RESEARCH MISCONDUCT AND ITS FEDERAL REGULATION: THE ORIGIN AND HISTORY OF THE OFFICE OF RESEARCH INTEGRITY – with personal views by ORI's former Associate Director for Investigative Oversight

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ABSTRACT:

Misconduct in science and research became the subject of significant public attention and Congressional scrutiny beginning in the 1970s and 1980s, which led to public statements, policies, and finally formal federal regulations being promulgated by Government agency officials. The Office of Research Integrity (ORI) in the Department of Health and Human Services was a major and very visible component of this process. This paper provides a detailed history of the first two decades of federal research misconduct regulations and of ORI's history (under extremely difficult and unfair challenges), including personal views by the former ORI chief investigator and associate director.

NOTE: The author was formerly (1987 to 2006) an employee of the Federal Government, serving as a senior official of the Office of Scientific Integrity (1989-1992) and later the ORI (1992-2006). The personal remembrances and reflections expressed here are his own; they do not reflect any endorsement by the ORI nor the Federal Government.

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KEYWORDS:

history of misconduct regulations, office of research integrity, office of scientific integrity, research misconduct, office of inspector general, scientific misconduct

LEXICON:

AAAS:	American Association for the Advancement of Science;
AAU:	Association of American Universities;
ALJ:	HHS/DAB Administrative Law Judge;
ASH:	HHS' Assistant Secretary for Health;
DAB:	HHS' Departmental Appeals Board;
DEI:	ORI's Division of Education and Integrity;
DIO:	ORI's Division of Investigative Oversight;
FBI:	Federal Bureau of Investigation;
HHS:	U.S. Department of Health and Human Services;
ILO:	NIH's former Institutional Liaison Office;
IOM:	Institutes of Medicine USA;
NAS:	National Academy of Sciences USA;
NCI:	NIH's National Cancer Institute;
NIH:	HHS' National Institutes of Health;
NIMH:	HHS' National Institute of Mental Health;
NPRM:	Notice of Proposed Rulemaking;
NSF:	National Science Foundation;
NSABP:	NCI's National Surgical and Adjuvant Breast and Bowel Program;
OIG:	Office of Inspector General [here, at HHS or NSF];
OHRP:	HHS' Office of Human Research Protections;
OPRR:	NIH's former Office for Protection from Research Risks;
ORI:	HHS' Office of Research Integrity;
OSD:	other serious deviation [in the early federal misconduct definitions];
OSI:	NIH's former Office of Scientific Integrity;
OSIR:	PHS' former Office of Scientific Integrity Review;
OSTP:	U.S. Office of Science and Technology Policy;
PHS:	HHS' U.S. Public Health Service;
RIO:	Research Integrity Officer

Early History of Research Misconduct and Public and Congressional Scrutiny in the 1980s

This paper is on the history of the Federal research misconduct regulations and the Office of Research Integrity (ORI), on the twentieth anniversary of its creation (including some personal views by the author, who was a senior official in ORI from 1989 to 2006, as well as some contrasts with its sister office in the National Science Foundation (NSF) Office of Inspector General), and it begins with a summary of the public and Congressional controversy over misconduct in science in the 1970s and 1980s.

Misconduct in science is not new – even Newton, Mendel, and Pasteur have been suspected in recent years of having manipulated their data more than a century ago. But between 1974 and 1981, twelve major cases of misconduct in science were made public, including four cases in 1980-1981 in medical and biomedical research funded by grants from the National Institutes of Health (NIH) at major eastern universities, followed by several more public cases in the early 1980s and 1990s. For example (Mitcham, 2003) (see his timeline):

> Summerlin's falsely painted mouse at Sloan Kettering in Good's lab (1974)
> Alsabti's plagiarism in dozens of papers at Jefferson Medical College (1978)
> Straus' oncology research fabrications at Boston University (1978)
> Soman's endocrinology data falsifications at Yale in Felig's lab (1980)
> Darsee's cardiology research fabrications at Harvard and Emory (1981)
> Long's cancer cell fabrications at Massachusetts General Hospital (1981)
> Spector's biochemical data fabrications at Cornell in Racker's lab (1981)
> Breuning's falsified mental health research at Pittsburgh under Braunwald (1983)
> Slutsky's radiology research falsifications at Univ. California San Diego (1985)
> Imanishi-Kari's alleged immunology falsifications at Tufts University (1986)
> Popovic's alleged retrovirus research falsifications at NIH under Gallo (1993).

Such cases were exposed in several books, including *Betrayers of the Truth* (Broad and Wade, 1982), *False Prophets* (Kohn, 1986), *Impure Science* (Bell, 1992), *Fraud and Misconduct in Medical Research* (Wells, 1993), *Science on Trial* (Sarashon,1993), *The Baltimore Case* (Kevles, 1998), and *The Great Betrayal: Fraud in Science* (Judson, 2004), as well as in the popular press, such as *Time* magazine's August 26, 1991, cover story: *Science Under Siege: tight money, blunders and scandals plague America's researchers*.

As summarized by Gold (1993), these public cases drew the attention of the United States Congress, including Representative Albert Gore, who held a House Science and Technology oversight subcommittee hearing in 1981. It was followed in 1988 by other NIH-oversight hearings on research fraud, by Rep. Ted Weiss' Government Operations subcommittee and by Rep. John Dingell Jr.'s Energy and Commerce oversight subcommittee. They claimed that the scientific community, including NIH, universities, and professional societies, had shown a general unwillingness to guard against fraud and misconduct in science. Counterclaims were

made at these hearings by many scientists, that science is "self-correcting." National Academy of Sciences (NAS) President Phillip Handler claimed in Congressional testimony in 1981 that misconduct in science was "grossly exaggerated by the press" and "the system succeeds in policing itself." NIH Director Donald Frederickson stated that no regulation "is necessary, for the natural sciences contain ultimate correctives for any debasement of the knowledge derived from research." A 1987 editorial by *Science* magazine Editor Daniel Koshland stated, "We must recognize that 99.9999% of all published reports are truthful and accurate. . . There is no evidence that the small number of cases that have surfaced require a fundamental change in the procedures that have produced so much good science" (Koshland, 1987).

As also noted by Gold (1993), Congressman Dingell in 1989-1990 used the services of Walter Stewart and Ned Feder, two of the self-designated investigators or "fraud-busters" [1] in intramural NIH research until 1993 (Stewart-Feder Reassignment, 1993), as well as the U.S. Secret Service's ink analysis [2] capability, to investigate several cases, including the Imanishi-Kari notebooks. NIH Director James Wyngaarden promised at Rep. Dingell's 1989 hearings to have a forensics expert included in each NIH investigation. At the end of his 1990 hearing, Rep. Dingell said he would refer all his subcommittee's materials to the Department of Health and Human Services (HHS) Office of Inspector General (OIG) and the U.S. Attorney's Office in Baltimore for possible criminal proceedings. Rep. Robert Roe also held a hearing before his Science, Space and Technology Committee in 1989; he noted that the responsibility for maintaining integrity in science belonged primarily to the science community, but it must effectively deal with issues of misconduct in science and that the Congress had a legitimate concern because the Government was funding science at increasing levels. [3]

As noted by Steneck (1994), various scientific societies, in response to this negative publicity, issued reports and principles to guide research. In 1975 the American Association for the Advancement of Science (AAAS) published a report (AAAS, 1975) and later hosted several conferences on ethical, investigational, and legal issues (as well as publishing articles in its *Professional Ethics Report*) on dealing with research misconduct, from the 1980s continuing well into the 2000s. Sigma Xi published in 1984, and later updated (Sigma Xi, 2000) a pamphlet, *Honor in Science*, with ethical guidance for research. The Association of American Universities (AAU) issued in 1988 a framework for universities to deal with research fraud (AAU, 1988). The NAS published a booklet, *On Being a Scientist*, in 1988, which was later updated (NAS, 2003). The Council of Biology Editors published in 1990 its *Ethics and Policy in Scientific Publication* (Council of Biology Editors, 1990).

Congressional and NIH or NSF Responses in the 1980s

In 1985 Congress passed the Health Research Extension Act, updating the U.S. Public Health Service (PHS) Act §493 (PHS, 1985), requiring that HHS establish formal regulations for applicant and awardee institutions to review "science fraud" reports and then for institutions to submit to HHS allegations of "substantial science fraud." Previously, the PHS agencies handled

cases and imposed administrative actions (sanctions) based on the inherent authority of the HHS effectively to administer and protect the integrity of PHS grant programs.

