

ORI NEWSLETTER

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DAB UPHOLDS MISCONDUCT FINDING; ANGELIDES DROPS CIVIL SUIT

In February, the Departmental Appeals Board (DAB), HHS, upheld ORI's finding of scientific misconduct against Kimon J. Angelides, Ph.D., which was based on an investigation conducted by the Baylor College of Medicine (BCM). As a result, he will be debarred from eligibility for Federal grants and contracts for 5 years and he will be required to retract falsified figures in five scientific publications.

Within hours of the DAB ruling becoming public, Dr. Angelides settled the \$25 million wrongful termination/defamation suit he filed against BCM, senior college officials, and members of the investigative committee. In the settlement, he agreed to accept the DAB decision and dismiss all claims against the defendants.

The DAB concluded that Dr. Angelides committed "intentional and conscious fraud" in five NIH grant applications seeking over \$4 million, and in five published scientific papers. It based its decision on evidence presented during a 2-week hearing in April 1998, which involved 40 witnesses, 24 volumes of exhibits, generated 2,100 pages of transcripts, and several hundred pages of post-hearing argument.

The decision spans 169 pages and contains insights into the reasoning the DAB may apply in future disputes. For example, Dr. Angelides argued that data relevant to his defense was missing and likely lost by BCM. The DAB rejected his assertion as not credible, ruling that such an assertion of missing data must be critically evaluated in light of the surrounding facts and evidence presented in the case. Similarly, the decision identifies some factors the DAB considered relevant in evaluating credibility. A fundamental element was the consistency of testimony. The DAB noted that "although the testimony to the Panel was often conflicting, the conflict was between Dr. Angelides and all of his colleagues, whose testimony was consistent with each other."

Chris Pascal, Acting Director, ORI, said civil suits, such as that filed by Dr. Angelides, could negatively impact the investigative process. HHS "is considering whether additional legal protections are needed" to shield institutions and scientists who serve on inquiry and investigative committees from lawsuits. ORI and the Department of Justice filed an *amicus curiae* brief endeavoring to secure such a privilege from suit. However, the court declined to rule on the issue and it remains an open question.

For a more detailed summary or to access the DAB decision, see the ORI website at <http://ori.dhhs.gov>.

ORI SEEKS ASSISTANCE IN DEVELOPING RESEARCH AGENDA

ORI is beginning a process designed to develop a research agenda focused on scientific misconduct and the responsible conduct of research. Early steps include the identification of background materials and, possibly, the commissioning of papers. Ultimately, ORI expects to sponsor a research conference.

ORI is soliciting potential topics for commissioned papers and the research conference. Existing background materials surveying the field would also be welcome. Commissioned papers would provide evaluative reviews of the literature and/or a conceptual framework for major areas of related research. The research conference would explore current and future opportunities in research on scientific misconduct and the responsible conduct of research. One of the goals of the conference would be to identify knowledge gaps needing special emphasis in future research, for example:

- What are the best ways to detect and prevent research misconduct?
- How can research integrity be promoted?
- How can standards be established for recording data and managing laboratories that will foster high quality, creative research?

All suggestions should be submitted by June 30, 1999, to Dr. Alicia Dustira, Division of Policy and Education, ORI. Phone: 301-443-5300. Fax: 301-443-5351. E-mail: adustira@osophs.dhhs.gov.

ON-SITE TECHNICAL ASSISTANCE AVAILABLE FROM ORI

On a pilot basis, ORI is offering a "quick response" technical assistance service to institutions that have determined an inquiry or investigation will be initiated, particularly to those institutions that have rarely or never handled a scientific misconduct allegation. A review of cases opened in 1996 - 1998 reveals that during each of these 3 years, investigations were opened by seven or eight institutions with no prior experience in conducting an investigation.

ORI can offer institutions with little or no experience an immediate on-site visit by an ORI scientist-investigator and attorney to advise institutional officials on the crucial initial steps for handling a misconduct case.

ORI can also provide guidance on analyzing the evidence (*e.g.*, image processing), developing and following up on investigative leads, and preparing the written investigation report. Call the Director, Division of Research Investigations, ORI, at the earliest possible step in the process (301-443-5330).

WHEN CAN INSTITUTIONS RELEASE CASE INFORMATION?

This is another article in ORI's continuing series devoted to questions raised by and of concern to institutions. Recently, we have had several requests for an opinion on when the Public Health Service (PHS) scientific misconduct regulation regarding confidentiality prevents disclosure of an institution's final decision on a scientific misconduct matter and when it would permit institutional officials to release some information.

