick Cancer Research and Development Center. ORI concurred with the factual findings and conclusions of the ABL report. One published paper (Science: 259:1314-1318) was retracted (Science: 264:492) as a result of the misconduct finding. Mr. Constantoulakis accepted the misconduct finding and agreed to a Voluntary Exclusion and Settlement Agreement under which Mr. Constantoulakis will not apply for Federal grant or contract funds and will not serve on PHS advisory committees, boards, or peer review groups for a five-year period beginning August 2, 1994.

Annmarie Surprenant, Ph.D., Oregon Health Sciences University. An inquiry and investigation conducted by the Oregon Health Sciences University (OHSU) found that Annmarie Surprenant, Ph.D. had misrepresented her academic credentials in a grant application for Public Health Service research funds. The OHSU found that Dr. Surprenant had falsely stated that she had earned an M.D. degree from the University of Illinois, Chicago in 1976. As a result of the OHSU investigation, Dr. Surprenant resigned from the OHSU faculty. During its oversight review of the OHSU report, ORI discovered that Dr. Surprenant had also falsely claimed to have earned an M.D. degree on two additional PHS research grant applications. Based upon the OHSU report, as well as the information obtained by ORI during its oversight review, ORI found that Dr. Surprenant engaged in scientific misconduct by falsely claiming to have earned an M.D. degree in three PHS research grant applications. Dr. Surprenant accepted the ORI finding and agreed to a Voluntary Exclusion and Settlement Agreement under which she will not apply for Federal grant or contract funds and will not serve on PHS advisory committees, boards, or peer review groups for a three-year period beginning June 8, 1994.

Anand Tewari, M.D., Stanford University. ORI conducted an investigation into possible scientific misconduct on the part of Dr. Tewari while he was a postdoctoral fellow in the Department of Surgery, Stanford University School of Medicine. ORI concluded that Dr. Tewari committed scientific misconduct in clinical research supported by an NIH grant by fabricating ophthalmologic examination results; fabricating and falsifying blood gas data; fabricating and falsifying values for glycerol determinations; falsifying standard errors and including

fabricated data on platelet counts in a published article, "Effects of interleukin-1 on platelet counts" [The Lancet 336:712-714 (1990)] and related abstracts; and providing to his supervisor summaries of data that included falsified and fabricated data, which were used in a PHS grant application. The published article containing the falsified and fabricated data was retracted on August 22, 1992 [The Lancet 340:496]. Dr. Tewari accepted the ORI findings and agreed to a Voluntary Exclusion and Settlement Agreement under which he may not apply for Federal grant or contract funds except for non-research training or the practice of clinical medicine and may not serve on PHS advisory committees, boards, or peer review groups for a five-year period beginning March 1, 1994.

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ORI ACTING TO PROTECT WHISTLEBLOWERS

The PHS regulations concerning misconduct in science require institutions to undertake "diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations." [42 C.F.R. REWRITE 50.103(d)(13)]

As reported in the March 1994 ORI Newsletter, ORI's institutional compliance reviews may include evaluating how whistleblowers are treated after bringing an allegation of misconduct to the institution's or ORI's attention. Institutions that permit retaliation against good faith complainants are in violation of their Federal assurance and may have their assurance of compliance reviewed as a result. Allegations of retaliation against whistleblowers are handled by ORI's Division of Policy and Education (DPE), which also is responsible for conducting compliance reviews.

ORI has intervened relatively early in some recent cases where whistleblowers appear at risk for retaliatory actions. DPE staff will consult with whistleblowers about their situation or concerns, remind the institution about its responsibility to protect whistleblowers, and monitor the steps being taken to ensure that whistleblowers don't suffer as a consequence of their actions.

An action can be considered retaliation if: (1) the complainant made an allegation that the institution or its officials had engaged in misconduct in science; and (2) an adverse action was taken by the institution, its officials or agents, against that person as a result of their making an allegation of possible misconduct to the appropriate institutional or ORI officials.

Based on ORI's experience to date, it is important for whistleblowers to make complaints of possible or threatened retaliation to institutional officials or ORI immediately after the incident occurs. This permits the institution to intervene and attempt to rectify the situation before the action is more difficult to correct.

