



Intent to Deceive:

Mental State and Scierter in the New Uniform Federal Definition of Scientific Misconduct

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The opinions expressed in this Article are solely those of the author, and do not represent official or unofficial policy positions of the White House Office of Science and Technology Policy (OSTP), the National Science and Technology Council (NSTC), or the Research Integrity Panel (RIP), or the views of any individual member of these entities.

The legal principle of “innocent until proven guilty,” which might be rephrased, “assume correct until proved wrong,” does not apply to scientific work; the burden of proof remains with those claiming new findings.

Dr. Robert Engler, member of the UCSD committee investigating scientific misconduct in the case of Robert A. Slutsky, M.D., in Robert Engler et al., 317 NEW ENG. J. MED. 1383, 1384 (1987).

I. INTRODUCTION

¶ 1 In the highly competitive world of late twentieth century science, it is almost impossible to insulate a laboratory from the threat of scientific misconduct. Just last year, scandal struck at the vanguard of U.S. biomedical research, when reports surfaced of fabricated data at the National Human Genome Research Institute (NHGRI).¹ The incident came to light in April of 1996, after a peer reviewer for the journal *Oncogene* chanced upon subtle data anomalies in a paper co-authored by NHGRI director Dr. Francis Collins. The paper contained a figure depicting the

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¹ The National Human Genome Research Institute (NHGRI), which changed its name from the National Center for Human Genome Research (NCHGR) on January, 14, 1997, funds U.S. research related to the international Human Genome Project. NHGRI also conducts an intramural (federal) genetics research program, housed within the National Institutes of Health (NIH).

lanes of a Western blot assay² for various proteins. The Oncogene reviewer noticed that the visual artifacts in each column or “lane” of the figure appeared strangely similar, although the pattern was only obvious if a portion of the figure was cut out, inverted, and compared to the remainder.³ The reviewer surmised that several portions of the figure were actually duplicates of the same image.

¶ 2 The reviewer contacted Collins to share his suspicions. Collins then tried without success to authenticate the data contained in the paper, launching an internal investigation that eventually implicated a graduate student in his own laboratory. Collins learned that over the course of several years the student had fabricated control data for several major cell line experiments. During this same period Collins and others in the laboratory had unwittingly published the invalid data in a series of important papers on the genetics of leukemia.⁴

¶ 3 This highly publicized episode of fraud at one of the nation’s marquee research institutes coincided with the launch of a new White House effort to improve the federal government’s regulation of scientific misconduct. In its role as the steward of federal funds, the government is concerned with the quality of the research process, and its product, the scientific record.⁵ The scientific record is the cumulative oral, written, and electronic repository of scientific knowledge, and becomes a tangible legacy of the investment of public research dollars.⁶ The scientific record also functions as an evolving database for public policy decisions that affect millions of lives. The federal interest in the integrity of the scientific record is frequently cited as an important justification for government regulation of the practice of science by federally funded researchers.⁷

¶ 4 Only certain acts by researchers pose a direct threat to the scientific record,⁸ and federal policymakers now use the term “research misconduct” to describe

² A Western blot assay is a diagnostic technique in which protein samples are immobilized on a solid support (e.g., filter paper), so that proteins from different experimental samples are displayed next to each other in “lanes.” Following immobilization, a chemical label (e.g., colored, fluorescent, or radioactive) is applied to the proteins, to permit visualization of the protein by the human eye or through other means of detection. See PETER M.B. WALKER, CHAMBERS SCIENCE AND TECHNOLOGY DICTIONARY 54, 967 (1988).

³ Western blot assays are typically presented as photographs or computer-generated scans of the data. With modern computerized editing techniques, such images can be easily manipulated and altered.

⁴ The student who confessed to misconduct at NHGRI has not been officially identified, and the case is the subject of an ongoing government investigation. Dr. Collins publicly acknowledged the fraud, however, and decided to retract two of the published papers and correct three others. See Eliot Marshall, *Fraud Strikes Top Genome Lab*, 274 SCIENCE 908 (1996).

⁵ See Robert M. Andersen, *The Federal Government’s Role in Regulating Misconduct in Scientific and Technological Research*, 3 J.L. & TECH. 121, 147 (1988). The federal government funds over \$9 billion dollars per year in support of over 32,000 research projects through the National Institutes of Health alone. See Sarah Glazer, *Combating Scientific Misconduct*, 7 THE CQ RESEARCHER 1, 6 (1997); OFFICE OF RESEARCH INTEGRITY, PROMOTING INTEGRITY IN RESEARCH: A FACT SHEET (1997). For 1997, the Office of Management and Budget estimates that total federal government expenditures to fund civilian basic research will exceed \$13 billion dollars. See EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF SCIENCE AND TECHNOLOGY POLICY, SCIENCE AND TECHNOLOGY: SHAPING THE TWENTY-FIRST CENTURY (A REPORT TO CONGRESS), at 7 (1997).

⁶ “Scientific record” is often used to refer to publications in peer-reviewed scientific journals, but might also encompass information in laboratory notebooks, abstracts, grant applications, contract proposals, progress reports, and scientific oral presentations. This and other background information was obtained by the author during a series of informal conversations with Sybil Francis, Senior Policy Analyst at the White House Office of Science and Technology Policy. Interviews with Sybil Francis, Senior Policy Analyst, White House Office of Science and Technology Policy (Jan. - May, 1997).

⁷ See Andersen, *supra* note 5, at 122.

⁸ For example, if a scientist fails to report income to the IRS, his behavior may be criminal, but it does not affect the integrity of his research. By contrast, if a scientist omits unfavorable data from a research report, his behavior, while not criminal conduct, would invalidate his published research and thus threaten the integrity of the scientific record. See COMMITTEE ON SCIENCE, ENGINEERING, AND PUBLIC POLICY, NATIONAL ACADEMY OF SCIENCES, NATIONAL ACADEMY OF ENGINEERING, INSTITUTE OF MEDICINE, ON BEING A SCIENTIST: RESPONSIBLE CONDUCT IN RESEARCH, VOLUME II (1994) [hereinafter RESPONSIBLE CONDUCT] (footnote continued)

wrongdoing that is primarily scientific in nature.⁹ As the incident at NHGRI illustrates, research misconduct by a single individual can seriously corrupt the scientific record with erroneous reports, while wasting years of effort and valuable resources.¹⁰

¶ 5 The nature and scope of the government's regulation of research misconduct first became controversial in the mid to late 1980s – an era of highly-publicized misconduct cases and Congressional hearings into “science fraud.”¹¹ Since that time, the issue of misconduct regulation has yet to be resolved to the satisfaction of scientists, regulators, or policymakers.

¶ 6 At present there is no uniform body of policies and procedures for handling allegations of scientific misconduct in federally funded research. Among the many agencies that either fund or conduct some form of scientific research, several have adopted misconduct regulations, but across the federal government there has been little consensus concerning how misconduct prohibitions should be interpreted and enforced.¹² Currently, the Research Integrity Panel (RIP) of the NSTC (an intra-governmental entity led by the OSTP), is attempting to draft new, uniform misconduct policies for the entire federal government. But the RIP faces a fundamental problem: there is substantial disagreement among various stakeholder groups over the very definition of the term “research misconduct.”¹³

¶ 7 This article will explore one important aspect of the broader definitional controversy: the question of whether scienter is (or should be) the necessary mens rea for research misconduct. The article will argue against a scienter requirement, and will advocate instead a gross negligence standard of culpability for the forthcoming uniform federal definition of scientific misconduct. The article will also urge that new regulations include language specifying the mens rea for the “research misconduct” offense.

¶ 8 Part I of this article traces the history of the current regulatory framework, and identifies the federal interests in regulating the conduct of publicly funded scientists. Part II reviews the concepts of mental state, scienter, and negligence, and considers the appropriate mens rea for research misconduct. Part II also describes how current regulatory definitions of research misconduct are ambiguous with respect to

(NAS manual for teaching research ethics, asserting that behaviors ranging from sexual harassment to misuse of funds are not scientific misconduct *per se*, but are instead unethical activities subject to ordinary legal and social sanctions).

⁹ The term “research misconduct” was adopted by government policymakers as a replacement for other similar terms – including “science fraud” and “scientific misconduct” – that might be perceived as limiting the scope of misconduct by restricting federal oversight to legally fraudulent acts or to basic science (as opposed to applied or social science) research. Some scientists have been outspoken in expressing their dissatisfaction with this shift in terminology from “fraud” to “misconduct,” viewing the change as overly expansive and driven by legal, not scientific concerns. See Howard K. Schachman, *What Is Misconduct in Science?*, 261 SCIENCE 148 (1993).

¹⁰ NHGRI director Collins characterizes the impact of the deception as “quite profound.” See Marshall, *supra* note 4, at 909.

¹¹ See Lisa C. Heinz & Daryl E. Chubin, *Congress Investigates Science Fraud*, 38 BIOSCIENCE, 559, 559-60 (1988).

¹² Misconduct allegations have not been limited to the federal biomedical, basic science, or engineering agencies. In 1997, charges of sloppy research and data fabrication were levied against the forensic science laboratory of the Federal Bureau of Investigation (FBI). The FBI lab performs extensive scientific analysis for state and federal law enforcement agencies, and evaluates forensic evidence in major federal crimes. See Robert Suro & Pierre Thomas, *Justice Dept. Cites Failures of FBI Lab: Evidence Was Flawed in Several Major Cases*, THE WASHINGTON POST, April 16, 1997, at A1 (citing a 1997 Justice Department report that found scientifically flawed analysis and inadequately trained researchers in the FBI Crime Lab).

¹³ See Rebecca Dresser, *Defining Scientific Misconduct: The Relevance of Mental State*, 269 JAMA 895 (1995) (noting that “an adequate definition of the targeted behavior has yet to emerge [resulting in] a disturbing lack of clarity regarding the specific conduct that ought to be the focus of professional, institutional, and government attention.”). Dresser asserts that “culpable mental state concepts should be explicitly incorporated into the regulatory definitions of scientific misconduct.” *Id.*

a scienter requirement, yielding inconsistent enforcement of existing regulations. Part III concludes that the government should effect a reasonable compromise between the federal interest in scientific integrity and the scientific community's strong tradition of autonomous self-governance, by applying federal sanctions to knowing, reckless, or grossly negligent acts of fabrication, falsification, or plagiarism. The federal government should not sanction scientists who commit "honest errors"¹⁴ or acts of simple negligence. To implement a gross negligence standard effectively, the paper offers suggested mental state language for the new federal definition of scientific misconduct.

II. BACKGROUND: SCIENTIFIC MISCONDUCT AND THE FEDERAL GOVERNMENT

A. *The Emergence of Federal Oversight*

¶ 9 Until recently, federal oversight of the scientific community has amounted to a remarkably informal relationship characterized by unwritten agreements and personal trust.¹⁵ The relative autonomy enjoyed by federally funded scientists reflects the twentieth century's cultural reverence for science, but also results from a clear decision by federal policymakers to promote a highly decentralized, unregulated approach to scientific research. The origins of this approach can be traced to July of 1945, when Vannevar Bush, Franklin Roosevelt's Director of Scientific Research and Development, outlined a visionary science policy for the post-World War II era in a report entitled *Science: The Endless Frontier*.¹⁶

¶ 10 Calling for the establishment of a new federal agency to fund scientific research, Bush wrote of the need for the government to promote a "pioneer spirit" among U.S. scientists. Bush advised Roosevelt to shift federal funds from the rigidly-controlled, highly centralized federal wartime research effort to academia, where scientific advances would result from "the free play of free intellects, working on subjects of their own choice, in a manner dictated by their curiosity. . . ." Bush called for the federal government to infuse the nation's scientific research institutions with new federal grants to which few strings would be attached. Above all else, Bush admonished, the President must safeguard scientists' traditional autonomy and "freedom of inquiry" by leaving control of the policies, personnel, methods, and scope of publicly funded scientific research to the institutions themselves.¹⁷

¶ 11 Vannevar Bush envisioned science as a frontier to be opened by iconoclastic researchers in university settings. He viewed academic institutions, not industry or the federal laboratories, as the fundamental source of scientific progress, "the wellsprings of knowledge and understanding."¹⁸ Bush's vision still animates United

¹⁴ According to Barbara Mishkin, an attorney in private practice who has handled a number of high-profile misconduct cases, examples of "honest error" would be typographical errors, transcription errors, or a failure to notice that equipment was not properly calibrated (assuming such a failure did not involve a gross error of scientific judgment). Telephone Interview with Barbara Mishkin, Partner, Hogan and Hartson, L.L.P., in Washington D.C. (April 9, 1997).

¹⁵ See PANEL ON SCIENTIFIC RESPONSIBILITY AND THE CONDUCT OF RESEARCH, COMMITTEE ON SCIENCE, ENGINEERING AND PUBLIC POLICY, NATIONAL ACADEMY OF SCIENCES, RESPONSIBLE SCIENCE: ENSURING THE INTEGRITY OF THE RESEARCH PROCESS, VOLUME I, at 19 (1992) [hereinafter RESPONSIBLE SCIENCE].

¹⁶ See VANNEVAR BUSH, SCIENCE: THE ENDLESS FRONTIER (A REPORT TO THE PRESIDENT), Chap. 1 (U.S. Gov't Printing Office, July, 1945).

¹⁷ *Id.*

¹⁸ *Id.*

States science policy in the late 1990's: today, approximately one-third of federal spending for basic research goes directly to academia, typically in the form of grants that fund projects initiated by individual researchers.¹⁹ Grant recipients are chosen after a competitive merit review conducted by an applicant's peers in the scientific community, rather than officials of the federal government.²⁰ Through peer review of grants, the scientific community – not the federal government – determines the disposition of a significant portion of the federal budget for basic science research.

¶ 12 Throughout the Cold War and the economic expansion of the 1960's, federal expenditures on scientific research increased at a rapid rate, but federal demands for accountability from scientists remained limited. Near the latter part of the twentieth century, however, inflationary pressures and a growing budget deficit beset the federal government. As a result, most federal expenditures, including the science and technology budget, were subjected to new scrutiny.²¹

¶ 13 With the heightened budgetary concerns of the 1970's and 80's came a series of widely reported science scandals, all featuring egregious misconduct by publicly funded academic researchers. Among the most widely-reported cases were the following: Stephen Bruening, a University of Pittsburgh psychologist, was indicted in 1988 for falsifying the results of National Institute of Mental Health (NIMH)-funded studies of the effects of Ritalin on retarded children; William Summerlin, a dermatologist at the Sloan-Kettering Institute during the 1970's, painted white mice with black ink to falsify the results of skin graft studies; John Darsee, a cardiovascular researcher on an NIMH fellowship at Harvard, fabricated raw data and repeatedly published fraudulent results in scientific journals; and John Long, a Hodgkin's disease researcher at Massachusetts General Hospital in the 1970's, fabricated data and published findings from "human" cell lines that he had reason to suspect were contaminated with monkey cells.²² These and other incidents created a public parade of horrors that brought the issue of scientists' accountability to the fore, and heightened skepticism about the ability of the scientific community to police itself.

