

ORI NEWSLETTER

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BOARD FINDS NO MISCONDUCT IN IMANISHI-KARI CASE

On June 21, 1996, the HHS Departmental Appeals Board decided that the evidence did not support a finding that Dr. Thereza Imanishi-Kari had engaged in scientific misconduct by falsifying and fabricating data in a scientific article published in the journal *Cell*, in notebook data submitted to NIH supporting that article, and in grant applications. The Board ruled that the Office of Research Integrity had not proved by a preponderance of the evidence that fabrication or falsification had occurred. The decision rested largely upon the Board's rejection of testimony propounded by the U.S. Secret Service which opined that much of the data submitted by Dr. Imanishi-Kari to support the paper had been deliberately fabricated.

EXONERATED RESPONDENTS REPORT CONSEQUENCES OF BEING ACCUSED

The majority of exonerated respondents perceive an accusation of scientific misconduct as having a mostly neutral impact on their careers, professional activities, and personal lives. However, a sizeable minority perceive the impact as negative, especially when they experienced severe negative consequences.

Less than half of the respondents were satisfied with the handling of their cases, the restoration of their reputations, and the maintenance of confidentiality.

These findings are based on responses from 54 of 108 respondents involved in closed cases prior to 1995 that did not result in a finding of scientific misconduct under the PHS definition. ORI records indicate that institutions impose administrative actions on some individuals exonerated of scientific misconduct because the investigation finds violations of other rules governing their behavior or inadequate job performance. Respondents in this study were not asked to indicate whether any of their reported consequences were due to such findings. However, three respondents reported that they were found to have committed other types of academic or professional misconduct.

Respondents found to have committed scientific misconduct were dropped from the study because the expected response rate would not produce the minimum number of cases (30) required for analysis by the OMB clearance process. The study was conducted by the Research Triangle Institute for ORI.

Sixty percent of the respondents reported experiencing one or

more negative consequences of being accused of scientific misconduct even though the allegation was unsupported; 17 percent reported severe consequences--loss of position, promotions or salary increase; 43 percent reported less severe consequences_threatened lawsuits, additional allegations, ostracism, reduction in research or staff support, delays in processing manuscripts or grant applications, and pressure to admit misconduct. Forty percent reported no negative consequences.

Ninety percent of the respondents who reported negative consequences indicated that the negative actions began during the inquiry and/or investigation and 65 percent reported the negative actions continued after the final determination. Institutional officials were cited as the major source of severe negative actions. Complainants were cited as the most frequent source of negative action--severe and less severe.

The overall impact of the allegation on their career was viewed as neutral by 57 percent, negative by 39 percent, and positive by 4 percent. The most frequently mentioned career dimensions viewed as negatively affected by the allegation were professional reputation, 46 percent; job mobility, 30 percent; and networking 24 percent. Professional activities negatively affected were presenting papers, 39 percent; research, 37 percent; chairing sessions, 30 percent; and serving in elected offices, 28 percent. In their personal lives, negative impacts were seen on mental health, 78 percent; physical health, 48 percent; self-esteem, 46 percent, self-identity, 39 percent; and spouse/partner, 37 percent. Positive effects were seen primarily on self-esteem, 11 percent, and friends, 11 percent.

Almost all of the respondents (94%) were still conducting research. Seventy-one percent were still working in the institution where they were accused of scientific misconduct. Seventy-five percent of the respondents who changed institutions thought the change was desirable. Nevertheless, 39 percent thought it was likely that there is a continuing stigma attached to being accused of misconduct; 54 percent thought it unlikely, and 11 percent did not know.

As many respondents were satisfied (44%) as dissatisfied with the handling of their cases. Major sources of dissatisfaction concerned the opportunity to review reports, protection against conflicts of interest, length of investigation, length of inquiry, confidentiality of proceedings, opportunity to defend themselves, and notification of allegations.

Thirty-nine percent of the respondents were dissatisfied with the efforts made by their institution to restore their reputation. Thirty institutions did nothing to restore the reputation of the respondent; four did so at the request of the respondent. Only nine respondents reported that their institution consulted with them about measures that could be taken to restore their reputations.

Nearly half of the respondents (47%) believed that their institution did all it could to maintain confidentiality. More than a third of the respondents (36%) stated that institutions failed to maintain confidentiality. Breaches in confidentiality were primarily attributed to the duration of the inquiry and/or investigation and information leaks.

A copy of the report on the "Survey of Exonerated Respondents in Research Misconduct Cases" is available from ORI in hard copy or on diskette. Please specify the format preference for your diskette: WordPerfect 5.1 or 6.1 or ASCII.