ORI believes that it is crucial that whistleblowers are protected from reprisal by their colleagues and from those that they have accused of misconduct. ORI is developing a more comprehensive policy on how institutions should respond to alleged retaliation under the current regulation and plans to announce it in a future ORI Newsletter.

ORI notes that the recent D.C. Circuit ruling in McCutchen v. DHHS (see page [9]) affirms ORI's ability to withhold the names of whistleblowers under the Freedom of Information Act since the complainants have a strong privacy interest in remaining anonymous because, as whistleblowers, they may face retaliation if their identities were revealed.

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SCIENTIFIC MISCONDUCT IDENTIFIED IN MEDLINE CITATIONS

Citations in MEDLINE, the public database on medical and biological publications, will now explicitly identify those publications which contain falsifications or misrepresentations that have been found to constitute "scientific misconduct" as defined by the Public Health Service regulation at 42 C.F.R. Part 50, Subpart A.

The citation's title in MEDLINE will contain the label "[Scientific Misconduct - see comments]." This label will be applied only after the findings of scientific misconduct has been published in the NIH Guide for Grants and Contracts.

The MEDLINE label will alert the scientific community that it should not rely upon some (or all) of the cited published data. It will also facilitate scholarly research on misconduct in research.

The MEDLINE user should continue to consult the NIH Guide for Grants and Contracts for a more detailed explanation of the misconduct finding. ORI reports may be obtained from ORI under the Freedom of Information Act.

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COMMISSION ON RESEARCH INTEGRITY BEGINS DELIBERATIONS

The Commission on Research Integrity began exploring issues related to misconduct in science during its first two meetings in an effort to define its mission and organize its effort.

The meetings were held in the Washington area on June 20 and July 25. Other meetings in 1994 have been scheduled for August 31, October 19, November 7, and December 1. Each meeting is open to the public and is announced in the Federal Register about two weeks in advance.

Among the issues discussed by several speakers were the definition of research misconduct including the "other practices"

clause; the parameters of fabrication, falsification, and plagiarism; the role of intent; burden of proof; due process protections; protection of whistleblowers; timeliness of inquiries and investigations; the hearing process; the role of institutions in investigations; collaboration between the PHS and institutions; institutional non-compliance with the regulation; and standards for scientific conduct.

The Commission also began exploring processes established by government agencies for responding to allegations of scientific misconduct including the PHS and the National Science Foundation, identified needed studies and analyses, and compiled a list of individuals, groups and organizations from which it may seek testimony.

Dr. Kenneth J. Ryan, Chair, said the mandate of the Commission would be defined both narrowly and broadly. He said the Commission would provide advice to the Secretary of HHS on the PHS effort to respond to scientific misconduct as well as provide advice to the academic and scientific communities on the improvement of research integrity. The Commission expects to complete its report by December 1995.

Correspondence to the Commission should be addressed to Henrietta Hyatt-Knorr, Executive Secretary, Commission on Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852.

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ORI PREVAILS IN CIVIL LITIGATION

On July 20, 1994, the U.S. District Court for the Western District of Pennsylvania granted the Government's motion for summary judgement in Hiserodt v. Shalala, C.A. No. 91-0224, thereby dismissing the remaining three counts of Dr. Hiserodt's complaint seeking declaratory and injunctive relief from the ORI's investigation and finding that Dr. Hiserodt engaged in scientific misconduct.

In upholding ORI's position, the court rejected Dr. Hiserodt's contention that the three-year ORI investigation and appeal process constituted an "inordinate delay" in violation of due process of law. The court further held that the ORI investigation was not barred under the doctrine of administrative res judicata because the scientific misconduct regulations provided that the ORI reserves the right to perform its own investigation at any time prior to, during, or following an institution's investigation. The court also rejected Dr. Hiserodt's claims that ORI denied him equal protection of the laws and violated his First Amendment rights to "research, publish on research, and to hold an academic position and enjoy academic freedom." In an earlier decision, the court dismissed Dr. Hiserodt's Administrative Procedure Act and due process claims.

