



Highlights of 1998 ORI Annual Report

The various activities of the Office of Research Integrity were designed to pursue a number of important goals during 1998. These goals include improving case management, fostering a partnership with institutions, ensuring institutional compliance with the U.S. Public Health Service (PHS) misconduct regulation, promoting research integrity, effectively meeting legal challenges, improving access to information, providing technical assistance, and facilitating interaction with other Federal agencies.

Improving Case Management

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.

ORI Decision in Angelides Misconduct Hearing Upheld

A Research Integrity Adjudications Panel was convened this past year by the Departmental Appeals Board (DAB) to review the scientific misconduct charges levied by ORI against Kimon J. Angelides, Ph.D. The Panel consisted of two permanent members of the DAB and a scientist from the University of California at San Francisco. ORI charged Dr. Angelides with falsifying and fabricating data in five scientific publications and five NIH grant applications and recommended that Dr. Angelides be debarred from participating in any grants, contracts, or cooperative agreements with the Federal government for a period of 5 years. The ORI charges arose out of an extensive investigation conducted by the Baylor College of Medicine (BCM), an investigation that resulted in Dr. Angelides' employment dismissal. Dr. Angelides appealed the ORI findings to the DAB. Between March 30 and April 9, 1998, a *de novo* evidentiary hearing was held in Houston, Texas. The parties called approximately 40 witnesses and submitted hundreds of exhibits, which resulted in transcript testimony of more than 2,100 pages. The final post-hearing briefs were filed the first week of October 1998, with additional filings on legal issues submitted in November 1998. A decision in ORI's favor was rendered in early 1999.

Management of Biomedical Research Laboratories Discussed in Arizona

A 3-day conference was held from October 1-3, 1998, in Tucson, Arizona, that promoted discussion between 140 presenters and attendees on the role of the laboratory director, the development and management of a research agenda, data management, quality control, collaborative research, mentoring, and the assignment of credit for productivity.

Conference participants decided that besides possessing the scientific skills needed to obtain the grant that initially establishes the laboratory, the director needs to exercise the skills of research, personnel, and business managers to successfully operate a biomedical research laboratory. Additional pressure to generate faculty salary support from grants, more emphasis on patenting and licensing research results, and less institutional and departmental support for core facilities, professional enrichment, and grant administration were also cited as additional challenges for researchers today.

As part of the knowledge base needed to support quality management in the lab, conference speakers also addressed topics related to the responsible conduct of research, including data management, collaborative research, assigning credit, and mentoring.

The University of Arizona is preparing to publish proceedings from the conference and ORI expects to co-host a second generation lab management conference in the next few years.

Scientific Misconduct Investigations, 1993-1997

ORI released a study of descriptive statistics that presented an analysis of the 150 scientific misconduct investigations closed by ORI from 1993-1997. The report found that 71% of the researchers found guilty of scientific misconduct in the 150 investigations closed by ORI from 1993 through 1997 were debarred from receiving Federal funds for periods ranging from 18 months to 8 years. The investigations resulted in 76 findings of scientific misconduct (51%) and 74 cases did not result in findings of misconduct (49%). Falsification was the most frequent type of misconduct that resulted in an investigation; it was involved in four of every five investigations either alone or in combination with other types of misconduct, especially fabrication. Fabrication was the second most frequent type of misconduct that resulted in an investigation; plagiarism was third. The full report is available on the ORI website at <http://ori.dhhs.gov>.

Federal Scientific Misconduct Officials Network Organized

The first meeting of the Federal Scientific Misconduct Officials Network was held at ORI on September 5, 1998. Twenty representatives from the following nine agencies attended: National Science Foundation (NSF), Office of Energy Research (DOE), Agricultural Research Service (USDA), Cooperative State Research Education Extension Service (USDA), Department of Veteran Affairs (VA), National Aeronautics and Space Administration (NASA), Department of Education (DOE), National Oceanic and Atmospheric Administration (NOAA) and ORI. The meeting was held to develop collaborative relations among the Federal agencies that have or are preparing regulations or procedures for responding to allegations of scientific misconduct in their intramural and extramural research programs.

Collaborative activities in which network members may engage include review of proposed regulations, guidelines or publications, the collection and sharing of data, the discussion of problem areas, and sponsorship of conferences and workshops. A second meeting was held at NSF on May 7, 1999.

ORI Workshop/Conference Program

Three regional conferences, co-sponsored with extramural institutions, were held during 1998, and planning began for four conferences in 1999. ORI staff also organized a symposium on misconduct in science and participated in an international conference in Poland.

Nearly 150 people attended a 2-day conference in Ann Arbor, Michigan, on February 10-11, 1998, on managing integrity in research, with an associated workshop on alternative dispute resolution, which ORI sponsored with the University of Michigan. On May 18-19, 1998, ORI and the University of North Carolina at Chapel Hill jointly sponsored a regional conference that explored issues in research integrity that challenge scientists in a variety of work settings. Several papers presented at the conference are being considered for publication. The first national conference on the management of biomedical research laboratories, co-sponsored by the University of Arizona and ORI, was held for 140 attendees from October 1-3, 1998, in Tucson, Arizona (See related article on page 2). In addition to the regional conferences, ORI

staff organized a 3-hour symposium entitled "Misconduct in Science: A Decade of Progress or Merely Years of Controversy?" on February 13, 1998, in Philadelphia, Pennsylvania, during the annual meeting of the American Association for the Advancement of Science. Symposium papers and commentaries were published as a special issue of *Science and Engineering Ethics* in April 1999.

In November 1998, ORI staff participated with representatives of four European countries who reported on their efforts to develop administrative procedures for responding to allegations of scientific misconduct and promoting good scientific practices during an international conference held in Poland. The conference was attended by about 70 persons from Canada, Denmark, England, France, Germany, Norway, Poland, Sweden, and the United States. Conference papers will be published in *Science and Engineering Ethics* in October 1999 or January 2000.

At year end, conferences and workshops were planned for San Diego, California, Houston, Texas, Bethesda, Maryland, and Montreal, Canada.

Meeting Legal Challenges

Liability Suit Against Baylor College of Medicine Dismissed

Dr. Angelides sued the Baylor College of Medicine (BCM) and several institutional officials in Texas State Court over various acts associated with his employment dismissal for scientific misconduct. Dr. Angelides' claims included wrongful termination, defamation, intentional infliction of emotional distress, illegal conversion of property, tortious interference with grants and contracts, wrongful imprisonment, conspiracy among members of the BCM scientific misconduct investigation committee, and negligent public disclosure of the BCM misconduct findings. The court dismissed at a preliminary stage several of the claims, including the claims for tortious interference with grants and contracts, conspiracy, and negligent public disclosure. However, the court let stand the claims for tortious interference with *prospective* grants and contracts, defamation, and the wrongful termination claim that provided the basis for the bulk of the suit. The BCM endeavored to dismiss the defamation claim by arguing that the institution and its employees were entitled to immunity from suit because their misconduct investigation was mandated by the Federal statute and regulations. However, the court refused to rule on the issue, reserving judgment for a later date. The suit was settled and dismissed immediately after the DAB ruling against Dr. Angelides was made public in early 1999.

Popovic Tort Claims Against ORI Are Dismissed

On February 27, 1998, the U.S. District Court for the District of Maryland dismissed the suit brought by Dr. Mikulas Popovic under the Federal Tort Claims Act. He had alleged negligence, invasion of privacy, intentional infliction of emotional distress, and refusal to hire for reasons contrary to public policy by the United States, and violation of due process by the former Director of the Office of Scientific Integrity (OSI), ORI's predecessor office. Dr. Popovic alleged that these actions occurred as a result of the several-year scientific misconduct investigation conducted by OSI and ORI. ORI had made proposed findings of scientific misconduct which were reversed by the DAB. The district court dismissed the suit by ruling that (1) the former Acting Director of OSI was entitled to qualified immunity for actions taken in her capacity as a Federal official, and (2) as a matter of law, the OSI/ORI investigation did not intentionally or recklessly inflict emotional distress on the plaintiff, but was a reasonable attempt to look into serious allegations of scientific misconduct surrounding the discovery of the AIDS virus. The U.S. Court of Appeals for the Fourth Circuit sustained the dismissal in 1999.

Complaints Filed Against Institutions for Conducting Investigations

Within the last few years, an increasing number of cases have been filed in Federal and State courts challenging institutions' ability to conduct scientific misconduct investigations. Three additional cases were filed in 1998, *Artzt v. Flawn*, and both State and Federal suits in *Kay v. Arizona Board of Regents*. In the former, Dr. Artzt, a researcher at the University of Texas, sued in State court researchers who made formal allegations of scientific misconduct against her and the University official who convened the inquiry. She alleged that they conspired to damage her reputation by making false, malicious, and defama-

tory accusations of scientific misconduct against her and also raised other related charges of libel actions. Dr. Artzt requested a judgment of \$2 million for actual damages and \$5 million for exemplary damages, as well as a permanent injunction against two University officials (President *ad interim* and Executive Vice-President and Provost *ad interim*). Her suit would require the University to restore Dr. Artzt's reputation by moving her laboratory, appointing her to an endowed professorship, moving her academic appointment to a different department, and issuing a press release publicizing these actions. The case was eventually settled.

In *Kay*, the plaintiff, a researcher at the University of Arizona, first filed a complaint in Federal court alleging that the procedures to be used in the public scientific misconduct hearing she requested violated Federal and State due process and Arizona statute and common law. However, the Federal court dismissed the claim without prejudice. Dr. Kay then filed a similar suit in Arizona State Court raising substantive and due process challenges to the University's misconduct procedures that were used to dismiss her. In 1999, the State court remanded back to the University the matter of Dr. Kay's termination for procedurally failing to follow its policies on termination of faculty members, declined to order her reinstatement or back pay, and dismissed the rest of her complaint.

Improving Access to Information

Two new publications were added to the ORI portfolio in 1998: *A Study of Inquiry Reports Not Submitted to ORI* and *Scientific Misconduct Investigations, 1993-1997*.

Publications under continued development in 1998 were *Guidelines for Responsible Whistleblowing*, *Guidance for Journal Editors*, *Guidelines for Respondents Accused of Misconduct*, and *Guidelines for Institutions Investigating Allegations of Possible Misconduct in Clinical Research*.

The new and improved ORI internet website (<http://ori.dhhs.gov>) was fully operational in 1998. Designed to be more informative, attractive, and user-friendly, new items were added monthly. The website continues to be a quick, effective, and inexpensive method for disseminating ORI resource materials.

Improving Institutional Policies

ORI processed 466 institutional policies during 1998 as part of an annual review of a 5 percent sample of policies, and as follow-up activities to the 1997 Annual Report on Possible Research Misconduct. ORI closed 267 reviews in 1998, which included 242 accepted policies and 25 inactivated assurances because policies were not submitted.