In 1986 the PHS published, in the *NIH Guide for Grants and Contracts,* initial PHS guidelines for handling allegations of "misconduct" in extramural research, defined as "serious deviations, such as fabrication, falsification or plagiarism, from accepted practices in the scientific community for carrying out research or in reporting the results of research," as well as "material failure to comply with Federal requirements affecting aspects of the conduct of research, e.g., the protection of human subjects and the welfare of laboratory animals" (PHS, 1986). NIH assigned the responsibility for handling cases of alleged misconduct in science to its central Institutional Liaison Office (ILO).

In 1987 the National Science Foundation (NSF) published a Notice of Proposed Rulemaking (NPRM), followed by a regulation, 45 CFR 689, on misconduct in science and engineering research, using a similar definition[1] (NSF, 1987). The NSF placed the authority over misconduct in science within its existing NSF OIG. It made a finding under this definition in 1990 for sexual harassment by a professor of a student doing field research; the NSF Inspector General and the NSF Deputy Director found the sexual malfeasance or harassment by this investigator to be an integral part of his performance as the mentor of students involved in field research on an NSF grant, including women who were encouraged to enter science (NSF, 1990). This NSF decision was heavily criticized by the academic community as being inappropriate under the misconduct definition (Schachman, 1993). NSF's regulation was amended in 1991 to include under the definition of misconduct in science, "retaliation of any kind against a person who reported or provided information about suspected or alleged misconduct and who has not acted in bad faith" [despite all the commenters arguing that retaliation was not "scientific misconduct" and should be handled differently] (NSF, 1991). The NSF amendment also deleted the 1987 clause on "failure to meet other legal requirements governing research" (NSF, 1991).

The HHS OIG issued a report in 1989 on misconduct in scientific research (OIG, 1989). Inspector General Richard Kusserow testified about this report at Rep. Dingell's hearing, stating

[1] The NSF regulation in 1987 defined "misconduct in science and engineering" as "fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from activities funded by NSF" as well as "failure to meet other legal requirements governing research" (NSF, 1987). NSF's preamble for its 1987 regulation stated that there was no need for a clause exempting "honest errors or honest differences in judgment or interpretation of data" [found in the parallel 1989 PHS definition] since "ordinary errors, ordinary differences in interpretations or judgments of data, scholarly or political disagreements, personal or professional opinions, or private moral or ethical behavior or views are not, and could never be, considered to be misconduct under this definition."

that HHS should have a more centralized system with an independent investigation office, an independent oversight board, and an independent decision-maker on scientific misconduct cases.[2]

Instead, in March 1989, PHS/HHS created an Office of Scientific Integrity (OSI) at NIH and an Office of Scientific Integrity Review (OSIR) in the HHS Office of the Assistant Secretary for Health (ASH). ASH James Mason appointed as OSIR Director, Lyle Bivens, Ph.D., a senior neuro-psychologist administrator from the HHS' National Institute for Mental Health (NIMH).

In early 1990, NIH Acting Director[3] William Raub appointed as OSI Director [after prior acting directors, Brian Kimes of NIH's National Cancer Institute (NCI) since March 1989, and Suzanne Hadley from NIMH since November 1989], Jules Hallum, Ph.D., microbiology professor and chairman from the University of Oregon Health Sciences Center, who had served on the Institute of Medicine (IOM) Committee on the Responsible Conduct of Research (IOM 1989 report). Raub stated that he wanted an academic scientist who would not be seen as a "science policeman" by the community. Hallum was certainly that: a kind, gentle, pipe-smoking senior who was seeking a "scientific dialogue method," not a "confrontational method" (Hallum and Hadley, 1990). Unfortunately, Hallum had no misconduct investigation experience nor understanding of what one can and cannot do in a Government bureaucracy (he really expected to be treated as a distinguished professor and university department chairman, as he had been for decades). As a consequence, the experienced Hadley directed almost all of the OSI investigations.[4]

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[2] The author learned that NIH officials knew the HHS Inspector General preferred that OIG handle all HHS investigations centrally, including scientific misconduct ones (as the NSF's OIG did, see above). Kevles (1998) quotes an early OSI official [unnamed, and unknown to the author] in Fall 1992 as saying: "One of the worst things that could happen to this enterprise [OSI] would be for it to become the science cops – for it to be taken over by the office of inspector general and managed and implemented by a bunch of gumshoes who had no experience or understanding or love of science."

[3] The departing NIH Director (James Wyngaarden interview by the NIH Historian, July 1989) stated: "I know Congress has been impatient and, to some extent, unbelieving that science can police itself. But if we don't do it, who will? This is not the kind of enterprise that subjects itself to random audit. That would be destructive of the fabric and fiber of science and the culture of science to move in that direction. As you know, I have in the past year, greatly expanded the office dealing with issues of scientific misconduct [ILO, then OSI]. . . And we're becoming much more vigorous in investigating those issues. . . Although, I regret, in a way, the fact that NIH has had to get into a regulatory area, I think it is unavoidable. I think it's irresponsible for us not to do so and to expect some other mechanism to do it. "

[4] Hadley held a Ph.D. in clinical psychology. She had been a chief investigator for NIMH in the Stephen Bruening case at the University of Pittsburgh (cited above), which led to his criminal prosecution. As noted by Kevles (1998), she accepted the OSI Deputy Director position in 1988-1989, hoping to become the Director when Kimes returned to NCI. Hadley was a very quick study in OSI, learning to read and speak the very complex research "languages" of immunology and retroviruses. She was also a tireless worker and demanding supervisor, who pushed her staff and herself in working many dozens of misconduct cases all at once (as well as personally handling the frequent Congressional and press information requests). In the author's view, a few times she was too aggressive in trying to pursue scientific misconduct findings, as the decision-maker in OSI cases. [Hadley later turned against OSI, when she left NIH and was detailed to Rep. Dingell's Office (see text below).]

In the Fall 1989, PHS published its formal regulation, 42 CFR 50 Subpart A (HHS, 1989). "Misconduct in science" was defined therein as "falsification, fabrication, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research," adding specifically that "it does not include honest error or honest difference in interpretations or judgments of data."

It is noteworthy (Price, 1994) that several changes had been made by PHS before issuing this final 1989 definition: (1) The qualifying "honest error" sentence had not been present in the 1986 *NIH Guide* nor the 1987 NSF definition; it was added when several NPRM commenters expressed concern that inadvertent errors in recording or reporting data or incorrect but honestly reached conclusions about the results might lead to findings of misconduct. (2) A word in the 1988 PHS NPRM, "deception," was deleted when commenters noted that deception can be an acceptable component of specific types of behavioral research. Some commenters preferred the phrase "scientific fraud" as used in the 1985 Health Research Extension Act by Congress, but the PHS had wanted to avoid confusion with "common law fraud" [which required proof that the perpetrator had knowingly made a false representation to the recipient to induce the recipient to rely upon that information, and the recipient did justifiably rely upon that information and suffered damage as a result]. (3) The clause in the 1986 *NIH Guide* policy that included violations of federal requirements for human subject protection and animal welfare (which were covered by other existing PHS policies or regulations) was deleted from the definition in 1989.

As noted below, the Congressional interest and involvement in cases at NIH continued into the 1990s. Gold (1993) summarized this early history of Congressional and media attention to misconduct in science as follows:

> Over the past decade exchanges between the scientific community and the Congress over questions of misconduct in science have been marked by tension over the legitimate roles and responsibilities of each group to address these issues. Similar tension has characterized other discussions of Congressional oversight or regulation of scientific research. Throughout these discussions Congress and its committees have affirmed their belief in the veracity of scientific research and the importance of the contributions of the research community to the nation. In fact, more often than not Congressional committees have argued that they are supporters of science and that they have an obligation and an interest to see that the enterprise remains healthy. Many authors have noted the role of the media in disclosing accounts of research misconduct as a key factor in bringing the misconduct issue to the attention of Congress. Another factor in the legislative review process is the growth in staff and oversight responsibilities that occurred in the Congress in the mid to late 1970s. A third factor is reports by Congressional staff that they receive

a constant, if somewhat low-level, stream of complaints from scientists who believe there is something wrong with the system. As long as these allegations have substance and are not seriously addressed by the institutions of science, it is likely that Congress will remain interested in the issue of misconduct.