¶ 14 In response to the scandals, Congress held hearings to investigate what appeared to be a growing epidemic of "science fraud." At the first such hearing, held in 1981 and chaired by then-Congressman Al Gore, representatives of the scientific community summarily dismissed legislators' concerns. In testimony before Gore's subcommittee, prominent scientists – including the president of the

¹⁹ The National Research Council reports that, as of 1995, federal spending for basic research (research that produces or expands new scientific knowledge and technologies, as opposed to applied research geared toward product demonstration and testing) was apportioned as follows: 39% to federal laboratories (in-house and contractor-run); 31% to academic institutions; 21% to industry; and 9% to non-profit and other institutions. See NATIONAL RESEARCH COUNCIL, *ALLOCATING FEDERAL FUNDS FOR SCIENCE AND TECHNOLOGY*, at 5 (1995).

²⁰ For example, a biomedical research proposal, which would typically be funded by the NIH, first undergoes merit review by an investigator's home institution. If approved, the proposal is sent to the NIH, where it is assigned to a study group assembled from among an applicant's peers in the scientific community. This "study section" debates the scientific merit of a grant application, and assigns a priority score to the proposal. Grant applications then receive a second level of review – again conducted by peer scientists rather than government officials – to determine funding for particular proposals. See Tammy L. Lewis & Lisa A. Vinler, *Storming the Ivory Tower: The Competing Interests of the Public's Right to Know and Protecting the Integrity of University Research*, 20 J.C. & U.L. 417, 422 (1994).

²¹ See COUNCIL ON COMPETITIVENESS, *ENDLESS FRONTIER, LIMITED RESOURCES: U.S. R&D POLICY FOR COMPETITIVENESS*, at 2 (April, 1996).

²² For additional discussion of scientific misconduct scandals, see generally Susan M. Kuzma, *Criminal Liability for Misconduct in Scientific Research*, 25 U. MICH. J.L. REFORM 357 (1992); and Beth Sise, *Scientific Misconduct in Academia: A Survey and Analysis of Applicable Law*, 28 SAN DIEGO L. REV. 401 (1991).

National Academy of Sciences (NAS) – characterized the wrongdoing in science as isolated and the wrongdoers as a handful of disturbed individuals.²³

¶ 15 In 1985, Congress passed a law requiring federally funded research institutions to report all instances of fraud and misconduct to the federal government.²⁴ This interim step failed to create a satisfactory mechanism for federal oversight of scientific research. In 1988, the misconduct controversy was rekindled anew, in the wake of a misconduct allegation against Dr. Tereza Imanishi-Kari, a scientist best known for her collaborations with the Nobel Prize-winning Dr. David Baltimore. When internal investigations by the Massachusetts Institute of Technology (MIT) and Tufts University exonerated Imanishi-Kari, Dr. Margot O’Toole, the “whistleblower” in the case, made her allegations public. Eventually, the matter came to the attention of Representative John Dingell, chair of the House Energy and Science Subcommittee on Oversight and Investigations. Dingell decided to hold his own hearings on scientific misconduct, featuring a re-opening of the Imanishi-Kari case.²⁵

¶ 16 Dingell was fresh from a crusade against fraud in defense contracting. He made no secret of the fact that he regarded federally funded science as inadequately regulated and open to abuses of the kind he had seen in the defense industry. His misconduct hearings were noteworthy largely for their combative atmosphere. When called as a witness, Dr. Baltimore – who had previously initiated a letter-writing campaign to vindicate himself and discredit the investigation – characterized Dingell’s questions as a personal slander and the hearing itself as a threat to academic freedom in the scientific community. By the close of the hearings, legislative action to increase federal oversight of scientific research seemed likely.²⁶

¶ 17 Before Congress could act, however, the Department of Health and Human Services (DHHS) established the Office of Scientific Integrity (OSI) within the National Institutes of Health (NIH). Contemporaneous with the creation of OSI, the National Science Foundation (NSF) established an inspector general’s office to investigate misconduct and financial mismanagement by NSF grantees.²⁷

¶ 18 DHHS assigned to OSI the responsibility for investigating allegations of scientific misconduct by NIH grantees. But OSI, which was staffed by scientists unfamiliar with legal process, quickly drew criticism for its inept investigations. In 1992, DHHS combined the functions of OSI with those of the Office of Scientific Integrity Review (OSIR) of the Office of the Assistant Secretary for Health, creating a new Office of Research Integrity (ORI) within the Office of the Secretary of

²³ See, e.g., *Fraud in Biomedical Research: Hearings Before the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology*, 97th Cong., 1st Sess. 66 (1981) (statement of Dr. Philip Handler, President, National Academy of Sciences).

²⁴ Health Research Extension Act of 1985, Pub. L. No. 99-158, § 493, 99 Stat. 820, 874-75 (1985) (codified as amended at 42 U.S.C. § 289(b) (1998)). The National Science Foundation (NSF) had preexisting general oversight authority over its grants program under the National Science Foundation Act of 1950, Pub. L. No. 507, § 11, 64 Stat. 149, 153-54 (1950) (codified as amended at 42 U.S.C. § 1870 (1998)).

²⁵ See *Scientific Fraud: Hearings Before the Senate Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce*, 101st Cong., 1st Sess. (1989).

²⁶ For further details on the congressional misconduct hearings and the Baltimore/Imanishi-Kari case, see generally Glazer, *supra* note 5. See also Daniel J. Kevles, *The Assault on David Baltimore*, THE NEW YORKER, May 27, 1996, at 94; Gina Kolata, *Inquiry Lacking Due Process*, N.Y. TIMES, June 25, 1996, at C3.

²⁷ See Glazer, *supra* note 5, at 11-12.

DHHS.²⁸ The new ORI has jurisdiction to investigate allegations of misconduct by any Public Health Service (PHS) grantee.²⁹

¶ 19 Following these regulatory actions, two major studies of research misconduct were conducted by advisory groups, and each raised new issues about the proper scope of federal oversight. The first study, entitled *Responsible Science: Ensuring the Integrity of the Research Process*, was published in 1992 by the National Academy of Sciences. The second, entitled *Integrity and Misconduct in Research*, was produced in 1995 by the Commission on Research Integrity – a panel of scientists and lawyers assembled in response to a 1993 congressional mandate and tasked to advise the Secretary of DHHS on misconduct policy.³⁰ The two studies did little to resolve the misconduct controversy. Their recommendations diverged on issues ranging from the effectiveness of peer review to the protections owed to “whistleblowers.”³¹ Even more problematic, each report proposed a new and distinctly different definition of research misconduct (see Part IIC).

¶ 20 When Republicans regained control of both houses of Congress in the 1994 elections, Representative Dingell lost his chairmanship, and congressional attention to research misconduct waned. In 1996, the White House initiated a move to reexamine federal misconduct policy.³² The White House Office of Science and Technology Policy (OSTP) asked the National Science and Technology Council (NSTC)³³ to draft a new definition of scientific misconduct and a set of policy principles that would facilitate a government-wide approach to misconduct regulation. In April of 1996, an NSTC subcommittee, the Committee on Fundamental Science (CFS), established a working group for this purpose. The group is known as the Research Integrity Panel (RIP), and is composed of scientists from the United States Department of Agriculture, the Department of Energy, the Department of Defense, the National Aeronautics and Space Administration, NIH, NSF, and OSTP.

¶ 21 The RIP met between April and August of 1996, heard from invited experts, and began drafting federal policies and a new definition of scientific misconduct. As of this writing, working papers containing the new policy and definition have been circulated among the federal science and technology agencies for review and comment. Although the RIP is revising its final report in response to agency

²⁸ See Public Health Service, Statement of Organization, Functions, and Delegation of Authority, 57 Fed. Reg. 24,262 (1992).

²⁹ The Public Health Service (PHS) consists of the NIH, the Centers for Disease Control and Prevention, the Food and Drug Administration (FDA), the Substance Abuse and Mental Health Services Administration, the Agency for Health Care Policy and Research, the Health Resources and Services Administration, the Agency for Toxic Substances and Disease Registry, and the Indian Health Service. The Office of Research Integrity (ORI), established in June, 1993, within the Office of the Secretary for Health and Human Services (§ 493 of the Public Health Services Act, 42 U.S.C. § 289(b)), oversees the integrity of the research activities of all PHS entities, with the exception of the FDA. See OFFICE OF RESEARCH INTEGRITY, ANNUAL REPORT 1995, at 1 n.3 (1996) [hereinafter ORI ANNUAL REPORT 1995] (available on-line for download in WordPerfect or Adobe Acrobat format at <<http://ori.dhhs.gov/other/material.html>>). Although the FDA is a PHS agency, it retains the authority to investigate alleged misconduct in FDA-regulated research. 58 Fed. Reg. 7140 (1993); 59 Fed. Reg. 2856 (1994).

³⁰ The Commission, often referred to as the “Ryan Commission,” after its chair, Dr. Kenneth Ryan of Harvard Medical School, released its report in 1995. See COMMISSION ON RESEARCH INTEGRITY, INTEGRITY AND MISCONDUCT IN RESEARCH: REPORT OF THE COMMISSION ON RESEARCH INTEGRITY, app. D (1995) [hereinafter RYAN REPORT].

³¹ Individuals who bring initial allegations of misconduct are often known as “whistleblowers.”

³² See Bruce Agnew, *Here We Go Again? Shaping A New Policy on Research Misconduct*, 8 J. NIH RESEARCH 25 (1996).

³³ The National Science and Technology Council (NSTC) is an inter-agency, cabinet-level council chaired by the President’s Science Advisor, with representatives from the major science and technology agencies.

comments, the new policies and the text of the uniform definition have not yet been finalized or made public.

B. The Current Regulatory Framework

1. Distinguishing “Research Misconduct” from Torts and Crimes

¶ 22 Despite continued debate over the limits of the definition, certain core behaviors are generally assumed to constitute “research misconduct”: fabrication (“making up” data or results or omitting valid, relevant data), falsification (inappropriately changing the outcome of an experiment), and plagiarism (appropriating – without proper attribution – the written work of another). Behaviors less directly related to the research process itself – such as sexual harassment or the embezzlement of grant funds – are not generally considered to be *research* misconduct for the purpose of federal regulation.³⁴

¶ 23 Often, serious incidents of misconduct do not resemble the offenses that have been defined by civil and criminal law. For example, misconduct is sometimes referred to as “science fraud,” but the common law torts of fraud or deceit require proof of (a) an *intentional misrepresentation* that is (b) *reasonably relied upon* by (c) a person who suffers *monetary damages* as a result.³⁵ The typical misconduct case involves damages that are more speculative than tangible (e.g., misconduct harms the “scientific record,” as opposed to damaging government property)³⁶ and the individual victims of a deceptive or “fraudulent” scientific practice may be difficult to identify.³⁷

¶ 24 Although a narrow range of scientific “fraud” may be reached by federal laws prohibiting the submission of false statements or claims to the government,³⁸ research misconduct is not a crime *per se*. There are several impediments to the criminal prosecution of research misconduct. First, the mens rea for the federal false statements law is “knowingly or willfully.”³⁹ This high threshold for culpability eliminates the possibility of prosecuting cases of reckless or negligent misconduct, irrespective of the significance of the harm caused. Prosecution of false statement cases also requires evidence of intent to deceive, and when a misconduct dispute turns on a researcher’s state of mind, complex matters of scientific judgment may create insurmountable confusion for a lay jury. Given their large caseloads and

³⁴ Fabrication, falsification, and plagiarism are not currently defined in NSF or PHS scientific misconduct regulations. For suggested definitions of fabrication, falsification, and plagiarism, see RESPONSIBLE SCIENCE, *supra* note 15.

³⁵ See W. P. KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS, ch. 18 (5th ed. 1984) [hereinafter PROSSER & KEETON].

³⁶ One recently-litigated case is a noteworthy exception. In 1994, a federal court in Maryland held a PHS researcher liable to the government for destroying another researcher’s cell line. The case was unusual because it involved the destruction of tangible government property (the cell line) with clear evidence of malicious intent – two key elements of the claim under Maryland trespass law. The government’s compensatory damages were limited to \$450.20, the cost of materials and technician time used in the creation of the cell line. *United States v. Arora*, 860 F. Supp. 1091 (D. Md. 1994), *aff’d per curiam*, 56 F.3d 62 (4th Cir. 1995).

³⁷ See Andersen, *supra* note 5, at 128.

³⁸ See 18 U.S.C. § 1001 (1988) (penalizing whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully falsifies or makes fraudulent or fictitious statements or representations); 18 U.S.C. § 287 (1988) (penalizing whoever knowingly makes a false, fictitious, or fraudulent, claim upon or against the United States to any department, agency or employee of the United States government). See also Kuzma, *supra* note 22, at 399-400 (examining existing federal statutes that have been used to prosecute scientific misconduct).

³⁹ 18 U.S.C. § 1001 (1988).

limited resources, prosecutors are likely to take on only those rare misconduct cases that present simple factual issues and clear evidence of deceptive intent.⁴⁰

¶ 25 Alternatively, if a researcher makes misrepresentations in a grant application, the government could bring a civil suit under the Federal False Claims Act.⁴¹ In such a case, the government must show that the researcher knowingly made false claims, and that the government suffered monetary damages as a result.⁴² Although specific intent to defraud is not required, the need to prove the defendant's awareness of falsity and the government's actual damages creates an obstacle to a successful lawsuit when the claim arises from research misconduct. Additional disincentives to civil litigation arise from the fact that in many cases, the costs the government will incur in civil litigation are likely to exceed the dollar value of the grant in question.

2. Administrative Procedures for Investigating and Sanctioning Misconduct

¶ 26 Administrative procedures are the government's primary means of investigating and sanctioning misconduct in federally funded science. Under the current regulatory scheme, host institutions bear the primary responsibility for investigating allegations involving researchers who are funded by either the National Science Foundation (NSF) or the Public Health Service (PHS). Agency grants are awarded to host institutions, not to individual researchers, and funding is conditioned upon institutional compliance with federal misconduct regulations.⁴³ When an institution completes a misconduct investigation, federal officials will review the institution's findings, and the federal agency may choose to accept the institution's conclusions or to begin an independent investigation.⁴⁴ Both NSF and PHS procedures now permit a formal appeal of an agency's misconduct findings: NSF regulations allow for a written appeal of investigator's findings prior to final adjudication, while Office of Research Integrity (ORI) findings may be appealed to the Research Integrity Adjudications Panel (RIAP) of the Departmental Appeals Board of the Department of Health and Human Services (DHHS) (see Part III.D).⁴⁵

¶ 27 If the agency determines, on the basis of its own or an institution's investigation, that a researcher has indeed committed misconduct, the agency will impose administrative sanctions. Agencies often require that researchers must retract publications containing falsified or fabricated data and submit to monitoring

⁴⁰ See OFFICE OF THE INSPECTOR GENERAL, NATIONAL SCIENCE FOUNDATION, SEMI-ANNUAL REPORT TO THE CONGRESS NO. 9, at 27-32 (1995) [hereinafter OIG REPORT NO. 9] (describing a series of scientific misconduct cases where the U.S. Attorney declined to prosecute, but where NSF pursued administrative sanctions under its scientific misconduct regulations). See also Kuzma, *supra* note 22, at 414 (proposing a new federal criminal statute specific to scientific misconduct).

