ORI NEWSLETTER

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COMPLAINANT WINS *QUI TAM* SUIT ON THEFT OF INTELLECTUAL PROPERTY

The University of Alabama at Birmingham (UAB) and four of its scientists have been ordered by a Federal judge to pay more than $1.9 million for committing "malicious acts of fraud" against the complainant by claiming her work as their own, according to news reports. The university plans to appeal the decision.

The lawsuit, filed under the False Claims Act, focused on dissertation research on cytomegalo-virus conducted by Dr. Pamela Berge at UAB while she was a graduate student at Cornell University. In her suit, Dr. Berge claimed that the defendants had stolen her intellectual property by reporting her research as their own. The defendants, Sergio Stagno, Robert Pass and Charles Alford, all professors of pediatrics, and Dr. Karen Fowler, a researcher, argued that the research they reported was based on their own work.

Two inquiries were reportedly conducted by UAB into the allegation, but no misconduct was found. Dr. Berge contacted ORI once, but did not file a formal allegation.

As a result of the jury verdict, the university was ordered to pay $l.65 million, triple the amount of the false claim of $550,000, of which Dr. Berge may be entitled to up to 30 percent because the Federal Government did not join in the suit, according to *Science*. In addition, the four scientists were ordered to pay Dr. Berge, an epidemiologist, $265,000 in compensatory and punitive damages. Under the *qui tam* provisions of the Act, private citizens may initiate a suit on the Government's behalf.

This is the third case involving scientific misconduct that has resulted in large awards or settlements. In 1994, another *qui tam* case filed against the University of Utah, the University of California at San Diego, and John L. Ninnemann, Ph.D., by J. Thomas Condie was settled for nearly $1.6 million. The case involved allegations of falsification and misrepresentation of research in grant applications and publications. The Federal Government joined Mr. Condie in this suit.

In 1993, a lawsuit involving allegations of plagiarism and retaliation filed against Dr. Marion Perlmutter, Dr. Richard Adelman, and the University of Michigan by Dr. Carolyn Phinney, a

research psychologist, resulted in a $1.2 million award.

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WHISTLEBLOWERS REPORT
CONSEQUENCES OF WHISTLEBLOWING

Whistleblowers in scientific misconduct cases are highly likely to experience one or more negative consequences as a result of their whistleblowing, but most perceived those consequences to have had a neutral impact on their careers, professional activities, and personal lives.

This is one of the findings of a survey conducted by the Research Triangle Institute for ORI of 68 whistleblowers involved in closed PHS misconduct in science cases.

Sixty-nine percent of the whistleblowers reported experiencing at least one negative outcome; 31% experienced none. Twenty-five percent reported serious consequences such as loss of position or denial of tenure, promotions, or salary increases.

About 62% of the whistleblowers perceived their whistleblowing to have had a neutral impact on their careers, professional activities, and personal lives; about 28% perceived a negative impact; and 10% perceived a mixed (positive and negative) impact.

Although few whistleblowers perceived positive consequences, 68% would make another allegation, 12% probably would, 10% were uncertain, and 10% would not.

Other negative consequences noted by whistleblowers include reduction in research support or travel funds; counter-allegations; delays in reviewing manuscripts or processing grant applications; and ostracism.

Whistleblowers attributed the negative consequences to institutional officials, respondents, colleagues, and professional societies. The most serious consequences were most frequently attributed to institutional officials. Whistleblowers experienced these consequences while the institution was responding to their allegations and after the inquiry or investigation was completed.

Whistleblowers perceived negative career effects more frequently on their reputations, promotions, research, income, job mobility, and collaborations. Negative effects on professional activities were perceived more frequently on research, collegial relations, committee memberships, and the chairing of sessions at

professional meetings. In their personal lives, the negative effects were perceived more frequently on their mental health, finances, physical health, and spouse. Positive effects were most frequently perceived on self-esteem and self-identity.

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INSTITUTIONS REPORT MISCONDUCT ACTIVITIES

Seventy-nine institutions were responding to allegations of scientific misconduct in 1994, according to the Annual Report on Possible Research Misconduct that each institution must file with ORI to remain eligible for PHS research funding.