Problems in the early years at OSI, 1989-1992

When OSI was created at NIH in 1989, it inherited from the NIH ILO (and from the HHS Alcohol, Drug Abuse, and Mental Health Administration) about 200 open casefiles, including the already very public immunology falsification and fabrication allegations made against Theresa Imanishi-Kari, who was an assistant professor at Tufts University associated with David Baltimore at the Massachusetts Institute of Technology (MIT). A lack of support at MIT for the postdoctoral whistleblower (Margot O'Toole) and an inquiry (finding no investigation warranted) had led to an aggressive Congressional investigation by Rep. Dingell [well documented in books by Sarasohn (1993), Kevles (1998), and Judson (2004)]. Another such case involved the retroviral research falsification allegations against Mikulas Popovic and Robert Gallo at NCI/NIH, which had led to intense political pressure from the NAS to defend their rights to fairness against challenges by the Government of France. Hadley was constantly bombarded with questions from the press, Congress, and NIH/HHS while trying to sort out the facts in the early 1990s.

In addition, James Abbs and the University of Wisconsin sued OSI and HHS in 1990 in Federal District Court in Wisconsin for "failing to publish" OSI's investigative procedures for public comment in the *Federal Register* under the Federal Administrative Procedures Act (as PHS had published its 1989 misconduct regulations) and for the alleged threat to Abbs's NIH grant funding because of OSI's entry of his name in an internal Government ALERT system (PHS, 1994).[5] The District Court judge in Madison agreed [Abbs v. Sullivan, 756 F. Supp. 1172, 1177 (W.D. Wis. 1990)]. Thus, the author had to stop the OSI investigation of Abbs's alleged falsification of a publication on Parkinson's disease patients, while HHS appealed the decision and published the OSI procedures (HHS, 1991). No other federal investigative office had ever been required to publish its standard operating procedures for investigations, and none have done so. The HHS appeal argued that OSI's procedures were not "federal rules" that required a public notice and comment period. In 1993, the Federal Appeals Court in D.C. reversed the District Court judge's decision, noting that Abbs had not suffered a demonstrable injury, so he had no standing (he was just under investigation pursuant to the properly published 1989 regulations, and the case was not "ripe for judicial decision") [Abbs v. Sullivan, 963 F.2d 918 (7th Cir. 1992)] (Kevles, 1998).

[5] PHS ALERT system of records is a Government file listing individuals who were found to have committed scientific misconduct in PHS-sponsored research; it includes persons about whom ORI has received an institutional investigational report finding scientific misconduct by the individual and for whom ORI/PHS has jurisdiction. Disclosures are limited to certain PHS officials who have a need to know for their administrative responsibilities (PHS, 1994)

Thus, this baseless suit by Abbs and Wisconsin just delayed the OSI process; after the reversal by the Appeals court, the University provided some research documents that OSI had requested a year earlier. Then the author resumed the ORI investigation with a panel of five expert scientists as advisors, and ORI made formal findings of falsification, for which Abbs signed a settlement agreement in 1995. The retraction of his falsified publication was done by the *Neurology* journal editor, Robert Daroff, himself (ORI findings against Abbs, 1995).

The settlement process for OSI/ORI cases, in use since the early 1990s, involved the ORI scientists evaluating evidence from ORI or institutional investigations, followed by extensive review and analysis by ORI investigative staff, all of whom discussed whether [4] to propose formal ORI findings of scientific/research misconduct and to recommend administrative actions to the ORI Director (and later to the ASH). These proposals were reviewed and pursued when warranted by the associated NIH/PHS counsels, who directly approached the respondent with the proposed findings and actions, to try to get them to agree to or to negotiate a formal settlement of the case in a written document (ORI scientists now approach the respondent directly). This settlement process was generally simplest and fastest for ORI and for the respondents, most of whom agreed to the proposed ORI settlements or, with their attorneys, negotiated an acceptable agreement. Respondents who were subjected to federal debarment (Government-wide Debarment and Suspension Regulations) could not receive federal funds for a given period (typically for three years, but ranging from one year to their lifetime).

For ORI to pursue actions against respondents who did not want to settle their ORI cases, ORI scientists and PHS counsels had to prepare for the ASH a formal legal charge letter, documenting the evidence and analysis. The ASH's approval of the charge letter and its transmission to the respondent could be followed by an appeal, with discovery, depositions, recruitment of experts, and a possible formal trial-like hearing (with witnesses who were cross-examined) before a Departmental Appeals Board (DAB) panel of HHS staff attorneys who acted as judges. This process typically took one to three years. Avoidance of this time-consuming and costly process led to extensive efforts to settle almost all of the OSI/ORI cases, often beneficial to both sides.

There were several personnel problems at OSI, made public in those early years:

> (1) In March 1991, OSI Deputy Director Hadley, at odds with Hallum, asked Raub to move her out of the OSI office (in the basement of NIH Building 31 next to the garbage cans), alone into the NIH Director's Office of Science Policy and Legislation in NIH Building 1, while retaining the lead on the two most difficult (Imanishi-Kari, and Popovic and Gallo) investigations. In June 1991, Hadley and her staff assistant mistakenly left a tape recorder running after an interview in the Popovic case, while the investigation committee deliberated, and they inadvertently sent a copy of that tape on request to his lawyer (Barbara Mishkin), breaching confidentiality of the committee. [5]

In March 1992, Hallum found that Hadley also had asked two trusted staff assistants to bring confidential OSI casefile documents to her to work on, outside of their secure setting in OSI, and she had given them to Rep. Dingell's staff. On being exposed, the OSI staffers were transferred elsewhere in PHS; Hadley relinquished her OSI files back to Hallum, and Hadley took a leave of absence.

In mid-1992, Hadley was recruited by Rep. Dingell and detailed by NIH to his Congressional committee, to assist in his investigation of the above cases into 1994, with his verbally overly aggressive staff assistants (Peter Stockton and Bruce Chaffin). There were ongoing public arguments between them and Director Healy. [6] Walter Stewart, also working with Rep. Dingell, released a confidential OSI draft report by Hadley on Imanishi-Kari to a Boston professor (Kevles, 1998), before its public release by ORI. When Democratic Rep. Dingell lost his committee chairmanship with a change in Congressional party balance, Hadley returned to NIH and then was detailed to a local D.C. university to work under a former NIMH Director. She finally retired quietly from NIH.

(2) OSI Director Hallum was reported, by one of the transferred staff members (see above) to have asked him to shred Hallum's personal notes from meetings of an OSI investigation committee for one of these cases. As a result, armed federal agents came to the Office to question Hallum about possible destruction of evidence. Although Hallum's doodles were not evidence in the case and were never to be used by Hadley to draft her investigation report, Hallum was dismayed by the agents' visit and the lack of NIH and HHS support for him (he also was dismayed by the U.S. Attorney in Baltimore refusing to prosecute Imanishi-Kari and her attorney for alleged abuse of the Federal system). Thus, in August 1992, as ORI was being created, Hallum retired back to Connecticut.

(3) The second OSI Deputy Director was publicly accused of sexual harassment of a female OSI staff member, and he was moved to another Federal agency.

Creation of ORI, out of OSI at NIH and of OSIR at PHS, in 1992 into the mid-1990s

When Bernadine Healy came from the Cleveland Clinic to be NIH Director from 1991 to 1993, she reportedly wanted keep tight reins on OSI (particularly in the sensitive Popovic/Gallo case), yet she did not like having the public and Congressional attention on OSI at NIH. Since OSI had (through HHS-designated authority to NIH) the responsibility for all HHS research agencies' extramural and intramural allegations and investigations of scientific misconduct, OSI really belonged at the HHS administrative level. [7]

Healy was attacked by Rep. Dingell at a hearing for her handling at the Cleveland Clinic of the Sharma case (see below), as well as what Rep. Dingell termed her lack of support for OSI's independence at NIH (NAS, 2002). As summarized by Kevles (1998) following his interviews with the principals, Healy found Hadley's draft investigation reports on these two major cases to

"read like a novel" and asked Hadley to recast one report; but Hadley refused (with Hallum's backing of her independence from the NIH Director), declaring that such a revision would alter the thrust of the report. Healy found Hadley's "rogue operation" lacked adequate supervision and attention to proper investigative procedures, becoming "too close" to the key whistleblower. Healy told Hallum to "rein Hadley in" and return her to OSI's office (see above). Rep. Dingell attacked Healy at his August 1991 hearing as "virtually obliterating" the progress that NIH, with Hadley in OSI, had made (Dingell had apparently used a chronology based on Hadley's notes). Finally, Hallum and Healy relieved Hadley of all her OSI duties, but, as noted above, Rep. Dingell got Hadley detailed from NIH to his Committee. Hadley then joined Rep. Dingell or his Congressional staff in bad-mouthing ORI staff (particularly on the Imanishi-Kari, Popovic, and Poisson[6] cases), including criticism of the OSI staff scientists who had been so devoted to Hadley and had supported her OSI investigations in the early 1990s.