I. Scientific Misconduct 1

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I. SCIENTIFIC MISCONDUCT

The investigative workload associated with allegations of scientific misconduct includes allegations, cases, and administrative closures. Queries are potential allegations of scientific misconduct and represent followup to the initial contact with a complainant to determine whether a case may exist. The ORI caseload includes oversight and review of institutional inquiries and investigations and the conduct of inquiries and investigations in the PHS intramural program or at extramural institutions under special circumstances (e.g., when the institution is unable or unwilling to do the inquiry or investigation, or multiple institutions are involved).

Allegations

Each allegation received by ORI is assessed against criteria that must be met in order to open a case. These criteria are:

1. The research in which the alleged misconduct took place must be supported by PHS funds or involve an application for PHS funds.

A search is made of computer records and publications for potentially related PHS grants, contracts, and cooperative agreements. Relevant grant applications and/or publications are obtained to determine the source of support.

2. The alleged misconduct meets the definition of scientific misconduct set forth in the PHS regulation.

ORI must assess whether the action reported, if found to be true, would represent “fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.”

Many allegations involve questions of “honest differences in interpretations or judgments of data” that are specifically excluded from the PHS definition. If the allegation involves possible financial misconduct, other regulatory violations, criminal acts, or civil matters (e.g., harassment claims), ORI refers the allegation to the appropriate office or agency. If the allegation involves a credit or authorship dispute between former collaborators, ORI refers the complainant to the responsible institution and official for resolution.

3. There is adequate information to proceed with an inquiry.

ORI may request additional information from the person who initiated the allegation, if the person is identified. If an allegation is made anonymously and there is not adequate information to proceed, ORI initiates a file and waits to see whether additional information is forthcoming.

Review of information available to ORI (such as grant applications, review summary statements, or correspondence with the funding agency) may result in a simple resolution of the allegation if it is found to have arisen because of a misunderstanding or incomplete information. However, substantive allegations that meet the three criteria listed above will lead ORI to request an institution to conduct an inquiry, or to ORI opening its own inquiry.

Although only about 15-20 percent of the allegations received result in a formal case being opened by ORI, all allegations are evaluated carefully for appropriate disposition. In certain situations, ORI requests additional preliminary information from an institution. Some assessments require appreciable ORI staff work at this phase.

In 1998, ORI received 112 allegations. The disposition of the allegations are presented in Table 1 below. Allegations become active cases when the criteria outlined above are met. However, allegations are administratively closed when they do not fall under ORI jurisdiction, cannot be referred to another agency, or are resolved through further inquiry and information. Allegations are referred to other agencies or offices when the allegation concerns the use of humans and animals in research, financial issues, research funded by other agencies, and so on. No action is possible when an allegation does not contain sufficient specific information to permit another disposition to be made.

Of the 112 allegations made to ORI in 1998, 57 (50%) were assessed in detail for a possible inquiry or investigation, 11 were immediately referred to other agencies, 42 were closed without further action, and 2 were referred to other agencies following detailed ORI assessment. Forty-seven of the fifty-five allegations (83%) that required in-depth review by ORI staff were resolved within 30 days (time from assignment to closure or opening of a formal case). The other two allegations were still under review at the end of the calendar year. Twenty-six of the forty-seven completed assessments resulted in formal cases.

Table 1: Initial Disposition by ORI of Allegations in 1998

Pre-Inquiry Assessment	57
No Action Possible Now Or No Action	42
Referred to Other Agencies	13
TOTAL	112

Cases

In 1998, 9 of the 32 closed misconduct cases resulted in sustained findings of scientific misconduct or PHS administrative actions. Summaries of these cases may be found in Appendix A. Summaries of the 12 investigations not resulting in findings of scientific misconduct may be found in Appendix B. At the end of the calendar year, ORI had 35 formal cases and 12 allegations under review.

The ORI caseload is divided into four elements, (1) institutional inquiries, (2) institutional investigations, (3) ORI inquiries, and (4) ORI investigations. (See Table 2.)

Institutional inquiries: Under the PHS regulation, institutions are not routinely required to report the conduct of inquiries to ORI unless they result in investigations. ORI may become involved in institutional inquiries when ORI receives an allegation directly from the complainant and then asks the institution to conduct the inquiry; under these circumstances, the institution is required to report the outcome of the inquiry to ORI. ORI then reviews the report to determine whether the conduct of the inquiry complied with the PHS regulation and was thorough, competent, and objective.

During 1998, ORI accepted 11 institutional reports on inquiries that did not recommend investigations. Falsification was the most frequent allegation examined in the inquiries (eight). ORI requested that 11 institutions conduct inquiries, accepted 11 reports, and carried four cases into 1999.

Institutional investigations: Institutions are required by the PHS regulation to report to ORI the initiation of an investigation and to submit a report to ORI upon completion of the investigation. The ORI reviews the report to determine whether the conduct of the investigation complied with the PHS regulation and was thorough, competent, and objective, and provided a basis for a PHS finding of misconduct. ORI continued monitoring 26 investigations in 1998 at institutions. During 1998, 20 new institutional investigations were opened and 18

were closed. Thirty-one investigations were carried into 1999.

ORI inquiries: ORI reviews all inquiries conducted into allegations of scientific misconduct within the PHS intramural research programs. In addition, ORI may conduct inquiries at extramural institutions if ORI determines there is a need to do so, e.g., a multicenter clinical trial or a small business. There was no activity in this category in 1998.

ORI investigations: ORI conducts investigations into allegations of scientific misconduct in the PHS intramural research programs. In addition, ORI conducts investigations at extramural institutions if the case involves special circumstances. ORI closed three investigations; one was intramural, and the other two involved multicenter clinical trials. One new ORI investigation was opened in 1998. This case involved naming a second respondent in an ongoing investigation involving a multicenter clinical trial. No ORI investigation was carried into 1999.

Table 2: **ORI Scientific Misconduct Caseload by Case Type during 1998**

<i>Case Type</i>	<i>Forwarded from 1996</i>	<i>Opened in 1997</i>	<i>Closed in 1997</i>	<i>Carried into 1998</i>
Institutional Inquiries	7	11	11	4 *
Institutional Investigations	26	20	18	31 *
ORI Inquiries	0	0	0	0
ORI Investigations	2	1	3	0
TOTAL	35	32	32	35

*In 1998, three institutional inquiries moved from an inquiry to an investigation. Therefore, there are three fewer inquiries carried into 1999 and three more investigations carried into 1999.

Administrative Closures

A case may be administratively closed when ORI concludes that no PHS funds or applications were involved, or that continuing effort will not produce sufficient evidence to resolve a case satisfactorily or further review indicates that the allegation does not fall under the PHS definition of scientific misconduct. No case was administratively closed by ORI in 1998.

II. INSTITUTIONAL COMPLIANCE

The PHS regulation on misconduct in science (42 C.F.R. Part 50, Subpart A) places several requirements on institutions receiving funds under the PHS Act, 42 U.S.C. § 289b. ORI monitors institutional compliance with these regulatory requirements through two programs, the Assurance Program and the Compliance Review Program. Notable actions and achievements in 1998 include:

- Completed the 1997 Annual Report on Possible Research Misconduct with a response rate of 86%. Forty-eight institutions reported opening 64 new scientific misconduct cases; a total of 73 institutions reported misconduct activities because of cases carried into 1997. Ninety-two percent of the responding institutions indicated they have the required policy for handling allegations of scientific misconduct.
- Inactivated assurances for 520 institutions for failure to submit an Annual Report, an institutional policy upon request, or a revised policy following review.
- Processed 466 institutional policies on handling allegations of scientific misconduct; requested 206 institutional policies for review, and increased the number of completed reviews to 1,021.
- Created an E-mail network containing 2,300 addresses to increase the capability of ORI to communicate rapidly with responsible officials at institutions with assurances, either individually or en masse, at a lower cost.
- Conducted 11 preliminary assessments of allegations made in institutional compliance and retaliation cases.
- Analyzed the policies created by 77 parent institutions and their 185 affiliates to determine whether viable systems for responding to allegations of scientific misconduct existed.
- Continuously updated the database containing scientific misconduct assurances for nearly 3,700 institutions to ensure that eligible institutions received their research awards without unnecessary delay.
- Maintained the PHS ALERT system and the PHS Administrative Actions Bulletin Board to track misconduct findings and the imposition of administrative actions.

A. Assurance Program

The Assurance Program is responsible for ensuring that PHS research funds are only awarded to eligible institutions. An institution is eligible when it has an active assurance on file with ORI stating that it has developed and will comply with an administrative process for responding to allegations of scientific misconduct in PHS-supported research that complies with the Federal regulation. An institution establishes an assurance by filing an initial assurance form or signing the face page of the PHS grant application form revised in 1996. Institutions keep their assurance active by submitting the Annual Report on Possible Research Misconduct, submitting their misconduct in science policy upon request by ORI, revising their misconduct in science policy when requested by ORI, and complying with the Federal regulation.

The Assurance Program meets its responsibilities by maintaining the assurance database, auditing awards to institutions, gathering and summarizing information from institutions in their Annual Report on Possible Research Misconduct, and reviewing institutional policies and procedures in collaboration with the Compliance Review Program.

Assurance Database

Maintaining an accurate assurance database is essential to the successful operation of the assurance program because the database is used by ORI and funding agencies to determine the eligibility of institutions to received PHS research funding.

As of December 31, 1998, there were 3,697 active assurances on file in ORI, including 168 from 32 foreign countries. During 1998, 321 institutions filed their initial assurance. ORI deleted 318 institutions because their assurance was inactivated. One hundred and twelve institutions voluntarily withdrew their assurance because they (1) did not expect to apply for PHS funds, (2) did not conduct research, (3) merged with another institution, or (4) went out of existence. ORI withdrew the remaining 206 assurances because the institutions did not submit their Annual Report on Possible Research Misconduct, did not submit a copy of their policies and procedures for responding to allegations of research misconduct upon request, or did not have policies and procedures that complied with the PHS regulation.

All of these changes had little impact on the total assurance database in 1998. (See Table 3.) The total number

of institutions with an assurance increased by 28. Categorically, institutions of higher education remained the same, research organizations, institutes, foundations and laboratories decreased by 4, independent hospitals decreased by 9, educational organizations other than higher education increased by 1, other health, human resources, environmental service organizations decreased by 12, the small business category increased by 61, and unclassified decreased by 9. The largest gain was in the small business category.