⁴¹ 31 U.S.C. § 3729-3733 (1988).

⁴² See *id.*

⁴³ See Lewis & Vincler, *supra* note 20, at 424 n.30 (citing 42 C.F.R. 50.105 (1992) which provides, in part, that "[a]n institution's failure to comply with . . . this subpart may result in enforcement action against the institution, including loss of [PHS] funding, and may lead to the OSI's conducting its own investigation.").

⁴⁴ Both NSF and ORI have established standards for institutional investigations, and the agencies may intervene at any point if an institution appears unable to conduct a timely, thorough, and unbiased investigation. See Debra Parrish, *Scientific Misconduct and the Plagiarism Cases*, 21 J.C. & U.L. 517, 520 n.12 (1995).

⁴⁵ See Opportunity for a Hearing on Office of Research Integrity Scientific Misconduct Findings, 57 Fed. Reg. 53125 (Nov. 6, 1992) (announcing an interim appeals process for individuals wishing to dispute PHS Office of Research Integrity (ORI) findings of scientific misconduct in research supported or conducted by the PHS).

of future work. In the most serious cases, active grants may be terminated and researchers may be debarred from receiving future federal funding.⁴⁶

¶ 28 Debarment actions and lesser administrative sanctions are an efficient means of publicly condemning, punishing, and deterring scientific misconduct – especially in comparison to lengthy, expensive, and uncertain civil or criminal litigation. The stigma that attaches to any sanction for misconduct is also uniquely damaging to a scientist, whose employment hinges upon his or her reputation in the scientific community.⁴⁷ In science, lifetime exclusion from federal funding is likely to be far more severe a penalty than a judgment imposing a civil or criminal fine.⁴⁸ Because many areas of scientific research are dependent upon government support, debarment from future grants may end a scientific career. One commentator has also likened debarment to a form of federal quality control, because it prevents additional federal money from being misspent on researchers who have proven themselves unfit “for the societal role of publicly supported scientist,” and who are unlikely to produce work of scientific distinction.⁴⁹

C. Federal Interests in Misconduct Regulation

¶ 29 Federal regulation of non-federal researchers (i.e., researchers outside the intramural program, the military, or federal laboratories) requires a nexus between the regulatory regime and a legitimate government interest.⁵⁰ The federal government has a broad general interest in protecting the public fisc but opponents of scientific regulation have questioned whether this federal interest is sufficient to justify regulating “research misconduct.” Critics of federal oversight assert that research misconduct is rare and regulation unnecessary, because dishonesty cannot survive in the climate of skepticism underlying the scientific method.⁵¹ Such critics argue that misrepresentation of important scientific findings will inevitably be exposed by unsuccessful attempts at replication, while minor misrepresentations of unimportant or trivial scientific findings will do little damage to the scientific enterprise.⁵² This idealized view of science as a self-correcting system is presented in the 1992 National Academy of Sciences report on research misconduct, which states.

Scientists have relied on each other and the traditions of their community for centuries to safeguard the integrity of the research process. This approach has been successful largely because of the widespread

⁴⁶ See ORI ANNUAL REPORT 1995, *supra* note 29, at 32-34 (asserting that one or more of the following administrative actions will be imposed after a finding of misconduct: 1) debarment; 2) prohibition against advisory service as a peer reviewer or consultant for the PHS; 3) required institutional certification of contributors to every PHS research application or report; 4) required institutional certification of data; 5) required institutional plan for supervision of the respondent’s duties; 6) retraction of article; 7) correction of article; and 8) any additional sanctions imposed by the institution. All researchers found to have committed misconduct are listed in the PHS ALERT system, a computer database used by PHS to facilitate checks against pending incoming PHS applications, awards and appointments).

⁴⁷ See Andersen, *supra* note 5, at 135-36.

⁴⁸ See Louis Guenin, *The Logical Geography of Concepts and Shared Responsibilities Concerning Research Misconduct*, 71 ACAD. MED. 595, 596 (1996).

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ In an editorial in the prestigious journal SCIENCE, editor Daniel E. Koshland Jr. made the controversial assertion that “99.9999 percent of [research] reports are accurate and truthful.” See Daniel E. Koshland, Jr., *Fraud In Science*, 235 SCIENCE 141 (1987).

⁵² See ALEXANDER KOHN, FALSE PROPHETS, at ix (1996).

acknowledgment that science cannot work otherwise. . . . Dishonest or untrustworthy individuals become known to their colleges through various mechanisms, including word of mouth and the inability of other scientists to confirm the work in question. Such irreproducible work is recognized and discredited through the processes of peer review and evaluation that are critical to making professional appointments, accepting work for publication, and awarding research support.⁵³

¶ 30 Despite this assertion, available evidence suggests that the self-correcting mechanisms of science may be more effective in theory than in fact. The shortcomings of peer review are well documented,⁵⁴ and the incentive structure of science tends to inhibit researchers from exposing fraud through replication or whistleblowing. It is difficult to obtain funding for a study that simply attempts to replicate prior work, and scientific journals prefer to publish original research, not failures to replicate. Many scientists are reluctant to question the authenticity of a colleague's data, because most whistleblowers suffer damage to their careers or reputations.⁵⁵ And, although documented cases of misconduct occur in only a fraction of the NIH grants funded every year,⁵⁶ studies indicate that a small but significant number of students and faculty are likely to witness or engage in plagiarism, data falsification, data fabrication, or other questionable scientific practices during their careers.⁵⁷

¶ 31 >From the perspective of the federal government, misconduct is not an illusory threat, and science is not an entirely self-correcting enterprise. Thus, regulation of publicly funded science is a legitimate means of protecting substantial federal interests. These interests arise from the government's obligation to prevent the misuse of public funds, preserve the integrity of the research process, and sustain public confidence in science.

¶ 32 Misconduct in science wastes public resources. When a report or proposal contains fraudulent data or plagiarized text, taxpayers fail to get what they have bargained for: namely, original research with scientific merit. Because most research builds upon prior work, false reports in the literature lead other scientists to waste time and resources in pursuit of baseless lines of inquiry.⁵⁸ Grant money awarded to a deceptive or incompetent investigator also results in an opportunity cost to the taxpayer, because the misused funds might have been awarded instead to another, more productive researcher.

¶ 33 A further justification for the federal regulation of science is the protection of public health and safety. The government must ensure the integrity of the data on which its decision-makers rely.⁵⁹ The slow, painstaking process of replication is a

⁵³ See RESPONSIBLE SCIENCE, *supra* note 15, at 18.

⁵⁴ See generally DARYL E. CHUBIN & EDWARD J. HACKETT, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY (1990) (describing shortcomings of the peer-review process).

⁵⁵ See RESEARCH TRIANGLE INSTITUTE, CONSEQUENCES OF WHISTLEBLOWING FOR THE WHISTLEBLOWERS IN MISCONDUCT IN SCIENCE CASES (June 1996) (a survey prepared for DHHS, noting that a majority of whistleblowers suffer some form of negative retaliation, with 12% reporting that they were fired as a direct result of their allegations).

⁵⁶ See Glazer, *supra* note 5, at 12 (noting that ORI found misconduct in only about 60% (24 of 41) of the cases it investigated in 1996).

⁵⁷ See *id.* at 12-13 (citing survey research on misconduct in academia). See also Judith P. Swazey et al., *Ethical Problems in Academic Research*, 81 AM. SCIENTIST 542, 542-553 (Nov.-Dec. 1993) (describing a survey of 2000 doctoral candidates and 2000 faculty members in university science departments, and reporting that 6% to 9% of respondents claimed direct knowledge of fabrication, falsification, or plagiarism by a faculty member).

⁵⁸ See Kuzma, *supra* note 22, at 392-93.

⁵⁹ See Andersen, *supra* note 5, at 122-24.

particularly unsuitable means of detecting misconduct in large-scale, multi-year drug trials or epidemiological investigations. In such clinical studies duplicative research is impracticable and prohibitively expensive. The deterrent effect of federal oversight is a valuable safeguard against misconduct in clinical research that would compromise federal decision-making.⁶⁰

¶ 34 Ultimately, the interests of scientists and the federal government converge around the need to preserve public confidence in scientific research. Science must compete with other discretionary spending priorities for a share of the shrinking federal budget. Misconduct scandals contribute to a perception that scientists are unwilling or unable to “put their house in order”⁶¹ – a perception that may undermine public willingness to pay for science, particularly for basic science that does not immediately produce new cures or new products. By defining the norms that govern professional conduct in science, careful federal regulation can help to reassure the public that tax dollars invested in scientific research are well spent.⁶²

III. SCIENTER AND SCIENTIFIC MISCONDUCT

A. *Mental State and the Concept of Scienter*

¶ 35 *Scienter*, the legal term that is often equated with the phrase “intent to deceive,” is an expression of the traditional view that criminal culpability requires a “guilty mind.”⁶³ Thus, it has often been said that a crime consists of two elements: a wrongful act (the *actus reus*), coupled with a conscious awareness of wrongdoing (*mens rea*).⁶⁴

¶ 36 Historically, however, the prosecution of common law crimes did not involve an inquiry into the *mens rea*, or guilty intent, of the accused. Instead, the law simply inferred the presence of intent from an accused person’s criminal behavior. General societal opprobrium was deemed to confer an awareness of wrongdoing upon the perpetrators of unambiguously immoral acts such as rape, murder, and robbery.⁶⁵

¶ 37 Commentators note that courts began to consider a criminal defendant’s subjective awareness of wrongdoing when legislatures started criminalizing acts that were not inherently morally repugnant. These new statutory offenses covered otherwise ordinary conduct that – under certain circumstances or in certain contexts – posed a threat to public health and safety, to the purity or fair distribution of natural resources, or to orderly business and financial dealings.⁶⁶

⁶⁰ See Kuzma, *supra* note 22, at 375, 390 (noting that scientific misconduct impairs federal decision-making, and that federal misconduct regulation will provide deterrence against fraudulent or shoddy research).

⁶¹ See Rosemary Chalk, *Fraud and Misconduct in Science: Putting Our House in Order*, in SCIENCE, TECHNOLOGY, AND SOCIETY: EMERGING RELATIONSHIPS 125, 125 (Rosemary Chalk ed. 1989) (noting that “recent preoccupation with fraud and misconduct in science has contributed to . . . a desire to restore integrity in the house of science.”).

⁶² See Kuzma, *supra* note 22, at 375, 390.

⁶³ See, e.g., *Holdridge v. United States*, 282 F.2d 302, 309 (8th Cir. 1960). For a discussion of the basic principles of criminal law, see generally WAYNE R. LAFAVE & AUSTIN W. SCOTT, JR., 1 SUBSTANTIVE CRIMINAL LAW (1986).

⁶⁴ See LAFAVE & SCOTT, *supra* note 63, at 297 (“[T]he judges have generally defined common law crimes in terms which require, in addition to prescribed action or omission, some prescribed bad state of mind.”).

⁶⁵ See Susan F. Mandiberg, *The Dilemma of Mental State in Federal Regulatory Crimes: The Environmental Example*, 25 ENVTL. L. 1165, 1177-78 (1995).

⁶⁶ *Id.* at 1178-79.

¶ 38 Unlike a common-law rapist or murderer, the violator of many such statutory offenses might not be expected to realize that his actions were morally wrong, much less criminal. In recognition of this fact, courts began to insist that prosecutors prove a defendant was actually aware of the circumstances that made his action culpable under the statute in question (i.e., to prove that the defendant acted with criminal intent).⁶⁷ This inquiry was ultimately formalized as the scienter requirement in many modern criminal statutes.

¶ 39 A countervailing jurisprudential trend also developed with the advent of federal regulatory crimes: in the regulatory context, courts would sometimes dispense with scienter altogether. If the legislature clearly intended to create a strict liability offense, or, alternatively, if the prohibited act had an element of inherent moral “wrongfulness” (i.e., the act was outside the course of normal behavior and was likely to cause serious harm to persons or property), courts would take a utilitarian stance, upholding the imposition of liability without proof of scienter.⁶⁸ This trend has faltered in the modern era, as the federal courts revert to a common law, scienter-oriented approach to statutes that are ambiguous with respect to mental state.⁶⁹

¶ 40 The terms scienter and mens rea were once used interchangeably, as labels for a morally blameworthy state of mind. Today, scienter retains its connotation as a synonym for criminal intent, but mens rea (or the term “mental state”) is often used in a broader sense, to describe the various levels of awareness that a defendant may have of the facts and circumstances of an offense.⁷⁰ This approach is embodied in the Model Penal Code (MPC), an effort by legal scholars and practitioners to systematize and codify centuries of criminal common law.⁷¹ The MPC is a comprehensive model criminal statute, undergirded by precise standards for defining the culpable mental element of every offense.

¶ 41 The MPC designates four levels of culpable mental state – a classification system that encompasses both intentional and unintentional conduct. Statutes written along MPC guidelines specify the *material elements* of a crime – the particular acts or omissions associated with an offense – and indicate the level of culpable mental state necessary for each material element. MPC language provides for the following mental states.

(1) *purposeful*, when the accused’s conduct manifests the desire or the intention to commit an offense;

⁶⁷ See *id.* (noting that for turn of the century “light police offenses,” and for many modern regulatory crimes, “[a]wareness of engaging in the behavior [is] not necessarily awareness of wrongdoing, and thus [does] not prove mens rea.”).

⁶⁸ See, e.g., *United States v. Balint*, 258 U.S. 250 (1922) (holding that scienter need not be alleged nor proven to indict or convict violator of the Narcotics Act). See also Mandiberg, *supra* note 65, at 1188 (noting that “[a]fter *Balint*, the federal courts often found that Congress had eliminated mens rea as a requirement in regulatory crimes.”).

⁶⁹ In one exemplar of this trend, the Court of Appeals for the District of Columbia in 1989, reversed the conviction of former Presidential aide, Franklyn Nofziger, for lobbying on behalf of private clients in violation of the Ethics in Government Act. The Act was worded ambiguously with respect to mental state, and government prosecutors argued that, like other regulatory or “public welfare” offenses, it did not require a showing of mental state. The Court reversed, finding that Nofziger’s conduct was not “inherently dangerous;” and thus scienter must be an implied element of the statute. *United States v. Nofziger*, 878 F.2d 442, 454 (D.C. Cir. 1989).

