ORI NEWSLETTER

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RESEARCHER ASSESSED DAMAGES FOR DESTRUCTION OF CELL LINE

The intentional destruction of millions of Alpha 1-4 cells amounted to the "tort of conversion" according to a recent opinion by the United States District Court in Maryland. *United States* v. *Arora*, No. 93-1281 (D. Md. 1994). District Judge Peter Messitte ruled on August 25, 1994, that Dr. Prince Kumar Arora of the National Institutes of Health must pay the Federal Government $450.20 in compensatory damages and $5,000 in punitive damages, plus costs of the civil suit, for intentionally destroying the Government-owned cells. Dr. Arora appealed the District Court's ruling on October 19.

In February of 1992, Dr. Yoshitatsu Sei and Dr. Garry Wong created the Alpha 1-4 cell line as part of a pioneering NIH project designed to study the immune properties of certain cell receptors. Dr. Arora was not involved in the Alpha 1-4 project. At the same time, Dr. Sei's working relationship with Dr. Arora, his mentor and collaborator on other projects, became strained due to an authorship dispute and other laboratory conflicts.

Based on the garnered evidence and potential motive against Dr. Sei, the District Court concluded that Dr. Arora did cause the death of the Alpha 1-4 cells. The judge ruled that Dr. Arora's actions amounted to the tort of conversion which is defined as: "[A]n intentional exercise of dominion or control over a chattel which so seriously interferes with the right of another to control it that the actor may justly be required to pay the other the full value of the chattel." *Arora*, slip op. at 14 (citing Restatement (Second) of Torts, § 22A(1)).

The District Court's opinion set a new precedent in the area of cell line conversion. Two other cases (one State and one Federal) held that a cause of action did not lie for conversion of cell lines. Judge Messitte distinguished the State opinion which found that the plaintiff, unlike the Government in Dr. Arora's case, did not have a property interest in the cells at issue. The Federal case was distinguished because it applied contract and patent law to the unauthorized use of cells, whereas neither contract nor patent law were applicable to Dr. Arora's intentional *destruction* of cells. Relying on a Supreme Court case which acknowledged that a living cell line is a property interest capable of protection, *Diamond* v. *Chakrabarty*, 447 U.S. 303 (1980), the District Court "[saw] no reason why a cell line

should not be considered a chattel capable of being converted." *Arora*, at 19.

In its final order of judgment against Dr. Arora, the District Court awarded the Government the market value of the Alpha 1-4 research materials plus the cost of recreating the Alpha 1-4 cells. While the compensatory damages amounted to a relatively modest sum, the Court also assessed $5,000 in punitive damages. Punitive damages may be recovered in cases of conversion under Maryland law. The amount of punitive damages was based on the delay in the research project caused by Dr. Arora's destruction of the cells. Moreover, the Court stated that Dr. Arora evidenced actual malice against Dr. Sei and that Dr. Arora knew that his actions might deprive the scientific community of the benefits of the Alpha 1-4 research.

The punitive damages were also awarded as a deterrent because Dr. Arora's actions "undermined the honor system that exists among the community of scientists, a system which is ultimately based on 'truthfulness, both as a moral imperative and as a fundamental operational principle in the scientific research process.'" Arora, at 24.

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ORI CLOSES 49 CASES

A new case management system designed to improve the productivity of ORI in completing cases has enabled ORI to significantly reduce its inherited backlog through the closing of 49 cases during the first 11 months of 1994.

The closed cases included 14 that had been initiated by the predecessors of ORI in 1989 or earlier. In November, the list of 63 ORI active cases contained only 16 cases that were initiated prior to 1993, including four begun in 1989 or earlier. Several additional cases were expected to be closed by the end of the year.

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ORI FINDS MISCONDUCT AGAINST DR. IMANISHI-KARI

ORI has issued a finding of scientific misconduct against Thereza Imanishi-Kari, Ph.D., and has recommended that she be debarred from receiving Federal funds for 10 years.

