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## Comment

# Scientific Misconduct in Academia: A Survey and Analysis of Applicable Law

*During the past decade, the public trust in science as a discipline and the integrity of scientists have been challenged by multiple reports of data falsification, plagiarism, and misrepresentation of research results. Misconduct in science has its origins in the culture of medical education, academic promotion policies, editorial peer review deficiencies, and lack of institutional action.*

*This Comment will define scientific misconduct, analyze its origins, and survey applicable federal agency regulations and federal laws that structure the response of the academic community to this complex problem. It concludes that additional institutional self-regulation and a more vigorous application of existing laws may be required to prevent and detect scientific misconduct.*

### I. INTRODUCTION

By the age of thirty, Dr. Stephen Breuning had achieved a national reputation from his studies on the drug treatment of the mentally retarded. Between 1979 and 1984, this research psychologist "produced one-third of the literature in the [field]."<sup>1</sup> His studies influenced several states to modify their treatment policies.<sup>2</sup> Breuning was working at the University of Pittsburgh in 1983 when Rob-

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1. Brand, *It was Too Good to be True*, TIME, June 1, 1987, at 59 (quoting Dr. Robert L. Sprague, Prof., Institute for Research and Human Development, University of Illinois, Urbana-Champaign, Ill.).

2. Byrne, *Breuning Pleads Guilty*, 242 SCI. 27, 27 (1988).

ert Sprague, a University of Illinois scientist collaborating with Breuning on a project, became suspicious of Breuning's results. Sprague noted an impossible 100% agreement on independently rated patient behavioral scores.<sup>3</sup> He further concluded that some of Breuning's studies could not have been completed in the time allotted.<sup>4</sup> Sprague communicated his concerns to the National Institute of Mental Health (NIMH), the federal agency that funded Breuning's work. An investigation on the matter was turned over to the University of Pittsburgh. Although Breuning confessed to falsifying some earlier work, the University reported to NIMH that it "[found] no serious fault with Dr. Breuning's activities."<sup>5</sup> NIMH subsequently initiated its own inquiry. Over three years after Sprague first notified NIMH, the agency concluded Breuning "knowingly, wilfully and repeatedly engaged in misleading and deceptive practices" in reporting research.<sup>6</sup> On September 19, 1988, Breuning pled guilty to two counts of false grant statements,<sup>7</sup> in violation of 18 U.S.C. section 1001.<sup>8</sup> This case represented the first federal criminal conviction for "scientific fraud."<sup>9</sup>

This case, although notorious, is unfortunately not unique. During the past decade, many incidents of data falsification, plagiarism, and misrepresentation of research results have been reported in both scientific journals and the mass media. Such reports not only challenge the integrity of scientists but erode public trust in the entire scientific enterprise. More significant is the potential harm to the public: fraudulent medical research can cause direct harm to patients; and, false data can be used to set public policy.<sup>10</sup> In addition, legal issues arise concerning the rights and responsibilities of the scientists involved, the universities in which their research is conducted, the agencies which fund it, and the periodicals which publish it.<sup>11</sup> Con-

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3. Anderson, *First Scientific Fraud Conviction*, 335 NATURE 389 (1988).

4. *Id.*; see also Roman, *When Good Scientists Turn Bad*, DISCOVER, Apr. 1988, at 50, 52.

5. *Maintaining the Integrity of Scientific Research: Hearing Before the Subcomm. on Investigations and Oversight of the Comm. on Science, Space, and Technology*, 101st Cong., 1st Sess. 183 (1989) [hereinafter *Maintaining the Integrity of Scientific Research*] (testimony of Dr. Robert L. Sprague).

6. HHS: Grants Administration; Debarment; Stephen E. Breuning, 52 Fed. Reg. 47,760 (1987); Anderson, *supra* note 3, at 389.

7. United States v. Breuning, Criminal No. K-88-0135 (D.C. Md. Nov. 10, 1988); see also Byrne, *supra* note 2, at 27 (Breuning pled guilty to two counts of submitting false research results in his application for more than \$200,000 in grant funds from NIMH. In return, the prosecution dropped a third charge that Breuning attempted to obstruct an NIMH investigation into his research).

8. 18 U.S.C. § 1001 (1988).

9. Anderson, *supra* note 3, at 389.

10. For a discussion of the significance of reliable scientific data in formulating public policy, see generally Note, *Of Reliable Science: Scientific Peer Review, Federal Regulatory Agencies, and the Courts*, 7 VA. J. NAT. RESOURCES L. 27 (1987).

11. Teich, *Foreword*, in AAAS-ABA NATIONAL CONFERENCE OF LAWYERS AND

cern over these issues has stimulated congressional inquiry<sup>12</sup> as well as dialogue among members of the scientific and legal communities to study the problem.<sup>13</sup>

This Comment will analyze scientific misconduct and survey applicable federal law that structures the response of the academic community to this complex problem. Part II presents an overview of the problem, including the definition of scientific misconduct, estimated prevalence, and causal and contributing factors. Part III examines the current federal agency regulations that govern the investigation of scientific misconduct cases. Policy, procedure, and considerations of due process and confidentiality in the conduct of investigations are also discussed. Part IV surveys the key federal agency, criminal, and civil sanctions available to punish those who commit scientific misconduct. These include: debarment from federal programs,<sup>14</sup> criminal prosecution under statutes governing false statements<sup>15</sup> and false claims,<sup>16</sup> and civil prosecution under the False Claims Act.<sup>17</sup> This Comment concludes that while the current provisions are a significant step toward achieving deterrence and responsible investigation of misconduct cases, a comprehensive program addressing the problem will require increased efforts directed at prevention and detection at the institutional level. If universities and members of the scientific community do not accomplish this voluntarily, additional federal regulatory measures may be required to safeguard the integrity of scientific research.

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SCIENTISTS, PROJECT ON SCIENTIFIC FRAUD AND MISCONDUCT: REPORT ON WORKSHOP NUMBER ONE at v (1988) [hereinafter NATIONAL CONFERENCE OF LAWYERS AND SCIENTISTS NO. 1] (available at AAAS Office of Public Sector Programs, 1333 H Street, N.W., Washington, D.C. 20005).

12. See *Maintaining the Integrity of Scientific Research*, *supra* note 5; *Federal Response to Misconduct in Science: Are Conflicts of Interest Hazardous to our Health? Hearing Before a Subcomm. of the Comm. on Government Operations*, 100th Cong., 2d Sess. (1988); *Scientific Fraud and Misconduct and the Federal Response. Hearing Before a Subcomm. of the Comm. on Government Operations*, 100th Cong., 2d Sess. (1988); *Fraud in Biomedical Research: Hearings Before the Subcomm. on Investigations and Oversight of the Comm. on Science and Technology*, 97th Cong., 1st Sess. (1981).

13. See generally NATIONAL CONFERENCE OF LAWYERS AND SCIENTISTS NO. 1, *supra* note 11.

14. 45 C.F.R. §§ 76.100-.510, 620.100-.510 (1990).

15. 18 U.S.C. § 1001 (1988).

16. 18 U.S.C. § 287 (1988).

17. 31 U.S.C. §§ 3729-3733 (1988).

## II. OVERVIEW OF THE PROBLEM OF SCIENTIFIC MISCONDUCT

### A. Formal Definition

The definition of misconduct in science is controversial because of concern over the meaning of fraud and misconduct and the role of honest error and differences in professional judgment.<sup>18</sup> Recently, the National Institutes of Health (NIH) of the Public Health Service (PHS) and the National Science Foundation (NSF), the two major funding sources of university research,<sup>19</sup> have promulgated standards for actionable misconduct in science. Under the NIH/PHS definition, misconduct 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."<sup>20</sup> The NSF definition is similar but more broad,<sup>21</sup> adding that retaliation against a person who in good faith reported suspected misconduct is also actionable.<sup>22</sup>

These definitions proscribe intentional dishonesty and contravention of accepted scientific practices. To prove a case of fabrication,

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18. See Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science, 54 Fed. Reg. 32,446, 32,447 (1989) [hereinafter PHS Final Rule] (to be codified at 42 C.F.R. pt. 50) (discusses public comments and federal departmental response to proposed definition of "Misconduct in Science").

19. See NATIONAL SCIENCE FOUND., VOL. 38, FEDERAL FUNDS FOR RESEARCH AND DEVELOPMENT: FISCAL YEARS 1988, 1989, AND 1990, at 35, 44-45 (in fiscal year 1990, universities will receive an estimated 64% of NIH funds and 75% of NSF funds for basic research, and 59% of NIH funds and 72% of NSF funds for applied research).

20. 42 C.F.R. § 50.102 (1990).

21. 56 Fed. Reg. 22,286, 22,287 (1991) (to be codified at 45 C.F.R. § 689.1). The current NSF definition states:

(a) "Misconduct" means

(1) fabrication, falsification, plagiarism, or other serious deviation 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.

*Id.* The NSF definition extends "misconduct" to cover not only research but all "activities funded by NSF." See *id.* This is a response to the fact that a substantial portion of NSF funding supports science and engineering education rather than research and in many NSF activities, research and education are inextricably mixed. *Id.* at 22,287.