Table 3: **Type of Institution with Active Assurance by Frequency, December 31, 1998**

Type of Institution	Frequency	Change
Institutions of Higher Education	881	0
Research Organizations, Institutes, Foundations and Laboratories	317	-4
Independent Hospitals	282	-9
Educational Organizations Other Than Higher Education	24	+1
Other Health, Human Resources, and Environmental Services Organizations	372	-12
Other (small business)	1,818	+61
Unclassified	3	-9
TOTAL	3,697	+28

E-Mail Network

A request for the E-mail address of the signing official was added to the 1997 Annual Report on Possible Research Misconduct as the initial step in establishing an electronic network that will facilitate communications with institutions that have an assurance. An electronic network has permitted ORI to efficiently and rapidly inform all institutions or various subsets of institutions about assurance program requirements and other ORI activities. For example, the E-mail network was used to notify selected groups of organizations of conferences and workshops.

Annual Reports on Possible Research Misconduct

To keep its assurance active, each institution must submit to ORI an Annual Report on Possible Research Misconduct (PHS form 6349) that provides aggregate information on allegations, inquiries, investigations, and other activities required by the PHS regulation. If the institution does not submit the required annual report, its institutional assurance lapses, and the institution becomes ineligible to apply for or receive PHS research funds.

The 1997 Annual Report forms were mailed in January 1998 to the 3,493 institutions that had an assurance on file with ORI as of December 1, 1997.

Completed Annual Reports were received from 2,997 institutions for a response rate of 86 percent. Five hundred and twenty assurances were inactivated, including 443 institutions that did not return their Annual Reports by the March 31 deadline and 77 institutions that voluntarily withdrew their assurances rather than submit the Annual Report. Many assurances were reactivated because annual reports were submitted after the due date. The 1997 report identified 95 institutions that did not have the required policies and procedures for handling allegations of scientific misconduct. In addition, it provided corrected information on the name of the responsible official or the institutional addresses of 581 institutions (19%). Institutions named 421 new responsible officials.

The Annual Report form requested institutions to report on (1) the availability of policies and procedures for responding to allegations of scientific misconduct, (2) the number of allegations of scientific misconduct received and the number of inquiries and investigations conducted, (3) actions taken to restore the reputation of exonerated respondents, (4) actions taken to protect the position and reputation of complainants, (5) what sanctions were imposed by institutions when misconduct was found, and (6) the number of bad faith allegations received.

Reported Misconduct Activity

Sixty-four new scientific misconduct cases were opened in 1997 by 48 institutions that conducted 56 inquiries and 19 investigations in response to 92 allegations, according to their 1997 Annual Report on Possible Research Misconduct. The decision to proceed to an inquiry in response to eight allegations had yet to be made when the reporting period ended.

A total of 73 institutions were responding to allegations in 1997 because 38 institutions were continuing to investigate allegations received before 1997 while 13 were dealing with allegations made prior to and in 1997.

In their submission, institutions report the receipt of allegations of scientific misconduct, the type of misconduct, and the conduct of an inquiry and/or allegation. Reportable activities are limited to alleged misconduct that falls under the PHS definition of scientific misconduct and involves research supported by the PHS.

Of the 48 institutions reporting new allegations in 1997, 35 were institutions of higher education, 6 were research organizations, 6 were independent hospitals, and 1 was another health, human resources, or environmental services organization.

The 92 new allegations reported in 1997 included 26 of fabrication, 34 of falsification, 8 of plagiarism, and 24 of other serious deviations. The number of new cases opened by the 48 institutions ranged from 1 to 4. Twenty-five cases involved multiple allegations.

B. Compliance Review Program

The Compliance Review Program is responsible for ensuring that institutions that apply for or receive PHS funds establish the required policies and procedures and comply with them and the PHS regulation in responding to allegations of research misconduct. In addition, the Compliance Review Program responds to retaliation complaints from whistleblowers and monitors the implementation of PHS administrative actions by institutions and PHS agencies.

Institutional Policy Reviews

ORI processed 466 institutional policies during 1998. Two hundred and six policies were requested in 1998; the other 260 policies were forwarded from 1997. In 1998, institutional policies were requested for the ORI annual review of a 5 percent sample of institutional policies, and as followup activities to the 1997 Annual Report of Possible Research Misconduct, (see below). ORI closed 267 reviews in 1998; 199 were carried into 1999. The closed reviews included 242 accepted policies and 25 inactivated assurances because policies were not submitted. Of the 199 open reviews, 171 require institutional action before further progress can be made.

Policy Review Database

A database, GenRev, was established in 1997 to consolidate information on the numerous reviews conducted by the assurance and compliance programs. The database contains relevant information on the reviews, such as the initial outcome of the review, the number of revisions required, and the policy approval date. As of December 31, 1998, GenRev contained information on 1,220 policy reviews conducted by ORI primarily since 1995. ORI completed 1,021 reviews; 199 are open.

Compliance Cases

In 1998, the ORI compliance caseload was increased by one, for a total of two open cases at the end of the year. Compliance cases involve compliance reviews of institutional handling of an allegation of scientific misconduct and/or retaliation complaints of the whistleblower.

At the beginning of 1998, a change was made in the method of tracking compliance cases. Because several of the alleged retaliation complaints reviewed previously by ORI were closed because of lack of jurisdiction, an assessment category was established to track these cases until PHS jurisdiction could be established. At the beginning of the year there were 4 open assessments; 11 new assessments were opened during 1998, and 11 assessments were closed during 1998. Cases were closed primarily because a determination was made that ORI did not have jurisdiction, or the complainant did not respond to ORI's request for additional documentation supporting the complaint. One retaliation complaint was found to be properly documented and fell within ORI's jurisdiction, and therefore was assigned a case number, and referred to the complainant's institution for investigation.

Table 4: **Summary of Compliance Cases, 1998**

Type of Case	Forwarded From 1997	Opened In 1998	Closed In 1998	Forwarded to 1999
Compliance Reviews	1	1	0	2
Assessments	4	11	11	4
TOTAL	5	12	11	6

Parent/Affiliate Study

A study was conducted of the policies that support the assurances submitted by 262 institutions, 77 parent institutions, and 185 affiliates to determine whether viable systems for responding to allegations of scientific misconduct existed at these institutions. To be viable, the policy of the parent institution had to comply with the PHS regulation and contain provisions covering its affiliates. In addition, an affiliate had to acknowledge the right of the parent institution to conduct investigations of allegations received by the affiliate. Sixty-two percent of the parent policies were returned to the institutions for revision because they did not comply with the PHS regulation or did not explicitly cover its affiliates. A report will be completed in 1999.

Implementation of ORI Administrative Actions

The implementation of ORI administrative actions is monitored through the PHS ALERT, a system of records subject to the Privacy Act. Individuals are entered into the PHS ALERT System when (1) ORI has made a finding of scientific misconduct concerning the individual, (2) the individual is the subject of an administrative action imposed by the Federal government as a result of a determination that scientific misconduct has occurred, (3) the individual has agreed to voluntary corrective action as a result of an investigation of scientific misconduct, (4) ORI has received a report of an investigation by an institution in which there was a finding of scientific misconduct concerning the individual and ORI has determined that PHS has jurisdiction, or (5) FDA has determined that there is sufficient reason to believe that official action is warranted against the individual for violation of an FDA regulation governing research.

Information on each individual in the system is limited to name, social security number, date of birth, type of misconduct, the name of the institution that conducted the investigation, a summary of the administrative actions imposed as a result of the misconduct, and the effective and expiration dates of the administrative actions.

The system was computerized in 1994 to facilitate checks against incoming applications, pending awards, and proposed appointments to PHS advisory committees, boards, and peer review groups.

On January 1, 1998, ORI listed the names of 67 individuals in the system. During the year, ORI added 10 and removed 26 names. On December 31, 1998, the names of 51 individuals were in the system.

ORI added these 10 names after 5 respondents agreed to a voluntary exclusion agreement, and 5 others were found to have committed scientific misconduct in institutional reports to ORI. Twenty-six names were removed during the year because the term of the administrative actions expired.

Of the 51 names in the system at year end, 45 individuals have had administrative actions imposed by ORI, and 6 remain as a result of an institutional report in which there was a finding of scientific misconduct.

During 1998, three individuals whose names had been entered as a result of an institutional report were subse-

quently subjected to an administrative action, with all agreeing to a voluntary exclusion.

In 1997, the FDA began to publish on the Internet a Debarment list as well as a Disqualified/ Restriction/Assurance list for clinical investigators sanctioned by the FDA. Because of the overlap in the FDA lists and the PHS Administrative Actions Bulletin Board (AABB), which is also available on the internet, the PHS AABB carried the FDA information only until the end of 1997. Thereafter, only information regarding individuals sanctioned by ORI was listed on the AABB, and information regarding FDA sanctions can be viewed separately on the FDA internet sites.

III. EDUCATION AND OUTREACH

ORI education and outreach activities continued to expand in 1998. Notable actions and achievements include:

- Produced four publications—*Scientific Misconduct Investigations: 1993-1997*, the *1997 ORI Annual Report*, *A Study of Inquiry Reports Not Submitted to the ORI*, and the *Report on the 1997 Annual Report on Possible Research Misconduct*. An ORI staffer served as a co-editor for a special issue on scientific misconduct published by *Science and Engineering Ethics*.
- Continued development of four other publications—*Guidelines for Responsible Whistleblowing*, *Guidelines for Respondents Accused of Misconduct in Science*, *Guidance for Journal Editors: Managing Research Misconduct Allegations*, and *Guidelines for Institutions Investigating Allegations of Possible Misconduct in Clinical Research*.
- Conducted three research integrity workshops in collaboration with institutions—the University of Michigan, the University of North Carolina at Chapel Hill, and the University of Arizona. Helped organize an international conference on scientific misconduct that involved representatives from 9 countries. Held an update workshop for NIH Research Integrity Officers.
- Organized the Federal Scientific Misconduct Officials Network to develop collaborative relations among the Federal agencies that have or are preparing regulations or procedures for responding to allegations of scientific misconduct in their intramural and/or extramural research programs.
- Submitted a proposal for an evaluation study of guidelines for the conduct of research adopted by medical schools or their components. The study was funded in April 1999.
- Redesigned, reorganized, and expanded the ORI website to facilitate access to information about scientific misconduct and research integrity.
- Gave 25 presentations at conferences, workshops, or meetings, and published one journal article.

Publication Program

Two publications were added to the ORI portfolio in 1998 and three serial publications continued - the *ORI Annual Report*, the *Report on the Annual Report on Possible Research Misconduct*, and the quarterly *ORI Newsletter*. These publications were posted on the ORI web page, and copies of the reports were available upon request from ORI.

Scientific Misconduct Investigations, 1993-1997

ORI released a study of descriptive statistics that presented an analysis of the 150 scientific misconduct investigations closed by ORI from 1993-1997. The findings are summarized in the highlights section (see page ii). The full report is available on the ORI website at <http://ori.dhhs.gov>.