Fifty institutions received new allegations of scientific misconduct in 1994. Forty-two institutions were continuing to process allegations made in 1993. Thirteen of the institutions were responding to allegations made in 1993 and 1994.

In their annual reports, 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. Annual reports were filed by 3021 institutions for 1994.

Of the 50 institutions reporting new allegations in 1994, 39 were institutions of higher education; five were research organizations; one was an independent hospital; two were other health, human resources, or environmental service organizations; and three were small businesses.

Sixty-four new cases were opened by the 50 institutions in 1994. The number of new cases opened by these institutions ranged from one to four. These cases involved 89 allegations, including 23 of fabrication, 29 of falsification, 10 of plagiarism and 27 of other practices. Twenty-three cases involved multiple allegations.

The 79 institutions that reported activity on their annual reports conducted 88 inquiries and 55 investigations in 1994 including 56 inquiries and 20 investigations stemming from new allegations. The number of inquiries conducted by an institution ranged from zero to eight. The number of investigations conducted by an institution ranged from zero to four.

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REPORT OF THE 1993 PLAGIARISM CONFERENCE PUBLISHED

A 250-page report is available on computer diskette of the 1993 Conference on Plagiarism and Theft of Ideas, sponsored by the ORI and the American Association for the Advancement of Science.

This two-day public conference was held in June 1993 at the National Institutes of Health. It focused on the institutional handling of allegations of plagiarism and their societal context. The twelve speakers included professors or administrators from research universities, journal editors, and officials of professional associations. The 150 attendees included whistleblowers, integrity officers, scientists, and administrators from across the United States. They participated in active discussions of the issues.

Contact Karen Gorirossi at ORI, 5515 Security Lane, Suite 700, Rockville, MD 20852 (phone 301 443-5330 and fax 301 594-0039). Specify the format preference for your diskette type: WordPerfect 5.1 or 6.1 or ASCII.

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CIRCUIT COURTS DENY APPEALS

The Third Circuit Court of Appeals upheld the decision of the District Court for the Western District of Pennsylvania granting the government's motion for summary judgement, thereby dismissing the complaint of Dr. John C. Hiserodt, for declaratory and injunctive relief from the ORI investigation and finding, and administrative actions. *Hiserodt v. Shalala*, No. 95-3504, slip. op. (3rd Cir. July 5, 1995).

The Fourth Circuit Court of Appeals affirmed the decision of the District Court in Maryland requiring Dr. Prince Kumar Arora, NIH, to pay the Federal Government compensatory and punitive damages of $5,450.20, plus costs of the civil suit, for intentionally destroying government-owned cells used in research. *United States v. Arora*, No. 94-2387, slip. op. (4th Cir. May 25, 1995).

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INSTITUTIONS TAKE STEPS TO RESTORE REPUTATIONS

Institutions rely heavily on the confidentiality of their administrative process for handling allegations of scientific misconduct to protect the reputation of accused individuals. They also take additional steps to restore the reputation of

exonerated individuals, according to their 1994 Annual Report on Possible Research Misconduct.

Federal regulations require institutions applying for or receiving PHS funds to "afford the affected individual confidential treatment to the maximum extent possible" and undertake "diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed."

In one case, according to the institution, the exonerated individual was relocated in a different environment with institutional funding for an 18-month period. In another case, the institution reported that the individual was counseled by the dean and associate dean for research. In a third case, the institution provided defense in civil litigation.

Two steps frequently taken by institutions were to send information of "not found guilty of misconduct" to all parties involved including complainant, respondent, witnesses, panel members, department chair, national or state agency, and to clean the personnel files of all documents regarding the allegations.

The information is usually contained in letters from the president, dean, or other high-level administrator. Besides those involved in the process, letters may be sent to senior administrators, professional societies, the home institution or all individuals to whom the person was interested in having the information disseminated. In a highly publicized case, the president, provost, and integrity officer issued public letters that were printed in the university newspaper.

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INITIAL ASSURANCE FORM DELETED; ANNUAL REPORTS CONTINUE

The PHS Grant Application Form 398 has been revised so that institutions submit their Initial Assurance Regarding Misconduct in Science by signing the face page of the application rather than by submitting PHS form 6315 to the ORI. By signing the new application form, an institution declares that it has complied with all the requirements codified at 42 C.F.R. Part 50, Subpart A, including establishing and following an administrative process for responding to allegations of scientific misconduct that involve PHS-supported research.