22. This addition is based on NSF's belief that such retaliation is not only a serious deviation from accepted practices in the scientific community, but it can also be a furtherance of the misconduct being reported. *Id.* at 22,287. The explicit inclusion of retaliation in the NSF definition of misconduct is not inconsistent with the NIH/PHS approach. *Id.* The NIH/PHS regulations require awardee institutions to have policies and procedures that provide for "undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations [of misconduct]." 42 C.F.R. § 50.103(d)(13) (1990).

falsification or plagiarism,<sup>23</sup> it must be shown that a scientist knowingly made up or misrepresented information during the course of government-funded research.<sup>24</sup> Unlike the common law tort model of fraud,<sup>25</sup> proof that someone relied upon the misrepresentation or was damaged as a result is not required.<sup>26</sup> Serious deviation from accepted practices or "scientific malpractice" is misconduct if the behavior amounts to gross negligence or intentional action comparable to falsification or plagiarism.<sup>27</sup> Deviant practices that might constitute intentional misconduct under these definitions include failure to acknowledge collaborators, selective omission of data to favor hypotheses, and simultaneous multiple submission of an article to journals.<sup>28</sup>

### B. *Prevalence and Scope*

There is little confirmed data on the prevalence of scientific misconduct. However, federal agency experience and independent studies are informative. Together they suggest a great deal of misconduct goes undetected and the number of reported cases and allegations is increasing, particularly in the medical field.

In recent years, both the NIH and the NSF received an increase in allegations of misconduct. As of 1987, the NIH received about twenty misconduct-related allegations per year.<sup>29</sup> It currently receives approximately 150 per year.<sup>30</sup> Between 1980 and 1987, twelve

23. Fabrication or "dry-labbing" refers to the partial or wholesale forgery of data. Falsification is the false reporting of observations and methods. Plagiarism is the appropriation of another's words, ideas, or data. See Chubin, *Research Malpractice*, 35 *BIO-SCIENCE* 80, 81 (1985) [hereinafter *Research Malpractice*]; Chubin, *Misconduct in Research: An Issue of Science Policy and Practice*, 23 *MINERVA* 175 (1985).

24. Anderson, *The Federal Government's Role in Regulating Misconduct in Scientific and Technological Research*, 3 *J.L. & TECH.* 121, 127 (1988).

25. See PROSSER AND KEETON ON THE LAW OF TORTS, 728 (5th ed. 1984) (tort cause of action for deceit includes five elements: (1) a false representation of fact; (2) made by one with knowledge or belief that the representation is false; (3) the representation was made with intent to induce reliance upon it; (4) others justifiably rely; (5) damages result from such reliance).

26. Anderson, *supra* note 24, at 127.

27. *Id.* at 130.

28. *Id.*; see also *Research Malpractice*, *supra* note 23, at 81.

29. Woolf, *Deception in Scientific Research*, 29 *JURIMETRICS J.* 67, 73 (1988) (reporting on results of an interview with Mary Miers, Institutional Liaison Officer, Office of Extramural Research, NIH (July, 1987)). Of these, 10 to 12 per year were serious enough to investigate and one or two per year necessitated action. Between 1980 and 1987, about 15 allegations resulted in some type of sanction. *Id.*

30. Telephone interview with Alan Price, Senior Scientist, Office of Scientific Integrity, National Institutes of Health, Public Health Service (June 14, 1990). Ten to 20

charges of misconduct were reviewed by the NSF and found to require investigation.<sup>31</sup> Twenty-two misconduct allegations were received by NSF during the first half of fiscal year 1990.<sup>32</sup>

An analysis of the publicly reported cases of scientific misconduct was conducted by Woolf.<sup>33</sup> Twenty-six cases were reported between 1980 and 1987. In contrast, only fourteen cases were revealed between 1950 and 1970. Of those reported after 1980, twenty-two (85%) were medical-related, involving individuals who had M.D. degrees and/or were affiliated with medical schools, hospitals or medical research institutions. In over half of these cases, the primary factor in detection was follow-up on coworkers' suspicions.

Few efforts to survey the extent of scientific misconduct have been made. One 1988 study analyzed the responses of 259 deans whose institutions were affiliated with the Council of Graduate Schools.<sup>34</sup> Overall, twenty percent reported an instance of verified misconduct among their faculties during the past five years. The rate of misconduct increased with research intensiveness: among the subgroup "research universities"<sup>35</sup> the proportion was thirty-two percent. Sigma Xi, the honor society for science researchers, conducted a survey of its members in 1988.<sup>36</sup> Nineteen percent of the nearly 3800 respondents indicated they had direct knowledge of misconduct on the part of a professional scientist.<sup>37</sup> Respondents who had worked on a fed-

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per year are considered serious enough to warrant investigation. About 50 cases were closed in 1989, 25% of which resulted in a finding of misconduct and some kind of sanction. The current active caseload is 80 cases: 20 are being investigated by the NIH; 60 are being conducted by the host research institutions. *Id.*

31. Woolf, *supra* note 29, at 74 (reporting on results of an interview with Jerome Frigeau, Director of Division of Oversight and Investigation at the NSF (July, 1987)). Of these, at least seven were judged to be warranted. *Id.*

32. OFFICE OF INSPECTOR GENERAL, NATIONAL SCIENCE FOUND., SEMI-ANNUAL REPORT TO CONGRESS, NO. 2, OCT. 1, 1989 - MAR. 31, 1990, at 19. After preliminary review, only five were closed for lack of evidence or jurisdiction. Results of the remaining 17 are still pending. *Id.* The 1990 caseload is projected to be 45 cases. Telephone interview with Philip Sunshine, Counsel to the Inspector General, National Science Foundation (June 14, 1990).

33. Woolf, *supra* note 29, at 76-83.

34. Swazey, Louis, & Anderson, *University Policies and Ethical Issues in Research and Graduate Education: Highlights of the CGS Deans' Survey*, CGS COMMUNICATOR, Mar. 1989, at 1.

35. "Research universities" are those offering the full range of baccalaureate programs, are committed to graduate education through the doctoral level, and give priority to research. They obtain \$12.5 million or more in federal support annually and award a minimum of 50 Ph.D. degrees a year. CARNEGIE FOUND. FOR THE ADVANCEMENT OF TEACHING, A CLASSIFICATION OF INSTITUTIONS OF HIGHER EDUCATION 7 (1987).

36. Sigma Xi, *Sketches of the American Scientist* (1989), reported in OFFICE OF INSPECTOR GENERAL NATIONAL SCIENCE FOUND., SURVEY DATA ON THE EXTENT OF MISCONDUCT IN SCIENCE AND ENGINEERING, OIG 90-3214, at 4 (1990) [hereinafter NSF SURVEY DATA].

37. The question posed was "Excluding gross stupidities and/or minor slip ups that can be charitably dismissed (but not condoned), I have direct knowledge of fraud (e.g., falsifying data, misreporting results, plagiarism) on the part of a professional scien-

eral research grant were somewhat more likely to be aware of misconduct than those who had not. A 1987 study analyzed responses from 245 science researchers at a large high-ranking American university.<sup>38</sup> Thirty-two percent stated they had at some time suspected a colleague of falsifying data and thirty-two percent had suspected a colleague of plagiarism. While it is difficult to generalize from these varied studies because some had low response rates, they indicate a measure of known misconduct in the range of twenty percent.<sup>39</sup> With an estimated 5.3 million scientists and engineers employed in the United States,<sup>40</sup> scientific misconduct is probably more prevalent than the number of publicly reported cases suggests. However, more research is needed before the full extent of scientific misconduct is known.

### C. Causal and Contributing Factors

A number of factors are advanced to explain the occurrence of scientific misconduct. Some suggest it is the result of a pathological personality,<sup>41</sup> thus focusing on the individual malefactor. Others focus on organizational factors, including: (1) the culture of medical education; (2) changes in science; (3) pressure to publish; (4) failure of the editorial peer review system; and (5) reluctance on the part of institutions and journals to act on misconduct.

Medical education is implicated because a high number of misconduct cases involve those with an M.D. degree.<sup>42</sup> The "pre-med" syndrome, which begins with excessive emphasis on grades and competition in college, is thought to promote dishonesty.<sup>43</sup> In one study of 400 medical students at two Chicago medical schools, eighty-eight percent reported they had cheated at least once as pre-meds; a majority continued to cheat in medical school.<sup>44</sup> "[A] continuum from

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tist.'" *Id.* at 4.

38. Tangney, *Fraud Will Out — Or Will It?* NEW SCIENTIST, Aug. 6, 1987, at 62.

39. NSF SURVEY DATA, *supra* note 36, at 8-9.

40. NATIONAL SCIENCE FOUND., U.S. SCIENTISTS AND ENGINEERS: 1988, FINAL ESTIMATES, NSF 90-314, DETAILED STATISTICAL TABLES 9 (1990). Approximately 712,300 are employed in educational institutions, of which 531,300 are affiliated with four-year colleges and universities. *Id.*

41. McDonald, *Fraud in Scientific Research: Is it the Work of 'Psychopaths'?* Chron. Higher Educ., June 15, 1983, at 7, col. 1.

42. *See supra* text accompanying note 33.

43. Petersdorf, *The Pathogenesis of Fraud in Medical Science*, 104 ANNALS INTERNAL MED. 252, 252 (1986) [hereinafter *The Pathogenesis of Fraud*]; *see also* Petersdorf, *A Matter of Integrity*, 64 ACADEMIC MED. 119 (1989).