A Study of Inquiry Reports Not Submitted to ORI

A study of 21 institutional inquiry reports not submitted to ORI for review because an investigation was not recommended found that more than half of the reports did not contain the detailed information required to support that recommendation. The study reviewed reports on inquiries that were reported by institutions in their 1994 or 1995 Annual Report on Possible Research Misconduct. Because these inquiries did not proceed to an investigation, ORI did not previously request the reports and the institutions did not voluntarily submit them.

The study of inquiry reports addressed the following questions: (1) Were the inquiries being reported by institutions on the Annual Report subject to PHS jurisdiction? (2) Did the institutions sufficiently document the rationale for deciding an investigation was unwarranted? (3) Did the conduct of the inquiries comply with the PHS regulation?

Of the 21 inquiry reports, 12 (57%) did not contain allegations that fell under the PHS definition of scientific misconduct and/or did not document PHS support. Thirty-three percent of the inquiry reports contained information on no more than four of the nine criteria used to determine whether an investigation was warranted and another 28 percent were marginal, covering only five criteria. Fifty-two percent of the reports did not contain a reasoned analysis that linked the evidence to the conclusion. Seventy-one percent provided information on only three or fewer of the nine regulatory provisions with which institutions are required to comply in the conduct of inquiries. Fifty-seven percent of the reports

did not contain the detailed information required to justify the decision that an investigation was unwarranted. These reports were four pages or fewer; 33 percent of the reports were fewer than two pages. Five reports (24%) were 11 or more pages. This study suggested that institutions would benefit from additional technical assistance from ORI in preparing these reports.

Publications Under Development

Four other publications were in various stages of development. Two publications were under review within the Department and two others were still being written.

Guidelines for Responsible Whistleblowing

This publication provides information on the criteria that PHS uses for pursuing scientific misconduct cases, the development and reporting of allegations, the whistleblower's role in inquiries and investigations, protection against alleged retaliation, and other matters. The guidelines are under review.

Guidelines for Respondents Accused of Misconduct in Science

These guidelines provide information on the criteria that PHS uses for pursuing scientific misconduct cases, the process of evaluating allegations, collection of material evidence, the role of the accused in inquiries and investigations, the use of legal counsel, and retaliation against whistleblowers. This publication is in preparation.

Guidance for Journal Editors

This guidance suggests procedures for a collaborative effort between journal editors and ORI in addressing alleged scientific misconduct in manuscripts submitted or published in journals and the promotion of research integrity. The guidance is under review.

Guidelines for Institutions Investigating Allegations of Possible Misconduct in Clinical Research

This guidance covers cases involving multicenter clinical trials and outlines the special requirements for investigations involving patient records, the multiple sources of information available in these cases, and other Federal entities that may need to be informed and involved in the investigation. This publication is in preparation.

ORI Conferences and Workshops

ORI conducted three research integrity workshops in collaboration with institutions, helped organize an international conference on scientific misconduct, and held an update workshop for NIH Research Integrity Officers.

Michigan Conference Explored Research Integrity Issues

The University of Michigan (UM) and ORI sponsored a 2-day conference in Ann Arbor, Michigan, on February 10-11, 1998, "Managing Integrity in Research," with an associated "Alternative Dispute Resolution (ADR) Workshop." Nearly 150 people attended the conference, primarily faculty, graduate students, and research administrators with responsibilities at the universities for teaching, demonstrating, and encouraging high standards of integrity in biomedical research.

The keynote speaker was Dr. Harold Shapiro, President of Princeton University, former President of UM, and current Chairman of the President's National Bioethics Advisory Commission. The Commission was charged with quickly making recommendations regarding the ethics of the proposed cloning of human beings. Dr. Shapiro described the Commission's process of debate, involving scientists, academicians, philosophers, and religious leaders. The social and scientific implications of this debate were discussed by distinguished faculty and administrators from UM departments of medical affairs, counseling, economics, human genetics, philosophy, and business.

In a session on Designing Research Integrity Programs, senior administrators described unique approaches to encouraging integrity in research. Examples included training modules, a Bioethics Institute held each summer for faculty to develop ethical enrichment sections for their regular courses, a four-credit course for first-year graduate students that used small group discussions, videotapes, and student presentations, and some theme-based symposia that preceded development of a university policy on authorship requirements and on data management and retention.

In the session on Using Existing Organizational Mechanisms, speakers talked about solving a dispute between coauthors, the difficulties in an institutional review board's consideration of behavioral research (where some manipulation and deception of the human subjects is involved), some examples of unprofessional behavior between faculty and students, and the role of university

grants administrators in assisting faculty in meeting Federal agency reporting requirements.

A session on The Ethical Climate in the Academy included concerns about an undergraduate student's dependence on a faculty mentor in research and a discussion of the results of a survey of graduate student attitudes, and awareness of ethical issues. Particularly strong views were expressed on credit disputes and about controversial public cases. A university administrator outlined the need to address integrity in research at many levels, and demonstrated the ease by which digital immuno-protein images could be changed and falsified.

The session on Public and Media Perceptions reviewed the history of ORI's interactions with editors, the press, and Congress in various highly publicized misconduct cases. The role of lawyers and the difficulties in dealing with State freedom of information disclosures was discussed, standards of proof in scientific misconduct cases were compared to criminal and civil court actions, and the political history of scientific misconduct was summarized. University faculty and public relations staff were encouraged to deal forthrightly with alleged misconduct and humanize the public presentations of research.

The Emerging Issues session touched on issues related to potential liability of institutional committee members, the role of the whistleblower in detecting misconduct, and rehabilitation of respondents. Also covered were the legal issues surrounding institutional review boards and protection of human subjects, developing standards of care, pursuing emergency room research, and managed health care. Principles of humane use of animals in research, as well as controversies in genetic engineering and xenotransplantation, were also described. Other topics included principles of dealing with apparent conflicts of interest, problems of paperwork impeding sharing of research materials, and fears that industrial license restrictions may hinder faculty research and Federal agencies will assert rights to university inventions.

The ADR Workshop explored the role of the mediator and the principles of dispute resolution and its use in cases that do not fall under Federal definitions of scientific misconduct. UM reported that a voluntary process agreed to by two parties with a confidential complaint handler and mediator was quite effective. Many disputes in science are over authorship and credit for ideas and work among collaborators and coworkers. ORI does not consider such disputes under the definition of scientific misconduct, while the National Science Founda-

tion staff does in some circumstances. Participants were reminded to deal with allegations of falsification, fabrication, and plagiarism under their normal policies and procedures for scientific misconduct.

A detailed summary of the conference is on the ORI website and is also available from ORI upon request.

North Carolina Conference Discussed "Workplace" to "Marketplace" Integrity Issues.

ORI and the University of North Carolina at Chapel Hill jointly sponsored a regional conference on May 18-19, 1998. The conference explored issues in research integrity that challenge scientists in a variety of work settings--universities, industry, government, and other private, non-profit organizations.

The conference examined issues related to the introduction of the results of scientific research into the "marketplace" of modern society, including public policy decisionmaking, product development, national security, and training the next generation of scientists. In each marketplace setting, the incentives and disincentives to practicing research integrity were explored.

Sessions focused on Federal definitions, workplace incentives and disincentives for research integrity, the responsible use of data, secrecy in research, recordkeeping, mentoring, authorship issues, and ownership of ideas and data.

Scientific Misconduct: An International Perspective

Representatives of four European countries reported on their efforts to develop administrative procedures for responding to allegations of scientific misconduct and promoting good scientific practices during an international conference held in Poland in November 1998.

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

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

mittee. The DCSD has issued guidelines on (1) the presentation of research protocols and data documentation for basic research, as well as for clinical and clinical-epidemiological research, (2) the use and storing of research data, (3) authorship, and (4) collaborative agreements.

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

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

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

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

Imogen Evans, Medical Research Council (MRC), the leading research agency on human health in England, outlined the policy and procedure adopted by the MRC in December 1997 that formally covers about 3,000 staff employed in MRC units. Those in receipt of MRC grants in universities and elsewhere are expected to operate under similar policies. The policy and procedure will be evaluated after 2 years. (See *ORI Newsletter*, September 1998.)

The American Experience Lessons Learned

Ten lessons learned in implementing the PHS regulation on scientific misconduct since August 1989 were presented by ORI during the international conference on scientific misconduct in Warsaw:

- Responding to allegations of scientific misconduct involves an adversarial process rather than a dialogue among colleagues.
- Receipt of a scientific misconduct allegation is a low probability event with a potential for high impact.
- Researchers at any type of institution holding any academic rank may be accused and found guilty of scientific misconduct.
- Primary responsibility for responding to allegations of scientific misconduct belongs in institutions.
- The rights of respondents need to be protected because most allegations will not be sustained.
- Detection of scientific misconduct based exclusively on whistleblowers is inadequate.
- The process of responding to an allegation may be long, costly, and difficult.
- Institutional compliance must be externally monitored.
- Preventing scientific misconduct requires a comprehensive approach to quality control in research management.
- The knowledge base concerning scientific misconduct and research integrity needs further development.

A paper elaborating these lessons has been submitted to *Science and Engineering Ethics* along with other conference papers.

NIH Research Integrity Officers

An update workshop for NIH extramural program Research Integrity Officers (RIOs) was held on December 8, 1998. ORI staff outlined the role RIOs play in each stage of the investigative process and the information that would be provided to RIOs. In addition, steps institutions must take to remain in compliance with the regulation were explained and legal problems were addressed. The RIOs were also told about new developments and emerging issues related to scientific misconduct and re-

search integrity and the new initiatives being undertaken by ORI. Two RIOs discussed their roles within their respective institutes, shared their experiences, and provided feedback to ORI.

Federal Scientific Misconduct Officials Network Organized

The first meeting of the Federal Scientific Misconduct Officials Network was held at ORI on September 5, 1998. A summary of the meeting may be found in the Highlights section.

Study of Guidelines for the Conduct of Research

A proposal for a study, "Analysis of Guidelines for the Conduct of Research Adopted by Medical Schools or Their Components," was submitted in November 1998. The study population will be the 125 accredited medical schools in this country. The study will determine (1) how many medical schools or their component parts have such policies, (2) what issues are addressed by the guidelines, and (3) what behavior is recommended by the guidelines. The results will be used by ORI to create a resource document and to conduct workshops to assist institutions to develop or refine their guidelines for the conduct of research. The project should assist institutions to meet their obligation under the PHS regulation to "foster a research environment that discourages misconduct in research." The study was funded in April 1999.

ORI Website Development

A redesigned, reorganized and expanded ORI website was posted July 27, 1998, at <http://ori.dhhs.gov> to facilitate access to information about scientific misconduct and research integrity. The new format organizes the information in 10 sections--What's New, ORI Forms, Introduction to ORI, ORI Workshops and Conferences, ORI Publications, Regulations and Guidelines, Whistleblower Issues, Additional ORI Resources: Facts and Stats, PHS Administrative Actions, and Other Links.