In its final report, ORI made 19 charges of misconduct against Dr. Imanishi-Kari covering extensive fabrication and falsification in research reported under Public Health Service (PHS) grants, in attempts to cover-up her initial misconduct, and in grant applications. Dr. Imanishi-Kari is appealing the finding.

The initial allegation was based on work performed by Dr. Imanishi-Kari at the Massachusetts Institute of Technology. She subsequently moved to Tufts University.

According to the report, the initial misconduct was committed when Dr. Imanishi-Kari published significantly fabricated and falsified results of PHS-funded research in an article, "Altered Repertoire of Endogenous Immunoglobulin Gene in Transgenic Mice Containing a Rearranged Mu Heavy Chain Gene", in the journal *Cell* on April 25, 1986. The report further claims that Dr. Imanishi-Kari continued to falsify and fabricate research results in materials submitted to Federal investigators looking into the initial allegation, in a letter of correction submitted to *Cell*, and in two grant applications submitted to NIH.

Dr. Imanishi-Kari has appealed the ORI finding to the HHS Departmental Appeals Board. The Board appoints a three-member adjudication panel to hold a formal evidentiary hearing when an individual challenges an ORI misconduct finding. A hearing date had not been set at press time.

Dr. Lyle W. Bivens, ORI Director, said, "This case has a long history going back to one of ORI's predecessor organizations. Congressional hearings have been conducted on it, and we have seen it take many twists and turns. The resolution of this case has been one of ORI's priorities. I am pleased that ORI has been able to so thoroughly and completely resolve the many issues involved and conclude the case with findings based on solid fact."

ORI has recommended a debarment of 10 years in this case because of the extent of the scientific misconduct and the extensive cover-up. The usual debarment period is three years. A debarred individual is ineligible to receive Federal funding, including grants, cooperative agreements, and contracts. The final decision on debarment is made by the Deputy Assistant Secretary for Grants and Acquisition Management, HHS, following a recommendation by the Departmental Appeals Board.

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ANNUAL INSTITUTIONAL REPORT DUE MARCH 1

The form for the calendar year 1994 Annual Report on Possible Research Misconduct (PHS 6349) will be mailed on January 17, 1995, to all institutions that have an active assurance. **The Annual Report must be completed and returned to the ORI no later than March 1, 1995.**

Institutions must file an assurance with ORI to be eligible to receive funding from the Public Health Service. Once the initial assurance is filed, an institution is required to submit an annual report to ORI to keep the assurance active. An active assurance is required for the awarding of all PHS research grants, fellowships, and cooperative agreements.

If you have any questions regarding the Annual Report, contact Craig Fleischer or Doug Brown in the ORI Assurance Program at (301) 443-5300.

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OASH BULLETIN BOARD

Copies of the *ORI Newsletter* and other ORI publications are available through the Office of the Assistant Secretary for Health Electronic Bulletin Board System.

For access information and instructions, call (202) 690-6248.

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CASE SUMMARY:

RESEARCHER PLAGIARIZED MATERIAL FROM APPLICATION UNDER REVIEW

Gerald I. August, Ph.D., University of Minnesota Medical School. The ORI reviewed an investigation conducted by the University of Minnesota into possible scientific misconduct on the part of Gerald I. August, Ph.D., an Associate Professor of Psychiatry at the University of Minnesota Medical School. The University concluded that Dr. August committed scientific misconduct by plagiarizing materials in a Public Health Service (PHS) grant application which he obtained as a member of a PHS Special Study Section. ORI concurred with the University's findings. Dr. August accepted the misconduct findings and agreed to a Voluntary Settlement Agreement under which, for a five-year period beginning May 6, 1994, (1) Dr. August will not serve on PHS advisory committees, boards, or peer review groups, and

(2) he is to submit a certification with each document, application, or report he submits to a PHS component that the work of others contained in the document, application, or report is properly attributed.