⁷⁰ Mens rea can be viewed either normatively, in reference to moral blameworthiness, or descriptively, as a morally neutral “sliding scale” of awareness. See Mandiberg, *supra* note 65, at 1167, n.10 (citing GEORGE P. FLETCHER, *RETHINKING CRIMINAL LAW* 396 (1978)).

⁷¹ AMERICAN LAW INSTITUTE, MODEL PENAL CODE (1985).

(2) *knowing*, when an accused is aware of facts and circumstances that make his or her conduct culpable (under the MPC, knowing conduct also includes willful blindness or the intentional avoidance of guilty knowledge).

(3) *reckless*, when the accused acts in conscious disregard of a high probability that her conduct is culpable; or

(4) *negligent*, when the accused falls below a normative standard of conduct. Negligence requires only objectively determined fault (not subjective intent or awareness); an actor is negligent if he or she should have been aware of facts and circumstances creating an unreasonable risk from her conduct. Negligence as a culpable mental state is disfavored in the criminal law, perhaps because the unwitting or careless actor is viewed as less morally responsible than one who intentionally commits a crime. When criminal liability is imposed for negligent conduct, typically “gross negligence” in the form of conduct that is extremely dangerous or unreasonable is required.⁷²

¶ 42 Not all statutes are drafted according to MPC guidelines; some contain no reference whatsoever to mental state. Such laws, if interpreted literally, create “strict liability” – liability without consideration of fault or intent. In the absence of mens rea language, courts are likely to permit strict liability for certain offenses, particularly where the act in question poses serious, predictable risks to public health or safety. The Supreme Court has held that strict liability is permissible for some “public welfare” offenses. Specifically, the Court has refused to “read in” a scienter requirement where the accused arguably should have known that he or she was in possession of an inherently dangerous article or substance.⁷³ Consistent with this approach, courts have held acts such as carrying a weapon onto an airplane or selling narcotics without completing the required government form to be strict liability crimes. The prosecution of these crimes requires no inquiry into a defendant’s awareness of wrongdoing.⁷⁴

¶ 43 Unless a statute explicitly states that liability is to be imposed without fault, however, courts often look to legislative history, to the seriousness of an offense, and to public policy to determine whether the legislature intended (or should have intended) to require a particular mens rea for a given offense.⁷⁵ The risk posed by statutes or regulations without precise mental state language is unpredictable judicial decision making: a court interpreting such a statute may “discover” an implicit scienter requirement, forcing prosecutors to prove a defendant acted with the requisite level of intent.⁷⁶

⁷² *Id.* at § 2.02(2). See also LAFAVE & SCOTT, *supra* note 63, at 332 & n.5 (noting that the MPC would permit criminal punishment only when negligent conduct met the standard for “gross negligence”).

⁷³ See *United States v. Freed*, 401 U.S. 601, 607-10 (1971) (holding that indictment for violation of a provision of the National Firearms Act criminalizing possession of hand grenades does not require allegation of scienter).

⁷⁴ See *United States v. Balint*, *supra* note 68; and *United States v. Flum*, 518 F.2d 39 (8th Cir. 1975). Although commentators agree that the Court held in *Balint* that strict liability offenses require no awareness of wrongdoing, opinions divide over the extent to which the prosecution must prove awareness of specific facts (e.g., that a defendant convicted of violating the Narcotics Act actually knew that he was selling drugs, versus talcum powder or sugar). See Mandiberg, *supra* note 65, at 1187 n.102.

⁷⁵ See LAFAVE & SCOTT, *supra* note 63, at 342 (noting the unpredictable judicial interpretation of ambiguous statutes: “Criminal statutes which are empty of words denoting fault, but which do not affirmatively provide for liability without fault, have been dealt with in various ways by the courts Sometimes the court reads into the statute some requirement of fault, the absence of which constitutes a defense.”).

⁷⁶ *Id.*

¶ 44 The Supreme Court has held that in certain contexts, particular words in an ambiguous statute or regulation equate to the language of scienter. For example, federal securities laws, along with their implementing rules and regulations, contain several antifraud provisions that lack any reference to culpable mental state. When the Securities Exchange Commission (SEC) or private plaintiffs have brought enforcement actions or claims against negligent or reckless brokers, the Supreme Court has found, based on a contextual analysis of the wording of the statute and rules, that some clauses and provisions contain an inherent scienter requirement and others do not.⁷⁷ The Court has never clearly defined the substantive reach of the term “scienter,” and litigation continues today over whether or not recklessness is sufficient to meet this standard.⁷⁸

¶ 45 Similar litigation has arisen over ambiguously worded provisions in the Commodity Exchange Act and in a series of environmental protection statutes, each of which creates regulatory crimes with unspecified mens rea.⁷⁹ The present uncertainty surrounding the interpretation of these laws illustrates why drafters of statutes and regulations should be careful to specify the mental state that attaches to each material element of an offense. Equally important, drafters must clearly identify those offenses to which liability will attach without fault, as well as those requiring additional proof that the accused had the specific intent to commit a violation.

B. Liability in the Absence of Scienter: Negligence and Gross Negligence

¶ 46 Unlike the statutory and regulatory crimes discussed above, federal misconduct policy will be implemented through regulations imposing *civil* penalties.⁸⁰ Criminal laws, which prescribe punishment, require great certainty for conviction, and place a significant burden upon the prosecution: guilt in a criminal trial must be proven beyond a reasonable doubt. On the other hand, civil statutes are intended to compensate for losses or to discourage loss-creating conduct; therefore, civil

⁷⁷ For example, § 10(b) of the Securities Exchange Act of 1934 prohibits the use of “any manipulative or deceptive device or contrivance in contravention of such rules as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.” 15 U.S.C. § 78(j)(b) (1994) (Manipulative and deceptive practices). The Supreme Court found that words such as “manipulative” and “deceptive” implied a congressional intent to require scienter for a violation. In contrast, § 17(a)(2) of the Securities Act of 1933, which prohibits any person who is selling securities from using any means “to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order make the statements made, in light of the circumstances under which they were made, not misleading,” was determined by the Court to not require scienter, but rather, to permit culpability for negligent actions. See 15 U.S.C. § 77(q) (1994) (Fraudulent interstate transactions). See also *Ernst & Ernst v. Hochfelder*, 425 U.S. 185 (1976) (holding that scienter is required for any private cause of action for damages under Rule 10b-5 and section 10(b) of the Securities Exchange Act of 1934); and *Aaron v. Securities Exchange Commission*, 446 U.S. 680 (1980) (holding that scienter is required to enforce the antifraud provisions of Rule 10b-5 and section 10(b) of the 1934 Act, but that scienter is not required for the government to establish a violation of section 17(a) of the 1933 Act concerning untrue or omitted statements of material facts).

⁷⁸ For a comprehensive discussion of various judicial interpretations of scienter requirements under the Commodity Exchange Act and the Securities Exchange Act of 1934, see generally William D. Harrington, *Culpability and Its Content Under the Commodity Exchange Act*, 17 CONN. L. REV. 1 (1984). The question of whether Congress intended to eliminate recklessness as a culpable mental state under the Private Securities Litigation Reform Act of 1995 is currently before the Ninth Circuit, where the SEC has filed a brief in support of the plaintiff’s securities fraud complaint. See Brief of the Securities and Exchange Commission, *amicus curiae*, *In re Silicon Graphics Sec. Litig.*, Fed. Sec. L. Rep. 99,325 (N.D. Cal. 1996) (No. 96-0393). See also Karen Donovan, *Securities Law Review On Tap*, NAT’L L.J., April 14, 1997, at A6.

⁷⁹ See generally Harrington, *supra* note 78; see also Mandiberg, *supra* note 65, at 1169-77.

⁸⁰ See, e.g., 45 C.F.R. § 76.115 (1998) (stating that “[d]ebarment and suspension are serious actions which shall be used only in the public interest and for the Federal Government’s protection and not for purposes of punishment.”).

judgments require a lower standard of proof, and in theory carry less moral stigma than do criminal convictions.⁸¹ For these reasons, unintentional wrongdoing or negligence, although disfavored as a basis for criminal liability, is often a sufficient basis for civil liability.

¶ 47 Negligence liability turns on the reasonableness of a defendant's conduct, as opposed to the blameworthiness of his or her subjective state of mind.⁸² Under the precepts of tort law, which govern private civil causes of action, ordinary jurors determine whether a defendant has acted negligently by testing his or her conduct against the minimal standard of behavior or caution (referred to as the "standard of care") that would be employed by a reasonable person under similar circumstances. Simple negligence liability can be illustrated this way: if A's car collides with B's car one rainy evening, and B subsequently sues A for the cost of repairs, a jury of A's peers would first decide how a reasonable person *should* drive a car in rainy weather. If the jury finds that A failed to take the precautions of a reasonable driver, A is deemed negligent and the jury will hold him liable for B's damages.

¶ 48 The law demands a heightened standard of reasonableness, however, from those members of society who have professional training or expertise. The conduct of such persons is measured, not against the actions of a hypothetical "reasonable person," but against the minimal degree of skill and care that would be displayed by a competent fellow professional or expert.⁸³ Along with this greater duty of care, professional and expert groups are granted a special right under the law: they, not ordinary jurors, define the relevant standards by which their professional conduct will be judged. This practice makes the professions inherently self-regulatory, because it "gives [professionals] the privilege, which is usually emphatically denied to other groups, of setting their own legal standards of conduct, merely by adopting their own practices."⁸⁴

¶ 49 In deferring to professionals to define their own standard of care, the legal system acknowledges the critical role of judgment in professional behavior. Professionals undertake complex tasks that have uncertain outcomes. Professional behavior cannot be governed by comprehensive codes of conduct, or subjected to the ordinary person's conception of reasonableness.⁸⁵ Because professional judgment is so often opaque to a lay jury, fellow members of the defendant's profession, not jurors, are called upon as expert witnesses to determine the applicable standard of care in a negligence lawsuit.

¶ 50 Civil and criminal law also recognize a distinction between ordinary forms of negligence and gross negligence or gross incompetence. If ordinary negligence is defined as minor or isolated instances of carelessness, gross negligence requires either an extreme deviation from the standard of care or a repeated pattern of

⁸¹ Punitive damages and administrative fines are illustrative of the gray zone that divides civil and criminal law. For further analysis, see LAFAYE & SCOTT, *supra* note 63, at 16.

⁸² *Id.* at 328.

⁸³ See PROSSER & KEETON, *supra* note 35, at 185. Because it demands only the *minimal* degree of skill or care that would be exercised by a competent professional, the professional standard might be viewed as requiring less of professionals than the "reasonable man" standard requires of ordinary (non-professional) persons in similar circumstances. Prosser and Keeton maintain otherwise, characterizing the professional standard as an additional requirement beyond that of the "reasonable man" standard: "Professional persons in general, and those who undertake any work calling for special skill, are required *not only* to exercise reasonable care in what they do, *but also* to possess a standard minimum of special knowledge and ability." *Id.*

⁸⁴ *Id.* at 189.

⁸⁵ See Andersen, *supra* note 5, at 130.

consistently negligent errors.⁸⁶ Such a pattern indicates a defendant's plain indifference to professional standards, and his or her inability to function as a competent member of her profession.

¶ 51 Regulations imposing civil administrative sanctions for gross negligence (but not for ordinary or isolated instances of negligence) often govern interactions between professionals and the federal government. For example, Internal Revenue Service (IRS) regulations provide for the suspension or debarment of any attorney from practicing before the IRS for, *inter alia*,

giving a false opinion, knowingly, recklessly, or through gross incompetence, including an opinion which is intentionally or recklessly misleading, or a pattern of providing incompetent opinions on questions arising under federal tax laws.⁸⁷

¶ 52 The IRS defines gross incompetence as “conduct that reflects gross indifference, preparation that is grossly inadequate under the circumstances, and a consistent failure to perform obligations to the client.”⁸⁸ IRS regulations impose liability for exceedingly negligent conduct, but not for isolated instances of “ordinary” negligence.

¶ 53 Similarly, federal Medicare regulations permit the Inspector General of the Department of Health and Human Services (DHHS) to exclude from participation in the Medicare program any physician who consistently provides services “of a quality which fails to meet professionally recognized standards of health care,” who commits “gross and flagrant” or “repeated” violations of the Medicare provisions governing discharge decisions and claims for reimbursement, or whose license to practice medicine has been revoked for reasons bearing upon professional competence or performance.⁸⁹

¶ 54 Many of the same federal interests that justify administrative sanctions for grossly negligent or incompetent physicians and lawyers are implicated in the regulation of scientific misconduct. In each of these contexts, the government seeks to protect the integrity of a federal program by excluding from participation not only those individuals who would attempt to consciously defraud the government, but also those individuals who, although they may lack a conscious intent to deceive or defraud, have proven themselves unable to consistently meet the minimal standards of their chosen profession.

C. Scierter and Mental State in Scientific Misconduct Regulations

1. Wording of Current Definitions

¶ 55 Both the National Science Foundation (NSF) and the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) have adopted regulatory definitions of research misconduct. Other federal agencies have

⁸⁶ See LAFAVE & SCOTT, *supra* note 63, at 326. The authors note that not all statutes distinguish clearly between gross negligence, which requires exceedingly negligent *conduct*, and recklessness, which requires both grossly negligence conduct and some subjective awareness or risk. *Id.*

⁸⁷ 31 C.F.R. § 10.51(j) (1997) (IRS Regulations: Disreputable Conduct).

⁸⁸ *Id.*

⁸⁹ See 42 U.S.C. § 1320(a)(7) (1997); 42 C.F.R. pt. 455 (Exclusion of certain individuals and entities from participation in Medicare and State health care programs). Medicare regulations were amended to permit State health care agencies to apply for a waiver from the exclusion of a physician who is the sole community physician or the sole source of essential specialized services in the community. 59 Fed. Reg. 32, 125 (1994).

addressed misconduct in their own research programs, relying on either the NSF or PHS wording in drafting similar regulations.⁹⁰

¶ 56 Despite some important differences between the two versions, both the NSF and the PHS definitions proscribe the same set of core offenses. These core offenses are often referred to as “ffp,” an acronym for the terms “fabrication,” “falsification,” and “plagiarism.”

¶ 57 The NSF definition, adopted in 1991, reads as follows:

“Misconduct” means (1) fabrication, falsification, plagiarism, or other serious deviations from accepted practices in proposing, carrying out, or reporting results from activities funded by NSF; or (2) 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.⁹¹

¶ 58 The NSF definition is notable for the absence of language indicating what mental state or level of intent is required for each culpable offense. The PHS definition also lacks intent language, but does include an indirect reference to unintentional conduct, contained in a final clause that excludes “honest error” and “honest differences in interpretation” from the scope of the definition.