44. Barrett, *The Premed Machine*, WASH. MONTHLY, May 1985, at 41, 43.



cheating in college, to cheating in medical school in didactic areas, to cheating in clerkships in patient care" was observed.<sup>45</sup> In another study, medical students' attitudes on physician fraud and abuse in Medicare and Medicaid programs were examined.<sup>46</sup> Students' attitudes toward such practices as physicians billing for services not performed were unusually lenient. Most thought such behavior would go unpunished and favored mild penalties for program violations. Several justified violations because the programs were inefficient and reimbursed at a low rate. Cheating and lax attitudes toward fraud in medical school may lead to scientific misconduct later in a research career.

Another factor may be recent changes in science. Before World War II, scientific research was largely conducted by individual investigators.<sup>47</sup> A successful scientist now often presides over the research of a large group of junior scientists, increasing the chances of inadequate supervision.<sup>48</sup> In at least one misconduct case, the Darsee incident, inadequate supervision by the senior scientist was viewed as a contributing factor. John Darsee had fabricated data in his cardiology research at Harvard Medical School. His supervisor, Eugene Braunwald was in charge of two complete laboratories, was physician-in-chief to two of Harvard's hospitals and was continually heading meetings around the country.<sup>49</sup> The NIH investigating committee that found Darsee guilty of misconduct concluded that Braunwald's remoteness from daily laboratory operations helped keep Darsee's fabrication from discovery; a simple check of Darsee's notebook might have uncovered the misconduct early.<sup>50</sup>

Perhaps the most cited cause for scientific misconduct is pressure to publish research results. Woolf<sup>51</sup> has identified three arguments commonly made to explain this relationship. First, several cases of misconduct occurred in prestigious laboratories where supervisors published a great deal. Darsee's supervisor Braunwald, for example, published 171 papers in the five years preceding Darsee's 1981 incident.<sup>52</sup> A supervisor's high rate of publication might pressure a

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45. *Id.* at 43-44.

46. Keenan, Brown, Pontell & Geis, *Medical Students' Attitudes on Physician Fraud and Abuse in the Medicare and Medicaid Programs*, 60 J. MED. EDUC. 167 (1985).

47. LaFollette, *Beyond Plagiarism: Ethical Misconduct in Scientific and Technical Publishing*, BOOK RES. Q., Winter 1988-89, at 65, 67.

48. See Woolf, *Fraud in Science: How Much, How Serious?* HASTINGS CENTER REP., Oct. 1981, at 9, 12.

49. W. BROAD & N. WADE, *BETRAYERS OF THE TRUTH* 157 (1982).

50. Glazer, *Combating Science Fraud*, 2 EDITORIAL RES. REP. 390, 396 (1988).

51. Woolf, 'Pressure to Publish' is a *Lame Excuse for Scientific Fraud*, *Chron. Higher Educ.*, Sept. 23, 1987, at A52, col. 1.

52. *Id.* at A52, col. 3.

subordinate to achieve the same.<sup>53</sup> Second, several famous perpetrators were themselves prolific publishers. For example, Robert Slutsky, who falsified data at the medical school of the University of California at San Diego, produced one paper every ten days while a resident.<sup>54</sup> Third, untenured faculty members are more often found guilty of misconduct than tenured scholars. One reason may be the demands of our system of academic promotions, which stresses quantity of papers.<sup>55</sup> A recent study of academic promotion at Johns Hopkins University School of Medicine lends support to this theory.<sup>56</sup> During the three years preceding consideration for promotion, faculty members who were promoted had about twice as many publications as did nonpromoted faculty.

Shortcomings in the editorial review process is another factor contributing to scientific misconduct. Unlike other professions, science is not regulated by formal mechanisms such as licensure. Quality control is achieved through social mechanisms operating in the scientific community whereby researchers submit their work to the scrutiny of other scientists.<sup>57</sup> One of the principle mechanisms is editorial peer review, also called the referee system.<sup>58</sup> Here scientific journals send out submitted manuscripts to experts called referees. The referees are responsible for judging the merits of articles for publication and for spotting any irregularities in method or argument. Although such review is a point where scientific misconduct might be detected, it has proved unreliable in doing so.<sup>59</sup> It is asserted that plausible, internally consistent fabrications cannot be discovered in editorial peer review.<sup>60</sup> However, in some cases, referees failed to discover statistical errors and improbable achievements.<sup>61</sup> For example, among Darsee's eighteen published research papers, there was an average of

53. *Id.*

54. Engler, Covell, Friedman, Kitcher & Peters, *Misrepresentation and Responsibility in Medical Research*, 317 NEW ENG. J. MED. 1383, 1386 (1987) [hereinafter Engler].

55. See *The Pathogenesis of Fraud*, *supra* note 43, at 253.

56. Batshaw, Plotnick, Petty, Woolf & Mellits, *Academic Promotion at a Medical School*, 318 NEW ENG. J. MED. 741 (1988).

57. See Committee on the Conduct of Science, Nat'l Academy of Science, *On Being A Scientist*, 86 PROC. NAT'L ACAD. SCI. 9053, 9065 (1989).

58. See W. BROAD & N. WADE, *supra* note 49, at 61.

59. For example, of the 137 articles published by Slutsky, 48 were later found to be questionable and 12 were fraudulent. Engler, *supra* note 54, at 1383.

60. *Id.* at 1385; see also Relman, *Lessons from the Darsee Affair*, 308 NEW ENG. J. MED. 1415 (1983).

61. Engler, *supra* note 54, at 1385; see also Stewart & Feder, *The Integrity of the Scientific Literature*, 325 NATURE 207 (1987).

twelve errors and discrepancies per paper; one had as many as thirty-nine errors.<sup>62</sup> Most could be recognized simply by careful examination<sup>63</sup> and some were “so glaring as to offend common sense.”<sup>64</sup> A striking instance of the latter was a bizarre pedigree depicting a family with an unusual heart disease. Inspection revealed that a seventeen year-old male had four children, ages eight through four, making him eight or nine when he impregnated the mother of his first child.<sup>65</sup> Such errors raise serious doubts as to the ability of the peer review system to deter misconduct through detection.

Reluctance on the part of institutions and journals to act on scientific misconduct also contributes to the problem. Allegations of misconduct are usually investigated by the accused’s academic institution. Past tendencies favored suppression of problems and hostility toward those who brought allegations.<sup>66</sup> Thus, in the case of Jeffrey Borer, a cardiologist accused of misrepresenting research at Cornell University Medical College in 1981, a three-member panel convened by the dean decided after a six-hour inquiry that the charges warranted no further action.<sup>67</sup> Due to the persistence of accuser Jerome Jacobstein and his attorney, an NIH investigation was mounted, ultimately confirming many of the charges seven years after they first came to light. Given this protracted process, Jacobstein and other “whistleblowers” like him have too often incurred professional and personal sanctions including termination of employment,<sup>68</sup> loss of grant funding,<sup>69</sup> and hefty legal fees.<sup>70</sup> While institutions have been

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62. Stewart & Feder, *supra* note 61, at 209.

63. *Id.* at 207.

64. *Id.* at 208.

65. *Id.*

66. *Maintaining the Integrity of Scientific Research*, *supra* note 5, at 154 (testimony of Dr. Paul J. Friedman, Prof. of Radiology, Dean for Academic Affairs, University of California, San Diego, School of Medicine, La Jolla, CA).

67. See Jacobstein, *I Am Not Optimistic*, *Scientist*, Dec. 14, 1987, at 11, col. 1; Kolata, *After 7-Year Dispute, a Cardiologist is Disciplined*, *N.Y. Times*, Sept. 29, 1987, at C3, col. 3; *Part I: Chronicle of a Scientific Misconduct Case*, *Sci. & Gov't Rep.*, Nov. 1, 1986, at 1, col. 1.

68. See Hollis, *I Turned in My Mentor*, *Scientist*, Dec. 14, 1987, at 11, col. 1 (postdoctoral fellow Bruce Hollis, after questioning the research of supervising scientist Philip Lambert, stated he was given notice of termination from his academic appointment at Case Western Reserve University); see also Wilford, *Ex-Colleagues Turn Combatants*, *N.Y. Times*, May 22, 1990, at B10, col. 1 (researcher Dr. Heidi Weissman concluded she was dismissed from her position at Yeshiva University’s Albert Einstein College of Medicine and the Montefiore Medical Center in retaliation for legal action against colleague Dr. Leonard Freeman for scientific misconduct).

69. See Sprague, *I Trusted the Research System*, *Scientist*, Dec. 14, 1987, at 11, col. 1 (University of Illinois scientist Robert Sprague, after reporting concerns about Stephen Breuning’s research, found his research funding deferred and then reduced to 10% of that originally requested despite 16 years of prior continuous funding).