ORI had previously found Dr. Hiserodt guilty of scientific misconduct in 1993 based on extensive falsification in two grant applications to the National Institutes of Health and a fabricated notebook submitted to the grantee institution, the University of Pittsburgh. In a subsequent appeal to the Departmental Appeals Board, ORI's finding of scientific misconduct and administrative actions, including a five-year debarment and correction of the scientific literature, were upheld.

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NAS URGED TO DEVELOP RESEARCH GUIDELINES

The National Academy of Sciences (NAS) was urged to spearhead a campaign within the scientific community to develop guidelines for "good research practices" during the Convocation on Scientific Conduct held at the NAS on June 6-7.

The guidelines would address the "questionable research practices" identified in the recent NAS report, "Responsible Science: Ensuring the Integrity of the Research Process," including retention of data, maintaining adequate research records, assignment of authorship, access to unique research materials, and supervision of research subordinates.

Dr. Bruce Alberts, NAS President, recognized the need for such standards in his opening remarks: "Scientific conduct is something that most of us learned by osmosis, by watching how our mentors behave when we were young...The main message of this meeting, however, is that this method of teaching conduct is today not sufficient. As a community we need to do a better job of setting standards for scientific conduct. The old tradition simply is not adequate any more."

In later remarks, Dr. Alberts urged "the most outstanding scientists and the most recognized people on every campus" to become involved in establishing an atmosphere that promotes the responsible conduct of research at their institutions: "...I do not think the education program should be left only to specialists. They should involve outstanding faculty who will be recognized by students as setting the tone for the whole campus."

The NAS will issue a summary report on the convocation this fall.

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STUDY OF MEDICAL SCHOOL POLICIES UNDERWAY

In order to develop a better understanding of how institutions handle allegations of scientific misconduct, ORI is comparing a sample of medical school policies and procedures for handling allegations of scientific misconduct with the PHS scientific misconduct regulation, 42 C.F.R. Part 50, Subpart A. This in-house study will help ORI to: 1) gain a better understanding of compliance issues; 2) develop model policies and procedures

for use by institutions; and, 3) target its educational outreach. The study is anticipated to be completed in the late fall.

Medical schools were chosen because they received more than 50% of PHS's extramural research funds in 1993. The policies of one quarter of the 126 medical schools holding active PHS assurances are being examined. The study will sample both public and private institutions.

For more information about the study, contact Mary Scheetz at (301) 443-5300 or by E-mail : MSCHEETZ@OASH.SSW.DHHS.GOV.

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COURT UPHOLDS WITHHOLDING NAMES

The D.C. Circuit Court of Appeals ruled on August 5, 1994, that the Office of Research Integrity (ORI) is not required to disclose publicly the names of respondents and complainants in cases where there has been no finding of scientific misconduct. Charles W. McCutchen v. DHHS, Nos. 92-5372 & 92-5389. The Circuit Court reversed in part and affirmed in part the decision of the D.C. District Court in which Dr. McCutchen sought a list of all ORI scientific misconduct investigations under the Freedom of Information Act (FOIA). ORI does not release the names of respondents and complainants in cases where there is no finding of scientific misconduct.

The Circuit Court found that both respondent and complainant names could be withheld in "no misconduct" cases under Exemption 7(C) of FOIA which allows withholding of "records or information compiled for law enforcement purposes...." 5 U.S.C. REWRITE 552(b)(7)(C). For both respondents and complainants in "no misconduct" cases, the Circuit Court found that the "substantial" privacy interest in withholding their names outweighed the public interest in releasing the names.

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PRIVACY ACT SYSTEM OF RECORDS CREATED

ORI has proposed a new Privacy Act system of records, 09-37-0021 entitled "Public Health Service Records Related to Inquiries and Investigations of Scientific Misconduct, HHS/OASH/ORI." The notice was published on July 19, 1994, and, should public comment not lead to a contrary determination, the system was to become final on August 29. This system consists of records related to or collateral to current allegations, inquiries, or investigations of scientific misconduct and/or to actions that PHS has taken in connection with such allegations, inquiries, investigations, or findings. The records are primarily located in the Office of Research Integrity and will be maintained and retrieved by the name of the individual who is the subject of the records.