¶ 59 The PHS definition, adopted in 1989, reads as follows:

“Misconduct” or “misconduct in science” means 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. It does not include honest error or honest differences in interpretations or judgments of data.⁹²

2. Wording of Proposed Revisions

¶ 60 Soon after their implementation, the PHS and NSF misconduct regulations were formally reassessed by two advisory groups, each of which proposed its own revised definition of research misconduct. The first of these proposals is contained in *Responsible Science: Ensuring the Integrity of the Research Process*, the 1992 report of a study by the National Academy of Sciences (NAS); the second is found in the 1995 report of the congressionally-mandated Commission on Research Integrity (known as the Ryan Commission, after its chair, Dr. Kenneth Ryan of Harvard Medical School).

¶ 61 The NAS proposal was a somewhat naive attempt on the part of scientists to create a very narrow standard of culpability – one that would have broad appeal to the scientific community – while at the same time eschewing legal language and legal concepts such as “intent.” In drafting their new definition, the scientists who authored the NAS report adopted a minimalist approach, perhaps in the mistaken belief that the “ffp” terms are self-defining.⁹³

⁹⁰ For example, the Department of Agriculture, the Environmental Protection Agency, the Department of Veterans Affairs, and the Office of Naval Research have all adopted regulatory or provisional definitions based upon the NSF/PHS “ffp” model. Interview with Sybil Francis, *supra* note 6.

⁹¹ 45 C.F.R. § 689.1 (adopted July 1987, revised May 1991).

⁹² 42 C.F.R. pt. 50, subpt. A (1998) (Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science).

⁹³ In an editorial for the journal *SCIENCE*, Frederick Grinnell of the University of Texas Southwestern Medical School writes that the definition of misconduct should be limited to actions such as data fabrication or plagiarism, where “the intent to deceive is implicit in the action itself.” See Frederick Grinnell, *Ambiguity in the* (footnote continued)

¶ 62 The NAS definition reads as follows:

“Misconduct” in science is defined as fabrication, falsification, or plagiarism in proposing, performing, or reporting research. Misconduct in science does not include errors of judgment; errors in the recording, selection, or analysis of data; differences in opinions involving the interpretation of data; or misconduct unrelated to the research process.⁹⁴

¶ 63 In drafting this policy, NAS members attempted to pare down the language of the definition to make it, and the whole concept of federal misconduct regulation, more palatable to scientists.

¶ 64 The Ryan Commission, comprised of both scientists and lawyers, erred by going too far in the opposite direction. The Ryan proposal completely overhauled the existing definition of research misconduct, removing the familiar “ffp” language to which the scientific community has grown accustomed.

¶ 65 The Ryan Commission definition of misconduct reads as follows:

Research misconduct is significant misbehavior that improperly appropriates the intellectual property or contributions of others, that intentionally impedes the progress of research, or that risks corrupting the scientific record or compromising the integrity of scientific practices. Such behaviors are unethical and unacceptable in proposing, conducting, or reporting research, or in reviewing the proposals or research reports of others.

Examples of research misconduct include, but are not limited to, the following.

Misappropriation: An investigator or reviewer shall not intentionally or recklessly

- a. plagiarize, which shall be understood to mean the presentation of the documented words or ideas of another as his or her own, without attribution appropriate for the medium or presentation; or
- b. make use of any information in breach of any duty of confidentiality associated with the review of any manuscript or grant application.

Interference: An investigator or reviewer shall not intentionally and without authorization take or sequester or materially damage any research-related property of another, including without limitation the apparatus, reagents, biological materials, writings, data, hardware, software, or any other substance or device used or produced in the conduct of research.

Misrepresentation: An investigator or reviewer shall not with intent to deceive, or in reckless disregard for the truth,

Practice of Science, 272 SCIENCE 19, 333 (1996). A belief that intent language is unnecessary is common among scientists opposed to a revised definition of misconduct.

⁹⁴ The authors' intent to create a very narrow definition is indicated by the later assertion of NAS officials that their version “limited federal involvement to three precisely-defined categories: fabrication, falsification, and plagiarism.” Letter from Bruce Alberts, President, National Academy of Sciences, to Dr. William Raub, Science Advisor to the Secretary, Department of Health and Human Services, March 15, 1996 (available from the author upon request).

- a. state or present a material or significant falsehood; or
- b. omit a fact so that what is stated or presented as a whole states or presents a material or significant falsehood.⁹⁵

¶ 66 With its report, the Ryan Commission sought to “bridge legal and scientific perspectives” by defining new terms for misconduct offenses, terms that would couch the underlying concepts of “ffp” in legally enforceable language.⁹⁶ Although the Ryan proposal has positive attributes, including an explicit mention of culpable mental states, the text of the definition is densely worded and unwieldy. Particularly controversial was the Ryan Commission’s decision to replace “ffp” with new offenses (“misappropriation,” “interference,” and “misrepresentation,” or “mim”) – a choice that was met with howls of protest from the scientific establishment.⁹⁷ The new “mim” language is unacceptable to a number of influential scientists, some of whom reject the wording as “arcane and legalistic” and believe it would only create further controversy should it appear in the forthcoming federal definition.⁹⁸

¶ 67 The definitions currently in effect and the revisions proposed to date share two fundamental shortcomings. First, with the exception of the objectionably prolix Ryan Commission proposal, each lacks critical legal language specifying the mental state of culpable offenses. Second, none of the definitions deals adequately with the question of serious but unintentional (i.e., negligent) misconduct. Each definition divides the universe of possible misconduct into only (1) intentional offenses;⁹⁹ or (2) excusable negligence – what scientists often term “honest error,” in reference to cases where the errors involved are scientifically justifiable, or of little practical significance.

¶ 68 There are cases, however, where unintentional misconduct – a reckless or negligent act *committed without the specific intent to mislead or deceive* – exceeds the bounds of “honest error,” with serious implications for the integrity of the scientific record. For example, in 1996, NSF reported on several investigations of plagiarism by foreign-born scientists publishing in English-language journals. In one such case, the researcher in question copied and used, without attribution, entire sections of text from the published manuscripts of other researchers in the same field. NSF investigators found that the plagiarist acted, not with an intent to deceive, but with a

⁹⁵ The Ryan Commission established a scienter requirement for misconduct, but this requirement would also explicitly encompass actions taken in “reckless disregard for the truth.” See RYAN REPORT, *supra* note 30, at app. D, 19-20.

⁹⁶ The report emphasizes that any new federal definition must provide a “legal framework” for misconduct proceedings. *Id.* at 9.

⁹⁷ Members of the scientific community were reportedly “outraged” by the “mim” proposal, and they remain “jittery” about proposed federal misconduct reforms. See Rick Weiss, *Proposed Shifts in Misconduct Reviews Unsettle Many Scientists*, THE WASHINGTON POST, June 30, 1996, at A6. In response to the Ryan Commission Report, the president of the Federation of the American Society for Experimental Biology (FASEB) protested that the new definition was “totally unsatisfactory . . . overly broad, vague, unclear [and] unacceptable.” See Letter from Ralph A. Bradshaw, Ph.D., President, FASEB, to Kenneth J. Ryan, M.D., Chairman of the Commission on Research Integrity (Sept. 13, 1995) (available from the author upon request).

⁹⁸ See Letter from Bruce Alberts to Dr. William Raub, *supra* note 94 (stating that the “legalized” definition of misrepresentation “is heavily dependent upon such legal concepts as “material” and “reckless disregard for the truth. . . . If it adopts a definition that is so arcane and legalistic, the federal government could cripple U.S. science with a source of endless litigation and dispute.”).

⁹⁹ The Ryan commission includes in its definition of intent *constructive* intent, a legal concept that allows intent to be inferred where behavior is sufficiently reckless. See RYAN REPORT, *supra* note 30.

desire to communicate her findings precisely and effectively in a language with which she was unfamiliar.¹⁰⁰

¶ 69 Despite the lack of a malicious motive, such acts of plagiarism are not “honest error” in the sense of being harmless or excusable. Priority of discovery and publication are among the most valuable assets of a scientific career. Proper attribution of authorship in grant applications and scientific publication ensures that credit for discovery and funding for future work are properly distributed. Plagiarism, irrespective of the motive of the plagiarist, can threaten this system if undeserving researchers gain an unfair advantage in funding or employment by appropriating the work of others and representing it as their own.¹⁰¹

¶ 70 In many cases of alleged plagiarism, fabrication, or falsification, the subject of the allegations admits the act itself, but denies any intent to deceive.¹⁰² Unfortunately, due to ambiguities in the existing regulatory definitions of scientific misconduct, it is unclear whether the government can enforce administrative sanctions where evidence of intent to deceive is lacking.¹⁰³ The uncertainty is greatest within the PHS, where PHS-funded scientists have successfully appealed government findings in misconduct cases, and in so doing have raised doubts about whether, under existing federal regulations, any act of scientific misconduct is culpable absent clear evidence of scienter.¹⁰⁴

D. Scienter and Mental State in Scientific Misconduct Cases

¶ 71 The inadequacies of the current federal approach to misconduct became glaringly obvious when a series of accused scientists hired private attorneys and successfully challenged Public Health Service (PHS) misconduct findings. These challenges succeeded in part because, unlike the NSF – which has enjoyed a relatively smooth history of misconduct investigations and adjudications – the PHS began its regulation of misconduct with a set of ill-conceived, procedurally inadequate policies that could not withstand legal scrutiny.

¶ 72 Under the auspices of the original PHS investigative entity, the Office of Scientific Integrity (OSI), misconduct investigations and adjudications were handled exclusively by scientists who paid little attention to the procedural rights of accused

¹⁰⁰ See OFFICE OF THE INSPECTOR GENERAL, NATIONAL SCIENCE FOUNDATION, SEMI-ANNUAL REPORT TO THE CONGRESS NO. 13, at 28 (1996) [hereinafter OIG REPORT NO. 13].

¹⁰¹ As one commentator notes, federal resources are insufficient to fund all worthy grant proposals, and thus competition for grant money is intense. A researcher who seizes an unfair advantage in the funding process, does so at the expense of other talented researchers whose work would otherwise receive federal support. Elizabeth Howard, *Scientific Misconduct and Due Process: A Case of Process Due*, 45 HASTINGS L.J. 309, 324 (1994).

¹⁰² See, e.g., cases listed in OIG REPORT NO. 13, *supra* note 100, at 27-30.

¹⁰³ In contrast to cases where intent is ambiguous, in cases where the weight of the evidence points to intentional misconduct adjudication is more straightforward. In fact, many researchers accused of intentional misconduct “settle” their cases by entering into temporary funding exclusion agreements with the federal government, thereby avoiding permanent debarment from federal grant funding. The Office of Research Integrity (ORI) reports that of the 24 cases where ORI made a finding of intentional misconduct in 1995 (59% of total ORI misconduct investigations), in 19 cases the respondent researcher accepted the ORI findings and entered a voluntary exclusion agreement. Typically, these cases involved deliberate falsification or fabrication of research data reported in papers and grant applications. ORI ANNUAL REPORT 1995, *supra* note 29, at 22 (available for download in WordPerfect or Adobe Acrobat format at <<http://ori.dhhs.gov/other/material.html>>).

¹⁰⁴ See, e.g., Howard, *supra* note 101, at 318 (noting that after the DAB rulings, it is unclear whether only intentional misconduct is actionable, or whether the failure to observe a reasonable standard of care is sufficient for a finding of misconduct).

researchers.¹⁰⁵ When OSI was eventually restructured in 1992 as the Office of Research Integrity (ORI), attorneys were hired to guide the conduct of ORI investigations. In an attempt to provide adequate due process to accused researchers, ORI and its parent agency, the Department of Health and Human Services (DHHS), subsequently agreed to institute appellate proceedings, in which members of the DHHS Departmental Appeals Board (DAB) would review contested misconduct cases *de novo*. The special appellate board for misconduct cases within the PHS is known as the Research Integrity Adjudication Panel (RIAP).¹⁰⁶

¶ 73 In a series of contentious hearings, the RIAP has differed with the ORI over the proper scope of the PHS misconduct definition. Inconsistent RIAP rulings have left the standard of culpability within the PHS uncertain.¹⁰⁷ When adjudicating misconduct charges, the RIAP has focused in particular on the clause in the PHS definition that excludes “honest errors,” and has reversed misconduct findings in some cases for lack of proof of scienter.¹⁰⁸ As a result, some (though not all) misconduct experts now argue that the ORI must prove “intent to deceive” in order to bring a successful case against a PHS-funded researcher.¹⁰⁹ Such a standard would clearly differ from the one applied by National Science Foundation (NSF), which in some cases makes findings of misconduct without establishing intent to deceive.¹¹⁰

¶ 74 RIAP rulings are binding only in cases brought by ORI; they have no precedential authority for the NSF – a separate agency that promulgates and enforces its own regulations. Unlike the PHS, the NSF continues to interpret the “other serious deviations” clause of its regulatory definition to permit agency action against serious but unintentional misconduct (i.e., recklessness or gross negligence).¹¹¹

¶ 75 The RIAP decisions affect only one federal government entity, the PHS. Yet the entire scientific and science policy community continues to debate the import of

¹⁰⁵ The OSI was created by DHHS in 1989, and housed within the National Institutes of Health. The OSI functioned under a “scientific dialogue” model, in which panels of scientists informally investigated and reached conclusions about the validity of questioned research, without permitting legal counsel for the accused or other typical features of a legal process. See Glazer, *supra* note 5, at 8.

¹⁰⁶ The RIAP was established under the Departmental Appeals Board of DHHS in 1992. 57 Fed. Reg. 53,125 (1992). No similar revamping of misconduct procedures has occurred at NSF, perhaps because the agency’s cases have been less highly publicized, but also because NSF procedures afforded accused scientists somewhat more due process from the outset, including the right to file a written appeal prior to final adjudication.

¹⁰⁷ This uncertainty is apparent in the conflicting opinions of legal experts on misconduct. For example, Robert Charrow, an attorney and former DHHS official who has been an advisor to both the government and to accused scientists, states: “[t]he current definition has been sensibly interpreted by the HHS Departmental Appeals Board so that only conduct . . . undertaken with an intent to deceive is punishable.” Robert P. Charrow, *Miscalculated Risk: Redefining Misconduct is Unnecessary and Dangerous*, 8 J. NIH RESEARCH 61 (1996). Law professor Dan Burk also asserts that the DAB now requires intent as the mens rea for scientific misconduct. Dan L. Burk, *Research Misconduct: Deviance, Due Process, and the Disestablishment of Science*, 3 GEO. MASON INDEP. L. REV. 305, 337 (1995). In contrast to this assertion, attorney and misconduct expert Barbara Mishkin, who has successfully defended accused scientists before the RIAP, maintains that the panel has interpreted the definition to permit a showing of misconduct without an intent to deceive, although the burden remains on the government to prove that an accused scientist’s actions were not “honest error.” Interview with Barbara Mishkin, *supra* note 14.