However, institutions are still required to submit PHS Form 6349 "Annual Report on Possible Research Misconduct" to ORI. The

Annual Report requests data on misconduct allegations, inquiries, and investigations handled in the previous year and other activities required by the Federal regulation. ORI sends Form 6349 each January to all institutions that have an active assurance on file. That form must be completed and returned to ORI for the institution to remain eligible to receive PHS research funds.

Similar revisions were made last year to the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program grant applications (PHS Form 6246).

New application forms and instructions may be requested from the Grants Information Office at (301) 435-0714.

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SCIENCE CONDUCT GOES ON-LINE

Science magazine initiated an electronic project called "Science Conduct On-line." The interactive project includes ethical scenarios posted by a panel of five experts in scientific conduct. Readers can react to those scenarios and the panel responds on-line. This project can be reached on the World Wide Web through the Science magazine home page (http://www.aaas.org/science/science.html) under the section "Beyond the Printed Page."

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COMMISSION REPORT SLATED FOR DECEMBER

The Commission on Research Integrity expects to transmit its final report containing its recommendations on the handling of allegations of scientific misconduct and the promotion of research integrity to the Secretary of Health and Human Services and Congress in December.

Among the recommendations the Commission is considering are a new definition of scientific misconduct, a modification to the existing assurance on scientific misconduct that would require institutions to establish educational programs on the responsible conduct of research for all individuals supported by PHS research funding, a bill of rights and responsibilities for whistleblowers, and procedures for improving the processing of scientific misconduct allegations.

The Commission developed its recommendations during its June and late July meetings. A final draft of the report was reviewed by

the Commission during its last meeting on September 18-19 at the Washington Dulles Airport Marriott. The Commission's charter expires November 4, 1995.

For additional information on the Commission contact Henrietta Hyatt-Knorr at (301) 443-5300 or through Internet at hhyatt@oash.ssw.dhhs.gov.

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ORI PUBLICATIONS ON INTERNET

A variety of materials are available from ORI in printed form, computer diskette, or ORI's new home page on the World Wide Web of the Internet by pointing a WWW browser to http://phs.os.dhhs.gov/phs/ori/ori_home.html. To request a copy of the list of materials available from ORI, call (301) 443-5300; fax (301) 443-5351.

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CASE SUMMARIES

Gloria Clayton, R.N., Ed.D., Medical College of Georgia. ORI reviewed an investigation report from the Medical College of Georgia into possible scientific misconduct by Dr. Clayton, a professor of adult nursing. ORI found that Dr. Clayton fabricated the existence of subjects and associated data under a subcontract with the Gerontology Center at the University of Georgia for research on adaptation and mental health of the oldest old, supported by the National Institute of Mental Health. Dr. Clayton, who has admitted this fabrication, has accepted the ORI findings and agreed to a Voluntary Exclusion Agreement. Under the Agreement, Dr. Clayton is not eligible to apply for or receive any Federal grant or contract funds or to serve on any PHS advisory committee, board or peer review committee for a three-year period beginning May 25, 1995. In addition, Dr. Clayton has agreed to cooperate with the University of Georgia and the Medical College of Georgia in the submission of letters of correction to appropriate journals for publications shown to contain the fabricated data.

Denise R. Conrad, University of Iowa. ORI reviewed an investigation conducted by the University of Iowa into possible scientific misconduct on the part of Ms. Conrad, formerly a research assistant in the Department of Preventive Medicine, College of Medicine. ORI found that Ms. Conrad committed scientific misconduct by fabricating or falsifying data on questionnaires in a case control study of residential radon and

lung cancer supported by PHS. Ms. Conrad has accepted the ORI findings and agreed to a Voluntary Exclusion Agreement under which Ms. Conrad is not eligible to apply for or receive any Federal grant or contract funds for a three-year period beginning April 10, 1995. The fabricated or falsified data did not appear in any publication.