Presentations

Alicia Dustira, Deputy Director, DPE, organized, moderated and served as a panelist of a Science and Society Symposium on “Misconduct in Science: A Decade of Progress or Merely Years of Controversy?” at the AAAS Annual Meeting, in Philadelphia, PA, on February 14, 1998.

Alicia Dustira, Deputy Director, DPE, organized and moderated a concurrent session on science in the courtroom at “Research Integrity from the ‘Workplace’ to the ‘Marketplace’: A Conference for Researchers and Research Administrators” held at University of North Carolina at Chapel Hill, NC, on May 18, 1998.

Gail Gibbons, Attorney, OGC, prepared the materials and served as a panel member for the Interagency Suspension and Debarment Coordinating Committee Conference held in Washington, D.C. on June 9-10, 1998, for Federal attorneys and other agency representatives who participate in debarment and suspension issues. She spoke on legal problems and other practical considerations related to debarment and suspension in the nonprocurement area, including grants and cooperative agreements.

Samuel Merrill, Senior Investigator, DRI made a presentation and served as panelist for a mini-forum/luncheon entitled “Bioethics in Scientific Research” for the Minority Neuroscience Fellowship Program/National Institute of Mental Health, at the Society for Neuroscience meeting in Los Angeles, CA, on November 7-12, 1998. He spoke about the role of the expert consultant in scientific misconduct investigations.

Chris Pascal, Acting Director, ORI, gave opening remarks and spoke about public and media perceptions of academic approaches to integrity in research at the “Managing Integrity in Research” conference held in Ann Arbor, MI, on February 10, 1998.

Chris Pascal, Acting Director, ORI, gave a presentation on “Scientific Misconduct and Research Integrity for the Bench Scientist” at the Society of Experimental Biology and Medicine (D.C. Section), and the NIH Interinstitute Bioethics Interest Group Forum on Responsible Conduct in Biomedical Research at the National Library of Medicine on May 1, 1998.

Chris Pascal, Acting Director, ORI, spoke about and hosted a session on “Beyond Scientific Misconduct: Designing and Implementing an Institutional System of Research Integrity” during the Northeast section meeting of the Society of Research Administrators in Newport, RI, on May 6, 1998.

Chris Pascal, Acting Director, ORI, gave the keynote address on Federal definitions and approaches to misconduct at “Research Integrity from the ‘Workplace’ to the ‘Marketplace’: A Conference for Researchers and Research Administrators” held in Chapel Hill, NC, on May 18, 1998.

Chris Pascal, Acting Director, ORI, spoke about ORI’s upcoming regional conferences at the Council on Governmental Relations meeting in Washington, DC, on June 4, 1998.

Chris Pascal, Acting Director, ORI, gave a presentation entitled “ORI Perspectives: Purpose and Objectives for a Conference on Laboratory Management” at a national conference in Tucson, AZ, on October 1, 1998.

Chris Pascal, Acting Director, ORI, organized and spoke at a workshop on basic compliance issues for humans, animals, and research misconduct at the Society of Research Administrators 1998 Annual Meeting held in Philadelphia, PA, on October 18, 1998.

Chris Pascal, Acting Director, ORI, organized and spoke at an update from government offices with oversight responsibility and spoke about a systems approach to research integrity at the Society of Research Administrators 1998 Annual Meeting held in Philadelphia, PA on October 19, 1998.

Chris Pascal, Acting Director, ORI, organized a session on and spoke about problems and solutions beyond the Federal definition of scientific misconduct at the annual meeting of the National Council of University Research Administrators in Washington, DC, on November 2, 1998.

Alan Price, Branch Chief, DRI, gave a presentation on investigator and institutional responsibilities in ownership and management of data, common misconceptions and disputes to the University of Maryland at Baltimore Ethics Roundtable, Baltimore, MD, on February 26, 1998.

Alan Price, Branch Chief, DRI, gave a presentation on plagiarism versus credit disputes to a meeting of the Council of Biology Editors and the Association of Earth Science Editors joint conference, in Washington, DC, on September 11, 1998.

Alan Price, Branch Chief, DRI, gave a presentation on plagiarism versus credit disputes to the Greater

Washington Area Consortium on Research Integrity, hosted by the Association of American Medical Colleges, in Washington, DC, on December 14, 1998.

Lawrence Rhoades, Director, DPE, spoke about emerging issues in misconduct in science at the Conference on Managing Integrity in Research at the University of Michigan, in Ann Arbor, MI, on February 11, 1998.

Lawrence Rhoades, Director, DPE, gave a presentation on research integrity in biomedical research at the Extramural Staff Training Core Curriculum Course #4, Natcher Building, NIH, on March 2, 1998.

Lawrence Rhoades, Director, DPE, discussed the Annual Report on Possible Research Misconduct and proposed study of institutional guidelines for the conduct of research with the Council on Governmental Relations, in Washington, DC, on June 3, 1998.

Lawrence Rhoades, Director, DPE, gave a presentation on research integrity in biomedical research at the Extramural Staff Training Core Curriculum Course #4, Natcher Building, NIH, on July 20, 1998.

Lawrence Rhoades, Director, DPE, gave a presentation on the American experience and lessons learned at the “Conference on Scientific Misconduct: An International Perspective” held at the Medical University of Warsaw, Poland, on November 16, 1998.

Mary Scheetz, Program Analyst, DPE, served as moderator and panelist on “What, FF & P Doesn’t Stand for—Find, Finger, and Pillory?” at the 41st Annual Council of Biology Editors Meeting in Salt Lake City, UT, on May 3, 1998.

Mary Scheetz, Program Analyst, DPE, spoke about conflicts of interest in the peer review process at the 41st Annual Council of Biology Editors Meeting in Salt Lake City, UT, on May 5, 1998.

Mary Scheetz, Program Analyst, DPE, gave a presentation on the Federal perspective on misconduct as part of a Graduate Education and Research Awareness Seminar for Undergraduate and Graduate Faculty, Professional Staff and Graduate Students at the University of Maryland, Eastern Shore, Princess Anne, MD, on August 24, 1998.

Mary Scheetz, Program Analyst, DPE, discussed ethics in scholarly publishing: standards for publication

ethics at the Second International AESE/CBE/EASE Joint Meeting in Washington, DC, on September 12, 1998.

Published Articles

Price, A.R., “Anonymity and Pseudonymity in Whistleblowing to ORI about Misconduct in Biomedical Research,” *Academic Medicine* 73: 467-472 (1998).

Federal Register Notices

Findings of Scientific Misconduct. Notice. 63 Fed. Reg. 69630-69631 (Dec. 17, 1998). [Restrepo]

Findings of Scientific Misconduct. Notice. 63 Fed. Reg. 64966-64967 (Nov. 24, 1998). [Glennon]

Findings of Scientific Misconduct. Notice. 63 Fed. Reg. 53059-53060 (Oct. 2, 1998). [Berezniak]

Findings of Scientific Misconduct. Notice. 63 Fed. Reg. 49578-49579 (Sep. 16, 1998). [Park]

Findings of Scientific Misconduct. Notice. 63 Fed. Reg. 43183-43184 (Aug. 12, 1998). [Pender]

Findings of Scientific Misconduct. Notice. 63 Fed. Reg. 35933 (July 1, 1998). [Reisine]

Findings of Scientific Misconduct. Notice. 63 Fed. Reg. 19921-19922 (April 22, 1998). [Lowe]

Findings of Scientific Misconduct. Notice. 63 Fed. Reg. 19921 (April 22, 1998). [King]

Findings of Scientific Misconduct. Notice. 64 Fed. Reg. 169 (Jan. 4, 1999). [Paul]

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The number of requests for information under the Freedom of Information Act (FOIA) and the Privacy Act declined for the second year.

- compared to 90 in 1997 and 79 in 1996. Eight requests were carried into 1999 compared to 24 into 1998 and
- Eight Privacy Act requests were received in 1998 completed in the year of receipt; none were carried into the next year.

agency is required to publish a notice of its system of records when the information in the system is information about an individual that is retrieved by a personal identifier.

The inquiry and investigative records in ORI files are part of a system of records that was published in the *Federal Register*

Katrina Berezniak, M.A., University of Missouri-St. Louis (UMSL)

the UMSL, Ms. Berezniak's own admission, and information obtained by ORI during its oversight review, ORI

Department of Psychology, UMSL, engaged in scientific misconduct in clinical research supported by a National

ing of taped interviews of nine subjects. The scoring was conducted to measure inter-rater reliability in deter-

disorder. The falsified data did not appear in any publications and were not included in the study's database.

ment with ORI in which she voluntarily agreed, for the 2-year period beginning September 9, 1998, to exclude

and her participation in any PHS-funded research is subject to supervision requirements.

Brigham and Women's Hospital (BWH): Based on an

obtained by ORI during its oversight review, ORI found that Ms. Glennon, former research technician, Endocrine-

conduct arising out of biomedical research supported by two National Institutes of Health grants. Ms. Glennon

ing radioimmunoassays to determine angiotensin II concentrations. When the assays appeared not to be

assays over a 1-year period, she used numbers from previous standard curves and then used the fabricated stan-

II, thus producing false experimental results.

Ms. Glennon cooperated fully with the institutional in-

into a Voluntary Exclusion Agreement with ORI in which she voluntarily agreed, for the 3-year period beginning

any advisory capacity to PHS, and her participation in any PHS-funded research is subject to supervision re-

Cynthia King, Bienville Medical Group (BMG), Mississippi

Division of Research Investigations, ORI found that Ms. King, staff assistant, Bienville Medical Group, gaged in scientific misconduct in clinical research conducted as part of a multicenter clinical trial supported by

a National Institutes of Health contract. Ms. King falsified and/or fabricated data and information collected from patients for the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) at the clinical site in Terry, Mississippi. ORI acknowledges Ms. King's cooperation and assistance in completing its investigation. Ms. King entered into a Voluntary Exclusion Agreement with ORI in which she voluntarily agreed, for the 3-year period beginning April 6, 1998, to exclude herself from serving in any advisory capacity to PHS, and her participation in any PHS-funded research is subject to supervision requirements.

Patrina Lowe, Bienville Medical Group (BMG), Mississippi: Based on an investigation conducted by ORI's Division of Research Investigations, ORI found that Ms. Lowe, former staff member, BMG, engaged in scientific misconduct in clinical research conducted as part of a multicenter clinical trial supported by a National Institutes of Health contract. Ms. Lowe falsified and/or fabricated data and information collected from patients for the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) at the clinical site in Terry, Mississippi. ORI acknowledges Ms. Lowe's cooperation and assistance in completing its investigation. Ms. Lowe entered into a Voluntary Exclusion Agreement with ORI in which she voluntarily agreed, for the 3-year period beginning April 6, 1998, to exclude herself from serving in any advisory capacity to PHS, and her participation in any PHS-funded research is subject to supervision requirements.