This system is exempted under subsection (k)(2) and (k)(5) of the Privacy Act from the access, notification, correction and amendment provisions of the Privacy Act. Specifically for ORI records, this means that only if the investigation results in a finding of misconduct can the subject of the records gain access to the material after the case is finally closed. Access still will be denied to material that would reveal a confidential source.

Contact Ms. Barbara Bullman at (301) 443-5300 if you have any questions regarding the system or related exemptions.

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ANNUAL REPORT FORM CHANGED

ORI has added several items to the form entitled Annual Report on Possible Research Misconduct (PHS-6349) for calendar year 1994. In addition to indicating the date on which the institution's policies and procedures regarding research misconduct were last revised, institutions also will be asked to report on how these policies and procedures are disseminated to staff.

If an institution reports misconduct activity, it also will need to provide the following information:

CHAINMACRO(The efforts the institution made to restore the reputations of individuals in each inquiry or investigation who were not found guilty of misconduct.

) The efforts the institution made to protect the positions and reputations of the persons who made allegations of misconduct in good faith for each inquiry or investigation.

The 1994 Annual Report form will be mailed to institutions in January 1995.

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REVISED DAB HEARING GUIDELINES PUBLISHED

ORI published revised guidelines for hearings before the Research Integrity Adjudications Panel of the Departmental Appeals Board (DAB) in the Federal Register on June 9, 1994. These guidelines are intended to provide notice to the scientific community and the general public of the procedures followed by the DAB in conducting hearings on ORI findings of scientific misconduct. For copies of the notice, contact ORI's Division of Policy and Education, 5515 Security Lane, Suite 700, Rockville, MD 20852 (301) 443-5300.

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UPCOMING MEETINGS*

November 2-3 - "Educating for the Responsible Conduct of Research: The Mandate, the Intent and the Means." Boston, MA.

Sponsored by Public Responsibility in Medicine and Research, Association of American Medical Colleges, Tufts University Medical School, and NIH. Contact: PRIM&R, 132 Boylston St., Boston, MA 02116.

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CALL FOR PAPERS*

Science and Engineering Ethics, an international journal to be launched in January 1995, will explore ethical issues confronting scientists and engineers through refereed papers and reviews, editorials and letters, legal matters and news, and book and conference reports. For further information and to submit contributions, contact one of the editors: Dr. Stephanie J. Bird, Massachusetts Institute of Technology, Room 12-187, 77 Massachusetts Ave., Cambridge, MA 02139 (617) 253-8024, FAX (617) 253-1986; or Professor Raymond Spier, School of Biological Sciences, University of Surrey, Guildford, Surrey, GU2 5XH, UK tel/fax: +44(0)483-259265.

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PUBLICATIONS*

"Educating for the Responsible Conduct of Research: NIH Policy and Other Mandates", proceedings of a meeting held on April 1-2, 1993, are now available for purchase. The meeting was sponsored by Public Responsibility in Medicine & Research, the Association of American Medical Colleges, National Institutes of Health, and Tufts University School of Medicine. Copies of the conference report may be ordered by contacting PRIM&R, 132 Boylston Street, 4th Floor, Boston, MA 02116.

*Lists are neither exhaustive nor all inclusive. Nor, should any of the items listed or described be even remotely construed as being favored or endorsed by the Government.

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Comments? Suggestions? We would like to hear from you regarding the ORI Newsletter. THE EDITOR.

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Please Duplicate and Circulate this Newsletter to Offices, Departments, Committees, and Labs. Thank You.

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Office of Research Integrity
U.S. Public Health Service
5515 Security Lane, Suite 700
Rockville, Maryland 20852

Office of the Director	(301) 443-3400
FAX	(301) 443-5351
Division of Policy and Education	(301) 443-5300
FAX	(301) 443-5351
Assurances Program	(301) 443-5300
FAX	(301) 594-0042

Division of Research
  Investigations (301) 443-5330
  FAX (301) 594-0039
Research Integrity Branch/OGC (301) 443-3466
  FAX (301) 594-0041

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ORI NEWSLETTER

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