COURT DISMISSES FISHER SUIT AGAINST ORI, NIH and HHS

On June 25, 1996, a judge for the U.S. District Court for the District of Columbia ruled from the bench in favor of the Secretary, NIH, and ORI by granting HHS' motion for summary judgement and dismissing all claims filed by Dr. Bernard Fisher, the former Chair of the National Surgical Adjuvant Breast and Bowel Project, in *Fisher v. NIH, et. al.* Dr. Fisher alleged in a suit filed last year that the Department, NIH, and ORI had violated the Privacy Act by publicly disclosing information concerning Dr. Fisher and by retaliating against him. The Court ruled against Dr. Fisher on all counts and issued a written memorandum order on August 13. Dr. Fisher has appealed the ruling.

The judge ruled that the ORI files did not constitute a Privacy Act system of records at the time the alleged statements were made. Since then, ORI has established a system of records. The judge also concluded that Dr. Fisher had not shown a nexus between the ORI files and the public statements. There was no supporting evidence that the public statements were based on information retrieved from the ORI file.

The judge also ruled that the NIH database files of MEDLINE®, CANCERLIT®, etc., are not "records" for the purposes of the Privacy Act. He ruled that they were "about" the subject matter of the referenced articles, and not "about" the authors of those articles. A record under the Privacy Act must be "about" the

subject individual.

ATTEMPTS MADE TO RESTORE REPUTATIONS

Efforts to restore the reputation of exonerated respondents were reported in 75 of 92 cases reported by 96 institutions in their 1995 Annual Report on Possible Research Misconduct. Another 21 reported cases were inapplicable because they were still open or concluded with a finding of misconduct.

Maintaining confidentiality was the most frequent action taken, 73 cases. Letters were sent to parties involved in the case informing them that misconduct was not found, 52 cases. Material related to the allegation was not placed in or was removed from personnel files, 18 cases. In one case each, the institution published an article in a campus newsletter or newspaper, provided a positive letter of reference, and sent a letter of exoneration to all faculty and graduate students.

Two actions were taken in 41 cases; 1 action was taken in 23 cases; and 3 actions were taken in 11 cases. No actions were reported in 17 cases. An average of 1.6 actions occurred in each case; the mode and the median were two.

INSTITUTION UTILIZES GUIDELINES FOR RETALIATION COMPLAINT

Guidelines developed by ORI to assist institutions in responding to retaliation complaints from whistleblowers in scientific misconduct cases have been utilized by an institution for the first time.

The institution elected to conduct an investigation rather than submit the complaint to arbitration or reach a settlement with the whistleblowers. The investigation was conducted by a committee composed of three full-time tenured faculty members. During the four-month investigation, the committee interviewed 22 individuals including the whistleblowers and all of the alleged retaliators, and reviewed more than 1,650 pages of documents. The finding of no retaliation was reported in an extensive, well-documented report that included comments from the whistleblowers.

ORI found that the institution had substantially complied with the process outlined in the guidelines and informed the institution that it had met its obligation to undertake diligent efforts to protect the positions and reputations of the whistleblowers.

ACCUSED SCIENTIST SUES INSTITUTION AND OFFICIALS

In August 1995, Kimon Angelides, Ph.D., formerly a research scientist at the Baylor College of Medicine, filed a lawsuit against Baylor and several of its employees in Texas State court seeking damages for various elements surrounding his employment dismissal by Baylor. Dr. Angelides' suit states that he was dismissed by Baylor after the college determined that he had committed scientific misconduct. The suit was filed against not only Baylor but also numerous senior officials of the college and members of the committee that investigated the misconduct allegations.

Baylor was initially successful in removing the case to Federal court, arguing that the case involved the construction of Federal law relating to its obligations under the scientific misconduct provisions of the Public Health Service Act and the Federal regulations. Once in Federal court the defendants attempted to dismiss the case arguing, among other things, that they were entitled to immunity from suit. This central argument focused upon the theory that research institutions are under Federal statutory and regulatory obligations to investigate and act upon allegations of scientific misconduct and that, therefore, they should be entitled to the immunity protections a Federal employee would receive if engaged in the same endeavor.

The Federal district court denied the defendants' motion to dismiss and sent the case back to the State court finding that there was no Federal question upon which to base Federal court jurisdiction. The defendants have appealed the court's ruling to the United States Court of Appeals for the Fifth Circuit. Baylor's appellate brief is due to be filed on or about September 17, 1996. At press time, ORI was conferring with the Department of Justice to determine if an *amicus curiae* brief should be filed by the government in the case, but no decision had been reached.