70. See *Part I: Chronicle of a Scientific Misconduct Case*, *supra* note 67, at 3, col. 1 (Jacobstein spent \$13,000 in legal fees to pursue an investigation of colleague Jeffrey Borer’s research misconduct); see also Wilford, *supra* note 68, at B10, col. 3 (Dr. Weiss-

mandated to adopt fair and expeditious procedures to handle allegations of misconduct,<sup>71</sup> whistleblowers remain vulnerable and have mounted lawsuits to protect their interests.<sup>72</sup> Concern over potential lawsuits by those serving on academic investigative committees further complicates open inquiry.<sup>73</sup>

Fear of legal action has likewise inhibited journals from printing retractions of articles or publishing results of investigations of the prior work of scientists shown to have committed misconduct. The Slutsky investigation was impeded in this respect. The University of California San Diego faculty committee that evaluated Slutsky's 135 publications reported to the thirty journals involved whether each article was valid, questionable, or fraudulent, requesting publication of the conclusions.<sup>74</sup> Half required more letters over a two-year period to obtain a response. Of the thirteen journals that had valid articles, only five published statements to that effect. Of the seventeen that had any fraudulent or questionable articles, only nine printed state-

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mann spent \$500,000 in legal fees in her ordeal over Dr. Freeman's alleged misconduct).

71. See, e.g., ASSOCIATION OF AM. MEDICAL COLLEGES, FRAMEWORK FOR INSTITUTIONAL POLICIES AND PROCEDURES TO DEAL WITH MISCONDUCT IN RESEARCH (1989); ASSOCIATION OF AM. UNIVERSITIES & NATIONAL ASS'N OF STATE UNIVERSITIES AND LAND-GRANT COLLEGES, FRAMEWORK FOR INSTITUTIONAL POLICIES AND PROCEDURES TO DEAL WITH FRAUD IN RESEARCH (1988). Similar documents recommending institutions establish procedures to deal effectively with allegations of misconduct were promulgated as early as 1982. See ASSOCIATION OF AM. MEDICAL COLLEGES, THE MAINTENANCE OF HIGH ETHICAL STANDARDS IN THE CONDUCT OF RESEARCH (1982); ASSOCIATION OF AM. UNIVERSITIES, REPORT OF THE ASSOCIATION OF AMERICAN UNIVERSITIES COMMITTEE ON THE INTEGRITY OF RESEARCH (1982).

72. Some have brought action against the academic institution regarding its investigation into allegations of a colleague's or a superior's scientific misconduct. See, e.g., *Dong v. Board of Trustees of Leland Stanford Jr. Univ.*, 191 Cal. App. 3d 1572, 236 Cal. Rptr. 912 (1987) (faculty member who accused colleague of scientific misconduct, sued university for libel, infliction of emotional distress, and breach of implied covenant of good faith and fair dealing in investigation of allegations), *cert. denied*, 484 U.S. 1019 (1988); Gordon, *Lab Aide Sues U-M, Boss over Research*, Detroit News and Free Press, May 6, 1990, at 1A, col. 6 (University of Michigan research associate who reported professor falsified laboratory data, committed plagiarism, and stole her research filed suit against university and its investigating committee for negligence in treatment of allegations). Others have brought action directly against the individual accused of misconduct. See, e.g., *Weissmann v. Freeman*, 684 F. Supp. 1248 (S.D.N.Y. 1988) (author-researcher sued colleague for copyright infringement in deleting author's name from article and passing it off as colleague's own), *aff'd in part and rev'd in part*, 868 F.2d 1313 (2d Cir.), *cert. denied*, 110 S. Ct. 219 (1989).

73. See *Maintaining the Integrity of Scientific Research*, *supra* note 5, at 155 (in discussing an investigation into a case of misconduct at the University of California at San Diego, Professor Paul Friedman noted that "one of the things we talked about at our first committee meeting was are we going to get sued or are we liable for anything?").

74. Friedman, *Correcting the Literature Following Fraudulent Publication*, 263 J. A.M.A. 1416 (1990).

ments covering all the articles reported to them. Explicitly acknowledged by some of the journal editors, and implicit in the behavior of others who cited discussions with their attorneys, was concern over liability for libel to the author or coauthors. A similar concern blocked retractions of articles by Breuning<sup>75</sup> and delayed publication of an investigation of Darsee's publications.<sup>76</sup>

### III. REGULATORY FRAMEWORK FOR MISCONDUCT INVESTIGATIONS

The NSF and the PHS, of which NIH is a part, are both authorized by Congress to establish regulations regarding scientific misconduct at institutions receiving agency funds for research.<sup>77</sup> Final regulations to administer this directive were issued by PHS in 1989.<sup>78</sup> NSF's regulations were issued in 1987 and amended in 1991.<sup>79</sup> Besides providing formal definitions of scientific misconduct,<sup>80</sup> these agency regulations delineate responsibilities for the detection and investigation of alleged misconduct.

#### A. Policy and Procedure

A central feature of the NSF and the NIH/PHS agency regulations is the principle that awardee institutions bear the primary re-

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75. Hostetler, *Fear of Suits Blocks Retractions*, *Scientist*, Oct. 19, 1987, at 1, col. 4.

76. Boffey, *Major Study Points to Faulty Research at Two Universities*, *N.Y. Times*, Apr. 22, 1986, at C1, col. 3.

77. The PHS received its authority in 1985 when Congress enacted section 493 of the Health Research Extension Act. Health Research Extension Act of 1985, Pub. L. No. 99-158, § 493, 99 Stat. 820, 874-75 (codified at 42 U.S.C. § 289b (1988)). The NSF received general authority to establish regulations necessary for the administration of the NSF grant program under the National Science Foundation Act of 1950. National Science Foundation Act of 1950, Pub. L. No. 507, § 11, 64 Stat. 149, 153-54 (codified as amended at 42 U.S.C. § 1870 (1988)).

78. Responsibility of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science, 42 C.F.R. §§ 50.101-.105 (1990) (source: 54 Fed. Reg. 32,449 (1989)). The existing regulations focus on the responsibilities of awardee institutions faced with possible scientific misconduct. *See id.* The PHS recently proposed internal policies and procedures that focus on the responsibilities of PHS offices and officials that deal with possible scientific misconduct. Policies and Procedures for Dealing with Possible Scientific Misconduct in Extramural Research, 56 Fed. Reg. 27,384 (1991) (proposed June 13, 1991). The PHS is currently seeking public comment on these proposed policies. *Id.* at 27,384; *see also* 56 Fed. Reg. 40,340 (1991) (extending the public comment period).

79. Misconduct in Science and Engineering, 56 Fed. Reg. 22,286 (1991) (to be codified at 45 C.F.R. §§ 689.1-9) (current NSF amended regulations, effective May 14, 1991). The 1991 amendment to the NSF regulations was necessary to clarify the scope of the misconduct regulations and the Office of Inspector General's authority and procedures in misconduct cases. *Id.* at 22,286. The 1987 NSF regulations can be found at 52 Fed. Reg. 24,468 (1987) (amended 1991).

80. *See supra* notes 20-21 and accompanying text.

sponsibility for conducting investigations.<sup>81</sup> Most grants are awarded to institutions, rather than to individual researchers,<sup>82</sup> and awardee institutions must assume accountability for the performance of the supported activities.<sup>83</sup> The main criticism advanced against this policy is that there is a conflict of interest posed by an institution investigating one of its own researchers.<sup>84</sup> A disclosure of wrongdoing can compromise an institution's reputation and financial support, thus making it difficult to conduct an internal examination that is not biased in favor of the accused.

Despite this potential conflict of interest, this policy is efficient and convenient. Institutions, rather than the federal government, are often the first to learn of misconduct allegations and can quickly deal with those that stem from minor misunderstandings.<sup>85</sup> They also have direct access to laboratories, research data, and witnesses.<sup>86</sup> Furthermore, the regulations provide that both NSF and NIH/PHS retain the authority to proceed with their own independent investigation if necessary.<sup>87</sup> This provision is perhaps the most important mechanism in the regulatory framework available to counteract any bias that may result from internal investigations.

The NSF and the NIH/PHS set forth a two-tiered process to be used by institutions in dealing with allegations of misconduct. First, upon receiving an allegation or other information, the institution is required to conduct an "inquiry."<sup>88</sup> This inquiry is a preliminary fact-finding process to ascertain whether there is reason to believe scientific misconduct was committed.<sup>89</sup> If no substantive basis for the allegation exists, there is no obligation that this be reported to the awarding agency.<sup>90</sup> However, if the inquiry indicates the allegation is

81. 42 C.F.R. § 50.104(a)(6) (1990); 56 Fed. Reg. 22,286, 22,288 (1991) (to be codified at 45 C.F.R. § 689.3(a)).

82. Anderson, *supra* note 24, at 132.

83. See 42 C.F.R. § 50.102 (1990); see also Anderson, *supra* note 24, at 132.

84. Anderson, *supra* note 24, at 133; see also O'Toole, *Point of View: Scientists Must Be Able to Disclose Colleagues' Mistakes Without Risking Their Own Jobs or Financial Support*, Chron. Higher Educ., Jan. 25, 1989, A44, at A45, col. 2.

85. Anderson, *supra* note 24, at 134-35.

86. *Id.* at 135.

87. 42 C.F.R. § 50.104(a)(6) (1990); 56 Fed. Reg. 22,286, 22,289 (1991) (to be codified at 45 C.F.R. § 689.4(d)(3)).

88. 42 C.F.R. § 50.103(d)(1) (1990); 56 Fed. Reg. 22,286, 22,288 (1991) (to be codified at 45 C.F.R. § 689.3(a)(1)).

89. 42 C.F.R. § 50.102 (1990); 56 Fed. Reg. 22,286, 22,288 (1991) (to be codified at 45 C.F.R. § 689.1(c)).