Catherine Coyle, ISOLAB, Inc. An investigation conducted by the ISOLAB found that Ms. Coyle, a former laboratory technician, falsified and misreported the results of assays for fetal hemoglobin data generated for the multicenter study of hydroxyurea in sickle cell anemia at Johns Hopkins University supported by PHS under a cooperative agreement. Ms. Coyle admitted that she misrepresented data submitted to the clinical study. There were no publications involved. Ms. Coyle executed a Voluntary Exclusion and Settlement Agreement in which she has agreed not to 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 March 27, 1995.

Barbara Jones, St. Mary's Hospital, Montreal. ORI conducted an investigation into possible scientific misconduct by Ms. Jones while she was a data coordinator at St. Mary's Hospital. ORI concluded that Ms. Jones committed scientific misconduct by falsifying and fabricating the dates of tests or examinations required prior to study entry for two women entered on the Breast Cancer Prevention Trial (BCPT). The BCPT is coordinated by the National Surgical Adjuvant Breast and Bowel Project (NSABP) and supported by the National Cancer Institute and the National Heart, Lung, and Blood Institute. Because the BCPT is still in progress, no conclusions or results have been published and no clinical recommendations have been based on the results of the study.

Ms. Jones did not contest the ORI findings or administrative actions which require that, for three years beginning June 8, 1995, any institution which proposes Ms. Jones' participation in PHS-supported research must submit a supervisory plan designed to ensure the scientific integrity of her contribution. Ms. Jones is also prohibited from serving in any advisory capacity to the PHS for three years.

Terence S. Herman, M.D., Harvard Medical School. ORI reviewed an investigation conducted by Harvard Medical School into possible scientific misconduct on the part of Dr. Herman while he was an employee of that institution. ORI concurred with the factual findings as set forth in the institution's report, and finds that

Dr. Herman committed scientific misconduct by falsely reporting in a published article that research had been conducted according to a stated protocol when, in fact, Dr. Herman knew at the time that the protocol for tumor measurements had not been carried out exactly as described. The research was supported by grant awards from the National Cancer Institute and the National Center for Research Resources, NIH.

Dr. Herman accepted the misconduct finding as part of a Voluntary Settlement Agreement under which, for three years beginning March 30, 1995, any institution which submits an application for PHS support for a clinical research project on which his participation is proposed or which uses him in any capacity on PHS supported clinical research must concurrently submit a plan for supervision of his duties. The supervisory plan must be designed to ensure the scientific integrity of Dr. Herman's research contribution. Dr. Herman also is prohibited from serving on any PHS advisory committee, board, and/or peer review committee for a period of three years. He has agreed to submit a letter to the *International Journal of Radiation Oncology, Biology, Physics* requesting retraction of that portion of the article dealing with tumor response (Herman, et al., A Phase I-II Trial of Cisplatin, Hyperthermia and Radiation in patients with Locally Advanced Malignancies. *Int. J. Radiation Oncology Biol. Phys*. 17:1273-1278; 1989).

Farooq A. Siddiqui, Ph.D., Roswell Park Cancer Institute. ORI completed an investigation into possible scientific misconduct on the part of Dr. Siddiqui while he was an employee of Roswell Park Cancer Institute. ORI finds that Dr. Siddiqui committed scientific misconduct by misrepresenting data in a published article. The research was supported by a grant award from the National Cancer Institute, NIH.

Dr. Siddiqui agreed not to appeal the misconduct finding as part of a Voluntary Settlement Agreement under which, for two years beginning May 23, 1995, he will not apply as a principal or coprincipal investigator in any grants and cooperative agreements or as a principal or coprincipal in any contract or subcontract with the United States Government. Dr. Siddiqui also is prohibited from serving on any PHS advisory committee, board, and/or peer review committee for a period of two years. Also, for a two-year period, the institution where he is employed will supervise his performance of work on any covered transaction including a periodic review of primary data, and certify the accuracy of any such data used in any PHS grant application, contract proposal, or which is otherwise publicly reported. He

has agreed to submit a letter to the journal *Biochemica et Biophysica Acta* (BBA) to retract the article entitled "Purification and Immunological Characterization of DNA Polymerase-alpha from Human Acute Lymphoblastic Leukemia Cells" (BBA, 745:154-161, 1983).