As a result of the perceived breaches of confidentiality with Dingell staff members and outside attorneys described above, Healy directed her NIH Division of Management Survey and Review to conduct an intensive examination of OSI's security and management systems. While very time-consuming, detracting from the OSI staff time for investigation, the process was very helpful to OSI in the end. Healy provided funding for several huge file cabinets and safes, which could be locked securely in a separate file room, with access closely controlled and files monitored by a competent paralegal. Healy finally recommended, during this time of controversy, that OSI be moved out of NIH, to a new office at the HHS level.

ASH Mason agreed in 1992 (PHS, 1992), creating at the HHS level a new Office of Research Integrity (ORI), out of OSI at NIH and OSIR at the ASH's Office. In 1993, the ASH named Bivens from the latter office as ORI Director (following about half a year under an acting director[7]). Bivens was a long-time federal official, a scientist with skills in the bureaucracy and

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[6] Roger Poisson was a surgeon at the St. Luc's Hospital in Montreal, Canada, doing research under the NCI's National Surgical and Adjuvant Breast and Bowel Cancer Program (NSABP), coordinated by Bernard Fisher at the University of Pittsburgh. Poisson directed his research data managers to falsify the records for breast cancer patients, as human subjects in the lumpectomy versus mastectomy research trial, which were submitted to the University for enrollment of eligible subjects in the clinical trial. When Hadley worked under Rep. Dingell in Spring 1994, she and Rep. Dingell brow-beat ORI officials into investigating Fisher on his NSABP program as well. Fisher was removed as Principal Investigator by NCI during the investigation, but he was later cleared of any research misconduct [he then sued the University (and NCI and ORI) for personal damages, winning a $3 million settlement in 1997]. The Fisher case events triggered by Hadley and Rep. Dingell caused ORI a huge loss in the credibility that ORI, under Dorothy Macfarlane's DIO leadership, had built with federal clinical trial monitors and the clinical research community.

[7] The Acting ORI Director, J. Michael McGinnis, M.D., a epidemiologist and senior HHS official assigned to ORI, decided in December 1992 to accept an investigation report – which had been re-written by the staff of the former-OSIR [without involving in the previous six months the former-OSI scientists who had completed the original report and disagreed with the re-wording and findings], to pursue ORI findings against Popovich and Gallo, which were appealed by them to seek DAB hearings.

its politics. ORI's proposed findings of research misconduct and administrative actions then required approval by the ASH.

ASH Mason also decided in 1992 (PHS, 1992) that the DAB staff attorneys would conduct trial-like hearings for any respondents who appealed the proposed ORI/PHS misconduct findings or administrative actions against them. It is noteworthy that HHS officials committed millions of dollars annually from ORI's budget in support of the newly instituted DAB administrative hearings. The ORI/PHS counsels were told by HHS officials to expect six to eight hearings each year [even two or three of these trial-like hearings per year turned out to be an enormous load for the available PHS counsels, assisted by ORI scientists]. Charrow (2010) noted in regard to DAB: "Prior to being given responsibility over misconduct cases, the DAB adjudicated mind-numbing cases about the cost principles governing federal grants and the amount due states under the Medicaid program." [See 57 *Federal Register* 53.125 (Nov. 6, 1992). See also 45 Code of Federal Regulations, pt. 16, app. A, § B(a)(1).] Before 2005 [when trained HHS Administrative Law Judges (ALJs) took over all appealed ORI cases], the DAB hearings were mainly conducted by central HHS DAB staff attorneys (described, by other PHS counsels, as having no background in science and its cultural norms). For example, in the Angelides case (ORI findings against Angelides, 1999), ORI staff and PHS counsel found that they had to use a young child's book, written for Cold Spring Harbor Press publication without scientific jargon, to explain to the DAB attorneys about DNA/gene expression.[8]

In 1993 Congress established ORI under federal statutory authority at 42 U.S. Code §289b (NIH Revitalization Act, 1993), specifying that ORI be "an independent entity in HHS . . . headed by a Director, who shall be . . . experienced and specially trained in the conduct of research, and have

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[8] As noted in the *ORI Newsletter* (ORI, 1993C), the first DAB hearings before DAB staff attorneys (most often, Cecilia Sparks Ford and Judith Ballard) did not go well for ORI and its PHS counsels. DAB attorneys in two 1993 cases (Sharma, http://www.hhs.gov/dab/decisions/dab1431.html and Popovic, http://www.hhs.gov/dab/decisions/dab1446.html) ruled against ORI As a result of those DAB decisions, two other pending DAB hearings on ORI findings were dropped by ORI (Gallo case and Hamosh case). Later, in 1996, the long-standing Imanish-Kari case was lost by ORI at a DAB hearing http://www.hhs.gov/dab/decisions/dab1582.html. However, other respondents withdrew their DAB appeals. In addition, ORI did prevail in several earlier as well as later DAB hearings (see below).

Popovic later unsuccessfully sued Hadley and the Government for emotional distress and violation of due process rights in the OSI investigation, under the Federal Torts Claims Act (28 U.S. Code § 1346, 2671) in the U.S. District Court in Maryland [997 Federal Supp. 672 (1998)]. The Court found: "Whatever criticisms may be made of the OSI/ORI/U.S. Congress/"Hadley" investigations, they were not, as a matter of law, intentional or reckless, nor were they extreme and outrageous. In the white hot glare of the international controversy surrounding discovery of the AIDS virus, the record is clear that NIH made an overall reasonable attempt to look into serious allegations of scientific misconduct." http://www.leagle.com/xmlResult.aspx?page=4&xmldoc=19981669997FSupp672_11593.xml&docbase=CSLWAR2-1986-2006&SizeDisp=7

experience in the conduct of investigations of research misconduct." It is noteworthy that this Congressional requirement was met during neuro-psychologist and investigator Biven's tenure from 1993 to1996, and then in 2012 with the appointment of a social scientist who had long served as a university Research Integrity Officer (RIO), David Wright, Ph.D. [this followed the long service of a PHS counsel (Chris Pascal, 1999), followed by another HHS official acting as ORI Director, the two of them covering the period from 1996 to 2012].

Those left in OSI in the early-to-mid-1990s were very shaken by the departures of the several officials and staff, as noted above, as well as by the ongoing intense Congressional, scientific association, press, and public torment. So the OSI remaining staff hunkered down and depended on each other to keep working as determined professionals. Dorothy Macfarlane (as ORI's Investigations Division Director) and Barbara Williams and the author (Alan Price) as Divisional Branch Chiefs [with Nancy Davidian, a former NIH Appeals Officer, expert in NIH administrative policies] committed the Office to creating three huge notebooks with written procedures and solid evidence-security requirements for ORI professional investigators. Williams learned much on such matters from the Federal Bureau of Investigation (FBI) and the Secret Service (recruiting one such agent to handle office security and credentials), as well as sending all OSI investigators to the Federal Law Enforcement Training Center for instruction in the law and for practice in investigative interviewing. Many of the instructors there were former FBI agents, as were some of the consultants from the Reid and Associates Group, who brought videos to ORI to train the staff in interrogation and body language evaluation techniques. Williams also invited a local university forensic psychologist to conduct training in detecting deception. She established liaison with investigators in the HHS OIG, briefing them regularly on ORI cases and providing scientific advice on their cases, as well as working with them on investigations by several Assistant U.S. Attorneys around the country on *qui tam* suits for false claims in HHS grant applications.

ORI staff also worked hard to accelerate ORI's assessment of university investigations and to establish working relationships with institutional RIOs [8] across the Country, holding regional conferences for them and consulting with them, making suggestions on their investigation processes. The senior staff [9] in ORI became competent, recognized and respected by the RIOs and by peers in other federal investigational offices; ORI often acted [as it does today in 2013] as the lead office for advising other federal agencies on research misconduct issues and investigation techniques.