George A.S. Park, M.S., Wadsworth Center, New York State Department of Health (WC/NYSDH): Based on Mr. Park's own admission, information obtained by ORI during its oversight review, and a report prepared by the WC/NYSDH and accepted by the University at Albany, State University of New York, the awardee institution, ORI found that Mr. Park, former research technician, WC/NYSDH, engaged in scientific misconduct in research supported by a National Institutes of Health grant. Mr. Park falsified high pressure liquid chromatography data. The data were collected over an 8-month period in connection with a project to demonstrate the estrogen-like neurochemical and reproductive effects of the major metabolite of 3,4,3',4'-tetrachlorobiphenyl. The falsified data were presented at the Dioxin '97 conference in Indianapolis, Indiana, in August 1997 and published with the conference proceedings in *Organohalogen Compounds* 34:125-128 (1997). The conference organizer was notified of the falsifications in the presented data and published abstract. ORI acknowledges Mr. Park's cooperation with the Wadsworth Center during the investigation process. Mr. Park entered into a Voluntary

Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning August 31, 1998, to exclude himself from serving in any advisory capacity to PHS, and his participation in any PHS-funded research is subject to supervision requirements.

Saptarshi Paul, Ph.D., Fox Chase Cancer Center (FCCC): Based on a report forwarded to ORI by FCCC, Institute for Cancer Research, dated July 28, 1997, Dr. Paul's admissions, and information obtained by ORI during its oversight review, ORI found that Dr. Paul, former research associate, Molecular Oncology Division, FCCC, engaged in scientific misconduct in biomedical research supported by a National Institutes of Health grant. The project in question involved seeking improvements in cancer treatment through the development of agents that fight cellular resistance to drugs. Dr. Paul falsified an experiment on the uptake of all-trans retinoic acid (ATR) by HL60 cells conducted by several researchers during July 1997. Although this experiment was not published, the discovery of the falsified data led to admissions by Dr. Paul that he had altered an experiment and an acknowledgment that publications would need to be retracted. Several publications were retracted in whole or in part, and portions of two grant applications were retracted. Dr. Paul entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning December 18, 1998, to exclude himself from any contracting, subcontracting, or nonprocurement transactions with the United States Government, and to exclude himself from serving in any advisory capacity to PHS.

Benjamin S. Pender, B.S., Medical University of South Carolina (MUSC): Based on a report from MUSC, information obtained by ORI during its oversight review, and Mr. Pender's own admission, ORI found that Mr. Pender, former graduate student, Medical Science Training Program, MUSC, engaged in scientific misconduct in biomedical research supported by a National Institutes of Health (NIH) grant. Mr. Pender presented to the MUSC Shock Research Group (1) a blank autoradiographic film, which he represented to be a Northern blot, as evidence that he had conducted an experiment that he had not done, and (2) a photographic slide representing a Western blot analysis that he had falsified by using a computer to duplicate two sets of bands to misrepresent oligonucleotide treatments at different times and by misrepresenting the identities of two bands in one of the sets. Also, Mr. Pender falsified data from experiments with thromboxane B₂ and tumor necrosis factor alpha that were published and distributed in an abstract entitled "Antisense Oligonucleotide to G Protein Inhibits Endotoxin Stimulated Thromboxane (Tx) B₂ Production"

(Supplement to Shock 7:20, 1997). This data also was reported as Figure 4 of a submitted but unpublished and withdrawn manuscript and in the progress report for an NIH grant. Mr. Pender entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning July 31, 1998, to exclude himself from any contracting or subcontracting and from nonprocurement transactions with the United States Government, and to exclude himself from serving in any advisory capacity to PHS.

Terry D. Reisine, Ph.D., University of Pennsylvania (UP):

Based on investigation and hearing findings forwarded to ORI by the UP and ORI's oversight review of the evidence provided, ORI found that Terry D. Reisine, Ph.D., former Professor, Department of Pharmacology, UP, engaged in scientific misconduct in biomedical research supported by National Institute of Health grants. Dr. Reisine falsified results related to the measurement of cyclic AMP in cultured, transfected cells by falsely representing in manuscripts and publications the number of experiments conducted, and by falsifying and/or fabricating some of the substantive data presented in those manuscripts and publications. Moreover, Dr. Reisine attempted to falsify data by directing members of his laboratory to construct figures and tables with false values in the preparation of manuscripts. Dr. Reisine entered into a Voluntary Exclusion Agreement with ORI. The settlement was not an admission of liability on his part, and he denies having committed scientific misconduct. Pursuant to the Agreement, Dr. Reisine has agreed to exclude himself voluntarily from any contracting or subcontracting and from nonprocurement transactions with the United States Government for 3 years beginning on June 11, 1998, to exclude himself voluntarily from serving in any advisory capacity to PHS for 3 years beginning on June 11, 1998, and to submit letters to the journals listed below requesting correction of the following articles within 30 days of the effective date of the agreement:

- *The Journal of Biological Chemistry* (Kong, H., Raynor, K., Yasuda, K., Moe, S.T., Portoghese, P.S., Bell, G.I., and Reisine, T. "A single residue, aspartic acid 95, in the gamma opioid receptor specifies selective high affinity agonist binding." *J. Biol. Chem.* 268:23055-23058, 1993.)
 - The results in Table 1 are stated in the table legend to be based on four (4) experiments with calculated SEM values and Hill coefficients when, in fact, the majority of the listed compounds were tested only once, and a few tested only twice.

- Figure 2 data are stated in the figure legend to be the means of three (3) different experiments when, in fact, most of the results were based on a single experiment.
- *The Journal of Pharmacology and Experimental Therapeutics* (Raynor, K., Kong, H., Hines, J., Kong, G., Benevoc, J., Yasuda, K., Bell, G.I., and Reisine, T. "Molecular mechanisms of agonist-induced desensitization of the cloned mouse kappa opioid receptor." *J. Pharmacol. Exp. Ther.* 270:1381-1386, 1994.)
 - The figure legend for Figures 3A, 3C, and 3D claimed that the values shown were the average of three (3) different experiments when, in fact, the results were from only one (1) experiment.
 - The figure legend for Figure 4B claimed that the values shown were the average of four (4) different experiments when, in fact, the results were from only three (3) experiments.
 - Figures 3A, 3C, and 3D each show several levels of adenylyl cyclase inhibition that do not reflect the actual results obtained in duplicate cyclic AMP assays.
- *Molecular Pharmacology* (Reisine, T., Kong, H., Raynor, K., Yano, H., Takeda, J., Yasuda, K., and Bell, G.I. "Splice variant of the somatostatin receptor 2 subtype, somatostatin receptor 2B, couples to adenylyl cyclase." *Mol. Pharmacol.* 44:1016-1020, 1994.)
 - The legend for Figure 3A claims that three (3) experiments were performed when, in fact, only two (2) experiments were performed for the SSTR2B mutants.
 - The legend for Figure 3B claims that the values presented are the average of two (2) different experiments when, in fact, the inhibition curve shown was based on a single experiment.

Rocio del Carmen Restrepo, University of Illinois at Chicago (UIC): Based on an investigation report by the UIC as well as information obtained by ORI during its oversight review, ORI found that Ms. Restrepo, former research assistant, Department of Psychiatry, UIC, engaged in scientific misconduct in clinical research supported by a National Institutes of Health grant. The research focused on mental health services, with special emphasis on service delivery in relation to gender. The project on which Ms. Restrepo worked involved an assessment of the need for mental health services during pregnancy. Ms. Restrepo fabricated research data and submitted the data to the director of a project entitled "Prenatal Provider-Patient Encounter." Data were fabricated in the records of 41 patients, including dates on which Ms. Restrepo claimed to have conducted interviews in certain clinics, consent forms for patients, questionnaires from patients participating in the project, and false information in her "Study Daily Logs" that recorded each day's events. The fabricated data were not included in any publications. Ms. Restrepo entered into a Voluntary Exclusion Agreement with ORI in which she voluntarily agreed, for the 3-year period beginning December 7, 1998, to exclude herself from serving in any advisory capacity to PHS, and her participation on any PHS-funded research is subject to supervision requirements.

**Appendix B:
Summaries of Closed Investigations Not Resulting
in Findings of Scientific Misconduct**

Fabrication: The respondent, who was a clinical research assistant, allegedly fabricated responses on questionnaires received from eight study participants. The institution conducted an investigation and determined that the respondent had furnished three responses that were missing on a questionnaire received from one subject without first obtaining the responses from the subject. However, the institution found that the respondent had done this in an attempt to ensure that the subject would be given a clinical assessment due to the respondent's concerns about the subject's health, with the intent of subsequently obtaining the missing responses from the subject before entering them into the study database. Therefore, the institution concluded that there had been no intent to enter the false answers into data on the part of the respondent. The institution also concluded that there was insufficient evidence that the respondent had fabricated responses on the questionnaires from the other seven subjects. ORI accepted the institution's conclusions and did not make a finding of scientific misconduct.

Fabrication: The respondent, a post-doctoral research fellow, allegedly fabricated data on contraction and relaxation responses to vasoactive compounds of biopsies containing human blood vessels. The institution conducted an investigation into the matter and determined that the evidence supported an alternative explanation for how the questioned data were generated. ORI accepted the conclusion of the institution's investigation that there was insufficient evidence to make a finding of scientific misconduct.

Fabrication: The respondent, a research scientist, allegedly fabricated data on interview forms and failed to follow the research protocol in a study involving prevention of seizures. The study was supported by a National Institutes of Health grant. The institution conducted an investigation into the matter and determined that the respondent had failed to follow the study protocol in recording the results of interviews, constituting a serious deviation in research. However, ORI does not consider such protocol violations to fall under the PHS definition of scientific misconduct. The institution determined that there was insufficient evidence to support a finding that the respondent had fabricated interview data because of the time lag between patient interviews and the investigation of misconduct and the possibility that interviewer notes had been lost. ORI accepted this conclusion and did not make a finding of scientific misconduct in the case.

Falsification: The respondent, a post-doctoral fellow, allegedly falsified data in continuing research supported by PHS funds involving demyelinating diseases. ORI conducted an investigation into the matter. ORI found that there was insufficient evidence to prove that the respondent had committed scientific misconduct. ORI also concluded that proving that the respondent intended to commit scientific misconduct would be made more difficult because in some instances any apparent acts of falsification appeared trivial and their totality did not constitute a convincing pattern that favored the hypothesis. Further, the respondent did not publish any of the questioned data. The alleged falsifications were limited to laboratory notebooks and to an abstract that was not submitted and a draft manuscript. Thus, ORI concluded that further action was not warranted in this matter.