¹⁰⁸ See discussion of RIAP cases in text, *infra* Part. III.D.1-2.

¹⁰⁹ See discussion of disagreement among experts, *supra* note 107. The 1995 report of the Commission on Research Integrity noted the need to clarify the relationship of intent to scientific misconduct in any new federal definition. RYAN REPORT, *supra* note 30, at 10.

¹¹⁰ Telephone Interview with Monte Fisher, Counsel to the Inspector General, National Science Foundation (Apr. 15, 1997).

¹¹¹ *Id.*

the RIAP's reasoning, because the RIAP hearings represent the only direct legal test of a regulatory definition of research misconduct to date. No federal court has ruled on the legal adequacy of the existing definitions of misconduct, nor considered whether the offense of research misconduct actually requires proof of scienter.¹¹²

1. *The RIAP Cases: Sharma*

¶ 76 As of 1997, the RIAP has heard appeals and issued rulings in at least four cases of alleged misconduct in PHS-funded research.¹¹³ The DAB opinion in one of the first cases, that of Dr. Rameshwar Sharma, has been cited for the proposition that the definition of scientific misconduct requires proof of intent to deceive on the part of the accused researcher.¹¹⁴ A closer reading of the *Sharma* opinion suggests that the ruling was equivocal on this point.

¶ 77 Dr. Sharma, a researcher at the Cleveland Clinic Foundation, submitted grant applications to National Institutes of Health (NIH) that he would later concede contained erroneous information.¹¹⁵ The statements at issue gave the impression that Sharma was in possession of research data that did not actually exist at the time the grant was submitted. Possession of the data would have the effect of strengthening Sharma's application, thus increasing the likelihood that his research would receive grant funding.

¶ 78 During the course of a PHS investigation, Dr. Sharma admitted that his grant application did contain errors. He maintained, however, that the errors were inadvertent typographical mistakes and thus did not constitute intentional misconduct. An internal investigation by the Cleveland Clinic exonerated Dr. Sharma, due in large part to the absence of any conclusive evidence that he made false statements with an intent to deceive.¹¹⁶ OSI investigators disagreed, concluding that Sharma had indeed committed misconduct, as evidenced by a pattern of false statements in his grant submissions, and by his failure to amend his grant application when the errors were first brought to his attention by a supervisee.¹¹⁷

¶ 79 In charging documents, OSI originally accused Dr. Sharma only of committing intentional misconduct (lacking legal training, OSI investigators may not have appreciated the important distinction between intentional and unintentional

¹¹² In one of only a few true misconduct cases to reach federal appellate courts to date, due process challenges to a PHS investigation were dismissed for failure to exhaust administrative remedies, and the court did not address the definition of misconduct *per se*. *Abbs v. Sullivan*, 963 F.2d 918 (7th Cir. 1992).

¹¹³ See *In re Thereza Imanishi-Kari, Ph.D.*, DAB No. A-95-33, Decision No. 1582 (1996); *In re John C. Hiserodt, M.D., Ph.D.*, DAB No. A-93-117, Decision No. 1466 (1994); *In re Dr. Paul F. Langlois*, DAB No. A-93-30, Decision No. 1409 (1993); *In re Dr. Rameshwar K. Sharma*, DAB No. A-93-50, Decision No. 1431 (1993); and *In re Mikulas Popovic, M.D.*, DAB No. A-93-100, Decision No. 1446 (1993) (cases available on-line by searching at <<http://www.hhs.gov/search/>>) (Search in: "Departmental Appeals Board Decisions"; Search For: "Research Integrity Adjudications Panel").

¹¹⁴ On the heels of the *Sharma* and *Popovic* rulings, the ORI now advises institutions to prepare their investigational reports to meet the legal standards of the DAB; namely, such reports should "identify evidence that shows the respondent had a deliberate intent." See *Impact of Sharma and Popovic Decisions on Institutional Investigations*, ORI NEWSLETTER (Office of Research Integrity, U.S. Public Health Service), Vol. 2, No. 2, March 1994, at 1 (emphasis omitted) [hereinafter ORI NEWSLETTER] (available for download at: <<http://ori.dhhs.gov/newsltr/newsltrs.html>>).

¹¹⁵ *In re Sharma*, *supra* note 113.

¹¹⁶ Most misconduct investigations begin with a departmental inquiry, then, if warranted, a full-fledged university investigation at the host institution of the accused researcher. See Steven G. Olswang & Barbara A. Lee, *Scientific Misconduct: Institutional Procedures and Due Process Considerations*, 11 J.C. & U.L.1, 52, 55 (1984).

¹¹⁷ *In re Sharma*, *supra* note 113.

misconduct). This charge proved difficult to substantiate, but OSI nevertheless reached an official finding of misconduct in the *Sharma* case. When Sharma appealed to the RIAP, the appeals panel rejected an attempt by ORI attorneys (OSI had, by this point, been reorganized as ORI) to shift to a negligence standard of culpability. In response to ORI's argument that Sharma had breached his duty of care by submitting a grant application that contained erroneous statements, the RIAP declared that a negligence standard of culpability had not been explicitly provided for by PHS regulations.¹¹⁸

¶ 80 In light of the fact that the PHS definition seemed to the RIAP to exclude certain forms of negligence (i.e., "honest error"), and because none of the expert witnesses testified on appeal that typographical errors in grant submissions were a serious deviation from the standard of care of a competent researcher, the RIAP found no conclusive evidence supporting a negligence standard of culpability.¹¹⁹ The panel hinted at distinguishing features of the *Sharma* case, noting in passing that submitting an erroneous grant application might be a less serious infraction than publishing erroneous data.¹²⁰

¶ 81 The *Sharma* opinion appeared to suggest, but not to state conclusively, that the RIAP – the ultimate arbiter of misconduct cases within the PHS – might in the future uphold charges of unintentional (i.e., reckless or negligent) misconduct, if ORI could prove a serious deviation from accepted scientific practices. But in opinions subsequent to *Sharma*, the RIAP vacillated in interpreting the mens rea for misconduct.

2. Popovic, Hiserodt, and Imanishi-Kari

¶ 82 In the case of Dr. Mikulas Popovic, a former member of the laboratory of AIDS researcher Dr. Robert Gallo, ORI concluded that Popovic had falsified data that he reported in a research paper co-authored by Gallo and others. Popovic, who is credited with developing a technique that led to a commercial blood test for HIV, appealed the ORI finding. On appeal, ORI sought to argue that Popovic had been negligent, but the RIAP limited ORI to its original charge of intentional misconduct. As it had in *Sharma*, the RIAP concluded that to allow ORI to argue negligence on appeal would violate the accused scientist's right to adequate notice of the charges. The panel also determined that under the PHS definition of misconduct, ORI bore the burden of proving the absence of "honest error" by a preponderance of the evidence.¹²¹

¶ 83 Popovic was exonerated in an RIAP opinion that noted the outcome of the appeal would have been the same even if the panel had accepted ORI's theory of negligence.¹²² With the *Popovic* decision the RIAP also appeared to narrow the scope of the earlier *Sharma* ruling. The language of the *Popovic* opinion seemed to preclude

¹¹⁸ OSI originally alleged intentional misconduct based upon the inclusion of false statements in the grant application, but Dr. Sharma responded that his statements were not made with an intent to mislead. ORI did not raise allegations of negligence until a post-hearing brief. *Id.*

¹¹⁹ *See id.* ("We find that no persuasive evidence was presented at the hearing or in ORI's submissions to support the existence of a lesser standard applicable in this case than one involving intentional falsification.")

¹²⁰ *Id.*

¹²¹ *In re Popovic*, *supra* note 113.

¹²² The RIAP opinion notes that the lengthy investigation produced "no substantial evidence" to support any of the charges, even under a negligence standard of culpability, because ORI failed to prove that the statements at issue were false, much less purposefully so. The panel also ruled that ORI had the burden of proving the mistakes were other than honest errors. *Id.*

charges of recklessness or negligence against an entire category of PHS-funded researchers – those affiliated with the NIH. In *Popovic*, the RIAP explicitly took notice of the NIH Guidelines for the Conduct of Research. These guidelines – applicable to Dr. Popovic in his position as an NIH researcher, but lacking the legal force of PHS regulations – limit the scope of misconduct to “fabrication, falsification, plagiarism, or other practices motivated by [an] intent to deceive.”¹²³

¶ 84 The *Popovic* opinion might have signaled a *de facto* scienter requirement for the PHS definition, at least with respect to charges of falsifying data. On the heels of *Popovic*, however, in a grant application case that resulted in the debarment of Pittsburgh Cancer Institute researcher Dr. John Hiserodt, the RIAP took pains to reject such an interpretation, stating.

[W]e did not in *Sharma* hold that negligence in making erroneous statements was not scientific misconduct. . . . [yet] we also recognized that the definition of scientific misconduct adopted by PHS in 1989 acted as a limit on the scope of any proceedings and that the definition excluded “honest error” or any conduct which does not “seriously deviate” from accepted practices.¹²⁴

¶ 85 If the RIAP’s statement in *Hiserodt* meant that negligent serious deviations *are* culpable misconduct, the panel’s approach to its most significant and highly publicized case to date seems inconsistent with this standard. The RIAP’s decision in the appeal of Dr. Theresa Imanishi-Kari ended a controversy that had dragged on for almost a decade. In *Imanishi-Kari*, the RIAP once again precluded ORI from bringing charges of negligent or reckless misconduct against a PHS-funded researcher.¹²⁵

¶ 86 Dr. Imanishi-Kari was initially accused by a junior coworker of publishing scientific papers that contained invalid data. The allegations arose when the junior researcher, Dr. Margot O’Toole, was unable to replicate the results of some of Imanishi-Kari’s published experiments. When Dr. Imanishi-Kari was asked to produce her laboratory notebooks during the course of the ORI investigation, ORI alleged that she fabricated notebook entries to give the false impression that the notebooks were a contemporaneous record of her experimental results.¹²⁶

¶ 87 The RIAP concluded that the evidence against Dr. Imanishi-Kari was more indicative of egregious carelessness than of deliberately falsified data.¹²⁷ As the panel noted, many of the researcher’s errors and alleged fabrications either contradicted or failed to support the conclusions of her published papers, and therefore did not reflect an intent to make the results appear more favorable.¹²⁸ The

¹²³ See *id.* (quoting NATIONAL INSTITUTES OF HEALTH, GUIDELINES FOR THE CONDUCT OF RESEARCH IN THE INTRAMURAL RESEARCH PROGRAMS AT NIH (1990)) (emphasis added).

¹²⁴ *In re Hiserodt*, *supra* note 113, at n. 5 (1994).

¹²⁵ *In re Imanishi-Kari*, *supra* note 113. The RIAP opinion notes that in this case, ORI did not allege charges other than intentional falsification until the appeal hearing; a failure that the RIAP termed “fundamentally unfair” to Dr. Imanishi-Kari. *Id.*

¹²⁶ *Id.* The opinion notes that an initial NIH investigation that found no misconduct on the part of Dr. Imanishi-Kari was set aside when Congressman John Dingell opened a new investigation and issued a congressional subpoena for the researcher’s data. *Id.*

¹²⁷ The Secret Service forensic analysis of Dr. Imanishi-Kari’s notebooks, which concluded that data had been falsified, was itself characterized by the RIAP as incomplete, sloppy, and inconclusive. The RIAP did note, however, that Dr. Imanishi-Kari’s work was “rife” with careless errors. *Id.*

¹²⁸ *Id.*

RIAP determined that this lack of any apparent pattern of dishonesty in Imanishi-Kari's errors was inconsistent with a systematic attempt to deceive.

¶ 88 Although the RIAP did take note of “a high rate of careless [and inconsistent] errors” in Dr. Imanishi-Kari's work,¹²⁹ appeals panel members declined to consider the possibility of negligent misconduct in her case. One commentator has suggested, however, that by failing to record and report her research data with sufficient accuracy, Dr. Imanishi-Kari did indeed fall below the acceptable standard of care for federally funded researchers, and was therefore negligent in fulfilling her professional responsibilities.¹³⁰

3. *Disparate Standards of Culpability*

¶ 89 In the wake of these RIAP decisions some commentators believe – perhaps mistakenly – that the question of whether misconduct requires “intent to deceive” has been decided in the affirmative.¹³¹ For its part, ORI has now decided to act as if an intent requirement is explicitly incorporated into the PHS definition.¹³² In practice, this means that the conduct of researchers funded by the PHS and the NSF will not be judged according to a uniform standard. Researchers who commit the same infractions may encounter disparate treatment, depending upon the source of their grant funding. This problem arises because the NSF, which relies heavily on the “other serious deviations” clause in its regulatory definition of misconduct, views its definition as containing an inherent “gross negligence” standard, while HHS seems to have adopted a scienter requirement.¹³³

¶ 90 Disparate standards of culpability are most evident in the two agencies' responses to allegations of plagiarism.¹³⁴ ORI acknowledges that it has dropped or declined to pursue plagiarism cases where ORI investigators could not establish scienter.¹³⁵ By contrast, NSF has made findings of plagiarism even absent evidence of a specific intent to deceive. For example, in a case detailed in a 1996 NSF Semiannual Report, the subject of an NSF investigation – a senior researcher and journal editor – was found to have committed plagiarism in a grant application containing eleven sections that were either “identical or substantially similar” to a review article by other researchers. The subject denied any intent to deceive,

¹²⁹ *Id.*

¹³⁰ In a commentary on the Imanishi-Kari verdict, Pamela Zurer writes “as a research scientist, I was taught to keep meticulous, contemporaneous notes of all my experiments in bound notebooks with sequentially numbered pages. . . . The pathetic patchwork that makes up Imanishi-Kari's records is less than convincing.” Zurer concludes that the RIAP mistakenly focused upon the ultimate replicability – rather than the accuracy – of Imanishi-Kari's data, failing to realize that “[i]t is not okay in science to make up your data, even if it turns out you have guessed correctly.” See Pamela Zurer, *In Scientific Misconduct Cases, Justice Isn't Always Blind*, CHEMICAL AND ENGINEERING NEWS, June 24, 1996, at 31.

¹³¹ See comments of Burk and Charrow, *supra* note 107.

¹³² See ORI NEWSLETTER, *supra* note 114. See also Parrish, *supra* note 44, at 523 (noting that “[m]any institutions, including ORI, have incorporated a requirement of an intent to deceive for a finding of . . . plagiarism.”).

¹³³ See OIG REPORT NO. 9, *supra* note 40, at 36 (concluding that “NSF's misconduct regulation does not require a finding of knowing or purposeful conduct for a finding of misconduct in science.”).

¹³⁴ See Parrish, *supra* note 44, at 553 (noting that the disparate treatment of identical allegations of plagiarism “perpetuates confusion in the scientific community regarding what constitutes plagiarism and scientific misconduct.”).