Marcel La Follette (2000) summarized this early OSI/ORI history:

> Looking back at the history of ORI, one cannot help but conclude that several factors inhibited a smooth start from the onset: the hot lights of media and Congressional attention, the tendency of Congress to micro-manage agencies (particularly this one), and the fact that, from the beginning, ORI was involved in investigating one of the most sensational cases in the history of American science. . . . Every action and decision of ORI was dissected by the interested parties at every step. It was not an auspicious

> beginning, and it gave ammunition to the critics of federal misconduct regulation. Fortunately, more careful attention to procedure, tighter management, and an expanding list of closed cases have now put the NIH [ORI] effort on a more steady course.

New policies in ORI in the 1990s

A 1990 OSIR Report noted that OSI/PHS had made five findings under the "other serious deviations" (OSD) clause [e.g., for false representation of control subjects' status or of research progress, selective data reporting, misuse of peer review materials, and failure to inform coauthors]. Many of the scientific and academic associations and individuals had reacted negatively to that OSD clause in the 1989 regulations (HHS, 1989) and to the 1991 *Federal Register* notice on OSI's procedures (HHS, 1991). These commenters argued that OSD allegations could be used to attack investigators doing pioneering research or using innovative methods that had not been universally adopted; of course, there were no such trivial cases pursued by OSI or universities. However, ORI Director Bivens agreed in 1992 that ORI would no longer consider allegations under that part alone of the 1989 regulatory definition of misconduct in science [it is noteworthy that essentially all of the older OSD cases might have been considered "falsification" or "plagiarism" instead of OSDs].

In addition, OSI had been overwhelmed with hundreds of allegations of so-called "plagiarism" between former collaborators who were arguing over who could use the words and products of their joint research (Fields and Price, 1993). As the author recommended, Director Bivens issued in 1993 an ORI policy statement that such "authorship disputes" would not be handled by ORI as "misconduct," but instead would be left to the collaborators and their institutions to resolve. That policy (ORI, 1994B) remains in effect at ORI today, and other agencies follow it.

Director Bivens also decided in 1992 to publish all ORI misconduct findings in the public *Federal Register*, *NIH Guide for Grants and Contracts*, *ORI Newsletter*, and *ORI Annual Reports*, and online at the ORI website (http://ori.hhs.gov) and the PHS Administrative Actions Bulletin Board (ORI, 1993B), specifying the respondent's name, institution, and precise findings of research misconduct and administrative actions. It is noteworthy that the NSF OIG has never done so.[9]

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[9] The NSF OIG reports on its misconduct findings in its public *Semi-Annual Reports to Congress* (http://www.nsf.gov/oig/) without naming the person who committed misconduct or their institution (simply stating, e.g., "a professor at a major northeastern university"). NSF has published the names of persons debarred by NSF from Federal funding, but without stating the reason for debarment (some were based on research misconduct findings, but the NSF debarment notices do not so state). One can search for such "exclusions" by name/agency at https://www.sam.gov/portal/public/SAM.

It is noteworthy that about 90% of NSF's findings have been for plagiarism-related misconduct, whereas ORI's findings have been over 90% for falsification and fabrication. While NSF OIG officials suggested this difference was due to the attention given to medically-related research (at NIH, for ORI), the author has always believed that this difference may instead be due to an under-reporting of the latter categories to NSF OIG -- not to a fundamental difference between physicists, mathematicians, social scientists and engineers (who mostly plagiarized on NSF funds) versus biomedical scientists (who mostly falsified and fabricated on HHS funds).

ORI and PHS wanted advice from the community as they moved forward and recovered from the early problems, so the ASH agreed to appoint a PHS Advisory Committee on Research Integrity and Misconduct. The author nominated an ethicist/historian colleague from the University of Michigan, Nicholas Steneck, to chair it. The Committee met from 1991 to 1993 and developed numerous ideas. Steneck (1994) summarized the history [10] of the Government-university debate:

> As university after university found in the 1970s and 1980s, cases involving scientific misconduct too often were not covered by the general rules governing academic conduct. Evidence is hard to collect. Experts are needed for investigations and adjudication. . . . This is not the way that most scientists and university policy makers saw this issue in the mid-1970s. . . More than any other factor, the widespread belief that error and fraud could be detected and corrected by the scientific community explains why scientists and the policy makers they advised on university campuses felt and have continued to feel no pressing need to institute policies and procedures for dealing with scientific misconduct. . . . Thus, as late as 1981 it was still being argued that misconduct in research is an isolated problem which could be kept in check through scientists' self-regulation. Over the next few years the belief in the inherent ability of scientists to protect their own integrity began to erode. . . . Just as there has been and continues to be a great confidence in the ability of science to police itself, so too there has been confidence that universities could easily handle scientific misconduct investigations in a prompt, efficient manner if called upon to do so. . . . The uneasiness that has emerged on the scientific-professional side of the Government-university partnership in science is endemic to discussions of science policy today. . . After more than a decade of debate and attempts at policy formation, the future is still far from clear.

Then Congress mandated in the NIH Revitalization Act (1993) the creation of a Commission on Research Integrity to review the scientific misconduct regulation and its enforcement. Kenneth Ryan chaired the Commission through 1995, when it made 33 recommendations, which included a draft whistleblower protection regulation, requirements for training of all persons receiving PHS support on the responsible conduct of research, and strengthening of ORI (Commission on Research Integrity, 1995). Some of the Ryan Commission's other recommendations, as noted by Kevles (1998), were "blasted by the National Academy of Sciences and denounced by the Coalition of Biological Scientists" as being "so seriously flawed that it is useless as a basis for policy making and should be disowned" by HHS, including its proposed new and broader definition of misconduct in science as "misappropriation, interference, and misrepresentation," with outcomes of investigations to be made public (whether misconduct or no misconduct was found). These proposals were attacked as threatening scientists with "unpredictable and ill-defined charges" that would be "an open invitation to litigation." Some of its less controversial recommendations were implemented after review and reporting by committees of HHS officials

(HHS, 1996A; HHS, 1996B). At this time, ORI had not been initiating new investigations, only conducting intensive oversight analysis of institutional investigation reports and the questioned data.

In 1999, HHS adopted the new Federal-wide definition created in 1998 by the Office of Science and Technology Policy (OSTP) in the White House (Executive Office of the President, 2000), in consultation with ORI/HHS and other federal agencies. "Research misconduct" was defined as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results." The OSD clause (from the 1989 PHS definition) was eliminated.[10] HHS also confirmed that awardee research institutions have the primary responsibility for investigating research misconduct. HHS gave authority to each agency for its intramural programs, and to the HHS OIG for extramural programs, to conduct any necessary investigative fact-finding for HHS.

OSI and ORI had conducted dozens of inquiries and investigations in the 1990s, involving PHS agency intramural research as well as extramural institutional research. By 2000 ORI had already made public in its *ORI Annual Reports* [all available at http://ori.hhs.gov/annual_reports] findings of misconduct from eighteen such ORI investigations [Langlois, Poisson, Rosner, Shelley, and Sherer in 1993; Chagnon and Tewari in 1994; Bednarik, Jones, Kerr, Siddiqui, and Tanner in 1995; Abbs and Daubert in 1996; Lowe and King in 1998; Angelides (DAB-contested[11]) in 1999; and Qian in 2000]. When OIG was assigned in 1999 to take over the HHS "investigative fact-finding" role, OIG had little to no scientific expertise. Indeed, in some HHS OIG cases, the

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[10] The author notes, however, that numerous institutions have retained the "other serious deviations" clause in their institutional research misconduct definition. Officials of one top-tier university considered a report from an institutional investigation committee with an OSD-finding for a faculty member not meeting some undefined "university community standards" of research conduct and mentoring. ORI would not consider such a finding under the Federal definition's requirements (ORI has not used "OSD" since 1992).

[11] As noted above, ORI had lost cases at three DAB hearings (Sharma case in 1993, Popovic case in 1993, and Imanishi-Kari case in 1996). However, several respondents found by ORI to have committed falsification, fabrication, or plagiarism withdrew their DAB appeals before any hearing: Raphael Stricker and James Freisheim (ORI, 1993C), Catherine Kerr (ORI, 1994B), and James Gary Linn (ORI, 2010) – as well as Evan Dreyer (ORI, 2000), who withdrew his appeal during a DAB hearing. So ORI findings against them all were published.