90. However, NIH/PHS does require that the institution maintain sufficiently detailed documentation of inquiries to allow an assessment of the reasons for concluding that an investigation was not warranted, if necessary. 42 C.F.R. § 50.103(d)(6) (1990).

warranted, the institution proceeds to a more formal "investigation"<sup>91</sup> to determine if misconduct occurred. The institution's decision to initiate an investigation must be reported to the agency.<sup>92</sup> The institution is also required to notify the awarding agency at any time should specific exigencies exist.<sup>93</sup> An investigation is complete when a final report is submitted to the awarding agency.<sup>94</sup> In addition, certain time requirements must be adhered to for the inquiry and investigation stages.<sup>95</sup> The NIH/PHS regulations further require institutions to give assurance that they have a process consistent with the foregoing as a condition for receipt of research funds.<sup>96</sup> NSF, however, has no such requirement. Arguably, it should. Such a requirement is one means of ensuring that institutions develop a process for handling misconduct allegations satisfactory to the agency prior to awarding assistance.

### *B. Due Process and Confidentiality Considerations*

The NSF and the NIH/PHS regulations allow institutions flexibility in adopting procedures that provide due process to the accused in an investigation. The essential elements of due process are notice and an opportunity to respond.<sup>97</sup> The NIH/PHS regulations have general directives incorporating these features. A written report summarizing the evidence and conclusions of any inquiry is provided to the accused.<sup>98</sup> If an investigation is undertaken, the accused is

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NIH/PHS also requires that a written report be prepared summarizing the evidence reviewed, the relevant interviews obtained, and conclusions of the inquiry, and that it be provided to the individual against whom the allegation was made. 42 C.F.R. § 50.103(d)(1) (1990).

91. An "investigation" is a formal examination and evaluation of all relevant facts to determine if misconduct has occurred. 42 C.F.R. § 50.102 (1990); 56 Fed. Reg. 22,286, 22,288 (1991) (to be codified at 45 C.F.R. § 689.1(c)).

92. 42 C.F.R. § 50.104(a)(1) (1990); 56 Fed. Reg. 22,286, 22,288 (1991) (to be codified at 45 C.F.R. § 689.3(b)(1) & (2)).

93. Such exigencies include: (1) if immediate health hazards are involved; (2) if there is a need to protect the interests of individuals involved; (3) if the misconduct is serious or indicates a criminal violation. 42 C.F.R. § 50.104(b) (1990); 56 Fed. Reg. 22,286, 22,288 (1991) (to be codified at 45 C.F.R. § 689.3(b)(3)).

94. See 42 C.F.R. § 50.104(a)(4) (1990); 56 Fed. Reg. 22,286, 22,288 (1991) (to be codified at 45 C.F.R. § 689.3(b)(4)).

95. Under NSF regulations, an institution should complete any inquiry within 90 days and any investigation within 180 days. 56 Fed. Reg. 22,286, 22,288 (1991) (to be codified at 45 C.F.R. § 689.3(e)). Under NIH/PHS regulations, an inquiry must be completed within 60 days, an investigation is to be undertaken within 30 days of completion of the inquiry, and an investigation should ordinarily be completed within 120 days of its initiation. 42 C.F.R. §§ 50.103(d)(1), .103(d)(7), .104(a)(2) (1990).

96. 42 C.F.R. § 50.103(a) (1990). This assurance was to be submitted to the Office of Scientific Integrity of NIH/PHS no later than January 1, 1990 and updated annually thereafter along with certain information on allegations, inquiries, and investigations as the Secretary may prescribe. 42 C.F.R. § 50.103(b) (1990).

97. *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 546 (1985).

98. 42 C.F.R. § 50.103(d)(1) (1990).

interviewed whenever possible<sup>99</sup> and given an opportunity to comment on findings of the investigation.<sup>100</sup> Requirements for securing the necessary expertise to conduct an evaluation of the evidence in an inquiry or investigation<sup>101</sup> and for taking precautions against conflicts of interest on the part of individuals involved are also prescribed.<sup>102</sup> The NSF regulations do not specify minimum due process standards for institutional investigations,<sup>103</sup> although they are defined for independent NSF-conducted investigations.<sup>104</sup> Thus, the specific format of institutional misconduct investigations are largely subject to the individual institutions' procedures for disciplinary action. Such procedures generally do not approach the level of due process demanded in the courts.<sup>105</sup> In the context of public employment, an institution may even terminate a faculty member using "something less' than a full evidentiary hearing"<sup>106</sup> provided post-termination adjudicatory proceedings are available.<sup>107</sup> Because a scientist's career may be destroyed by a finding that misconduct was committed, it has been suggested that a high degree of due process in the investigation is in order.<sup>108</sup>

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99. 42 C.F.R. § 50.103(d)(7) (1990).

100. 42 C.F.R. §§ 50.103(d)(3), .104(a)(2) (1990).

101. 42 C.F.R. § 50.103(d)(8) (1990).

102. 42 C.F.R. § 50.103(d)(9) (1990).

103. However, the NSF regulations do specify that in cases other than those in which debarment is considered an appropriate disposition, the report received from any investigation confirming misconduct will be provided by NSF to the subject of the investigation who will be invited to submit comments for consideration. 56 Fed. Reg. 22,286, 22,290 (1991) (to be codified at 45 C.F.R. § 689.8(c)(2)).

104. *See id.* at 22,289 (to be codified at 45 C.F.R. § 689.5(b) (when an NSF-initiated investigation is conducted, written notice to the individuals to be investigated will be given, unless notification would prejudice the investigation or a criminal investigation is underway); *Id.* (to be codified at 45 C.F.R. § 689.5(d) (an investigation may include, *inter alia*: interviews with parties or witnesses, opportunity for the subject to be heard, and full adjudicatory hearings or other formal proceedings). For a discussion of NSF investigative procedures into allegations of scientific misconduct, see generally Anderson, *supra* note 24.

105. Mishkin, *Responding to Scientific Misconduct: Due Process and Prevention*, 260 J. A.M.A. 1932, 1932 (1988).

106. *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 545 (1985).

107. *Id.* at 547-48. For a discussion of constitutional due process in scientific misconduct investigations and dismissal proceedings, see Olswang and Lee, *Scientific Misconduct: Institutional Procedures and Due Process Considerations*, 11 J.C. & U.L. 51 (1984).

108. *See* Mishkin, *supra* note 105, at 1934-35 (commensurate with increased potential sanctions, due process for the accused should include written notice of charges, participation in the investigation by at least some scientists from institutions other than that of the accused, a list of witnesses to be called at the hearing, representation by an attorney at all stages of the formal proceedings, and opportunity to present evidence, call, examine and cross-examine witnesses).



Confidentiality, at least in the initial review of misconduct allegations, is also important because of the possible harm to the reputation of innocent individuals by incorrect charges and the need to protect accusers from retaliation. The NIH/PHS regulations set forth a general directive for institutions to afford the accused confidential treatment to the extent possible.<sup>109</sup> The NSF rules do not specify confidentiality for the accused undergoing institutional investigations but do require any investigatory documents obtained by NSF to be kept confidential to the extent permitted by law.<sup>110</sup> A similar provision is set forth in the NIH/PHS regulations.<sup>111</sup> The NIH/PHS rules further prescribe that institutions protect the privacy of those who in good faith report misconduct.<sup>112</sup> Likewise, the NSF will conduct investigations without revealing the identity of informants who wish to remain anonymous.<sup>113</sup> However, procedural safeguards notwithstanding, it has been observed that institutions cannot as a practical matter guarantee against disclosure of the identity of either the informants<sup>114</sup> or the subjects of misconduct reviews.<sup>115</sup>

### C. Agency Review of Investigations

The NSF and the NIH/PHS regulations provide for review of all final reports of misconduct investigations prior to the imposition of agency sanctions. Reports received by NIH/PHS are reviewed by the agency's Office of Scientific Integrity to determine whether the investigation was performed in a timely and competent manner.<sup>116</sup> Final recommendations for action are prepared by the PHS Office of Scientific Integrity Review and submitted to the Assistant Secretary for Health.<sup>117</sup> Reports received by the NSF are reviewed by its Office of Inspector General,<sup>118</sup> which provides notice to subjects of the investigation and obtains their comments prior to submitting any recommendations for action to the Deputy Director of NSF.<sup>119</sup> Final

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109. 42 C.F.R. § 50.103(d)(3) (1990).

110. 56 Fed. Reg. 22,286, 22,289 (1991) (to be codified at 45 C.F.R. § 689.4(b)).

111. 42 C.F.R. § 50.104(a)(1) (1990).

112. 42 C.F.R. § 50.103(d)(2) (1990).

113. 56 Fed. Reg. 22,286, 22,289 (1991) (to be codified at 45 C.F.R. § 689.4(b)).

114. See Anderson, *supra* note 24, at 146 (the accused often learns the identity of an informant because the accused knows the informant is the only one holding certain information, or the informant directly confronts the accused).

115. See Robinson, *The Law and University Procedures: An Institutional Perspective*, in AAAS-ABA NATIONAL CONFERENCE OF LAWYERS AND SCIENTISTS, PROJECT ON SCIENTIFIC FRAUD AND MISCONDUCT: REPORT ON WORKSHOP NUMBER THREE 91, 95-96 (1989) [hereinafter NATIONAL CONFERENCE OF LAWYERS AND SCIENTISTS No. 3] (available from AAAS Directorate for Science and Policy Programs, 1333 H Street, N.W., Wash., D.C. 20005).