The confidentiality provision of the PHS regulation requires that the affected individuals be afforded "confidential treatment to the maximum extent possible." 42 C.F.R. § 50.103(d)(3). Thus, although the regulatory language does not create an absolute bar to information disclosure, it does require institutions to take reasonable steps to maintain the confidentiality of the PHS component of the investigation until the respondent has made the matter public, or ORI has completed its oversight review and made a finding of scientific misconduct.

In ORI's view, this confidentiality provision relates only to the regulatory "scientific misconduct" investigation and reporting requirements mandated by the PHS Act and Federal regulations. It is not intended to preclude an institution from disclosing information regarding actions that may have been taken pursuant to the institution's internal procedures and the disclosure of those actions is not otherwise prohibited. This interpretation is consistent with ORI's long-standing policy that institutions may have the same, greater, or lesser standards under their own internal administrative policies and procedures than those mandated by the regulation. For example, in the course of an investigation, an institution may find conduct to be actionable under its internal standards and may impose administrative actions pursuant to findings made under those standards even though ORI would not make a finding under the PHS definition. See "ORI Addresses Ten Issues in Inquiries and Investigations," Office of Research Integrity Position Paper #2 (March 1995, updated June 1998). ORI's policy on this point has been acknowledged in a Federal district court decision which noted that "Even though the federal agency [ORI] to which the university reported may not have considered [the action] to constitute 'misconduct in science,' it recognized the University's right to hold such a practice to be unacceptable." *Shovlin v. University of Medicine and Dentistry of New Jersey*, No. CV97-634 (DRD) *slip op.* at 36 (D.N.J., April 3, 1998), *appeal docketed*, (3rd Cir. 1998).

Also, prior ORI policy permits institutions to notify journals regarding corrections or retractions (without mentioning the PHS component of the case) and to notify medical boards regarding physician professional conduct issues and law enforcement agencies in cases of suspected criminal conduct. See the ORI Model Policy at 15.

Thus, it is ORI's position that if an institution were to make a misconduct finding or take an administrative action regarding an individual, and its internal procedures allowed for the

disclosure of that finding or action, the disclosure would not violate the terms of the regulation assuming that the institution did not disclose that the individual was the subject of a federally-mandated misconduct inquiry or investigation, PHS scientific misconduct was involved, or that ORI was reviewing the case.

In summary, while ORI expects confidentiality of any information related to the PHS aspects of a misconduct inquiry, investigation, or ORI review, the PHS regulation does not prohibit disclosure of internal institutional actions otherwise permitted under an institution's policy and applicable State or Federal law. Institutions must decide for themselves what information, if any, may be released under its own administrative procedures. This places institutions in the same situation as they would be in responding to an internal complaint where no PHS issues were involved and were making a disclosure solely regarding that internal complaint.

4 COUNTRIES DESCRIBE SCIENTIFIC MISCONDUCT PROCEDURES AT WARSAW CONFERENCE

Representatives of four European countries reported on their efforts to develop administrative procedures for responding to allegations of scientific misconduct and promoting good scientific practices during an international conference held in Poland last November.

The "Scientific Misconduct: An International Perspective" conference, held at The Medical University of Warsaw was attended by about 70 persons from Canada, Denmark, England, France, Germany, Norway, Poland, Sweden and the United States. Conference papers have been submitted to *Science and Engineering Ethics*.

Daniel Andersen, the Danish Committee on Scientific Dishonesty (DCSD), reported that the committee closed 24 cases since it was established by the Danish Medical Research Council in November 1992. Scientific dishonesty was found in six cases and less severe deviations from good scientific practice in nine cases. Eighteen other cases were not considered pertinent by the committee.

The DCSD is a national committee that covers research in the health sciences regardless of funding source. "Cases can be brought directly to the committee without involvement of the local research institutions and the committee actually discourages any attempts to conduct local inquiries or investigations," Andersen said. The committee is composed of seven experienced researchers in the health sciences appointed by universities, scientific societies, and other research institutions, and an experienced jurist, a High Court Judge, as chairman. Andersen continued, "The committee has a broad mandate, including case management, prevention of scientific dishonesty, and advancement of good scientific practice."

Allegations received by the committee are sent to the respondent for comment. Those comments

are then sent to the whistleblower for comment. Several rounds of comments may be needed before the committee can decide whether an investigation is warranted. If so, a subcommittee of three impartial experts is appointed and outside experts may be used. The involved parties may comment on the composition of the subcommittee, and they must receive all the information known to and used by the subcommittee. The subcommittee report also is given to the parties for comment. The report and comments are then forwarded to the committee for its decision. No information is provided to external parties (including the news media) until a decision is made. If dishonesty is found, the institution of the respondent is informed; sanctions are the responsibility of the institution. If dishonesty is not found, an abstract devoid of identifiers is printed in the committee's annual report. The involved parties are free to use the decision as they wish, but the committee does not inform any third parties about its decision.