96 INSTITUTIONS REPORTED MISCONDUCT CASES

Ninety-six institutions reported that they were responding to allegations of scientific misconduct in 1995, according to the Annual Report they filed in March. Sixty-one institutions received new allegations of scientific misconduct in 1995; 47 institutions were continuing to process allegations made in 1994 or before, and 12 institutions were responding to allegations made both prior to and during 1995.

In their submissions, institutions report the receipt of an allegation of scientific misconduct, the type of misconduct, and

the conduct of an inquiry and/or investigation. Reportable activities are limited to alleged misconduct involving PHS-supported research, research training, or other research-related activities.

Of the 61 institutions reporting new allegations in 1995, 47 were institutions of higher education; 4 were research organizations; 8 were independent hospitals; 1 was another health, human resources, or environmental service organization; and 1 was a small business.

Eighty-one new cases were opened by the 61 institutions in 1995. The number of new cases opened by these institutions ranged from one to three. These cases involved 104 allegations, including 24 of fabrication, 46 of falsification, 13 of plagiarism and 21 of other serious deviations. Twenty-five cases involved multiple allegations. Four institutions did not report the type of misconduct.

The 96 institutions conducted 113 inquiries and 68 investigations in 1995, including 70 inquiries and 31 investigations stemming from new allegations. The number of inquiries conducted by an institution ranged from zero to nine. The number of investigations conducted by an institution ranged from zero to three.

MULTIPLE ACTIONS TAKEN TO PROTECT COMPLAINANTS

Two to 9 actions were taken by institutions to protect the position and reputation of individuals who make scientific misconduct allegations in good faith in 70 of the 113 misconduct cases reported by 96 institutions in their 1995 Annual Report on Possible Research Misconduct.

Two to 4 actions were taken in 44 cases; 5 to 9 actions in 26 cases. A single action was taken in 39 cases; no action was taken in 9. The average number of actions per case was three; the mode was one, the median was two.

Institutional actions appear to fall in four categories: (1) establishing policies and procedures, (2) preventive activities, (3) protecting positions, and (4) protecting reputations.

Twenty-nine of the 113 cases occurred at institutions that had established a policy prohibiting retaliation against complainants; 15 cases occurred at institutions that had created procedures for investigating retaliation complaints.

Five types of preventive activities were reported. Confidentiality was maintained, 78 cases; the respondent was cautioned against retaliating, 40 cases; department chairs and deans were reminded about the protections afforded to complainants, 35 cases; institutions monitored for possible retaliation, 33 cases, and institutions imposed sanctions on retaliator(s), 4 cases.

Institutions also took actions to protect the position of complainants. The employment of the complainant was protected in 29 cases, the complainant was relocated in 12 cases, and the complainant was provided assistance to restore his/her research program in 9 cases.

Two types of actions were taken to protect the reputation of complainants. Appropriate officials were informed that the allegation was made in good faith in 41 cases and institutions publicly acknowledged that the complainant did "the right thing" in 11 cases.

CASE SUMMARIES

Yahya Abdulahi, Ph.D., Clark Atlanta University (CAU): Based on the institution's report and ORI's own analysis, ORI found that Dr. Abdulahi, former Research Scientist, Department of Biology, CAU, committed scientific misconduct by plagiarizing words and concepts from a publication in the *Journal of Environmental Health* and by misrepresenting data in sections of a PHS grant application.

Specifically, Dr. Abdulahi's grant application contains extensive and significant plagiarism in the "Description," "Background and Significance," "Experimental Design and Methods," and "Literature Cited" sections and contains plagiarism and misrepresentation of data in the "Preliminary Studies" section. Dr. Abdulahi's actions were serious in that the plagiarism involved (1) the use of extensive sections of a publication without attribution, (2) misrepresented data, and (3) expropriation of the study concept.

Dr. Abdulahi has entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed, for the three-year period beginning July 16, 1996, to exclude himself from any Federal grants and cooperative agreements, and service on any PHS advisory committee, board, and/or as a consultant. No publications were required to be corrected as part of this Agreement.

Robert J. Altman, M.D., University of California at San Francisco (UCSF): Based on an investigation conducted by the institution as well as information obtained by ORI during its oversight review, ORI found that Dr. Altman, Research Fellow, Department of Obstetrics, Gynecology, and Reproductive Sciences, UCSF, committed scientific misconduct by fabricating and falsifying data in research supported by two NIH grants.