116. 42 C.F.R. § 50.104(a)(6) (1990).

117. 42 C.F.R. § 50.102 (1990).

118. 56 Fed. Reg. 22,286, 22,289 (1991) (to be codified at 45 C.F.R. § 689.8(a)).

119. *Id.* at 22,290 (to be codified at 45 C.F.R. § 689.8(c)(2)). However, if debar-

NSF actions include, *inter alia*: letters of reprimand; restrictions on a scientist's grant; and, debarment from receipt of agency funds for an individual found guilty of scientific misconduct.<sup>120</sup> Similar sanctions are available to the NIH/PHS.<sup>121</sup> These agency sanctions are in addition to any sanction an institution may impose.<sup>122</sup>

#### IV. SANCTIONS FOR SCIENTIFIC MISCONDUCT

##### A. Debarment

The stiffest sanction either the NIH/PHS or NSF may propose for scientific misconduct is debarment. An individual who is debarred is excluded from financial and nonfinancial assistance under federal programs,<sup>123</sup> including research grants.<sup>124</sup> Debarment by one agency has a government-wide effect as to all other federal programs.<sup>125</sup>

The debarment regulations require that an individual first receive notice of the charges.<sup>126</sup> The individual may then submit information in opposition to the debarment.<sup>127</sup> If the submission raises a genuine issue of material fact, the individual accused is afforded the opportunity to appear with a representative, submit evidence, present witnesses, and confront any witness the agency presents.<sup>128</sup> The proceedings are recorded,<sup>129</sup> and written findings of fact are prepared.<sup>130</sup>

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ment is considered to be appropriate, the case is referred to the debarring official (either the NSF Deputy Director or a designee) and the investigation report is provided to the subject as part of the notice of proposed debarment. This notice includes instructions on how to pursue an appeal. *Id.* at 22,289-290 (to be codified at 45 C.F.R. § 689.8(c)(1)(i)-(iii)).

120. *Id.* at 22,288 (to be codified at 45 C.F.R. § 689.2(a)). Interim or temporary restrictions are also available to the NSF, including suspension of an active grant or proscribing particular research activities. *Id.* (to be codified at 45 C.F.R. § 689.2(b)).

121. These are currently proposed for inclusion in the NIH/PHS regulations. Policies and Procedures for Dealing with Possible Scientific Misconduct in Extramural Research, 56 Fed. Reg. 27,384, 27,393 (1991) (proposed June 13, 1991).

122. Academic institutional actions for scientific misconduct may involve termination for cause of the faculty scientist. *See Olswang and Lee, supra* note 107, at 58.

123. 45 C.F.R. §§ 76.100(a), 620.100(a) (1990).

124. 45 C.F.R. §§ 76.110(a)(1)(i), 620.110(a)(1)(i) (1990).

125. 45 C.F.R. §§ 76.100(a), 620.100(a) (1990). A similar action, suspension, can be invoked by an agency to exclude a person temporarily from participating in federally assisted programs pending completion of an investigation and ensuing legal or debarment proceedings. 45 C.F.R. §§ 76.105(u), 620.105(u) (1990). *See generally* 45 C.F.R. §§ 76.400-420, 620.400-420 (1990) (suspension procedures).

126. 45 C.F.R. §§ 76.312, 620.312 (1990).

127. 45 C.F.R. §§ 76.313(a), 620.313(a) (1990).

128. 45 C.F.R. §§ 76.313(b)(1), 620.313(b)(1) (1990).

129. 45 C.F.R. §§ 76.313(b)(2), 620.313(b)(2) (1990).

Any debarment action imposed must be established by a preponderance of the evidence.<sup>131</sup> Where the individual was convicted of a crime or received a civil judgment against him on a similar set of facts, this standard is deemed satisfied.<sup>132</sup> The period of debarment is for a time commensurate with the seriousness of the cause.<sup>133</sup> In the case of Stephen Breuning, who was debarred for misconduct associated with a grant supported by the PHS, the period was ten years.<sup>134</sup>

### B. Criminal Sanctions: False Statements and False Claims

Criminal prosecution is another means of sanctioning a scientist who engages in scientific misconduct. Serious types of misconduct have been prosecuted by various agencies of the federal government under 18 U.S.C. section 1001, the false statements statute.<sup>135</sup>

The statute is construed broadly,<sup>136</sup> "much more broadly than is necessary to catch miscreants in the scientific community."<sup>137</sup> The statute imposes criminal penalties on a defendant who: (1) knowingly and willfully, (2) made a statement that was (3) false, (4) material, and (5) in a matter within the jurisdiction of a department or agency of the United States.<sup>138</sup> As in other criminal prosecutions, a

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130. 45 C.F.R. §§ 76.314(b)(1), 620.314(b)(1) (1990).

131. 45 C.F.R. §§ 76.314(c)(1), 620.314(c)(1) (1990).

132. *Id.*

133. 45 C.F.R. §§ 76.320(a), 620.320(a) (1990). Generally, this period should not exceed three years unless circumstances warrant. 45 C.F.R. §§ 76.320(a)(1), 620.320(a)(1) (1990). In the recent case of Stanford University psychologist Philip Berger, the period of debarment imposed for scientific misconduct was three years. Berger had reported that human subjects in some studies were drug-free when in fact they were on medication. He also used as normal control subjects individuals who were identified as memory impaired in another study. Palca, *Scientific Misconduct Cases Revealed*, 248 *Sci.* 297 (1990).

134. HHS: Grants Administration; Debarment; Stephen E. Breuning, *supra* note 6, at 47,760.

135. Section 1001 provides that:

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than \$10,000 or imprisoned not more than five years, or both.

18 U.S.C. § 1001 (1988).

136. See *United States v. Rodgers*, 466 U.S. 475, 480-82 (1984); *Bryson v. United States*, 396 U.S. 64, 70 (1969); *United States v. Bramblett*, 348 U.S. 503, 507-08 (1955); *United States v. Gilliland*, 312 U.S. 86, 93 (1941) (construing the predecessor to section 1001); *United States v. Adler*, 380 F.2d 917, 922 (2d Cir.), *cert. denied*, 389 U.S. 1006 (1967).

137. Edgar, *Criminal Law Perspectives on Science Fraud*, in NATIONAL CONFERENCE OF LAWYERS AND SCIENTISTS NO. 3, *supra* note 115, at 139.

138. *United States v. Whitaker*, 848 F.2d 914, 916-17 (8th Cir. 1988); *United States v. Brantley*, 786 F.2d 1322, 1326 (7th Cir.), *cert. denied*, 477 U.S. 908 (1986);

successful prosecution under section 1001 requires that each of the applicable elements be proven beyond a reasonable doubt.<sup>139</sup> The requisite "statement" covers both sworn and unsworn statements,<sup>140</sup> oral and written.<sup>141</sup> Materiality is established if the statement was merely capable of influencing the exercise of a government function.<sup>142</sup> No actual reliance or loss as a result of the statement need be shown.<sup>143</sup> The element of "knowingly and willfully" is satisfied if the defendant acts deliberately and with knowledge of the falsity of the statement,<sup>144</sup> or with a reckless disregard of the truth and a con-

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United States v. Notarantonio, 758 F.2d 777, 785 (1st Cir. 1985); United States v. Fitzgibbon, 619 F.2d 874, 879 (10th Cir. 1980); see also United States v. Gahagan, 881 F.2d 1380, 1382 (6th Cir. 1989); United States v. Seay, 718 F.2d 1279, 1284 (4th Cir. 1983), cert. denied, 467 U.S. 1226 (1984); United States v. Lichenstein, 610 F.2d 1272, 1276 (5th Cir.), cert. denied, 447 U.S. 907 (1980). See generally Peterson and Parker, *The Federal "False Statements" Statute: Workhorse of White Collar Prosecutions*, 25 GA. ST. B.J. 85 (1988); Survey, *White-Collar Crime: A Survey of the Law*, 18 AM. CRIM. L. REV. 169, 273-80 (1980).

139. See Moore v. United States, 429 U.S. 20, 22 (1976); United States v. White Horse, 807 F.2d 1426, 1429 (8th Cir. 1986); United States v. Alvarez, 755 F.2d 830, 842 n.12 (11th Cir.), cert. denied, 474 U.S. 905 (1985).

140. See United States v. Adler, 380 F.2d 917, 922 (2d Cir.), cert. denied, 389 U.S. 1006 (1967); see also United States v. Des Jardins, 772 F.2d 578, 580 (9th Cir. 1985).

141. See United States v. Beacon Brass Co., 344 U.S. 43, 46 (1952); United States v. Massey, 550 F.2d 300, 305 (5th Cir. 1977); see also United States v. Worthington, 822 F.2d 315, 317-19 (2d Cir.) (making of check drawn on knowingly fictitious bank is a false statement under section 1001), cert. denied, 484 U.S. 944 (1987); United States v. Des Jardins, 772 F.2d at 580 (section 1001 conviction for false oral, unsworn statement to customs agent). Each false statement made in separate documents or transactions constitutes a separate count of the offense. See United States v. Segall, 833 F.2d 144, 147-48 (9th Cir. 1987) (three separate statements made by customs broker sufficient to support conviction for each of three separate counts of violating section 1001 in matter within jurisdiction of customs service); United States v. Guzman, 781 F.2d 428, 433 (5th Cir.) (two false representations of name made in separate documents in matter within jurisdiction of Social Security Administration constitute separate offenses of section 1001), cert. denied, 475 U.S. 1143 (1986).