Falsification: The respondent, an associate professor, allegedly altered experimental data for collaborative experiments involving kidney tissue research. The institution conducted an investigation into the matter. The institution determined that there was a history of difficulties in the relationship between the respondent and the complainant and that in part the allegations involved an authorship dispute. The institution also concluded that the respondent's conduct during the collaborative research did not reflect high standards of professional behavior but that the evidence did not support a finding of scientific misconduct. ORI accepted the institution's finding and concluded that there was insufficient evidence to warrant a finding of scientific misconduct.

Falsification: The respondent, the principal investigator (PI) at one site of a multicenter clinical trial, allegedly falsified monthly screening logs for that trial on seven occasions and submitted the altered forms to the trial's coordinating center. The institution conducted an investigation into the matter. The institution found that monthly screening logs had been falsified on seven occasions and that several research approval forms also had been altered. The institution determined that the study coordinator at the questioned site had been responsible for the records. The institution concluded that the respondent had neglected some of his responsibility as PI by not responding to and correcting recurring problems regarding data that had been submitted to the coordinating center. However, the institution found that this neglect on the part of the respondent did not constitute scientific misconduct. ORI accepted the institution's conclusion and did not make a finding of scientific misconduct on the part of the PI.

Falsification: The respondents, a graduate student and mentor, allegedly falsified research results in a published

paper involving a study of messenger RNA in tumor and National Institutes of Health grants. The institution conducted an investigation and determined that inappropriate

However, the investigation committee found the student to be poorly trained in research methods and the mentor

sis. Based on the available evidence, ORI found insufficient evidence of an intent to deceive on the part of

the mentor had reviewed the original data and had been aware of the extent of data selection done by the stu-

misconduct in this case.

Falsification

allegedly falsely reported research in a study involving the characterization of glutamate receptors by intention-

falsifying experimental conditions described in an abstract. The research was supported by a National Insti-

investigation and determined that the respondent had not knowingly falsified data or reported falsified infor-

the institution's investigative report and its conclusion and did not make a finding of scientific misconduct in

Falsification: The respondent, a staff scientist, alleg-

clinical trial involving breast cancer research. The institution conducted an investigation into the matter. The

fied and was not the result of an honest error. An internal audit of all clinical trial records for patients for which

apparent falsification in a nonPHS-supported study as well as a pattern of errors and incomplete data reporting,

terminated, the institution concluded that no further action was warranted. ORI accepted the institution's re-

data falsification was related to PHS-supported research and numerous errors by the respondent indicated care-

misconduct or propose further PHS action.

Falsification

allegedly falsified data in a research experiment on chemically-treated DNA oligonucleotides. The institution

tion determined that there was credible evidence to conclude that tampering with the samples of the questions

experiment had occurred. However, the institution did not find any evidence to indicate that the respondent had tampered with the samples. Thus, the institution did not find scientific misconduct on the part of the respondent. ORI accepted the institution's finding and concluded that there was not sufficient evidence to warrant a finding of scientific misconduct, since it was not possible to determine who was responsible for the apparent falsification of data.

Falsification/Fabrication: The respondent, who was a professor and senior clinical trial investigator, allegedly falsified and/or fabricated research records and data submitted to the coordinating center of a multicenter clinical study involving bladder cancer. The institution conducted an investigation into the matter. The institution determined that some discrepant data were the result of inadvertent errors made by the nurse coordinator, who was under the supervision of the respondent. The institution further concluded that the respondent had failed to provide adequate training and supervision to the nurse coordinator, which led to these errors. However, the institution concluded that the respondent was not the individual responsible for apparently altered data submitted to the coordinating center. ORI accepted the institution's determination that insufficient evidence existed to make a finding of scientific misconduct.

Falsification/Fabrication: The respondent, a staff nurse, allegedly falsified and/or fabricated data in a nutrition research study supported by a National Institutes of Health contract. After conducting an investigation, the institution determined that the respondent had committed scientific misconduct by fabricating a response on a questionnaire and by deviating from the study protocol by not contacting the subject before adding or filling in certain information. However, ORI did not consider the deviation from the study protocol, on its own, as falling within the PHS definition of scientific misconduct. Also, under the PHS standards, ORI found there was insufficient evidence to prove that the respondent had intended to falsify or fabricate the questionnaire entry. Therefore, although ORI accepted the institution's report, it did not make a finding of scientific misconduct.

¹OGC tracks all civil and criminal litigation cases related to ORI's mission. Many cases, especially those in which ORI is named a party, require active participation with the Department of Justice, including sharing of information, discovery, the taking of depositions, preparation of briefs and pleadings, and strategy decisions. The litigation summaries provided here do not include *qui tam* cases which are under seal, and therefore, are not yet publicly reported, cases in which ORI has only a peripheral interest, nor cases in which a complaint has not yet been filed or an indictment issued.

fliction of emotional distress, refusal to hire for reasons contrary to public policy, and due process violations against the United States. Dr. Popovic also brought claims of due process violations against the former director of the Office of Scientific Integrity (OSI), ORI's predecessor agency. Dr. Popovic alleged that these actions occurred as a result of the scientific misconduct investigation conducted by OSI and ORI. ORI made findings of misconduct against Dr. Popovic which were reversed by the HHS Departmental Appeals Board (DAB). In 1997, the district court partially granted the defendants' motion for summary judgment, dismissing three counts of the complaint, and on February 27, 1998, the court dismissed the remaining two counts and refused Dr. Popovic's request to reconsider the previous dismissal. The court ruled that the former Acting Director of OSI was entitled to qualified immunity for actions taken in her capacity as a federal official. It stated that there was no constitutional right not to be investigated for suspected violations by a federal agency authorized to conduct such investigations. The court further ruled that Dr. Popovic was not entitled to any particular set of due process protections during the course of the investigation, which was merely preparatory to a further evidentiary proceeding before the DAB and that Dr. Popovic consistently received appropriate due process throughout the investigative and adjudicative process. Next, the court held that Dr. Popovic was not deprived of any liberty interest for future employment. Finally, the court held that as a matter of law, the OSI/ORI investigation did not intentionally or recklessly inflict emotional distress on Dr. Popovic, but was a reasonable attempt to look into serious allegations of scientific misconduct surrounding the discovery of the AIDS virus. Dr. Popovic appealed the dismissal, and on December 2, 1998, the Fourth Circuit heard oral argument. His appeal was denied in 1999.

v. Arizona Board of Regents, No. C328309 (Sup.Ct. Ariz., filed August 17, 1998). Dr. Marguerite Kay filed suit against the University of Arizona in State court claiming wrongful discharge and violations of the Arizona Administrative Procedure Act, A.R.S. § 12-901, *et seq.*, and the United States and Arizona Constitutions. She claimed that the alleged violations occurred because the institution terminated her employment as a tenured professor without providing her with the required substantive or procedural due process and without adherence to the policies of the Arizona Board of Regents. The University had conducted several investigations and found that Dr. Kay had committed, in addition to other internal institutional charges, PHS scientific misconduct. After the inquiry, investigations, and subsequent public administrative hearing, the institution terminated her in

1998. ORI is conducting an oversight review of the PHS related portion of the institution's investigations. As discussed in the Highlights section of this report, Dr. Kay's Federal case was dismissed. The State court remanded back to the University its dismissal of Dr. Kay for further proceedings. The Federal court specifically stated that it did not dismiss or terminate the administrative proceeding nor was it ruling on the scientific misconduct issues. Rather, it concluded that she had a fair opportunity to present her case during the scientific misconduct proceedings which did not offend constitutional principles of due process. In 1999, the State court held that the University did not follow its termination procedures for faults, but specifically did not rule on the scientific misconduct issues.

v. University of Medicine and Dentistry of New Jersey, et al. No. CV97-634 (DRD) *slip op.* (D. N.J., April 3, 1998), *appeal docketed*, (3rd Cir. 1998). In February 1997, Dr. Francis Shovlin sued the University of Medicine and Dentistry of New Jersey (University) and named officials and employees of the University under the Civil Rights statutes, 42 U.S.C. § 1983 *et seq.*, for allegedly taking retaliatory action against him because he supported several individuals (including himself) who the University investigated for scientific misconduct. The University did not make a finding of scientific misconduct against Dr. Shovlin, a coauthor on two papers at issue in one of several allegations. Dr. Shovlin also contended that the actions of the defendants violated the 1st and 14th Amendments, and that they acted as part of a conspiracy. On April 3, 1998, the district court dismissed the complaint stating, among other things, that Dr. Shovlin was "clearly out-of-order to attack the [scientific misconduct] inquiry as a ploy by the administration" and that the "Investigatory Panel conducted a thorough study." The court noted that "Even though the federal agency [ORI] to which the university reported may not have considered duplicate publications to constitute 'misconduct in science,' it recognized the University's right to hold such a practice to be unacceptable." The court also refused to recognize Dr. Shovlin's 14th Amendment claims that the University violated procedural and substantive due process rights by failing to appoint him to academic positions and by disseminating erroneous information regarding the scientific misconduct proceeding. The court held, among other things, that due process does not extend to prospective interests or benefits, such as academic appointments, unless one can demonstrate a legitimate claim of entitlement. Nor did the court accept Dr. Shovlin's claim based on alleged damage to his reputation because he had not shown that he suffered from any accompanying deprivation such as a subsequent denial of employment due to the alleged defamatory conduct. Dr.

Shovlin's motion for reconsideration was denied, and in September 1998, he filed an appeal to the Third Circuit. The Third Circuit set a briefing schedule for 1999.

U.S. ex rel. Karuturi v. John Wayne Cancer Institute, et al., No. 95-7939-CMB (C. D. Cal., filed Nov. 21, 1995). Dr. Satyanarayana Karuturi filed this *qui tam* action under the False Claims Act (FCA), 31 U.S.C. § 3730(b). Dr. Karuturi alleged that the John Wayne Cancer Institute (JWCI) and other defendants submitted false claims for payment to the National Cancer Institute (NCI) by failing accurately to describe research results in grant applications and progress reports submitted to NCI. The United States declined to intervene, and Dr. Karuturi elected to pursue his complaint independently. On January 20, 1998, the district court dismissed all defendants except JWCI and all claims except for (1) FCA charges for certain specified grant applications, and (2) wrongful termination due to retaliation under the whistleblower section of the FCA, 31 U.S.C. § 3730(h). A hearing was scheduled for early 1999 on JWCI's motion to dismiss the wrongful retaliation claim based upon a prior State court ruling on this issue in favor of JWCI.