¹³⁵ See, e.g., ORI ANNUAL REPORT 1995, *supra* note 29, at 20 (In a description of cases resulting in findings of no misconduct, ORI indicates that despite strong evidence of plagiarism, the agency does not pursue misconduct charges where the evidence is insufficient to substantiate an intent to deceive on the part of the accused researcher.)

insisting that the similarities were the inadvertent result of his reliance on his own notes taken from the works in question. NSF concluded that even in the absence of intent, the researcher had been “grossly negligent” in failing to “properly acknowledge his sources.” Although intent was not established, NSF found the researcher to have committed plagiarism all the same.¹³⁶ Under its current standard, ORI might not have pursued the case.

¶ 91 Plagiarism is only one research offense for which regulatory enforcement has been rendered uncertain by ambiguities in the wording of misconduct definitions. The lack of precise mental state language in the definitions of scientific misconduct has left the entire scope of sanctionable conduct uncomfortably vague, and has rendered standards inconsistent from one agency to another.¹³⁷

¶ 92 Imprecision in the language of the definition may serve to mask policy disputes between agencies over how and to what extent the federal government should intrude upon the practice of science.¹³⁸ There are some regulators and policymakers, particularly those at NSF, who would vest great discretion in federal oversight officials, particularly in the application of the “serious deviations” clause.¹³⁹ Meanwhile, others, especially scientists, continue to argue for the narrowest, most self-limiting definition of misconduct possible. The federal government is attempting to resolve this difficult policy issue through a careful, consensus-building exercise in drafting a uniform definition. Should this effort fail, the ambiguities of the current definition will inevitably lead the federal courts to make misconduct policy by default.

IV. MENTAL STATE PROVISIONS FOR THE NEW UNIFORM FEDERAL DEFINITION OF SCIENTIFIC MISCONDUCT

A. Arguments for and Against a Scierter Requirement

1. Negligence in Science

¶ 93 Professionals are liable for negligence, and scientists are clearly professionals.¹⁴⁰ In a private lawsuit, a professional may be held liable for negligently failing to meet a profession’s standard of care, even if she never perceived the risk of her conduct nor intended any harm to result. Unlike the doctor or lawyer who provides

¹³⁶ See OFFICE OF THE INSPECTOR GENERAL, NATIONAL SCIENCE FOUNDATION, SEMI-ANNUAL REPORT TO THE CONGRESS, NO. 15, at 41 (1996) [hereinafter OIG REPORT NO. 15] (available upon phone request or for download in PDF format at <<http://www.nsf.gov/cgi-bin/getpub?oig15>>). For grant submissions, the NSF takes a “constructive intent” view of plagiarism: the agency considers that an author who submits a grant to NSF has certified its originality. Thus, the agency does not require a culpable mental state where a *de facto* violation of this certification exists in the form of significant plagiarism in a grant application. When “the subject seriously deviated from accepted practice,” the plagiarism is significant. NSF’s standard of culpability is effectively a form of “strict liability” – liability imposed without regard to mental state. *Id.*

¹³⁷ See Dresser, *supra* note 13, at 895 (asserting that “a disturbing lack of clarity regarding the specific conduct that ought to be the focus of professional, institutional, and governmental attention . . . has generated vague regulatory provisions that create the possibility of unfair punishment and leave scientists uncertain of the boundaries between permissible and impermissible behavior.”).

¹³⁸ *Id.*

¹³⁹ See Donald E. Buzzelli, *The Definition of Misconduct in Science: A View from NSF*, 259 SCIENCE 584 (1993) (describing how regulators must be permitted to exercise judgment under flexible standards for defining research misconduct).

¹⁴⁰ A *profession* is a “vocation requiring knowledge of some department of learning or science;” a *professional* is “one who engages in one of the learned professions.” WEBSTER’S UNABRIDGED DICTIONARY 1544 (1996).

professional services to private individuals, however, the federally funded researcher serves society at large. Should society, acting through the federal government, apply the same negligence standard of professional liability to the conduct of scientists?

¶ 94 A series of scientific and legal commentators have maintained that negligence should not fall within the scope of a federal definition of scientific misconduct. Their rationales are varied, ranging from sympathy for those scientists who make negligent errors, to the fear that overexpansive regulation will discourage scientific innovation. They argue that scientific negligence, while “pathetic,” is not “reprehensible” or deserving of federal sanctions.¹⁴¹

¶ 95 Other commentators take a more extreme position, insisting that the federal government has no business sanctioning any form of scientific conduct (even reckless behavior) that is undertaken without a specific intent to deceive. Advocates of a scienter requirement in the federal definition maintain that scientists should never be expected to conform to norms of professional conduct, because the practice of science is inherently ambiguous¹⁴² and the freedom to deviate from scientific orthodoxy must be protected from the chilling effect of federal regulation.¹⁴³

¶ 96 This latter argument confuses a critical distinction between innovative and incompetent research. Innovation, characterized by creativity and insight, fuels scientific breakthroughs. But the innovative researcher who challenges an orthodox theory or develops a radically new technique will not gain the respect of her peers unless she also observes the time-honored traditions of the scientific profession. For her research to be deemed credible she must test her new hypotheses according to the standards of her discipline, carefully recording her observations and accurately reporting her results.¹⁴⁴ Although the innovative scientist might deviate from the orthodox approach to *conceptualizing* a research problem, as a competent professional she will adhere to well-defined norms for executing and publishing the research itself.

¶ 97 The freedom to be grossly negligent in the collection, analysis, and reporting of data is not a necessary precursor to intellectual innovation. Nor will the absence of

¹⁴¹ See, e.g., Burk, *supra* note 107, at 315 (asserting that “unlike willful deceit or overreaching, self-deceit and even incompetence are perhaps pathetic, but probably not reprehensible.”).

¹⁴² See Grinnell, *supra* note 93, at 333 (claiming that misconduct cannot be dealt with by applying standards of conduct, because ambiguity is “inherent in the normal practice of science,” and “[u]nless we understand that ambiguity is an inherent feature of research, we may find the practice of science restricted in ways that make creative insight far more difficult.”).

¹⁴³ See Bruce Alberts & Kenneth Shine, *Scientists and the Integrity of Research*, 266 SCIENCE 1660, 1661 (1994) (stating that “[w]e must recognize that good science resembles art more than it resembles the law, accounting, or government. If scientific research is beset with paperwork and regulation, much of the joy and creativity in doing science could disappear. . . .” and that “scientific heresies are critical to the advancement of science, but could well be chilled by oppressive implementation of [a rule extending the definition of scientific misconduct beyond fraud and plagiarism].”). See also Burk, *supra* note 107, at 338 (stating that “scientific heresies are critical to the advancement of science, but could well be chilled by oppressive implementation of [a rule extending the definition of scientific misconduct beyond fraud and plagiarism].”).

¹⁴⁴ In their amicus brief to the Supreme Court in the case of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the American Association for the Advancement of Science and the National Academy of Sciences describe what is normative about the scientific method: “Scientists accept a scientific explanation for an event when that explanation is corroborated by experiments using accepted methodologies and when it is consistent with other accepted explanations. Corroboration is generally based on the correct prediction of observed events or results. In some fields, such as cosmology, consistency with general theory may be especially important. In other fields . . . such as biochemistry, experimentation provides the primary means for evaluating hypotheses. In still other fields, such as astronomy, observation rather than experimentation is relied upon to corroborate theoretical predictions. At its core, however, science is a process of evaluating testable propositions to assure conformance with observable reality.” Brief for the American Association for the Advancement of Science and the National Academy of Sciences as Amici Curiae in Support of Respondent at 9, *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

federal regulation safeguard the process of scientific discovery. Ironically, the innovative scientist may have more to fear from the scientific establishment itself than from federal oversight: there is frequent acknowledgment among scientists that the grants peer review system, through its tight control of research resources and its tendency to support established theories and researchers, tends to stifle innovation, while rewarding orthodoxy and the pursuit of mainstream lines of inquiry.¹⁴⁵

2. *The Nature of Scientific “Malpractice”*

¶ 98 Some scientists argue that where research misconduct is suspected, the ideal solution is simply “more science” – allowing the process of replication to weed out flawed research.¹⁴⁶ This approach is not only impractical (it is commonly noted that the incentive system of modern science is structured so as to discourage replication),¹⁴⁷ but more importantly, a focus on outcomes or data as measures of the integrity of a piece of research misconstrues the essential nature of misconduct, which is a corruption of the *process* of scientific research.

¶ 99 The distinguishing feature of what Daryl Chubin has termed “scientific malpractice” is not a failed experiment, but rather the failure of a scientist to conduct a study with due care.¹⁴⁸ The findings of the most scrupulous researchers may never be replicated by later investigators, and failure to replicate alone does not raise the specter of scientific misconduct. The research process will always involve unavoidable mistakes, false starts, and wrong guesses, so a professional standard of conduct in science must be uniquely tolerant of “honest errors.”¹⁴⁹ The term “malpractice” in a scientific context should be reserved for conduct that compromises the integrity of the research process. According to the National Academy of Sciences (NAS), the research process is compromised whenever

¹⁴⁵ The scientific grants peer review system is unique in the freedom with which it distributes federal research monies with little government oversight. Established scientists and researchers evaluate the scientific merit of proposed research and determine who among their peers is deserving of federal funds; both courts and the government defer to this allocation. See Burk, *supra* note 107, at 345.

It has been observed that through this system of peer review, allowing professional societies and scientific journals to apply sanctions for misconduct could have a chilling effect on innovation analogous to that exerted by “medieval [professional] guilds.” See Warren Schmaus, *An Analysis of Fraud and Misconduct in Science*, in AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE – AMERICAN BAR ASSOCIATION NATIONAL CONFERENCE OF LAWYERS AND SCIENTISTS, PROJECT ON SCIENTIFIC FRAUD AND MISCONDUCT, REPORT ON WORKSHOP NUMBER ONE, Sept. 18-20, 103 (1987) [hereinafter AAAS-ABA REPORT]. Yet in defense of peer review and self governance, the National Academy of Sciences has protested that demands for accountability “interfere with the traditional autonomy granted to science.” See RESPONSIBLE CONDUCT, *supra* note 8, at 32.

¹⁴⁶ See Burk, *supra* note 107, at 317-18; and Dan L. Burk, *Legal Process in Ryan Report Requires Reconsideration*, THE SCIENTIST, Sept. 16, 1996, at 9 (suggesting that “uninteresting results” that are false or inaccurate do no harm if not replicated, because no one relies on them, and arguing that scientific disputes should be resolved through “scientific dialogue,” replication of results, and non-adversarial mediation).

¹⁴⁷ See Robert L. Engler et al., *Misrepresentation and Responsibility in Medical Research*, 317 N. ENG. J. MED. 1383, 1385 (1987) (noting that “[r]eplication, once an important element in science, is no longer an effective deterrent to fraud because the modern biomedical research system is structured to prevent replication – not to ensure it.”). For a detailed critique of modern peer review, see generally DARYL E. CHUBIN AND EDWARD J. HACKETT, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY (1990).

¹⁴⁸ See Daryl E. Chubin, *Research Malpractice*, 35 BIOSCIENCE 80 (1985).

¹⁴⁹ See Patricia K. Woolf, *Deception in Scientific Research*, in AAAS-ABA REPORT 42 (noting that, in rapidly evolving fields of research, error is initially likely, and therefore misconduct standards must reflect a tolerance for honest error).

scientists fail to adhere to “honest and verifiable methods” in all aspects of their professional work.¹⁵⁰

¶ 100 Close encounters with perversions of the research process may cause otherwise skeptical scientists to favor greater accountability for publicly funded researchers. In 1985, Dr. Robert Engler, a professor of medicine at the University of California, San Diego, was asked to help investigate irregularities in the research of Dr. Robert A. Slutsky, a resident and non-salaried associate professor at the UCSD Medical School.¹⁵¹ According to Engler’s subsequent account of the investigation, Slutsky became the subject of a formal inquiry after publishing more than 100 peer-reviewed journal articles, mostly during his residency. Only when a member of a university committee evaluating Dr. Slutsky for a faculty appointment detected duplicate data in several papers was this astonishing publication rate (what Engler describes as “unreasonably high productivity”) questioned.¹⁵²

¶ 101 An indeterminate number of Slutsky’s publications contained fraudulent data; many were later publicly retracted by Slutsky’s attorney. Yet for years, Slutsky was able to forestall suspicion by establishing collaborative relationships with researchers in other departments, and then presenting these collaborators with “gift” authorships that the recipients had no incentive to question. Many of Slutsky’s co-authors either failed to review the data and the manuscripts that bore their names, or knowingly accepted authorships despite having made no contribution to the manuscript or research.¹⁵³

¶ 102 Because the harm to the scientific record was eventually repaired by retraction of the fraudulent papers, it could be argued that the damages resulting from Slutsky’s “malpractice” were minimal. Of course, this argument discounts the resources expended to train Slutsky and to finance his research. But Engler and his colleagues point out that the harms Dr. Slutsky visited upon the scientific community were more extensive than simply wasted resources or the introduction of error into the scientific record; Slutsky also tarnished the careers of his associates. The graduate students and young researchers who collaborated with Slutsky on research projects – some of which were legitimate studies involving years of painstaking work – had to remove the collaborative publications from their resumes at a point in their careers when accruing publications is critical. In some cases, reputations were unfairly tainted by the scandal.¹⁵⁴

¶ 103 Slutsky’s co-workers and a journal editor who reviewed his manuscripts were reluctant to report their suspicions about his work to Slutsky’s department head, especially in the absence of any direct proof that Slutsky had deliberately fabricated data.¹⁵⁵ Given this unwillingness of other scientists to aggressively protect the integrity of the scientific record, Engler and colleagues now suggest that the concept of misconduct ought to extend beyond intentional wrongdoing. They concludes that “fraud is not the only kind of culpable misrepresentation,” and propose holding

¹⁵⁰ See RESPONSIBLE SCIENCE, *supra* note 15, at 18-19. (This NAS report advocates that science should remain in large part a “self-regulatory system, in which the integrity of the research process is preserved through “scientists’ reliance on each other and the traditions of their community.”).

¹⁵¹ See Engler et al., *supra* note 147, at 1383 n.*, 1388.

¹⁵² *Id.* at 1383, 1386.

¹⁵³ *Id.* Engler notes that while some co-authors were “too flattered or too embarrassed” to request that their names be removed as authors of Slutsky’s publications, other, more senior researchers expected or demanded gift authorships in return for providing funding or facilities. *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.* at 1387.

researchers responsible for serious “careless errors – cases in which the scientist had no intent to deceive but the information that would have provided reason to doubt the accuracy of the statements made was available.”¹⁵⁶ Such a standard would permit sanctions for reckless or grossly negligent conduct, even where evidence of intent to deceive is unavailable or unpersuasive.