142. United States v. Land, 877 F.2d 17, 20 (8th Cir.) cert. denied, 110 S. Ct. 243 (1989); United States v. Gafyczk, 847 F.2d 685, 691 (11th Cir. 1988); United States v. Rodriguez-Rodriguez, 840 F.2d 697, 700 (9th Cir. 1988); United States v. Brantley, 786 F.2d 1322, 1326 (7th Cir.), cert. denied, 477 U.S. 908 (1986); United States v. Notarantonio, 758 F.2d 777, 785 (1st Cir. 1985); see also Kungys v. United States, 485 U.S. 759, 770 (1988).

143. United States v. Rodriguez-Rodriguez, 840 F.2d at 700; United States v. Campbell, 848 F.2d 846, 852 (8th Cir. 1988); see also United States v. Kwait, 817 F.2d 440, 445 (7th Cir.), cert. denied, 484 U.S. 924 (1987).

144. United States v. Guzman, 781 F.2d 428, 431 (5th Cir.), cert. denied, 475 U.S. 1143 (1986); see also United States v. Carrier, 654 F.2d 559, 561 (9th Cir. 1981). Proof of actual knowledge of federal agency jurisdiction, however, is not required for a conviction under section 1001. United States v. Yermian, 468 U.S. 63, 69-70 (1984).

scious purpose to avoid learning the truth.<sup>145</sup> The statement in question must be proven false; if it is ambiguous, it must be proven false under any reasonable interpretation.<sup>146</sup> The jurisdictional element is satisfied when a federal agency has the power to exercise authority with regard to the matter where the statement was made.<sup>147</sup> Thus, any application or report submitted for a research grant to a government agency by an individual who knows that it contains false or fabricated data is a violation of this statute.<sup>148</sup> The submission of another's words as one's own also constitutes a violation.<sup>149</sup> Furthermore, it is not necessary that the false statement be presented directly to any agency of the government as long as federal funds are involved.<sup>150</sup> Thus it is sufficient for liability if a submission for a grant is supported by a publication appearing elsewhere that the applicant knows is based on data that is falsified or fabricated.<sup>151</sup> It is under this statute that Stephen Breuning was successfully prosecuted by the U.S. Attorney's Office for submitting false data to the PHS in support of a grant.<sup>152</sup>

Criminal sanctions may also be imposed for scientific misconduct under 18 U.S.C. section 287, the criminal false claims statute.<sup>153</sup> Here the government must prove beyond a reasonable doubt that the defendant: (1) made or presented a claim to a United States government agency; (2) that the claim was false, fictitious, or fraudulent; and (3) that the defendant knew the claim was false, fictitious, or

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145. *United States v. White*, 765 F.2d 1469, 1482 (11th Cir. 1985); *see also* *United States v. Evans*, 559 F.2d 244, 246 (5th Cir.), *cert. denied*, 434 U.S. 1015 (1978).

146. *United States v. Adler*, 623 F.2d 1287, 1289 (8th Cir. 1980); *see also* *United States v. Gahagan*, 881 F.2d 1380, 1384 (6th Cir. 1989); *United States v. Race*, 632 F.2d 1114, 1120 (4th Cir. 1980).

147. *United States v. Rodgers*, 466 U.S. 475, 479 (1984); *United States v. Oren*, 893 F.2d 1057, 1064 (9th Cir. 1990); *see also* *United States v. Gibson*, 881 F.2d 318, 322 (6th Cir. 1989).

148. *Edgar*, *supra* note 137, at 139.

149. *Id.* at 140.

150. *United States v. Brantley*, 786 F.2d 1322, 1326 (7th Cir.), *cert. denied*, 477 U.S. 908 (1986); *United States v. Petullo*, 709 F.2d 1178, 1180 (7th Cir. 1983); *United States v. Wolf*, 645 F.2d 23, 25 (10th Cir. 1981); *see also* *United States v. Gibson*, 881 F.2d at 322; *United States v. Suggs*, 755 F.2d 1538, 1542 (11th Cir. 1985).

151. *Edgar*, *supra* note 137, at 140.

152. *United States v. Breuning*, Criminal No. K-88-0135 (D.C. Md. Nov. 10, 1988).

153. Section 287 provides that:

Whoever makes or presents to any person or officer in the civil, military, or naval service of the United States, or to any department or agency thereof, any claim upon or against the United States, or any department or agency thereof, knowing such claim to be false, fictitious, or fraudulent, shall be imprisoned not more than five years and shall be subject to a fine in the amount provided in this title.

18 U.S.C. § 287 (1988).

fraudulent.<sup>154</sup> In contrast to a false statements offense, a false claims violation requires proof of a claim and its actual presentation to the government. The term "claim," as held by the Supreme Court, "reaches beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the [g]overnment to pay out sums of money."<sup>155</sup> A claim is false, fictitious, or fraudulent if it is untrue and known to be untrue when made.<sup>156</sup> The element of making and presenting a claim is broadly construed. The defendant need not make a direct demand to any agency or department of the United States; claims submitted through an intermediary will suffice.<sup>157</sup> Furthermore, it is not necessary that the claim actually be honored.<sup>158</sup> However, knowledge of the claim as false or fraudulent is a requisite. Courts have differed on the culpability sufficient to satisfy this element: some require knowledge of falsity,<sup>159</sup> some specify an intent to defraud,<sup>160</sup> and still others hold that knowledge can be inferred

154. *United States v. Computer Sciences Corp.*, 511 F. Supp. 1125, 1134 (E.D. Va.), *rev'd on other grounds*, 689 F.2d 1181 (4th Cir. 1982), *cert. denied*, 459 U.S. 1105 (1983); *see also* *United States v. Jackson*, 845 F.2d 880, 883 (9th Cir.), *cert. denied*, 488 U.S. 857 (1988); *United States v. Causey*, 835 F.2d 1289, 1292 (9th Cir. 1987); *United States v. Ferguson*, 793 F.2d 828, 831 (7th Cir.), *cert. denied*, 479 U.S. 933 (1986); *United States v. Slocum*, 708 F.2d 587, 596 (11th Cir. 1983). *See generally* Overly, *Government Contractors, Beware: Civil and Criminal Penalties Abound for Defective Pricing*, 20 LOYOLA L. REV. 597, 627-30 (1987); Survey, *supra* note 138, at 281-86.

155. *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968) (construing intent of language of the original False Claims Act, which had both criminal and civil provisions (now separately codified at 18 U.S.C. sections 287 and 1001 (1988), and 31 U.S.C. sections 3729-3733 (1988), respectively)); *see also* *United States v. Jackson*, 845 F.2d at 883 (approving an instruction on a definition of "claim" as a demand for money or transfer of public property or an attempt to cause the government to pay out sums of money).

156. *See* *United States v. Dorotich*, 900 F.2d 192, 194 n.2 (9th Cir. 1990); *United States v. Irwin*, 654 F.2d 671, 683 n.15 (10th Cir. 1981), *cert. denied*, 455 U.S. 1016 (1982), *overruled on other grounds*, *United States v. Daily*, 921 F.2d 994, 1004 n.11 (10th Cir. 1990); *United States v. Milton*, 602 F.2d 231, 233 n.6 (9th Cir. 1979). A fraudulent claim, as opposed to one that is false or fictitious, may also require an intent to deceive. *See* *United States v. Irwin*, 654 F.2d at 683 n.15; *United States v. Milton*, 602 F.2d at 233.

157. *United States v. Blecker*, 657 F.2d 629, 633-34 (4th Cir. 1981), *cert. denied*, 454 U.S. 1150 (1982). *See also* *United States v. Campbell*, 845 F.2d 1374, 1382 (6th Cir.) (where a physician submits a Medicare claim to the government through an insurer, and the physician knows that the treatments were unnecessary, the physician is liable under section 287), *cert. denied*, 488 U.S. 908 (1988).

158. *United States v. Coachman*, 727 F.2d 1293, 1302 (D.C. Cir. 1984); *see also* *United States v. Miller*, 545 F.2d 1204, 1212 n.10 (9th Cir. 1976) (filing of false tax return to obtain an unjustified refund will suffice to establish a false claim under section 287), *cert. denied*, 430 U.S. 930 (1977).

159. *United States v. Precision Medical Laboratories, Inc.*, 593 F.2d 434, 443 (2d Cir. 1978); *see also* *United States v. Blecker*, 657 F.2d at 634.

160. *United States v. Campbell*, 845 F.2d at 1383; *see also* *United States v. Rifien*,

from a reckless disregard for the truth and a conscious effort to avoid learning the truth.<sup>161</sup> Although neither willfulness nor materiality appear in the statute, some courts apply them as standards or elements while others do not.<sup>162</sup> Thus, depending on the jurisdiction, a scientist who knowingly makes false or fraudulent entries in a grant application presented to a government agency is in violation of section 287. Such an allegation may be supported by reason that the act of supplying false information constitutes a fraudulent attempt to cause the government to pay money to finance research.