The DCSD has issued guidelines on authorship, collaborative agreements, and other areas. "It was not the intention to create quite new principles for good scientific practice. Rather, it was the intention to make explicit rules which already were well accepted by leading scientists but which had never been issued in a clear text," Andersen said.

Laurence Schaffar-Esterle, INSERM, the primary agency for biological, medical and health research in France, reported that INSERM established a Committee on Scientific Integrity in June 1998 to develop procedures for preventing scientific misconduct and responding to allegations.

To prevent scientific misconduct, Schaffar-Esterle said the committee is emphasizing good laboratory practices (GLP), especially research documentation that includes "the raw data, the modalities of any data processing, and explicit written descriptions of the methodological approach, including the methods of randomisation, the statistical treatment, and the quantitative or qualitative criteria related to selecting the experiments and the results."

"In France," Schaffar-Esterle reported, "the legislative framework governing clinical trials and human subjects research has resulted in their generally excellent conformity with good clinical practices, thereby ensuring not only necessary respect for individuals but also the quality and reliability of the data. Laboratory research, however, does not always comply sufficiently with the rules of good laboratory practice." INSERM is developing a preliminary guide to GLP. The committee recommended that GLP be included in the evaluation of laboratories and researchers. The process recommended by the committee for responding to allegations of scientific misconduct in the 260 research laboratories operated by INSERM includes the appointment of a Scientific Integrity Officer who reports directly to the Director-General of INSERM and is assisted by regional correspondents. Allegations are reported to the Scientific Integrity Officer or the regional correspondents. Procedures include an inquiry followed by an investigation when warranted, separation of the investigative and adjudicative phases, maintenance of confidentiality, use of outside experts, imposition of sanctions, correction of the literature, restoration of reputations, punishment for bad faith allegations, and actions designed to prevent a

repetition of the misconduct.

Schaffar-Esterle said, "Even though each institution must remain responsible for responding to allegations of scientific misconduct within its doors, INSERM would like to see national, European, and international co-ordination about the methods of such response."

Christoph Schneider, Deutsche Forschungsgemeinschaft (DFG), the major research funding agency in Germany, reported that the German Rectors' Conference (HRK) has drawn up model guidelines for procedures to deal with allegations of scientific misconduct that are based on the recommendations of the international commission on professional self-regulation in science established by DFG in June 1997. (See *ORI Newsletter*, June 1998.) The HRK guidelines are available at <http://www.hrk.de>.

After reviewing three cases that led to the creation of the international commission, Schneider said, "What the three cases have in common is that none of the institutions involved was prepared for dealing with the misconduct allegations when they were confronted with them. All necessary procedures had to be invented step by step during their implementation." He added, ". . . above all [there was in one case] the abominable situation of graduate students in the group faced with the choice of condoning, or actively participating in, their superiors' misconduct or leaving the group to face an uncertain future."

Most universities and research institutes in Germany are expected to issue regulations on responding to allegations of scientific misconduct in the next year or two because the DFG General Assembly in June 1998 adopted the recommendations of its international commission, including one that ties eligibility for funding to the availability of internal procedures to safeguard good scientific practice, according to Schneider.

Imogen Evans, Medical Research Council (MRC), the leading research agency on human health in England, outlined the policy and procedure adopted by the MRC in December 1997 that formally covers about 3,000 staff employed in MRC units. Evans said, "Those in receipt of MRC grants in universities and elsewhere are expected to operate under similar policies." The policy and procedure will be evaluated after 2 years. (See *ORI Newsletter*, September 1998.) Evans said the MRC procedure was designed to (1) comply with employment law, (2) embody the principles of natural justice towards those who are the subject of an allegation, (3) protect whistleblowers, and (4) achieve an appropriate balance between confidentiality and publicity.

"The emphasis throughout is not only on impartiality and thoroughness but also on reasonable speed in reaching just conclusions; a protracted inquiry is in no-one's best interests," she said.

Evans continued, "The MRC is also convinced that it is equally important to achieve a working culture that fosters integrity. Thus education and training in good research practices are fundamental to the prevention of research misconduct."