Furthermore, ORI prevailed at three other DAB hearings in the 1990s, with ORI findings being published: Paul Langlois in 1994: http://www.hhs.gov/dab/decisions/dab1409.html, John Hiserodt in 1994: http://www.hhs.gov/dab/decisions/dab1466.html, and Kimon Angelides in 1999: http://www.hhs.gov/dab/decisions/dab1677.html.

Another DAB appeal by a former Michigan State University graduate student, Maie Elkassaby, was withdrawn when ORI and the institution confirmed her acceptance of responsibility in a dispute over research records, and they withdrew their misconduct findings (ORI, 1994A).

OIG agents had asked assistance from OSI/ORI scientists in evaluating the evidence and case strategy. Many in the PHS community understood that assigning "OIG to conduct necessary misconduct investigations for HHS" would lead to none being done -- that the effort was simply to "defang" ORI. However, only one ORI research misconduct case (involving a small business) was ever referred to the HHS OIG for investigative activity assistance (from 1999 to date in 2013).

Nonetheless, as noted above, ORI investigators did work with HHS OIG agents (as well as FBI agents) on investigations conducted by Assistant U.S. Attorneys in the Department of Justice around the Country who were handling *qui tam* civil suits and prosecutions under the Federal False Claims Act, 31 United States Code §3729 [*e.g.*, the Department of Justice was involved late in the Eric Poehlman case (2005); he was found guilty and sentenced to a year in prison, as well as personally fined for his crimes, and he was also debarred from federal funding by HHS]. However, ORI retained for HHS the oversight responsibilities for all of the extramural and intramural cases of research misconduct in HHS-related research. [11]

In the early 1990s, OSI/ORI initiated a series of regional conferences, in cooperation with local universities, to introduce the Office to the new RIOs and to educate them about policies and procedures, as well as listen to their concerns. The author also created in 1990 an OSI workshop at NIH for 25 distinguished editors, to meet and talk off the record, as well as in 1993, in collaboration with Mark Frankel at AAAS, a conference at NIH on plagiarism and theft of ideas.

In 1999, under the author's direction, Williams prepared a new ORI program, Rapid Response for Technical Assistance, which was published in the *ORI Newsletter* and ORI website (ORI Technical Assistance), offering to provide advice and detailed assistance to institutional RIOs [12] on their handling of allegations, evidence, investigations, and follow-up to misconduct allegations (particularly useful, as ORI had stopped initiating its own investigations by the late 1990s). DIO's program has successfully provided advice in dozens of cases annually. In recent years, DIO's intensive oversight review of allegations and investigation reports, including exhaustive review of original laboratory notebooks and computer files received from institutions, has focused on sophisticated forensic image and digit analysis (ORI Forensic Tools).

ORI also prepared in the 1990s, and HHS published in 2000, an NPRM for the protection of research misconduct whistleblowers (HHS, 2000). Federal employees were already covered by the federal Whistleblower Protection Act (1989). However, President Bush's Administration (2001 through 2009) did not want to press for more Government regulation [the proposed extramural whistleblower protection regulation remains "pending" to date in 2013].

Revised regulations by HHS and NSF in the early 2000s

In 2002, NSF [13] published revised regulation, 45 CFR 689 (NSF, 2002), adopting the OSTP definition and dropping the 1991 NSF regulation's clause on "retaliation as misconduct."

Following an earlier NPRM, HHS published in June 2005 its revised regulation, 42 CFR 93 (HHS, 2005), which included the OSTP definition: "Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. (a) Fabrication is making up data or results and recording or reporting them. (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. (d) Research misconduct does not include honest error or differences of opinion."

The 2005 revised HHS regulation resulted in a number of other changes [see ORI website discussion (ORI, 2005)]. It broadened the definition of "research" to include any "systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied." It also included new requirements for PHS findings: "A finding of research misconduct made under this part requires that -- (a) There be a significant departure from accepted practices of the relevant research community; and (b) The misconduct be committed intentionally, knowingly, or recklessly; and (c) The allegation be proven by a preponderance of the evidence."

It is noteworthy that in the eight years since the revised HHS regulation went into effect (June 2005, to date in 2013), ORI has not made a finding of misconduct committed "recklessly."[12] It is also noteworthy that the "preponderance of the evidence" (over 50%) standard of proof, formalized in the 2005 HHS regulation, had been informally adopted since 1989 by NIH/PHS

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[12] Some institutions have tried to make such findings for reckless misconduct. However, in the author's experience as an expert consultant for seven years, there is a danger in institutions using the "reckless" standard too loosely. For example, the author has seen investigation committees and officials propose or make findings of research misconduct for a professor being a poor mentor -- or for failing to do forensic image analysis on figures for publication (when the professors had trusted a graduate student or postdoctoral fellow to publish the same raw-data figure that they had showed to the professor earlier).

The author notes that, in the prior decade, two distinguished, nationally-prominent professors had missed such manipulation of images by their graduate students or postdoctoral fellows (until it was detected by others during manuscript review by a journal or after the publication process); these professor were praised for making rapid public retractions of the falsified research publications (ORI findings against Urban under Hood, 1995; ORI findings against Kumar under Hood, 1996; and ORI findings against Hajra under Collins, 1997). No one ever publically accused these professors of being "responsible for the research misconduct" that was committed by their graduate students or postdoctoral fellows.

counsels who were advising OSI/ORI; this was the same standard of proof that had been used in HHS administrative law and federal debarments for decades.[13]

In the 2005 regulation, HHS also instituted a six-year time-limitation for making allegations after a misconduct event: "This part applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation of research misconduct. (b) Exceptions to the six-year limitation. . . (1) Subsequent use exception. The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record[14] that is alleged to have been fabricated, falsified, or plagiarized."

Another section of the 2005 HHS research misconduct regulation [42 C.F.R. Part 93, Subpart E (http://ori.hhs.gov/FR_Doc_05-9643)], eliminated the earlier role played by HHS staff attorneys on the DAB. Instead, a trained HHS ALJ conducts any appeals proceeding, including a possible hearing if warranted, with advice from scientific experts whom the ALJ could appoint.
The ALJ would transmit the ruling (on whether the ALJ upheld the ORI/PHS findings of research misconduct and proposed administrative actions) as a recommended decision to the ASH, for final

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[13] However, it became clear in the 1990s (and remains clear in 2013) to the author and other scientists in OSI/ORI who review institutional reports of scientific and research misconduct, that institutional committees and officials are often uncomfortable using such a low standard of proof. Given the serious impact on reputations and careers from allegations and findings of misconduct in science, they appeared to prefer using some level that is closer to a "clear and convincing standard" or to a "beyond a reasonable doubt standard" (generally without so stating in the investigation reports and notification letters to ORI). ORI even found that one major public university in Maryland had formally adopted in the early 1990s a "beyond a shadow of a doubt" standard, which is a literary (not a legal) standard.

[14] "Research Record" is defined in the 2005 HHS regulations as: ". . . the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding."

The author has argued in a few of his consulting cases that the mere **citation** in a biographical sketch for an NIH grant application (or in a *curriculum vitae*) of a paper containing allegedly falsified results, **without** referring to the allegedly falsified data or results that constitute the "research record," should **not** be a basis for invoking the exception to the six-year time limitation (in order to pursue an issue that arose over six years earlier and thus would fall outside the regulation). For example, asking a professor (who cited papers, published a decade or two ago, in their biographical sketch or *curriculum vitae* in the past 6 years) to produce research records for the cited postdoctoral work done in another laboratory, where the records were left 15 or 20 year ago – and to defend images that were alleged to have been modified by someone (unnamed) in ways that could not be seen by the naked eye (only detected by sophisticated forensic image analysis available in the last decade) – is very difficult and often extremely unfair to the professor to defend such decade-old papers against new charges of falsification. The author's argument – that the "later reuse" clause be read as being restricted to a later citation of the actual falsified data that constitutes the misconduct-related research record (not merely the citation to the paper's author, title, and journal site) -- has not been tested in any appeal, to date in 2013.

decision by the ASH – and then by the ASH, for cases of debarment, to the HHS debarring official.[15]

As noted by former PHS Counsel, turned defense attorney, Charrow (2010), this appeal system at HHS [14] can be challenging to the appellant:

> First, as a practical matter, few if any scientists will have the resources to seek full review by the DAB. . . . Second, recent changes in the regulations have made an appeal to the DAB less attractive. . . access to an appeal [hearing] is no longer automatic. To qualify you must now specify those aspects of the ORI finding that are factually incorrect and why they are incorrect. Even if you were to prevail at the DAB, the ALJ decision is no longer a true ruling as in the past, but now "constitutes a recommended decision to the Assistant Secretary for Health."