Specifically, Dr. Altman fabricated an experiment related to an ovarian cell line injected intraperitoneally into 12 nude mice. The resulting data were reported in (1) a manuscript in page proof entitled "Inhibiting vascular endothelial growth factor arrests growth of ovarian cancer in an intraperitoneal model" (*Journal of the National Cancer Institute*); (2) a manuscript entitled "Vascular endothelial growth factor is essential for human ovarian carcinoma growth in vivo," submitted to the *Journal of Clinical Investigation* (JCI manuscript); and (3) a published abstract entitled "Vascular endothelial growth factor is essential for ovarian cancer growth in vivo" (*Society for Gynecologic Investigation*, abstract #079). Further, in the JCI manuscript, Dr. Altman (1) falsified the number of subjects with ovarian tumors from whom he obtained sections of tissue for examination of the expression of vascular endothelial growth factor (VEGF) purportedly by both *in situ* hybridization and immunohisto-chemistry, and (2) falsely reported that VEGF expression was examined by *in situ* hybridization and immunohistochemistry in papillary serous- (n=7) and mucinous-(n=5) cystadeno-carcinomas, when the number of surgical cases involving papillary serous tumors was four and the number of mucinous tumors was zero. Dr. Altman examined VEGF expression in only three papillary serous tumor specimens, one specimen both *in situ* and by immunohistochemistry and the remaining two solely by immunohistochemistry.

Dr. Altman has entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed, for the three-year period beginning June 11, 1996, to exclude himself from any Federal grants and cooperative agreements, and service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

The above voluntary exclusion shall not apply to Dr. Altman's future training or practice of clinical medicine whether as a medical student, resident, fellow, or licensed practitioner, unless that practice involves research or research training.

Eric T. Fossel, Ph.D., Beth Israel Hospital/Harvard Medical

School (BIH/HMS): Based on ORI's analysis of the relevant evidence and conclusions submitted by the Harvard Medical School Committee on Faculty Conduct, ORI found that Dr. Fossel, former Harvard Medical School Associate Professor of Radiology at Beth Israel Hospital, committed scientific misconduct by reporting falsified research results in a PHS grant application.

Specifically, Dr. Fossel altered nuclear magnetic resonance (NMR) data in the Multicenter Breast Trial (MCBT) such that the NMR test, purporting to detect from a patient's blood sample a predisposition toward malignancy or a relapse, appeared to be more accurate, sensitive, and specific than was actually the case. Premised on these falsely reported results, Dr. Fossel proposed in a PHS grant application that the National Cancer Institute provide funds to complete the MCBT.

Dr. Fossel has entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed, for the three-year period beginning May 9, 1996, to exclude himself from any Federal grants and cooperative agreements, and service on any PHS advisory committee, board, and/or peer review committee, or as a consultant. No scientific publications were required to be corrected.

Vipin Kumar, Ph.D., California Institute of Technology (CIT): Based upon a report forwarded to the ORI by CIT as well as information obtained by ORI during its oversight review, ORI found that Dr. Kumar, formerly a scientist at CIT, engaged in scientific misconduct in biomedical research supported by PHS funds.

Specifically, ORI found that Dr. Kumar committed scientific misconduct by falsifying and/or fabricating Figures 2a and 2b in a scientific paper published in the *Journal of Experimental Medicine*, 170:2183-2188 (1989) (*JEM* paper). ORI accepted the CIT conclusion that Dr. Kumar "freely admitted" that he mislabeled the lanes in Figures 2a and 2b. Although he denies that he intended to deceive anyone, CIT concluded in its report that the "deliberate presentation of duplications of one experiment which are labeled to indicate they came from separate DNA samples deceives the reader as to the real source of the DNA in the experiment, where the central point of the experiment is the similarity of results among different sources." ORI also accepted the CIT conclusion that he presented Figure 2c of the *JEM* paper "in a very misleading fashion." The central observation of the *JEM* paper is that both alleles of the alpha chain of the T-cell receptor gene are frequently rearranged.

This conclusion was based, in part, on Figure 2c, which CIT found had been labeled in a misleading fashion that led the reader to believe that the heavy band at the top of the blot was an 8kb restriction fragment (i.e., representing an internal control) rather than undigested material that failed to enter the gel. Examination of the original film indicates that there was no evidence that the second alpha chain rearranges in mature T-cells. Thus, ORI further accepted the CIT conclusion that Figure 2 was intentionally falsified and/or fabricated and that, as a result, "one of the main scientific results of this paper was not substantiated by the original data." In addition, ORI found that Dr. Kumar committed scientific misconduct by falsifying and/or fabricating Figure 5b of a manuscript that was submitted for publication to the journal *Cell* (*Cell* manuscript), but was later withdrawn. ORI accepted the CIT conclusion that lanes 6, 7 and 8 of Figure 5b are the same as lanes 11, 12 and 13, respectively, even though they are labeled as being from different samples. ORI also accepted the CIT conclusion that Dr. Kumar made a number of other materially misleading statements in the *Cell* manuscript that were not supported by the primary data. Based upon the findings of scientific misconduct in the CIT Report, the *JEM* and *Cell* papers were retracted prior to ORI's findings in this case.