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CASE SUMMARY:

GRADUATE STUDENT FABRICATED DATA

Jacqueline Edberg, Villanova University. The ORI reviewed an investigation conducted by Villanova University into possible scientific misconduct on the part of Jacqueline Edberg, a former Master's degree student in the Psychology Department at Villanova University. ORI concluded that Ms. Edberg committed scientific misconduct by fabricating data on two experiments for a project supported by the National Institute of Mental Health. Ms. Edberg has been debarred from eligibility for and involvement in grants, other Federal assistance awards and contracts and has been excluded from serving on PHS advisory committees, boards, or peer review groups for a three-year period beginning October 20, 1994. The fabricated data did not appear in any scientific publication.

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ORI PROVIDES WORKING DEFINITION OF PLAGIARISM

Although there is widespread agreement in the scientific community on including plagiarism as a major element of the PHS definition of scientific misconduct, there is some uncertainty about how the definition of plagiarism itself is applied in ORI cases.

As a general working definition, ORI considers plagiarism to include both the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work. It does not include authorship or credit disputes.

The theft or misappropriation of intellectual property includes the unauthorized use of ideas or unique methods obtained by a privileged communication, such as a grant or manuscript review.

Substantial unattributed textual copying of another's work means the unattributed verbatim or nearly verbatim copying of sentences and paragraphs which materially mislead the ordinary reader regarding the contributions of the author. ORI generally does

not pursue the limited use of identical or nearly-identical phrases which describe a commonly-used methodology or previous research because ORI does not consider such use as substantially misleading to the reader or of great significance.

Many allegations of plagiarism involve disputes among former collaborators who participated jointly in the development or conduct of a research project, but who subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive language, or other product of the joint effort. The ownership of the intellectual property in many such situations is seldom clear, and the collaborative history among the scientists often supports a presumption of implied consent to use the products of the collaboration by any of the former collaborators.

For this reason, ORI considers many such disputes to be authorship or credit disputes rather than plagiarism. Such disputes are referred to PHS agencies and extramural institutions for resolution.

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INSTITUTIONS REPORT MISCONDUCT ACTIVITIES

Seventy-two institutions were responding to allegations of scientific misconduct in 1993, according to the Annual Report of Possible Misconduct in Science that each institution must file with ORI to remain eligible for PHS research funding.

Fifty-three institutions received new allegations of scientific misconduct in 1993. Twenty-six institutions were continuing to process allegations made in 1992. Seven of the institutions were responding to allegations made in 1992 and 1993.

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 3,009 institutions for 1993.

Of the 53 institutions reporting new allegations in 1993, 37 were institutions of higher education; five were research organizations; eight were independent hospitals; two were other health, human resources, environmental service organizations; and one was a small business.

Sixty-seven new cases were opened by the 53 institutions in 1993. The number of new cases opened by these institutions ranged from one to four. These cases involved 86 allegations, including 23 of fabrication, 29 of falsification, 15 of plagiarism, and 19 of other practices. Fifteen cases involved multiple allegations.

The 53 institutions conducted 63 inquiries and 26 investigations in 1993. The number of inquiries conducted by an institution ranged from zero to four per institution. The number of investigations conducted by an institution ranged from zero to three.

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ORI ANNUAL REPORT PUBLISHED FOR 1993

ORI closed 28 cases in 1993 including 16 investigations and 12 inquiries. The 16 investigations resulted in 10 findings of scientific misconduct. Seventy-nine cases were carried into 1994.

By the end of 1993, ORI had initially found 27 individuals committed scientific misconduct. ORI findings have prevailed in 22 cases; 5 others were overturned, withdrawn, or settled in conjunction with the newly implemented hearing process.

As of December 31, 1993, there were 3,232 active institutional assurances on file in ORI, including 175 assurances from institutions in 22 foreign countries. Institutions must file an assurance with ORI to be eligible for PHS research funding.

Besides these facts, the ORI Annual Report 1993 also reports on the steps ORI took in 1993 to improve its internal operations, increase institutional capabilities, and foster research integrity, as well as the resolution of major legal issues.

The ORI annual report also provides summaries of the 16 investigations closed in 1993, as well as a descriptive statistical analysis of those investigations. In addition, the report contains a listing of ORI conferences and training courses, project support, *Federal Register* notices, misconduct activities reported by institutions, publications, and presentations.

