ORI NEWSLETTER

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PIONEERING DATA ON EMF EFFECTS WERE FALSIFIED AND FABRICATED

Included among ORI's misconduct findings in this issue is one for falsification of published data on the effect of radiation from electromagnetic fields (EMF) on calcium levels in thymocytes, by Robert Liburdy, Ph.D., former staff scientist, Lawrence Berkeley National Laboratory (LBNL). Based on additional evidence, ORI's findings independently affirm the findings and conclusions of the LBNL investigation. See **CASE SUMMARIES**. Dr. Liburdy purported to show for the first time in a laboratory setting that cellular exposure to EMF altered the process of calcium signaling, which is critical to a number of important cellular functions, such as protein synthesis and cell division. These studies were potentially important because of public concern about a possible link between EMF and cancer or other diseases.

Coverage of this case in the scientific and popular press raised several important questions regarding the ORI findings: 1) are the ORI findings simply a matter of scientific interpretation over how the data were graphically presented in the figures? 2) did three experts independently review the facts and disagree with ORI's findings? and 3) are the scientific conclusions of these papers still valid? Based on the information ORI received from LBNL and directly from Dr. Liburdy, ORI will attempt to clarify these issues.

First, this is not a case involving a matter of data interpretation or the graphic techniques used by Dr. Liburdy to present his data in the three figures at issue. The evidence demonstrates that Dr. Liburdy intentionally falsified or fabricated data presented in the figures. For example, Dr. Liburdy fabricated four experimental traces in one figure by selecting discrete points representing only 7% of the data he had recorded, where the full set of data did not support the published effect. In addition, he did not reduce the primary data to calcium values, a step that was required to compare the experimental differences he claimed to have measured, and he did not repeat the experiment.

In the other two figures, Dr. Liburdy subtracted a large, spontaneously rising, background level of calcium concentration, but he claimed in both papers that the baseline was stable and constant, and he failed to describe his manipulations of data. The evidence also shows that Dr. Liburdy algebraically manipulated data in two figures to create dramatic differences between the experimental and the control data that was not present in the first figure and not significant in the second. Finally, he fabricated additional data points to cover up an unstable test condition revealed by his manipulations in the first case, and to change the timing of the experimental test in the second.

Second, Dr. Liburdy's own experts did not review all of the data or other evidence, including that

identified by ORI, in this case. In contrast, two scientists who were experts in the EMF field or in the experimental techniques used by Dr. Liburdy and who served as consultants to ORI during its oversight review, agreed with ORI's conclusion that Dr. Liburdy published falsified data.

Third, ORI believes the data falsifications in these three figures undermine the validity of the scientific conclusions in these two papers. Experts in the field can easily make this determination for themselves. The ORI analysis, which includes plots of Dr. Liburdy's raw data, is available from ORI under the Freedom of Information Act.

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ORI SUPPORTS DEVELOPMENT OF RCR WEBSITE

A website designed to assist any institution to develop a program on the responsible conduct of research (RCR) will be developed over the next 2 years with support from ORI.

Construction of the website will be a collaborative effort involving Michael Kalichman, University of California, San Diego; Francis Macrina, Virginia Commonwealth University; and Jeff Kahn, University of Minnesota.

"Although a number of very effective, thoughtful programs have developed across the country, no network provides ready communication about the goals, resources, tools, or methods for such programs," Kalichman said. "As a result, the design and implementation of a new program in responsible conduct of research (RCR) training can be frustrating, if not intimidating."

The website is expected to be posted on the Internet by fall 2000; further evolution and elaboration is scheduled for the second year. Initially, the website will contain (1) recommendations for designing a RCR program, (2) options and formats for RCR programs, (3) guidelines, requirements, and procedures related to RCR programs, (4) resources for organizing an RCR program, (5)case studies and software for designing more cases, (6) descriptions of established RCR programs, (7) links to institutional RCR websites and ethics centers, and (8) test instruments to evaluate RCR programs.

"The distinguishing features will be ready access to a variety of up-to-date materials, the ability to easily identify and select the elements needed to construct a viable RCR course or program, and an ongoing means for evaluation of methods and materials," Macrina said.

The second year will be devoted to soliciting additional materials from RCR instructors at 20 or more institutions, modifying the site framework to accommodate new resources, annotating available resources, and seeking continuing support.