Since 1996, no ORI/PHS findings of research misconduct have been overruled by the DAB. Since 2005 (to date in 2013), in response to four such appeals, no formal hearings have been held by the ALJs, who have upheld the ORI/PHS findings and recommended administrative actions.[16]

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[15] Several appeals filed with the DAB since 2005 were dismissed by the assigned ALJ under the 2005 HHS research misconduct regulations, without a formal appeal hearing being held (all such cases being decided in favor of ORI's findings and PHS' proposed administrative actions):

(1) Rebecca (Marcus) Uzelmeier in 2007: http://www.hhs.gov/dab/decisions/dab1677.html
[her debarment-appeal suit in Federal District Court was dismissed in 2008: http://www.gpo.gov/ /fdsys/pkg/USCOURTS-dcd-1_07-cv-00753/pdf/USCOURTS-dcd-1_07-cv-00753-1.pdf

(2) Scott Brodie in 2010: http://www.hhs.gov/dab/decisions/dab1677.html
He was granted the opportunity to pursue a hearing by the ALJ on whether his falsifications were intentional and on the length of the debarment period; his debarment-appeal suit to Federal District Court was dismissed in 2011: http://www.gpo.gov/fdsys/pkg/USCOURTS-dcd-1_10-cv-00544/pdf/ USCOURTS-dcd-1_10-cv-00544-2.pdf.

(3) Philippe Bois in 2011: http://www.hhs.gov/dab/decisions/civildecisions/cr2366a.pdf.
His appeal suit for a hearing was upheld on one of two ORI findings in Federal District Court in 2012: www.gpo.gov/fdsys/pkg/USCOURTS-dcd-1_11-cv-01563/pdf/USCOURTS-dcd-1_11-cv-01563-0.pdf. However, he settled on an ORI finding in 2013 without any ALJ hearing: http://www.gpo.gov/fdsys/pkg/ FR-2013-04-18/pdf/2013-09134.pdf.

[16] As outlined above, in the eight years under the revised HHS regulation (from June 2005 to date in 2013), the HHS ALJs have granted no formal hearings for such appeals; they have found the appellants have not yet raised issues that would require further adjudication. The author notes that some defense attorneys have expressed the opinion that the revised HHS/ORI regulation has turned the process for appeal of ORI findings – with notice of proposed PHS findings by ORI often after one or several years of review within ORI following an institutional investigation finding -- from "scientific debates with ORI" into "legal arguments with ALJs," making appeals untenable.

Final Personal Observations

As summarized in this paper and in the numerous historical books, review articles, as well as public, Congressional, and Government statements cited herein, there has been a tortuous history of scientific/research misconduct since the 1970s, coupled with the history of the OSI/ORI since 1989, and the related federal policies and regulations in 1989 and 2005. As a scientist/official who was working in OSI/ORI from 1989 to 2006, and who has tracked and consulted on cases and these issues privately to date in 2013, it is clear to the author that OSI/ORI had a very difficult start from 1989 to 1996, under intense pressure from Congress, the press, difficult respondents and their attorneys, and Government officials. But ORI pressed forward and recovered fully, and its credibility has continued to blossom in the 2000s. Those who stayed in OSI/ORI, during and after these difficult years, rebuilt the investigative division with documented policies and procedures, security, forensic experts in image analysis and digit analysis, competent analysis in ORI investigations and oversight cases, and welcomed outreach and assistance to RIOs across the Country. Many of the OSI scientists from that era have retired, but some are still there to lead the younger, strong scientists who have replaced them; they have learned to analyze such complex cases competently, carrying on the tradition and the commitment to upholding integrity in research that ORI proudly established in the 1990s and continued into the 2000s. ORI is often publicly cited for its expertise and findings in institutional policies and procedures, institutional RIO and counsel speeches and papers, news media (like *Science* magazine), and focused Internet blogs (like SciFraud, *The Scientist*, and Retraction Watch), and by many individuals who share ORI‘s devotion to integrity in research.

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ENDNOTES:

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1. Another such self-designated "fraud-buster" at NIH was Charles McCutchen, who was the helpful secondary complainant in the Abbs case (see below). McCutchen unsuccessfully sued HHS [*McCutchen v. DHHS,* 30 F.3d 183 (D.C. Cir. 1994)] to try to get access to the names of all the complainants and the names of all the respondents who were **not** found guilty of scientific misconduct in the confidential OSI files, to do his own analyses (ORI, 1993A).

2. The Secret Service's glass thin-layer chromatography plates (on which the ink analysis was done, showing the notebook ink was sometimes years newer than the dates on the pages) were demanded in discovery for the HHS hearing process by Imanishi-Kari's lawyer, Bruce Singal, for scientific evaluation by his own expert. He later mailed back the plates loosely packaged, guaranteeing that they would arrive broken back at ORI. Secret Service agents then told ORI they would never again provide such evidence to ORI.

3. Adil Shamoo, Professor of Biochemistry and Molecular Biology at the University of Maryland Baltimore (and Editor of *Accountability in Research)*, proposed random data audits as an alternative to check for the integrity of publicly funded research results, wherein scientist-auditors would match the raw data records with the published research records (Glick and Shamoo, 1993). See also his comment in *Nature* 439: 784 (2006), with the proposal that he renewed in his talk at the "ORI at 20" Research Integrity Leadership Conference in 2013.

4. ORI makes its own determination, based on institutional investigation reports and additional detailed analysis of the research records, as to whether to pursue institutional findings with ORI findings. However, contrary to Charrow's statement about ORI acting to "reverse" an institutional finding (Charrow, 2010), ORI has never done so and has always made clear that the institution makes its own determinations, which stand under institutional authority (unless the institution should later change them). ORI does not "overturn" an institutional finding; rather, ORI simply declines to pursue some institutional misconduct findings, for various reasons (as Charrow knows from defense cases). As the author learned, a Harvard counsel once told ORI and Harvard colleagues, "We have higher research standards than the Federal Government."

5. Attorney Robert Charrow wrote a book (Charrow, 2010) that included his observations on research misconduct issues, including this historical incident. In the early 1990s, he labeled the OSI staff as "a bunch of yahoos" [after the primitive legendary creatures in the mud in *Gulliver's Travels; s*ee also his critique in the *Journal of NIH Research* 3: 103-106 (1991)]. ORI staff had a similar affection for him. His book chapter contains several errors of fact about OSI cases, most glaringly his false statement that "he [James Abbs, see case discussion above] terminated the interview when the OSI team refused to permit his attorney to be present." In fact, the author had told Abbs months earlier that he could bring his attorney, who did indeed attend. [In fact, his attorney demanded (against standard federal investigative processes) that they be allowed to attend OSI's confidential interviews of Abbs' coauthors and staff, who had witnessed his questioned research and paper. When the NIH counsel and the author rejected that demand, Abbs and his attorney left the interview without answering any of the questions on the issues that the author had told him were to be discussed.] It is noteworthy in this vein that Charrow had been one of the PHS lawyers who wrote the 1989 misconduct regulations and then left the Government for private practice, where he was observed by other PHS counsels as attacking these same regulations and OSI/ORI while

serving as a defense attorney. Kevles (1998) quotes Charrow as saying of the ORI: "We created a monster, and now it is time to bury it." Charrow and his colleagues had little success in trying to do that.

6. As noted in the NAS historical summary (NAS, 2002): "OSI suffered a "scientific backlash" (Hamilton, D.P. 1991. *Science* 253: 1084–1086) by some scientists and associations that criticized OSI as being too "zealous" (Davis, B., 1991, *The Scientist* 5: 12) and being staffed by investigators reminiscent of the "Keystone Cops" (Wheeler, D.L., 1991, *Chronicle of Higher Education,* p. A5). Others suggested that OSI was staffed by "failed scientists" [see quotations in a national news article (Recer, Associated Press, 1991)]. The author personally knows these politically-driven labels were grossly unfair and inappropriate [see text below on the OSI/ORI staff's solid scientific and administrative credentials].