B. The Issue of Scope

¶ 104 The central issue in defining the culpable mental state for scientific misconduct is one of scope: with a scienter requirement in the definition, the range of sanctionable conduct would be quite narrow. Alternatively, a negligence standard would create sanctionable offenses out of conduct that some scientists and policymakers wish to place beyond the reach of the federal government’s investigative machinery.¹⁵⁷

¶ 105 Underlying the issue of scope is a policy making tension between the federal interest in thorough regulatory oversight and the scientific community’s tradition of autonomous self-governance.¹⁵⁸ This tension might best be resolved if scientists were regarded – and came to view themselves – as professionals, with corresponding privileges and responsibilities.¹⁵⁹ For scientists, professionalism would justifiably include both the freedom to define the proper boundaries of scientific conduct, and an accountability to society and to the federal government for grossly negligent failures to meet a professional standard of care. As one scientific commentator concludes, “It is reasonable to ask that scientists not be punished for innocent mistakes, but it is not reasonable to expect that grossly negligent scientific practices supported by federal government funding are outside the realm of government intervention.”¹⁶⁰

¶ 106 Both the Ryan Commission and the National Science Foundation (NSF) have described the regulation of misconduct as an opportunity for the scientific community to develop its own “common law” of professional behavior.¹⁶¹ NSF in particular has stressed the significance of flexible professional standards for evaluating misconduct. In an analysis of definitional issues, one NSF official writes that scientists who cling to the notion of a “highly codified” definition will find that

¹⁵⁶ *Id.* at 1383. The authors also state that, even in the absence of an intent to deceive, a careless failure to verify the accuracy of a publication bearing a researcher’s name is a culpable act of negligence. *Id.* at 1384.

¹⁵⁷ According to Mark S. Frankel of the American Association for the Advancement of Science (AAAS), “[t]o the extent that you can limit the definition, you can limit the scope of government involvement.” Glazer, *supra* note 5, at 9.

¹⁵⁸ In the National Academy of Sciences publication RESPONSIBLE SCIENCE, science is repeatedly described as a “self-regulatory system,” in which scientists “have relied on each other and the traditions of their community for centuries to safeguard the integrity of the research process,” an approach that has been successful due to the “widespread acknowledgment that science cannot work otherwise” RESPONSIBLE SCIENCE, *supra* note 15, at 18.

¹⁵⁹ Commentator Patricia Woolf notes that defining professional standards for the practice of research is increasingly important as it becomes common for scientists to testify as experts in cases with controversial scientific issues. See Woolf, *supra* note 149, at 37.

¹⁶⁰ See Roland W. Schmitt, *Misconduct in Science*, 262 SCIENCE 1195, 1195 (1993).

¹⁶¹ See OIG REPORT NO. 13, *supra* note 100, at 26 (noting that the NSF interprets 45 C.F.R. § 689.1(a)(1) as “empowering NSF to take action against serious violations of the ‘common law’ of the scientific community.”). Donald Buzzelli of NSF asserts that the agency’s definition of misconduct as a “serious deviation” from professional standards is a “heuristic” one that doesn’t fully define misconduct, but indicates where to look for the answer. See Buzzelli, *supra* note 139, at 647.

strictly-worded rules of behavior “would not truly reflect the subtly of the ethical norms actually operative among practicing scientists.”¹⁶²

¶ 107 Yet powerful figures within the scientific community have professed an aversion to legal concepts such as the “common law” of professional misconduct. Dr. Bruce Alberts, president of the NAS, has described the “case law” approach of the Ryan Commission, in which the parameters of misconduct would evolve as a common law of adjudicated cases develops, as a notion “totally alien to scientists and the scientific process.”¹⁶³ In Alberts’ stated view, a federal definition of misconduct should be self-limiting, enumerating each and every culpable offense, and foreclosing the application of flexible professional standards.¹⁶⁴

¶ 108 As with other professions such as law or medicine, self-regulation should ideally be the first line of oversight for scientific misconduct,¹⁶⁵ but the use of public funds for science demands accountability that extends further. Regulators should recognize, of course, that the analogy between negligence in scientific research and negligence in the professions of medicine or law is imperfect,¹⁶⁶ because error plays a unique role in the advancement of human knowledge through research. Law and medicine require adherence to well-established procedure, but research is so fundamentally a process of unguided trial and error that a greater tolerance for mistakes is required.

¶ 109 Unfortunately, the wide-ranging harms visited upon society by research errors can be as significant, if not more so, than the harms to individuals that result from the malpractice of doctors and lawyers. Research concerning AIDS drugs, toxic contamination, or violence prevention (to name a few examples) provides the basis for medical, legal, and policy decisions affecting literally millions of lives. Serious errors in such research – whether committed intentionally or not – endanger the integrity of the scientific record, threaten public health and safety, and waste scarce public resources. Although scientists often argue that only deliberate attempts to fabricate, falsify, or plagiarize warrant the risk to career and reputation posed by a federal misconduct investigation, serious negligent errors are equally deserving of federal oversight. Indeed, as NAS recognized in a 1994 publication.

[B]y introducing preventable errors into science, sloppy or negligent research can do great damage – even if the error is eventually uncovered and corrected. Though science is built on the idea of peer validation and acceptance, actual replication is selective [?] researchers can waste months or years of effort because of erroneous results, and public confidence in the integrity of science can be seriously undermined.¹⁶⁷

¹⁶² See OIG REPORT NO. 13, *supra* note 100, at 28.

¹⁶³ Letter from Bruce Alberts to Dr. William Raub, *supra* note 94.

¹⁶⁴ See OIG REPORT NO. 15, *supra* note 136, at 27.

¹⁶⁵ Members of licensed professions such as law and medicine are subject to broad, general fitness and conduct provisions, under which each profession imposes its own disciplinary actions. Few informal codes of behavior have been adopted by scientific societies, however; nor are there formal means of licensing or professional discipline in science. See Karen A. Goldman & Montgomery K. Fisher, *The Constitutionality of the “Other Serious Deviations from Accepted Practices” Clause*, 37 JURIMETRICS 149, 161 (1997) (“The practice of many licensed occupations is subject to broad misconduct standards . . .”).

¹⁶⁶ In an article describing the new NSF misconduct policies, then Deputy General Counsel Robert Andersen observed: “This regulation of scientific misconduct will operate in much the same fashion as the process by which standards are established in medical malpractice cases . . . physicians adopt surgical and other procedures as standard medical practice. Substantial variation from those standards, without justification, constitutes actionable negligence.” See Andersen, *supra* note 5, at 129.

¹⁶⁷ See RESPONSIBLE CONDUCT, *supra* note 8.

C. The Need for Explicit Mental State Provisions in the New Federal Definition of Research Misconduct

¶ 110 To create unambiguous and legally enforceable standards, explicit mental state language must be incorporated into the new federal definition of research misconduct. Scientists who resist this idea have expressed fear and loathing of legalisms that carry little meaning for researchers whose conduct they are intended to guide.¹⁶⁸ This objection fails to acknowledge that the definition itself will one day become a law, making precise legal wording of the standards embodied in the definition of pivotal importance. The National Science and Technology Council (NSTC) is likely to present the new uniform misconduct definition as a model regulation intended for adoption by all federal agencies that conduct or fund research. When promulgated by each agency as a final regulation, the definition will create legal responsibilities for every federally funded researcher.

¶ 111 Regulations reflect policy decisions, but their main function is legal: they provide a framework for investigating and adjudicating violations, and for sanctioning violators.¹⁶⁹ Regulations must be properly worded to avoid legal ambiguity and to convey precise legal meanings. As the history of cases brought before the Research Integrity Adjudications Panel (RIAP) illustrates, a definition of misconduct phrased without mental state terms is not “clear, explicit, and precise,”¹⁷⁰ but rather is vague, indeterminate, and subject to inconsistent legal and judicial interpretations.

D. Proposed Mental State Language for the New Federal Definition of Research Misconduct

¶ 112 There appears to be a broad consensus among scientists, regulators, and policymakers that inconsequential or excusable negligence (i.e., “honest errors”) should not constitute grounds for federal misconduct investigations.¹⁷¹ Yet, should the drafters of the new definition include a scienter requirement, the federal misconduct standard will not hold researchers to the level of accountability that society normally demands from members of a professional class. A reasonable compromise should be sought between the autonomy interests of scientists and the regulatory interests of the federal government.¹⁷² Such a compromise might be struck if regulators were to distinguish between ordinary and gross negligence, applying federal sanctions only to grossly negligent misconduct.¹⁷³

¹⁶⁸ See Letter from Bruce Alberts to Dr. William Raub, *supra* note 94.

¹⁶⁹ See RYAN REPORT, *supra* note 30, at 12 (noting that “[a] definition provides a legal framework for formal proceedings.”); see also Robert P. Charrow, *A Primer on Research Ethics: Learning to Cope with the Federal Regulation of Research*, 5 J. NIH RESEARCH 76 (1993) (noting that the federal oversight of science evolved through a legal process: “laws were enacted, regulations issued, and policies adopted . . . the process that will be used to judge the propriety of arguably problematic conduct is likely to be a legal process.”).

¹⁷⁰ See RESPONSIBLE SCIENCE, *supra* note 15, at 20.

¹⁷¹ See, e.g., Andersen, *supra* note 5, at 126 (asserting that “[m]inor inadvertent mistakes that occur during research surely should not be labeled misconduct.”).

¹⁷² Scientists frequently cite peer review and replication as hallmarks of an enduring tradition of self-governance in science. See RESPONSIBLE SCIENCE, *supra* note 15. Until recently, disputes within the scientific community – including arguments about everything from data to personnel practices – were handled, if at all, on an informal basis by department heads, lab chiefs, deans, and university-based grievance committees. See Weiss, *supra* note 97, at A6.

¹⁷³ The NSF Deputy General Counsel suggested in 1988 that the “osd” (other serious deviations) phrase in the misconduct definition encompasses only those unintentional behaviors that constitute “aggravated or gross negligence.” See Andersen, *supra* note 5, at 130. If “osd” were to be eliminated, gross negligence would not be punishable unless explicitly incorporated into the new federal definition of research misconduct.

¶ 113 This objective can be accomplished if the drafters of the NSTC model definition append mens rea language to the existing “ffp” framework. The Ryan Commission’s attempt to replace “ffp” with more legally meaningful terms was roundly denounced in the scientific community, creating considerable pressure for drafters to retain the terms fabrication, falsification, and plagiarism, which have taken on an almost talismanic quality in the misconduct debate. At a minimum, however, the NSTC’s Research Integrity Panel should attempt to give “ffp” some substantive meaning by defining each term, and by providing examples of conduct that clearly falls within the ambit of the definition.

¶ 114 The scientific community has also pressured RIP drafters to reject the “other serious deviations from accepted scientific practices” clause, which has served as a “back door” means of sanctioning reckless and grossly negligent conduct. Despite the position of those at the National Science Foundation (NSF) who argue that the wording is similar to that found in other professional standards of conduct,¹⁷⁴ the conclusion of all three misconduct policy studies to date is that “other serious deviations” is unacceptably vague language.

¶ 115 But rather than relying on the controversial “other serious deviations” clause, with the judicious use of legal terminology misconduct can be defined so as to make clear that recklessness and gross negligence are culpable mental states.¹⁷⁵ The mens rea provisions of the model definition might then read as follows.

Research misconduct is defined as (1) significant, and (2) knowing, reckless, or grossly negligent -

Fabrication, falsification, or plagiarism (however these terms are defined by the RIP).¹⁷⁶

Significant means an act or omission that has the potential to seriously threaten the integrity of the scientific record.

Knowing means having actual knowledge of, or acting in conscious disregard of information indicating that an act or omission constitutes fabrication, falsification, or plagiarism.

Reckless means acting in reckless disregard of a substantial risk that an act or omission constitutes fabrication, falsification, or plagiarism.

Grossly negligent means a highly unreasonable departure from the minimal level of care that would be exercised by a competent researcher in the same field of research, or a pattern of negligent conduct that consistently reflects gross indifference to professional standards.

¹⁷⁴ See Goldman & Fisher, *supra* note 165, at 161, 166. See also Buzzelli, *supra* note 139, at 585, 647-48.

¹⁷⁵ It is important to note that some officials at NSF maintain the definition can never be successfully limited to “ffp,” even if mental state language is added, because “ffp” must be defined excessively broadly in order to capture conduct now covered under the “other serious deviations” clause. For example, in order to reach an alleged case of the “misappropriation” of a virus without resorting to the “osd” clause, the NSF claims that the PHS was forced to consider the conduct a form of plagiarism, defining it as the “misappropriation of intellectual property.” NSF insists that such a broad extension of the traditional meaning of the term plagiarism is akin to using an “osd” standard. See ORI REPORT NO. 13, *supra* note 100, at 26.

¹⁷⁶ Issues surrounding the proper definition of “ffp” and the “scientific record” are beyond the scope of this paper; however, any language that is eventually adopted by NSTC should include precise mental state modifiers for the “ffp” terms.

* *Proof of specific intent to mislead or misrepresent is not required; however, research misconduct does not include simple negligence (sometimes termed "honest error").*

V. CONCLUSION

¶ 116 The NSTC's new definition of research misconduct will help the government to clarify the responsibilities and obligations of publicly funded researchers. The definition will also underscore the federal interest in the integrity of the research process. But if the new definition is to serve as a model for uniform federal misconduct regulations, it must be carefully drafted to accomplish the legal purpose for which it is ultimately intended.

¶ 117 The new definition should create a standard of culpability that covers knowing, reckless, and grossly negligent fabrication, falsification, and plagiarism. The government should not require proof of scienter (i.e., "intent to deceive") for a finding of misconduct; however, the definition should continue to exclude liability for simple negligence or "honest errors." The text of the definition should contain legal terms specifying the mens rea of the scientific misconduct offense.

¶ 118 As it regulates misconduct, the government should also consciously make reference to the explicit and implicit norms and standards of the scientific profession. A mens rea of gross negligence in the new federal definition would *require* government misconduct officials to do so, because gross negligence is determined in reference to objective standards of professional conduct. More importantly, misconduct cases cannot be decided fairly *unless* regulators consider scientists' own norms of behavior. NSTC should not accede to demands for a definition consisting of formulaic rules that would prevent the exercise of discretion by regulators. Rather, in crafting a new definition, federal policymakers should consider the following view of misconduct regulation, as expressed by the Inspector General of the National Science Foundation.

"We believe it is far preferable to face squarely the necessity for judgments about community standards and to encourage reasoned and responsible exercises of judgment than to pretend that the exercise of judgment can be eliminated from misconduct cases, or to covertly exercise judgment in ways that avoid scrutiny."¹⁷⁷

¹⁷⁷ See OIG REPORT NO. 13, *supra* note 100, at 28.