A copy of the *ORI Annual Report 1993* may be obtained from the Division of Policy and Education, ORI.

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ORI RESPONDS TO FASEB ON PRIVACY ACT SYSTEM OF RECORDS

The Federation of American Societies for Experimental Biology (FASEB) has made a number of misleading and inaccurate public statements recently at meetings and in their newsletters about routine uses identified in the Privacy Act System of Records established for ORI case files. ORI wishes to correct the record on several points.

The Privacy Act notice regarding ORI files was not intended to, and will not, change the way ORI operates, which is to protect to the maximum extent possible the interests of all parties in scientific misconduct cases. It does **not** represent a change in policy, contrary to what FASEB appears to believe. And the notice most assuredly does not mandate that ORI open up its files to anyone who asks to see them, as was stated explicitly in a newsletter of one of FASEB's constituent societies.

The Privacy Act requires Federal agencies that maintain files that are retrieved by personal identifier (name, social security number, etc.) to formally establish a system of records and, among other things, to define "routine uses" for disclosing information in the file, so that the Federal agency can carry out its business and fulfill its responsibilities.

Although ORI has previously retrieved its files by institution rather than by the names of respondents, ORI is now establishing a system of records under the Privacy Act which will allow filing and retrieval by the respondent's name.

The System Notice was published in the *Federal Register* on July 19, 1994, and interested parties were invited to comment on the notice and the routine uses. ORI received a letter from FASEB on August 26 that objected to several of the routine uses. ORI met with the President of FASEB and other FASEB representatives on September 30 to discuss the issues of concern.

Following that discussion, ORI made a number of revisions in the routine uses. Many of these changes are fully responsive to concerns expressed by FASEB, as well as by other organizations or entities. These revisions include a statement that any disclosure from ORI files must be limited to only that information necessary to accomplish the purpose of the routine use, clarification of the routine uses to reflect that information is released only after a final finding of scientific misconduct has been made, and notification that information released by ORI does not deal with scientific quality issues but

is based on scientific misconduct findings. These changes were communicated to FASEB on October 27.

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MISCONDUCT MODEL POLICY AND MODEL INSTRUCTIONS DEVELOPED

Over the years, ORI has received numerous requests for assistance in the development of the required policy statement for handling allegations of misconduct in science and the conduct of inquiries and investigations. To respond to these needs, ORI has developed two documents as guidance for extramural institutions to help them comply with the PHS regulations (42 C.F.R. Part 50, Subpart A). They are: *Draft ORI Model Policy for Responding to Allegations of Scientific Misconduct, and Draft ORI Model Instructions on Investigating Allegations of Scientific Misconduct at Extramural Institutions*.

These models are intended for two slightly different purposes. ORI has designed the Model Policy primarily for use by institutions that need to develop scientific misconduct policies for the first time. The Model Instructions were developed to help institutions respond to allegations of misconduct by providing detailed guidance. The Model Instructions could serve as a source book for institutions for conducting inquiries and investigations.

Both documents are still in draft form because ORI requested comments on both drafts in November from the top 20 PHS grantee institutions receiving PHS funding and from 20 smaller institutions, including hospitals, research foundations, and medical centers. The external review of these models is an important part of their development. Because they are being reviewed by institutional officials who would use them in real situations, this "reality check" is critical if they are ultimately to become useful guides to institutions.

ORI is not mandating the adoption of these models, nor is ORI implying that institutions must adopt the models in order to be in compliance with Federal regulations. ORI is simply seeking to provide assistance to institutions in dealing with issues of scientific misconduct.

Copies of either model will be available in early 1995 from the Division of Policy and Education at (301) 443-5300.

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COMPLIANCE REVIEWS IDENTIFY FREQUENT POLICY DEFICIENCIES

In conducting compliance reviews, ORI has found that institutional policies frequently do not address certain provisions that are contained in the Federal regulation. Although silence in an institution's policies and procedures with respect to 42 C.F.R. Part 50, Subpart A does not necessarily indicate noncompliance, the omissions increase the likelihood that individuals applying the university policies and procedures might be unaware of certain Federal requirements and may fail to comply with them.