CASE SUMMARIES

Ms. Janell Bodily, B.S., M.S.W., University of Utah (UU): ORI finds that Ms. Bodily, former interviewer, Health Education Department, College of Health, UU, engaged in scientific misconduct in research by intentionally falsifying patient signatures and responses to questions for at least 75 patient interviews for an NIMH-funded research project which involved annual interviews with indigent patients. The falsified information was damaging to the research project because of substantial time and additional money to re-interview patients. Since the data for the previous year could not be recollected, the response rate for that year was substantially below the response rate for other years of the study and may have reduced the overall statistical reliability of the multi-year study. For 3 years beginning January 25, 1999, Ms. Bodily is prohibited from receiving Federal grant, contract, or cooperative agreement funds and from serving in any advisory capacity to PHS.

Ms. Nellie Briggs-Brown, Rush-Presbyterian-St. Luke's Medical Center (RPSLMC): ORI found that Ms. Briggs Brown, a former employee in the Department of Neurology, engaged in scientific misconduct in clinical research by falsifying seven monthly screening logs for a NINDS-funded study involving stroke victims and submitted the same logs with altered dates on multiple occasions to the University of Iowa Coordinating Center, and falsified several Human Investigation Committee (HIC) research approval forms. By submitting false logs, Ms. Briggs-Brown compromised the analyses of the study, and her falsifications on the HIC forms disguised the fact that the study had not been reapproved by the HIC, as required by Federal regulations. For 3 years beginning January 25, 1999, she is prohibited from serving in any advisory capacity to PHS, and her participation on PHS-funded research is subject to supervision requirements.

Saptarshi Paul, Ph.D., Fox Chase Cancer Center (FCCC): ORI found that Dr. Paul, a former research associate, Molecular Oncology Division, engaged in scientific misconduct in biomedical research funded by a NCI grant by falsifying an experiment on the uptake of all-trans retinoic acid (ATR) by HL60 cells conducted by several researchers during July 1997. Although this experiment was not published, discovery of the falsified data led to Dr. Paul's admissions that he altered an experiment, and an acknowledgment that publications would need to be retracted. Several publications were retracted in whole or in part, and portions of two grant applications were retracted. Beginning December 18, 1998, Dr. Paul is prohibited from receiving Federal grant, contract, or cooperative agreement funds, and from serving in any advisory capacity to the PHS for 3 years.

Mr. Thomas Philpot, R.N., B.S.N., (RPSLMC) and Northwestern University (NWU): ORI found that Mr. Philpot, former data manager for the National Surgical Adjuvant Breast and Bowel Project (NSABP) at RPMC and McNeal Cancer Center, formerly an NSABP affiliate of

NWU, engaged in scientific misconduct in clinical research supported by two NCI cooperative agreements by intentionally falsifying and/or fabricating follow-up data on seven separate reports related to three patients enrolled in NSABP clinical trials for breast cancer. Inaccurate information regarding patient status and date of death could have resulted in an over- or underestimate of the treatment benefits since length of survival and length of disease-free survival were primary study points. For 3 years beginning January 19, 1999, Mr. Philpot is prohibited from serving in any advisory capacity to PHS, and his participation on any PHS-funded research is subject to supervision requirements.

Ms. Rocio del Carmen Restrepo, University of Illinois at Chicago (UIC): ORI found that Ms. Restrepo, a former research assistant, Department of Psychiatry, UIC, engaged in scientific misconduct in clinical research supported by a grant from NIMH by fabricating data in the records of 41 patients, including dates on which she claimed to have conducted interviews in certain clinics, fabricating patient consent forms and questionnaires from patients participating in the project; and submitting false information in "Study Daily Logs" that recorded each day's events. For 3 years beginning December 7, 1998, Ms. Restrepo is prohibited from serving in any advisory capacity to the PHS, and her participation on any PHS-funded research is subject to supervision requirements.

Seamer N. Roy, Ph.D., New York Blood Center (NYBC): ORI found that Dr. Roy, a former assistant member, Laboratory of Membrane Biochemistry, NYBC, engaged in scientific misconduct by intentionally falsifying the claim reported in S.N. Roy, B. Kudryk, and C.M. Redman, *J. Biol. Chem.* 270:23761-23767 (1995) ("*JBC 270* paper") that he had obtained the expression of wild type and mutant fibrinogen in yeast cells. Dr. Roy falsified the claim by "spiking" various samples with fibrinogen. Also, he intentionally falsified data reported in a figure of the *JBC 270* paper by using a different exposure of the same autoradiogram later reported in S. Roy, A. Sun, and C. Redman, *J. Biol. Chem.* 271:24544-24550 (1996) ("*JBC 271* paper"). The falsified autoradiogram of the *JBC 270* paper was described differently, though correctly, in the *JBC 271* paper. The *JBC 270* paper has been retracted. For 3 years beginning January 7, 1999, Dr. Roy is prohibited from receiving Federal grant, contract, or cooperative agreement funds and from serving in any advisory capacity to the PHS.