Kahn said, "This site will not only make it possible for virtually any institution to develop an RCR program, but would also increase general awareness about what is being done--and what

can be done--to enhance instruction in RCR." If you have any suggestions or materials you think should be included on this website, contact Dr. Kalichman at kalichman@ucsd.edu.

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SENIOR SCIENTISTS URGED TO SUPPORT RESEARCH INTEGRITY TRAINING

Participants in a workshop that was part of the May 13-14 conference on educating for responsible conduct in research considered the need for senior scientists to understand that research integrity training is important in today's research environment.

The tools available to raise this awareness include both "sticks" and "carrots." Making appeals to reason may also be helpful. The "sticks" available to institutions include making training mandatory for everyone, drawing attention to scandals, and conducting regulatory audits. The "carrots" include having training that is useful and interesting, giving continuing medical education credit to clinical investigators, and using training as a mechanism for efficient grant administration.

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ORI CONTINUES IMPROVING CASE MANAGEMENT DURING 1998

According to the *ORI Annual Report - 1998* published this month, ORI's caseload remained stable during 1998, with 32 new cases opened and 32 cases closed. Thirty-five cases remained open at the end of the year. Nine of the thirty-two cases closed (28%) resulted in findings of scientific misconduct. Historically, ORI has made a finding of scientific misconduct in about 1/3 of its cases.

ORI continues to reduce the amount of time for resolution of misconduct cases. In 1998, ORI completed its review and closed 100% of its oversight cases within 1 year of the final institutional decision on the case, with a mean processing time of 5.2 months. Also, ORI closed two of three cases involving direct ORI investigations within 1 year of their opening.

At the end of the year, 10 cases remained open that were opened prior to 1997. One case was awaiting a decision following a hearing by the Departmental Appeals Board. One case was suspended pending resolution of a related criminal case. For 3 of the 10 cases, proposed settlement agreements or charge letters were sent to the respondents prior to the end of the year, and ORI was awaiting a response. Two cases awaited final action on an appeal at the institution before ORI could complete its review.
Copies of the report are available upon request or from ORI's website located at **http://ori.dhhs.gov**.

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COMMON FEDERAL DEFINITION AND PROCEDURE

Publication of the proposed common Federal definition of scientific misconduct and the procedure for responding to such allegations was pending at press time. After publication in the Federal Register, the document will be posted on the ORI website at **http://ori.dhhs.gov** during the 60-day comment period.

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INSTITUTIONS CONTINUE TO REPORT DECLINE IN MISCONDUCT ACTIVITY

The amount of misconduct activity-receipt of an allegation or conduct of an inquiry or investigation-reported by institutions in their 1998 Annual Report on Possible Research Misconduct was the least amount reported in the last 5 years and continued a decline in activity for the third consecutive year. The number of new cases, however, remains substantial.

Misconduct activity was reported by 67 institutions in 1998. Forty-one institutions received 69 new allegations that resulted in the opening of 54 new cases. Thirty-nine institutions were still processing allegations made prior to 1998 and 13 institutions were responding to allegations made prior to and during 1998.

In their submission, 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.

For 1998, institutions reported receiving 69 new allegations, including 22 of falsification, 15 of fabrication, 10 of plagiarism, and 22 others. Of the 41 institutions reporting new allegations in 1998, 34 were institutions of higher education, 2 were research organizations, 4 were independent hospitals, and 1 was a small business.

The 54 new cases opened by the institutions in 1998 resulted in 38 inquiries and 7 investigations by the end of 1998. Some cases were closed following a preliminary assessment of the allegations or the allegations were received too late to begin or complete an inquiry or investigation that year. The number of inquiries and investigations conducted in 1998 reflect the overall trend in misconduct activity.

The 67 institutions reporting misconduct activity in 1998 conducted 74 inquiries and 29 investigations in response to allegations made in 1998 and before. The number of inquiries conducted by an institution ranged from zero to four. Also, the number of investigations conducted by an institution ranged from zero to four.

Table 1: Frequency of Institutions Reporting Misconduct Activities, Institutions Reporting New Cases, New Allegations and New Cases Opened, 1994-1998.

Year	Institutions Reporting Cases	Institutions Reporting New Cases	New Allegations	New Cases
1998	67	41	69	54
1997	73	48	92	64
1996	88	54	127	70
1995	96	61	104	81
1994	79	50	89	64

Table 2: Frequency of Inquiries and Investigations Conducted in Response to New Allegations, 1994-1998.