ORI and Dr. Kumar agreed to resolve the case through a negotiated settlement and limited voluntary exclusion agreement, which the parties agreed shall not be construed as an admission of liability or wrongdoing on the part of the Dr. Kumar. He has also submitted a letter to ORI in which he summarizes his response to ORI's findings. Dr. Kumar has agreed to exclude himself voluntarily from serving in any advisory capacity to the PHS, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three years beginning June 19, 1996. He has also agreed to exclude himself for 18 months from any Federal grants and cooperative agreements, beginning June 19, 1996. This provision does not apply to a currently pending PHS grant application involving Dr. Kumar.

In addition, any institution that uses Dr. Kumar in any capacity on PHS-supported research must concurrently submit a plan for supervision of his duties designed to ensure the scientific integrity of his research and a certification that the data provided by Dr. Kumar are based on actual experiments or are legitimately derived and that the data, procedures and methodology are accurately reported in the application or research report, for a period of 3 years beginning June 19, 1996.

Michael W. Washabaugh, Ph.D., Johns Hopkins University (JHU):

Based on an investigation conducted by the institution as well as information obtained by ORI during its oversight review, ORI found that Dr. Washabaugh, Associate Professor of Bio-chemistry, Department of Biochemistry, School of Hygiene and Public Health, JHU, committed scientific misconduct by reporting falsified and/or fabricated research data in two NIH grant applications.

Specifically, Dr. Washabaugh (1) reported falsified results of experiments concerning the number of DTNB (5, 5'-dithiobis [2-nitrobenzoate]) reactive thiols in native thiamin-binding protein in a grant application entitled "Mechanism of a periplasmic permease," and (2) re-ported falsified and/or fabricated portions of data presented in two separate figures to support his hypo-thesis of thiamin binding to thiamin binding protein in grant applications entitled "Mechanism of a periplasmic permease" and "Mechanisms of enzymic and non-enzymic thiamin reactions."

Dr. Washabaugh has entered into a Voluntary Exclusion Agreement with ORI in which he agreed, for the four-year period beginning May 7, 1996, to exclude himself from any Federal grants, cooperative agreements and service on any PHS advisory committee, board, peer review committee, or as a consultant. No scientific publications were required to be corrected as part of this Agreement.

GERMAN UNIVERSITY WITHDRAWS DOCTORATE IN MISCONDUCT CASE

Earlier this year, two years after he allegedly was caught trying to manipulate the results of a laboratory experiment based on his thesis, the University of Bonn withdrew the doctorate it had awarded to a chemistry researcher.

According to a July 11, 1996, news story in *Nature*, this may be the first case of its kind reported in Germany, and the accused is likely to challenge the decision in court.

Guido Zadel, a former doctoral student at the university's Institute of Organic Chemistry was awarded his Ph.D. at the end of 1993. He claimed to be able to produce an excess of "right-handed" or "left-handed" molecules using a static magnetic field during a chemical reaction.

Other research groups had not been able to reproduce his results. Even though Zadel reportedly was caught replacing the samples of one experiment with his own mixtures, he continues to insist that

his results are legitimate and reproducible. He contends that he had proof in his laboratory notebooks which were stolen and that a colleague replicated the experiment.

GOVERNMENT-WIDE DEFINITION OF RESEARCH MISCONDUCT

The Office of Science and Technology Policy in the White House is spearheading the development of a definition of research misconduct that will be applicable to all federally funded research.

The definition is being developed by a panel of the Committee on Fundamental Science within the National Science and Technology Council. Representatives from NIH, NSF, and other Federal agencies are on the panel.

Besides the definition, the panel is also charged with developing guidelines for the respective roles that Federal agencies and research institutions should play in ensuring the integrity of the scientific record.

CALL FOR ABSTRACTS*

January 15, 1997. Abstracts are due for the Third International Congress on Peer Review in Biomedical Publication set for September 17-21, 1997, in Prague. For more information, contact Annette Flanagan, JAMA, 515 N State, Chicago, IL 60610, USA; tel: 001-312-464-2432; fax 001-312-464-5824; London WC1H JR UK; tel: 44-171-387-4499; fax: 44-171-383-6418; email: 100730-1250@compuserv.com.

**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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