Robert J. Thackeray, R.N., M.P.H., University of Pittsburgh (UP): ORI found that Mr. Thackeray, a former program coordinator, Multi-center AIDS Cohort Study (MACS), Department of Infectious Diseases and Microbiology, Graduate School of Public Health, UP, engaged in scientific misconduct in research supported by NIAID. Mr. Thackeray falsified and/or fabricated research data that he recorded from various tests that he conducted on voluntary subjects enrolled in the MACS. The falsified data were not included in any publications. For 3 years beginning January 19, 1999, Mr. Thackeray is prohibited from serving in any advisory capacity to the PHS, and his participation on any PHS-funded research is subject to supervision requirements.

BETHESDA CONFERENCE TO FOCUS ON TEACHING RESEARCH INTEGRITY

A conference designed to provide pragmatic advice regarding course development and didactic methods for teaching the responsible conduct of research will be held May 13-14, 1999, at the Bethesda Marriott in Bethesda, MD, under the co-sponsorship of Public Responsibility in Medicine and Research (PRIM&R) and ORI. "Educating for the Responsible Conduct of Research in the Next Millennium: New Dilemmas, Continuing Questions, and Effective Strategies" will be the fourth conference that PRIM&R has developed on these issues. Other co-sponsors include the Association of American Medical Colleges, the Applied Research Ethics National Association, NIH, and Tufts University School of Medicine.

The conference will explore the new frontiers of science that are continually expanding and presenting new ethical dilemmas. Some of the topics to be examined include cloning, xenotransplantation, genetic enhancement, and conflicts posed by interactions between managed care and the clinical and research enterprise. In addition, the research community continues to grapple with increasingly complex aspects of research conduct—such as data management, authorship, mentoring, and conflicts of interest. Instruction in the development of training programs to prepare researchers to respond responsibly to the challenges that these topics present will be offered, as well as a broad-based discussion with the audience following the formal presentations. An entire plenary session will be devoted to building new educational programs in the responsible conduct of research.

The conference workshops have been designed to meet the interests and needs of course developers and instructors, deans, research administrators, and trainees. Trainees will have the opportunity to complete a program that should satisfy the NIH requirement for instruction in the responsible conduct of research.

For further information, contact Joan Rachlin, Exec. Dir., PRIM&R, 132 Boylston St., 4th Floor, Boston, MA 02116; Phone: 617-423-4112; Fax: 617-423-1185; E-mail: primr@aol.com.; <http://www.aamc.org/research/primr>.

EDITORS TO CONSIDER AUTHORSHIP ISSUES

A one-day retreat on authorship issues, the results of which may provide the catalyst for development of authorship standards in medical and scientific disciplines, will be held May 24, 1999, at The Queen Elizabeth Hotel in Montreal, under the co-sponsorship of the Council of Biology Editors (CBE) and ORI.

The CBE is composed of editors and publishers of many of the world's leading medical and scientific journals. In addition to its interest in authorship issues generally, ORI will discuss the

opportunities for ORI and scientific journals to collaborate in responding to allegations of scientific misconduct.

For additional information, contact CBE Authorship Forum, 11250 Roger Bacon Dr., Suite 8, Reston, VA 20190; Fax: 703-435-4390; E-mail: cbehdqts@aol.com; <http://www.cbe.org/cbe>.

CONFERENCE PROPOSALS DUE JUNE 1

ORI is seeking proposals from institutions, professional associations, and scientific societies that wish to collaborate with ORI in developing a conference or workshop on scientific misconduct allegations or the promotion of research integrity. The amount of funding available generally would be from \$5,000 to \$20,000. ORI intends to hold four to six regional conferences or workshops each year in strategic locations around the country.

June 1, 1999, is the due date for conferences proposed for January 2000-June 2001. Proposal instructions are available on ORI's home page (<http://ori.dhhs.gov>) or by calling Dr. Alicia Dustira at 301-443-5300, email: adustira@osophs.dhhs.gov.

MEETINGS

May 13-14, 1999 "Educating for the Responsible Conduct of Research in the Next Millennium: New Dilemmas, Continuing Questions, and Effective Strategies" in Bethesda, MD. See story on page 7.

May 24, 1999 "Authorship in Biomedical Publications: Progress and Challenges" in Montreal, Canada. See story on page 7.

May 26-29, 1999 "Teaching Research Ethics" workshop in Bloomington, IN. Contact Kenneth D. Pimple, Poynter Center, Indiana Univ., 618 East Third St., Bloomington, IN 47405; Tel: 812-855-0261; Fax: 855-3315; E-mail: pimple@indiana.edu.

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