Annual Report	Inquiries	Investigations
1998	38	7
1997	56	19
1996	61	25
1995	70	31
1994	56	20

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INSTITUTIONS REPORT NO BAD FAITH ALLEGATIONS

No bad faith allegations were reported by the 41 institutions that reported new misconduct activity on their 1998 Annual Report on Possible Research Misconduct. The ORI Model Policy for Responding to Allegations of Scientific Misconduct states that "an allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation." Data were requested on bad faith allegations because of the concern within the scientific community about such allegations and because many institutional misconduct policies state that such acts are subject to disciplinary action.

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ORI CONSIDERING ELECTRONIC TRANSMISSION OF ANNUAL REPORT

Submission of an e-mail address for the responsible official at each institution is becoming

increasingly important as ORI explores the feasibility of electronically transmitting the Annual Report on Possible Research Misconduct.

"We would like to reduce the burden on institutions and ourselves," Chris Pascal, Acting Director, ORI, said. "About 80 to 85 percent of the Annual Reports report no change and only about 2 percent report misconduct activity. If we can automate most of the process, we can reduce everyone's burden and still maintain an accurate database for checking institutional eligibility for funding."

Currently, the assurance database contains an e-mail address for 3,177 of the 4,039 responsible institutional officials in the network, about 79%. Responsible officials may submit their e-mail address to dbrown@osophs.dhhs.gov or jbutler@osophs.dhhs.gov.

A 90 percent response rate, the highest to date, was achieved for the 1998 Annual Report on Possible Research Misconduct by the March 31, 1999, deadline. Assurances were inactivated for 516 institutions because 440 institutions did not return their Annual Report by the deadline, and 76 institutions voluntarily withdrew their assurance rather than submit the Annual Report.

The Annual Report form was mailed January 11, 1999, to 3,509 institutions including 150 foreign institutions that had an assurance on file with ORI as of December 1, 1998. Seventy-four percent of the institutions responded by the March 1 deadline. A second mailing produced an additional 542 responses by the March 31 final deadline.

Two hundred and forty-two institutions indicated that they did not have the required policies or did not answer the question. However, 133 of these institutions do have policies on file with ORI and were so informed so that they could correctly respond on the next Annual Report. Policies were requested for review from the remaining 109 institutions.

Five hundred and sixty-six institutions changed their responsible official or their address. Four hundred and fifteen officials and 188 addresses were new. Thirty-seven of these institutions made both changes.

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CASE SUMMARIES

Deborah Arenburg, University of Maryland (UM): ORI found that Ms. Arenburg, former Research Associate, Maryland Psychiatric Research Center, UM, engaged in scientific misconduct arising out of certain biomedical research supported by two National Institute of Mental Health grants. Ms. Arenburg was responsible for administering and scoring neuropsychological, neurological, and cognitive tests on patients during the course of two studies. These studies were entitled "Neural Basis of the Deficit Syndrome of Schizophrenia" (Study No. 1) and "Clozapine Treatment of Schizophrenic Outpatients" (Study No. 2) and were

supported by the above-referenced grants. ORI found that Ms. Arenburg failed to conduct the required tests on 3 patients in Study No. 1, and on 10-12 patients in Study No. 2. Instead, Ms. Arenburg fabricated the experimental records for those tests and she admits to fabricating the data. The fabricated data were included in a publication, "Association Between Eye Tracking Disorder in Schizophrenia and Poor Sensory Integration," *American Journal of Psychiatry* 155(10):1352-1357, 1998. The principal investigator on the grants at issue reanalyzed the research data, eliminating all data produced by Ms. Arenburg, and found no significant difference in the results. A correction, including the reanalyzed data, was published in the *American Journal of Psychiatry* 156(4):603-609, 1999. Ms. Arenburg accepted the ORI finding and entered into a Voluntary Settlement Agreement with ORI in which she voluntarily agreed, for the 3-year period beginning July 15, 1999, to exclude herself from serving in any advisory capacity to the PHS and submit to special supervision for participation in any PSH-sponsored research.