7. OSI's sister office at NIH, the decades-old Office for Protection from Research Risks (OPRR), had similar HHS-wide regulatory authority (over protection of human and animal subjects in PHS research). Later, OPRR's human subjects division was also moved out of NIH to the HHS level, becoming the Office for Human Research Protections (OHRP). It is noteworthy that OHRP makes findings of regulatory violations against institutions, not against individuals; while OPRR and OHRP could have pursued debarment of individuals who abused human subjects (like ORI does for individuals whom ORI found to have committed research misconduct), these other offices have left the possible pursuit of such debarment actions to the individual PHS funding agencies [that rarely has been done, except for financial fraud].

8. In the author's experience at OSI/ORI through the 1990s, the best and most committed of the first RIOs – to the fair and thorough handling of allegations and investigations of research misconduct -- included: [EAST COAST] Margaret Dale at Harvard Medical School, Jerome Rosenberg at University of Pittsburgh, Joseph Corless at Duke University Medical Center; Karen Putterman at University of Medicine and Dentistry of New Jersey, and Estelle Fishbein, Julie Gottlieb, and Sheila Garrity at Johns Hopkins University; [MIDWEST] Grainne Martin at University of Iowa, Brenda Russell at University of Illinois Chicago, Todd Guttman and Lynne Olson at Ohio State University, Christina Gunsalus at the University of Illinois Champagne-Urbana, Peter Dunn at Purdue University, Judy Nowak at University of Michigan, and David Wright at Michigan State University; [SOUTH] Thomas Walsh at University of Florida, Leonard Zwelling at M.D. Anderson Cancer Center; and Edward Conradi with Cynthia Karr at Medical University of South Carolina; and [WEST COAST] Paul Friedman and Jerry Schneider at University of California at San Diego, Karl Hittelman at University of California at San Francisco, and Cheryl Cameron at University of Washington.

9. In all these interim years of the 1990s, OSI/ORI had a fine core group of honest, hard-working, and dedicated ORI investigation division members. In addition to the four investigators named above (Dorothy Macfarlane, M.D., and NCI clinical trial auditor; Nancy Davidian, Ph.D., biochemist; Alan Price, Ph.D., biochemist and university associate vice president; and Barbara Williams, Ph.D., geneticist), ORI had: John Dahlberg (Ph.D., virologist/immunologist, now ORI Deputy Director); Kay Fields (Ph.D., molecular biologist); John Krueger (Ph.D., cardiac biophysicist, who developed ORI forensic droplets for image analysis); James Mosimann (Ph.D., statistician, who developed forensic digit analysis for ORI); Samuel Merrill (Ph.D., anatomist); Marshall Narva (Ph.D., psychologist); Peter Abbrecht (M.D./Ph.D., physician and bioengineer); and John Butler (B.A., accountant and data base manager). All had many years of successful university, federal, or corporate research and/or research administration experience (most of the scientists had directed university or federal research laboratories).

ORI also had excellent staffers (paralegal Sheila Fleming, data base manager Gary Lipshultz, assurance

coordinators Carolyn Bowman and Susan Hart, writer/editor Karen Gorirossi, and administrative assistants Tracy Morgan and Barbara Boyd, as well as several devoted file technicians). Most of these investigators retired in the 2000s.

OSI/ORI was ably advised in 1989 and the early 1990s by NIH/PHS counsels: Robert Lanman and Susan Sherman [and by Kendra Dimond, assigned to OSI by Healy], then Debra Parrish, Gail Gibbons, and Peter Poon; followed by Marcus Christ, Stephen Godek, and many other PHS counsels later.

10. See also follow-up article by Steneck (1999).

11. HHS published a Statement of Organization, Functions, and Delegations of Authority for ORI in 2000 (HHS, 2000A). Under that authority:

ORI's Director will "(1) Oversee and direct Public Health Service (PHS) research integrity activities on behalf of the Secretary. . . (2) recommend to the Assistant Secretary for Health for decision, findings of research misconduct and administrative actions in connection with research conducted or supported by the PHS; (3) coordinate the development of research integrity policies designed to ensure that subjects of investigations and whistleblowers are treated fairly, including clear specification of what constitutes misconduct, a fair hearing process, appropriate time limits on pursuing allegations, and specific whistleblower protections; (4) manage the financial resources and provide overall administrative guidance in carrying out the activities; and (5) oversee and direct the research misconduct and integrity activities of the office, including the oversight of research misconduct inquiries and investigations, education and training in the responsible conduct of research, activities designed to promote research integrity and prevent misconduct, and research and evaluation programs." – and

ORI's Division of Investigative Oversight Director will: "(1) review and monitor investigations conducted by applicant and awardee institutions and intramural research programs; (2) evaluate investigations and investigatory findings of awardee and applicant institutions, intramural research programs, and the Office of Inspector General and develop and recommend to the ORI Director, findings of research misconduct and proposal [sic] administrative actions against those who committed misconduct; (3) assist the Office of the General Counsel (OGC) in preparing and presenting cases in hearings before the Research Integrity Adjudications Panel of the DHHS Department Appeals Board; (4) provide information on DHHS policies and procedures, as requested, to individuals who have made an allegation or have been accused of research misconduct; and (5) establish and implement a program of advice and technical assistance to entities that conduct inquiries and investigations, or otherwise respond to allegations of research misconduct."

12. For additional input to ORI from the institutional officials community, the author recruited as a consultant in the early 2000s, David Wright, an experienced RIO and Professor at Michigan State University (since 2012, he has been ORI's Director). Through the 2000's, he advised ORI's Division of Investigative Oversight (DIO) on misconduct case strategies and outside activities. Later he was retained as well by ORI's Division of Education and Integrity (DEI) to develop the ORI Boot Camps for RIOs and counsels, as well as to advise on and participate in intramural research on research integrity in ORI with Sandra Titus.

In addition, Nicholas Steneck, a Professor at the University of Michigan, was recruited from Michigan to ORI under the Intergovernment Personnel Act in the 2000s, to work on the responsible conduct of research, integrity education, research conferences, and development of related ORI handbooks and publications, with Sandra Titus and Mary Scheetz in DEI.

13. The author and other OSI scientists initiated in 1991 visits with NSF OIG scientists and counsels, and several of them requested a re-visit at ORI in 1993, to discuss as professional colleagues our policies and mutual cases. ORI's scientists and PHS counsels were dismayed by the publication of a non-collegial legal article by NSF OIG counsels and scientists (Herman et al., 1994). It criticized the "scientific dialogue process" at the PHS, while it somehow disregarded that -- while such an idea had been discussed in 1990-1991 by Hallum for OSI -- it been discarded in 1991with publication of OSI's investigative procedures and in 1992 with the initiation of the DAB's due process hearings. The NSF authors claimed in this paper that the ORI/PHS processes might be in violation of the Privacy Act and Administrative Procedures Act, as well as the U.S. Constitution. They inappropriately disclosed the existence of ORI's three massive investigation procedures manuals (ORI had shared these procedural manuals with the NSF in confidence). Nonetheless, ORI staff members ignored this self-serving NSF article (which appeared while Rep. Dingell and Abbs were criticizing ORI, as described above), when ORI scientists and counsels visited NSF OIG in 1995 and 1998, as professional colleagues.

14. Charrow also contrasted the HHS appeals process with the NSF appeals processes: "The NSF system does not provide either an independent or a trial-like review [as does HHS's system]. Rather, the recommendations of the [NSF] OIG are forwarded to the [NSF] deputy director, who reviews the recommendations and may confirm the recommendations or call for additional evidence. The regulations also permit an appeal from the deputy director's decision to the [NSF] director, but there is no indication of what criteria are to be used by the director" (Charrow, 2010).

NSF posted debarment regulations at 620.830, 620.835, 620.845, and 620.855 (part of the Government-wide debarment regulations, 2003). NSF OIG noted in 1994: "If the deputy director, who is the debarring official [and who is the adjudicator for NSF] finds that there is a genuine dispute over material facts, the regulations entitle the person to a hearing . . . with the full panoply of due process protections . . ." But no respondent in NSF research misconduct cases has ever (to date in 2013) had such a debarment appeal hearing; instead, negotiated settlements are done by NSF (as they are in also most HHS cases).