ËPolicy coverage—The institution's policies and procedures should apply to **all individuals** engaged in research that is supported by or for which support is requested from the Public Health Service (PHS), not just the faculty. This includes scientists, trainees, technicians, students, fellows, volunteers, guest researchers, or collaborators.

ËPurpose of the inquiry—The inquiry should be limited to gathering information and determining whether an allegation or apparent instance of misconduct warrants an investigation. Once this threshold is reached, the institution should move to an investigation where conclusions are made about whether misconduct occurred and who is responsible.

ËRole of the complainant—The role of the complainant is only to raise the question of possible misconduct. It is the institution's responsibility to inquire into the matter, see if it is an easily resolvable misunderstanding or whether there is sufficient evidence of possible scientific misconduct to warrant further investigation.

Once the allegation is made, the complainant should cooperate with the inquiry or investigation, but does not have to prove the case or provide the only source of expertise to counter the respondent's claims. If the science is complex and there is not appropriate expertise on the inquiry committee to analyze and resolve all the allegations, an investigation probably should be recommended.

ËProtection of the complainant—The institution is required to protect the position and reputation of the complainant. This includes preventing the respondent or others who are supportive of the respondent from acting in ways that damage the complainant's reputation or jeopardize his or her position.

ËAppropriate expertise—If the inquiry committee requires additional expertise, the institution should make it available. Alternatively, the inquiry committee may recommend conducting an investigation, if needed, to thoroughly examine the issues raised. Investigative committees should contain members with the appropriate expertise, or have experts available for them to consult.

ËAvoid conflicts of interest—Institutions are required to "take precautions against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation." This may include providing outside expertise from uninvolved parties when evaluating the explanations of the respondent or those whose actions are in question.

ËConfidentiality—Institutions are required to protect the privacy of those who in good faith report apparent misconduct, as well as afford other affected individuals confidential treatment, to the maximum extent possible. The steps taken to maintain confidentiality should be outlined for those who conduct inquiries or investigations.

ËRestoration of reputations—Institutions are required to undertake "diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed." It would be helpful if institutional procedures outlined the possible steps to be taken in these cases.

ËReporting requirements—Section 50.104 of the regulation outlines the reporting requirements to ORI. Many policies include reporting certain information to funding agencies, but it should be noted that ORI is not a funding agency but a separate regulatory office within the PHS.

ËRelevant dates—In conducting compliance reviews, it would be helpful to ORI if the institution's reports noted dates regarding the receipt of the allegation, the appointment of the inquiry and investigative committees, and the dates of the committee meetings. Each institutional report should also be dated by the Committee and by the deciding official.

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COMMISSION ON RESEARCH INTEGRITY PLANNING REGIONAL MEETINGS

Three regional meetings will be held by the Commission on

Research Integrity to solicit testimony from bench scientists, post-doctoral fellows, graduate students, laboratory directors, and university administrators and other interested persons. At press time, the meetings were scheduled for San Francisco in February, Chicago in March and Boston in April.

The Commission will meet in the D.C. area in January to hear presentations from representatives from scientific societies and professional associations. Meetings are open to the public and announced in the *Federal Register*. Information may also be obtained by contacting Henrietta Hyatt-Knorr at (301) 443-5300.

In October, the Commission heard from respondents and their attorneys, and representatives from the Office for the Protection from Research Risks and the Departmental Appeals Board. It met in November to hear from the NIH Director and other intramural and extramural officials. It met in December to hear from whistleblowers, respondents, witnesses, and their attorneys.

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MEETINGS: January 7-9, 1995. "Ethics in Neurobiological Research with Human Subjects" Sponsored by Friends Medical Science Research Center, Inc. Contact: Adil Shamoo, Conference Chairman, Friends Medical Science Research Center, Inc., 2330 W. Joppa Road, Suite 103, Lutherville, MD 21093, telephone: (410) 823-5116.*

*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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