Robert P. Liburdy, Ph.D., Lawrence Berkeley National Laboratory (LBNL): ORI found that Dr. Liburdy, former staff biochemist at LBNL, engaged in scientific misconduct in biomedical research by intentionally falsifying and fabricating data and claims about the purported cellular effects of electric and magnetic fields (EMF) that were reported in two scientific papers: (1) Liburdy, R.P. "Biological interactions of cellular systems with time-varying magnetic fields. *Annals of the New York Academy of Sciences* 649:74-95, 1992 ("*ANYAS* paper"); and (2) Liburdy, R.P. "Calcium signaling in lymphocytes and ELF fields." *FEBS* Letters 301:53-59, 1992 (the "*FEBS* Letters paper"). The *ANYAS* and *FEBS* Letters papers were supported by a National Cancer Institute, National Institutes of Health, grant. The *ANYAS* and *FEBS* Letters papers reported data indicating that EMF exert a biological effect by altering the entry of calcium across a cell's surface membrane. EMFs, which are ubiquitous forms of radiation that arise from diverse sources such as power lines, home wiring, and household appliances, have been of public concern for potential health effects. Dr. Liburdy's claims were potentially very important when published in 1992 because they purported to link EMF and calcium signaling, a fundamental cell process governing many important cellular functions. Dr. Liburdy has entered into Voluntary Exclusion Agreement with ORI and as part of the agreement, Dr. Liburdy neither admits nor denies ORI's finding of scientific misconduct. Dr. Liburdy has voluntarily agreed to exclude himself from Federal grants, contracts, or cooperative agreements, and from serving in any advisory capacity to PHS for the 3-year period beginning May 28, 1999, and to submit letters to the journals *ANYAS* and *FEBS* Letters, requesting retraction of Figure 12 of the *ANYAS* paper and of Figures 6 and 7 of the *FEBS* Letters paper within 30 days of the date of the agreement.

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NOTABLE QUOTE

"The Scientific Endeavor is Based on Vigilance, Not Trust." Jonathan King, Professor of Molecular Biology, M.I.T., *Science and Engineering Ethics* 5(2): 215-217.

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"GAG" PROVISIONS UNENFORCEABLE; VIOLATE RESPONSIBILITIES & LAWS

Recently, a whistleblower asked for ORI's advice on a settlement, which contained an agreement with an institution not to report allegations of scientific misconduct to ORI. ORI's position is that this "gag" provision violates the institution's responsibilities to disclose misconduct under the Public Health Service Act, 42 U.S.C. § 289b, the regulatory whistleblower protection provision, 42 C.F.R. §50.103(d)(13), and public policy. Federal law requires institutions to notify ORI of the outcome of misconduct investigations and, under certain circumstances, of alleged misconduct prior to the conclusion of an investigation. Contracting to conceal misconduct would violate the institution's obligation to disclose misconduct to ORI.

Furthermore, courts have held that similar "gag" provisions violate whistleblower protection laws. In *Connecticut Light & Power* v. *U.S. Dept. of Labor*, 85 F.3d 89 (2d Cir. 1996), the court held that the whistleblower provision of the Energy Reorganization Act was violated by an employer's mere proffer of a settlement which restricted communications between the employee and a Federal agency. In *EEOC* v. *Cosmair, Inc*., 821 F.2d 1085, 1089 (5th Cir. 1987), the court held that the whistleblower provision of the Age Discrimination in Employment Act prohibited an employer from suspending payments under an agreement in which the employee waived his right to file a charge with the EEOC, but later filed such a charge.

Finally, the courts in *Town of Newton* v. *Rumery*, 480 U.S. 386, 392 (1987) and *Davies* v. *Grossmont Union High School District*, 930 F.2d 1390, 1396 (9th Cir. 1991) held that an agreement is void if the interest in its enforcement is outweighed by a public policy. "[R]esearch conducted by the National Institutes of Health enjoys enormous support from Congress and the American people. [It] is recognized that continued support is dependent upon confidence in the integrity of the scientific process, in individual researchers, and in institutions which accept federal funds." H.R. Conf. Rep. No. 100, 103d Cong., 1st Sess. 19 (1993). Thus, ORI believes that the public's interest in disclosure of research misconduct would outweigh an institution's interest in settling the dispute with the whistleblower.

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CONFERENCE PROPOSALS DUE FEBRUARY 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.

Proposals are welcome anytime, although **February 1, 1999**, is the next due date for the review cycle. Proposal instructions are available on ORI's home page (**http://ori.dhhs.gov**) or by

calling ORI at (301) 443-5300, e-mail: adustira@osophs.dhhs.gov.