U.S. ex rel. Cantekin v. University of Pittsburgh, et al., No. 91-0715 (W.D. Pa., filed May 1991). Dr. Erdem I. Cantekin, filed this *qui tam* action under the False Claims Act (FCA), 31 U.S.C. § 3730(b), against the University of Pittsburgh and others alleging that they defrauded the United States by making false financial disclosure statements in applications for federal grants. The United States declined to intervene, and Dr. Cantekin pursued the suit independently. In 1997, the district court dismissed Dr. Cantekin's pre-October 27, 1986, FCA claims, Dr. Cantekin's consolidated state whistleblower action, his FCA whistleblower action against the individual defendants, his claim of civil conspiracy, and his claim for breach of contract. On February 9, 1998, the district court denied Dr. Cantekin's motion for reconsideration, but rejected defendants' arguments that Dr. Cantekin's *post*-amendment claims should also be dismissed. However, in April 1998, the court did dismiss those false claims charges, and Dr. Cantekin again filed for reconsideration. On September 4, 1998, the court granted the University's motion for summary judgement with respect to the post-October 27, 1998, conduct. Based on evidence submitted by NIH, the court ruled that the grant application and instructions in effect at that time were unclear and subject to varying interpretations with respect to what was required in the "other support" section. Further, a disclosure by one defendant in earlier applications and in a 1987 letter negated any possible finding that he knowingly

submitted a false or fraudulent claim. Thus, the court held that there was insufficient evidence of record to create a genuine issue of material fact to support plaintiff's claims. Dr. Cantekin appealed to the Third Circuit.

U.S. ex rel. Scott v. Dr. Robert J. McKenna, Jr., et al., No. CA96-5176CBM (C.D. Ca. filed July 25, 1996). Ms. Lucinda Scott, filed this *qui tam* action under the False Claims Act, 31 U.S.C. § 3730(b), *pro se*, against Dr. Robert J. McKenna, Jr. and other defendants including various physicians, nurses, hospitals, and the University of California at Irvine (Irvine). Ms. Scott alleged that false claims were submitted to the Health Care Financing Administration (HCFA), NIH, and the Department of Energy. In particular, Ms. Scott alleged that the defendants inappropriately billed HCFA for unapproved lung reduction surgery and misrepresented specifics about the surgical procedure, including mortality rates. Ms. Scott also filed a scientific misconduct allegation with ORI, but ORI determined that only one of the named defendants had submitted a grant application to the NIH, and the application wasn't funded. In 1997, the United States declined to intervene, and Ms. Scott pursued the case independently. In March 1998, the district court granted the defendants' motions to dismiss, but on April 30, 1998, Ms. Scott filed an amended complaint, again alleging that the defendants violated the FCA by submitting false claims, including false statements regarding data collected on patients to the National Heart, Lung, and Blood Institute to obtain research grants. On August 27, 1998, the district court dismissed with prejudice Ms. Scott's claims against defendants Irvine and the Tustin Rehabilitation Hospital, but declined to dismiss the claims against Dr. McKenna and other named physicians and hospitals. In dismissing Ms. Scott's claim against Irvine, the court determined that she failed to plead her claims with sufficient particularity to show that Irvine had personal and direct knowledge of facts relevant to fraud. Her claim against the Hospital was dismissed because the court held that she failed to state a cognizable claim for liability by the Hospital. The case remains pending against the remaining defendants.

CASES CLOSED IN 1998

U.S.A. v. Hôpital Saint-Luc, et al., No. 500-05-005930-951 (C.S. Montreal, Canada, filed 1995). On July 3, 1998, St. Luc Hospital paid \$395,000 (Canadian) to the United States to settle this case in which the United States filed breach of contract claims against St. Luc Hospital and the University of Pittsburgh. The U.S. sought recovery of PHS grant funds related to breast cancer research fabricated by a St. Luc researcher, Dr. Roger Poisson. ORI investigated Dr. Poisson for scientific misconduct, and he was debarred for 8 years. NIH previously recovered grant funds from the University of Pittsburgh through a negotiated settlement based upon ORI's finding of scientific misconduct against Dr. Poisson.

Polsby v. Shalala, Consolidated CA No. DKC-88-2344 *slip op.* (D. Md. March 28, 1996); *aff'd* No. 96-1793 *slip op.* (4th Cir. Oct. 21, 1998). Dr. Maureen Polsby originally alleged violations by NIH of the Civil Rights Act of 1964. However, she expanded her claim to assert that a contributing factor to the alleged violations was ORI's failure to initiate a scientific misconduct investigation, even though an NIH inquiry determined that there was no basis for such an investigation. In 1996, the case went to trial and the Judge ruled in favor of HHS, concluding that Dr. Polsby had failed to prove her claims of gender discrimination. Dr. Polsby then appealed to the U.S. Court of Appeals for the Fourth Circuit *pro se*. On October 21, 1998, the Fourth Circuit denied Dr. Polsby's appeal. The court stated that although the district court dismissed her claims on the basis of a Fourth Circuit decision that was subsequently reversed by the Supreme Court, any error in applying the former standard was harmless. The Fourth Circuit further stated that its review of the record showed that the evidence failed to support Dr. Polsby's claims of post-employment retaliation. Dr. Polsby's motion for reconsideration was also denied.

Kay v. Arizona Board of Regents, et al., No. 98-146 TUC-RMB, *slip op.* (D. Ariz. April 24, 1998). In March 1998, Dr. Marguerite Kay filed suit for injunctive relief against the Arizona Board of Regents, the University of Arizona, the President of the University, and the Committee on Academic Freedom and Tenure (CAFT), a standing committee of the general faculty of the University. The University was investigating Dr. Kay on a number of charges, including scientific misconduct. She alleged that the procedures for the University's formal hearing on these charges (1) violated federal and state Constitutional due process and (2) violated state statute and com-

mon law. On April 24, 1998, the Federal court denied Dr. Kay's request for injunctive relief and dismissed the case without prejudice. In dismissing the case, the court noted the University's argument that failure to proceed with the scientific misconduct investigation could jeopardize its Federal research funding and that these were administrative, not court proceedings. The court also stated that it appeared that the plaintiff had been provided a meaningful hearing, meaningful time to prepare, panel selection was unbiased, and all matters presented for consideration were indicative of due process, not its denial.

U. S. ex rel. Woolf v. Regents of the University of California, et al., No. 97CV1192-J(RBB) (S.D. Cal. 1998). In February 1997, Dr. Nigel Woolf, a researcher at the University of California, San Diego, filed this complaint under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), against the University of California and numerous named and unnamed employees and officials of the University. Dr. Woolf claimed that beginning as early as 1991, the defendants had applied for and received NIH and Veterans Administration grants based on fabricated data and false claims which had been the subject of a scientific misconduct investigation by the University. In 1997, the United States declined to intervene, and in January 1998, the court unsealed the case. Dr. Woolf then voluntarily requested that the case be dismissed without prejudice.

U.S. ex rel. Sharma v. University of Southern California, et al., No. CV96-4050 (C.D. Cal. April 6, 1998). In June 1996, Dr. Ramesh Sharma, filed this complaint under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b). Dr. Sharma alleged that a researcher and the University of Southern California (USC) submitted falsified experimental results and/or methodology about studies exploring the treatment of atherosclerosis in several PHS grant applications. Dr. Sharma also alleged that the defendants conducted experiments on animal subjects that had not been approved by USC's animal care and use committee and that they submitted falsified protocol synopses describing research conducted on animal subjects. In 1997, the United States declined to intervene, and Dr. Sharma elected to pursue his complaint independently. On April 6, 1998, the parties reached a settlement, and the judge dismissed the case. The total amount of the settlement under the FCA was approximately \$160,000. Subsequently, Dr. Sharma challenged the terms of the settlement. The United States filed an *amicus* regarding the apportionment of attorneys fees and the amount of the award.

Jalisi, et al. v. Cleveland Clinic Foundation, et al., No. 1:96 CV 1406 (D. Ohio, Feb. 1998). In June 1996, Dr. Hasan Jalisi, filed suit against The Cleveland Clinic Foundation (CCF), his former lab chief, and other CCF employees based, in part, on issues related to scientific misconduct allegations raised by Dr. Jalisi. Dr. Jalisi alleged that the defendants (1) failed to follow the Federal regulations on scientific misconduct, (2) breached an employment agreement, (3) violated 15 U.S.C. § 1125(a) [false designations of origin, false descriptions, and dilution forbidden] by misrepresenting Dr. Jalisi's research and breaching promises and representations, (4) intentionally interfered with Dr. Jalisi's career and prospective economic advantage, (5) retaliated against a whistleblower, (6) defamed him; and (7) engaged in unfair competition and discriminatory pay practices. The defendants countersued alleging, among other things, defamation, interference, and emotional distress. ORI had previously reviewed Dr. Jalisi's allegations of scientific misconduct and administratively closed the case for lack of jurisdiction because no connection with PHS funding could be found. In December 1997, at the request of CCF, ORI's Acting Director provided an affidavit in Dr. Jalisi's case regarding the extent of ORI's jurisdiction over extramural scientific misconduct cases for which there is no PHS funding. The parties reached a confidential settlement agreement in February 1998.

Artztv. Flawn, et al., No. 98-02287 (200th D.C. Travis County, filed March 2, 1998). Dr. Karen Artzt, a researcher at the University of Texas, filed suit in Texas State Court against (1) the two researchers who had made formal allegations of scientific misconduct against her, (2) the University's official who convened the misconduct inquiry, and (3) two senior University officials as representatives of the institution. Dr. Artzt alleged that the defendants conspired to damage her personal and professional reputation by making false, malicious, and defamatory accusations of scientific misconduct. She also alleged libel, intentional infliction of emotional distress, conspiracy to inflict severe emotional distress, tortious interference with contractual relations, business relations and prospective business relations, and conspiracy to tortiously interfere with contractual and business relations. The case was settled in Spring 1998, but the terms of settlement were not disclosed.

CRIMINAL LITIGATION²

U.S.A. v. Resnick, No. 96-0706, (S.D. Fla. filed Aug. 21, 1996). Dr. Lionel Resnick has been charged with violations of 18 U.S.C. §§ 1341 and 1342 (mail fraud), and § 1957 (money laundering). The indictment alleges that Dr. Resnick and his corporation, Vironc, Inc., sought to defraud Mt. Sinai Lab of the proceeds due it from the University of Miami and All Children's Hospital for AIDS-related testing performed at the Mt. Sinai Lab. The indictment alleges that Dr. Resnick and Vironc arranged with the University and All Children's for testing previously done at Mt. Sinai to be done by Vironc and that invoices should be submitted to Vironc. However, the testing continued to be performed at the Mt. Sinai Lab by Mt. Sinai personnel using Mt. Sinai equipment. The trial was originally scheduled to begin June 2, 1997, but was postponed while the parties were in settlement discussions. In early 1999, Dr. Resnick pled guilty to 18 counts of mail fraud and, among other things, was sentenced to 2 years in prison on the criminal charges, and a 5-year Medicare and Medicaid exclusion, which is the equivalent of a government-wide debarment, on the civil charges.

²The above criminal litigation list does not include ongoing criminal matters which are still in the investigational stages, or for which no indictment has been sought.