James Urban, M.D., Ph.D., California Institute of Technology. ORI found that Dr. Urban engaged in scientific misconduct. This finding is based on an investigation by the California Institute of Technology (CIT) which concluded that Dr. Urban committed serious errors in judgment and serious scientific misconduct by fabricating research data in two scientific papers that were published in the journal *Cell*. The first paper is J. Urban, V. Kumar, D. Kono, C. Gomez, S. Horvath, J. Clayton, D. Ando, E. Sercarz, and L. Hood, "Restricted Use of T Cell Receptor V Genes on Murine Autoimmune Encephalomyelitis Raises Possibilities for Antibody Therapy," *Cell* 54: 577-592 (1988). The second paper at issue is J. L. Urban, S. J. Horvath and L. Hood, "Autoimmune T Cells: Immune Recognition of Normal and Variant Peptide Epitopes and Peptide-based Therapy," *Cell* 59: 257-271 (1989). Specifically, the CIT report states that Dr. Urban admitted that he fabricated two control lanes reported in Figure 5 of the *Cell* 54 paper. With respect to the *Cell* 59 paper, the CIT report states that Dr. Urban admitted that he circulated draft copies of the manuscript that contained fabricated data in order to circumvent both the internal and external review processes.

Dr. Urban has accepted the ORI findings and agreed to exclude himself voluntarily, for a period of three years beginning June 2, 1995, from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in grants and cooperative agreements of the United States Government as defined in 45 C.F.R. Part 76 and 48 C.F.R. Subparts 9.4 and 309.4 (Debarment Regulations). This voluntary exclusion does not apply to Dr. Urban's current or future practice of clinical medicine or training, whether as a resident, fellow, or licensed practitioner, unless that practice involves the proposing, conducting, or reporting of biomedical or behavioral research or research training. Dr. Urban also agreed to exclude himself voluntarily from serving on any PHS advisory committees, boards, and/or peer review committees for the same three-year period. ORI acknowledges that Dr. Urban cooperated with the CIT Investigation Committee during its investigation of allegations of scientific misconduct and with ORI in its resolution of this matter.

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NOTICE PUBLISHED TO RESTORE REPUTATION OF RESEARCHER

For the first time, ORI is publishing a notice of an investigation that did not result in a misconduct finding at the request of the respondent to assist in the restoration of his reputation.

ORI publishes summaries of investigations that did not result in misconduct findings in its Annual Report for instructional purposes, but they are edited to protect the privacy and reputation of individuals.

ORI takes this unprecedented step because this investigation involved a clinical trial and media coverage, particularly in the *Chicago Tribune*. The notice of findings has also been published in the *Federal Register* and the *NIH Guide for Grants and Contracts*.

David Plotkin, M.D., Memorial Cancer Research Foundation of Southern California. ORI investigated allegations that clinical trial data forms submitted from the Memorial Cancer Research Foundation of Southern California (MCRF), Los Angeles, contained falsified and fabricated information. The data forms were submitted to the Statistical Office of the National Surgical Adjuvant Breast and Bowel Project (NSABP) at the University of Pittsburgh. The NSABP project at MCRF received funding from the National Cancer Institute (NCI), with Dr. Plotkin as principal investigator.

In mid April 1994, the *Chicago Tribune* obtained a copy of an April 1990 NSABP Audit Report that indicated there was a "serious problem . . . with respect to the accuracy of the data reported to the NSABP" from the MCRF. A *Chicago Tribune* reporter reviewed records on some subjects entered on NSABP trials at MCRF and found apparent discrepancies between reported data and medical records. Much of the questioned data was related to the B-06 clinical trial which compared lumpectomy (with or without radiation therapy) to total mastectomy for the treatment of breast cancer.

ORI reviewed records and data on 59 patients reported to NSABP between 1973 and 1994 and did not find falsification, fabrication, or deliberate misrepresentation on the part of Dr. Plotkin or his staff. ORI found that many of the discrepancies originally identified by the NSABP and the *Chicago Tribune* were the result of a review of incomplete records, honest error on the part of one or more of the participating parties, or

differences in interpretations or judgments of the facts.

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PUBLICATIONS*

"Legal Protections for the Scientific Misconduct Whistleblower" *Journal of Law, Medicine & Ethics*, 23 (1995):88-95. Peter Poon, Research Integrity Branch, OGC, reviews Federal and state whistleblower protections, as well as the specific protections for scientific misconduct whistleblowers.

*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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