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NOTABLE QUOTE

"I am convinced that the scientific community, if it wants to enjoy relative freedom from regulatory oversight, must itself address the issues of the extent of misconduct and . . . questionable practices, as well as the means for achieving proper quality control and self-audit." Kenneth J. Ryan, former Chairman, Commission on Research Integrity. *Science and Engineering Ethics* 5(2):274, 1999.

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ETHICS IN RESEARCH TRAINING COURSE

The National Institutes of Health and the Department of Mental Health Law and Policy at the University of South Florida will be offering a course in 2000 entitled "Ethics in Research: An Intensive Training Course Focusing on Behavioral Health Services." For details, see http://www.fmhi.usf.edu/mhlp/ethics/ethics.html.

More information, including scholarships and registration fees will be posted on the web site this fall. Space is limited. Anyone interested in this training should send their name, address, and e-mail address as soon as possible to:

Kelly M. Lyon, B.A., Coordinator, Education and Training Programs, Department of Mental Health Law & Policy, University of South Florida, Phone: (813) 974-7623, Fax: (813) 974-9327, E-mail: Lyon@fmhi.usf.edu.

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ORI CONDUCTING STUDY OF INSTRUCTIONS TO AUTHORS

ORI is conducting a study of instructions to authors published by journals to determine what provisions they contain that are related to scientific misconduct, research integrity, or the responsible conduct of research.

The study focuses on the instructions to authors contained in 42 journals that have published articles for which corrections or retractions were requested because of their involvement in a scientific misconduct case.

The analysis will determine what topics are covered in the instructions to authors other than manuscript preparation and what behavior is required under each topic covered. Topics related to scientific misconduct, research integrity, or the responsible conduct of research include referral of suspicious manuscripts, authorship qualifications, responsibility of authors, required

data deposit, financial disclosure, conflicts of interest, publication claims, corrections, and retractions.

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National committees on scientific dishonesty in 4 Nordic countries have accepted 47 cases for investigation since they were established in the 1990s, completing 37 investigations that resulted in 9 findings of dishonesty, according to an article by Magne Nylenna and colleagues in *The Lancet* on July 3.

The Nordic countries that have established such committees are Denmark, Finland, Norway, and Sweden. Iceland, the fifth Nordic country, does not have a committee. The Danish Committee on Scientific Dishonesty has carried the largest caseload.

Table 1: Activity by national committees on scientific dishonesty in four Nordic countries since establishment.

Misconduct Activity	Denmark 1992	Finland 1994	Norway 1994	Sweden 1997	Total
Cases received	45	7	9	7	68
Cases investigated	25	7	8	7	47
Investigations completed	24	5	4	4	37
Dishonesty finding	4	2	0	3	9

The most frequent allegation that led to an investigation was disputed authorship. The range of allegations are in Table 2. The dishonesty findings were based on plagiarism, attributing authorship without permission, soliciting ghost authorship by a company, distorting research results by falsely reporting methodology or sample size or selectively excluding subjects, breaching an agreement on the use of material furnished by another laboratory, and publishing collaborative work as a single author.

Table 2: Number of investigated cases by type of alleged misconduct.

Misconduct	Cases
Disputed authorship	16
Manipulation of data	8
Wrongful use of data	8
Theft of data	6
Fabrication of data	5
Plagiarism	5
Twisted statistics	4
False description of methods	3

Other 8

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STUDY OF MEDICAL SCHOOL GUIDELINES

A study of guidelines for the conduct of research adopted by 125 accredited U.S. medical schools or their components began in August. The study will seek to (1) determine the extent to which medical schools or their component parts have adopted guide-lines for the conduct of research, (2) ascertain what topics are addressed in the guidelines, and (3) analyze the behavior recommended in the guidelines.

The study results will be used to develop workshops and create a resource document for institutions.

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MEETINGS

February 24-27, 2000. Association for Practical and Professional Ethics (APPE) Ninth Annual Meeting in Washington, DC. Meeting includes Sixth Intercollegiate Ethics Bowl. Contact APPE, Indiana Univ., 618 East Third St.,Bloomington, IN 47405; Tel: (812) 855-6450; Fax: 855-3315; E-mail: appe@indiana.edu.

May 17-20, 2000. "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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