The penalties for false claims and false statements offenses vary with the date of commission. Sections 287 and 1001 provide for a maximum prison sentence of five years for each violation.<sup>163</sup> For offenses committed prior to December 31, 1984, the monetary penalties contained in the statutes apply.<sup>164</sup> For those committed after December 31, 1984, an individual can be fined as much as \$250,000.<sup>165</sup>

In addition to sections 287 and 1001, other criminal statutes might also be implicated in certain cases of scientific misconduct. For example, if the elements of an applicable criminal statutory offense cannot be established, a scientist might still be liable under 18 U.S.C. section 2.<sup>166</sup> Section 2 criminalizes aiding and abetting a

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577 F.2d 1111, 1113 (8th Cir. 1978). *Contra* United States v. Milton, 602 F.2d at 234 (intent to defraud not an element of section 287 offense); *see also* United States v. Maher, 582 F.2d 842, 847 (4th Cir. 1978) (section 287 does not require a specific intent to defraud), *cert. denied*, 439 U.S. 1115 (1979).

161. *See* United States v. Gold, 743 F.2d 800, 821-22 (11th Cir. 1984), *cert. denied*, 469 U.S. 1217 (1985); United States v. Holloway, 731 F.2d 378, 380-81 (6th Cir.), *cert. denied*, 469 U.S. 1021 (1984); United States v. Cook, 586 F.2d 572, 579-80 (5th Cir. 1978), *cert. denied*, 442 U.S. 909 (1979).

162. The willfulness standard has been approved as applied in jury instructions in section 287 prosecutions. *See* United States v. Milton, 602 F.2d at 233 n.6; United States v. Maher, 582 F.2d at 845-47; *But see* United States v. Ferguson, 793 F.2d 828, 831 (7th Cir. 1986) (government need not prove defendant acted willfully), *cert. denied*, 479 U.S. 933 (1986); United States v. White, 765 F.2d 1469, 1472 (11th Cir. 1985) (section 287 omits willfulness as an element); United States v. Irwin, 654 F.2d 671, 682 (10th Cir. 1981) (willfulness is not an essential element of section 287), *cert. denied*, 455 U.S. 1016 (1982); *overruled on other grounds*, United States v. Daily, 921 F.2d 994, 1004 n.11 (10th Cir. 1990); United States v. Cook, 586 F.2d at 575 (same). Materiality has been deemed an element of section 287. United States v. Pruitt, 702 F.2d 152, 155 (8th Cir. 1983); United States v. Adler, 623 F.2d 1287, 1291 n.5 (8th Cir. 1980). *Contra* United States v. Elkin, 731 F.2d 1005, 1009 (2d Cir.), *cert. denied*, 469 U.S. 822 (1984); United States v. Irwin, 654 F.2d at 682.

163. *See supra* notes 135 and 153.

164. Section 1001 provides for maximum fine of \$10,000. 18 U.S.C. section 1001 (1988). Section 287, prior to amendment in 1986, provided for the same. Public law 99-562 amended section 287, substituting "imprisoned not more than five years and shall be subject to a fine in the amount provided in this title" for "fined not more than \$10,000 or imprisoned not more than five years, or both." Pub. L. No. 99-562, § 7, 100 Stat. 3169 (1986).

165. 18 U.S.C. § 3623(a) (1988) (repealed 1984) (for offenses committed after December 31, 1984 and before November 1, 1987); 18 U.S.C. § 3571(b) (1988) (for offenses committed on or after November 1, 1987).

166. Section 2 provides that:

principal to violate a criminal statute. Thus, a scientist who counsels or otherwise causes another individual to carry out the proscribed acts may be liable for the substantive offense of false statements or false claims under a section 2 prosecution. In the case of Stephen Breuning, counts one and two of the false statements conviction were under section 2, aiding and abetting.<sup>167</sup>

### *C. Civil Sanctions under the Federal False Claims Act*

Cases of scientific misconduct may also invoke civil sanctions pursuant to the federal civil False Claims Act (FCA).<sup>168</sup> Commonly considered a tool against defense contract fraud, the FCA authorizes the government or a private *qui tam* plaintiff<sup>169</sup> to bring an action to recover on a false claim upon the United States. The 1986 amendments to the FCA<sup>170</sup> greatly expand the feasibility of such suits, increasing the likelihood that those who engage in scientific misconduct will be held liable for FCA penalties and damages. Two cases of scientific misconduct were recently filed under the amended FCA provisions.<sup>171</sup>

31 U.S.C. section 3729(a) delineates conduct giving rise to liability under the FCA.<sup>172</sup> The elements of a claim under the FCA are:

(a) Whoever commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission, is punishable as a principal.

(b) Whoever willfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal.

18 U.S.C. § 2 (1988).

167. *United States v. Breuning*, Criminal No. K-88-0135 (D.C. Md. Nov. 10, 1988).

168. 31 U.S.C. §§ 3729-3733 (1988).

169. "A *qui tam* action is one in which the plaintiff sues for himself and on behalf of the government to recover a penalty under a statute which provides that part of the penalty is awarded to the party bringing the suit and the remainder of the penalty is awarded to the government." *United States ex rel. Wis. v. Dean*, 729 F.2d 1100, 1102 n.1 (7th Cir. 1984). See also *United States ex rel. LeBlanc v. Raytheon Co.*, 729 F. Supp. 170, 171 n.1 (D. Mass 1990), *aff'd*, 913 F.2d 17 (1st Cir. 1990), *cert. denied*, 111 S. Ct. 1312 (1991). *Qui tam* is derived from the latin expression "*qui tam pro domino rege quam pro seipso*," which means "he who as much for the king as for himself." See Note, *The History and Development of Qui Tam*, 1972 WASH. U.L.Q. 81, 83 (1972).

170. False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (codified at 31 U.S.C. §§ 3729-3733). See generally Oparil, *The Coming Impact of the Amended False Claims Act*, 22 AKRON L. REV. 525 (1989); Waldman, *The 1986 Amendments to the False Claims Act: Retroactive or Prospective?*, 18 PUB. CONT. L.J. 469 (1989).

171. Palca, *Old Law Puts a New Wrinkle in Fraud Probes*, 247 Sci. 802 (1990).

172. Section 3729(a) provides, in relevant part:



(1) that the defendant presented or caused to be presented to an agent of the United States a claim for payment, or made or used or caused to be made or used a record or statement to get a claim against the United States paid or approved; (2) that the claim and record or statement were false or fraudulent; (3) that the defendant knew of the falsity or fraud; and (4) that the United States sustained damages as a result.<sup>173</sup> Liability for each false claims offense carries a civil penalty as high as \$10,000 plus three times the amount of damages sustained by the government.<sup>174</sup> These figures represent an increase over those in the old FCA,<sup>175</sup> which provided for \$2,000 penalties and double damages.<sup>176</sup>

The standard of liability and burden of proof are expressly delineated in the amended FCA. These are lower than those required by courts construing the old FCA, which failed to delineate such standards. Under the language of the old FCA, some courts applied a clear and convincing standard of proof for civil FCA prosecutions.<sup>177</sup> The amended FCA requires that all elements of a cause of action be established by a preponderance of the evidence.<sup>178</sup> The standard of liability is knowledge of the information, including actual knowledge, or deliberate ignorance or reckless disregard of the truth.<sup>179</sup> Proof of specific intent to defraud, held a requisite by some courts under the

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(a) Liability For Certain Acts. — Any person who —

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; . . . is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person. . . .

31 U.S.C. § 3729(a) (1988).

173. See *United States ex rel. Stinson v. Provident Life*, 721 F. Supp. 1247, 1258-59 (S.D. Fla. 1989); *United States v. Board of Educ. of Union City*, 697 F. Supp. 167, 174 (D.N.J. 1988); *United States v. Diamond*, 657 F. Supp. 1204, 1205 (S.D.N.Y. 1987); *Blusal Meats, Inc. v. United States*, 638 F. Supp. 824, 827 (S.D.N.Y. 1986), *aff'd*, 817 F.2d 1007 (2d Cir. 1987); *United States ex rel. Fahner v. Alaska*, 591 F. Supp. 794, 797-98 (N.D. Ill. 1984); *United States v. Lawson*, 522 F. Supp. 746, 750 (D.N.J. 1981).

174. 31 U.S.C. § 3729(a) (1988).

175. The "old FCA" refers to the False Claims Act prior to the 1986 Amendments. The latest version of the old FCA appears at 31 U.S.C. sections 3729-3731 (1982) (amended 1986).

176. 31 U.S.C. § 3729 (1982) (amended 1986).

177. See *United States v. Ekelman & Associates, Inc.*, 532 F.2d 545, 548 (6th Cir. 1976); *United States v. Lawson*, 522 F. Supp. 746, 749-50 (D.N.J. 1981). *But see Federal Crop Insurance v. Hester*, 765 F.2d 723, 727-28 (8th Cir. 1985) (preponderance of the evidence standard deemed appropriate); *United States v. Thomas*, 709 F.2d 968, 971-72 (5th Cir. 1983) (applying a preponderance of the evidence standard).

178. 31 U.S.C. § 3731(c) (1988).

179. 31 U.S.C. § 3729(b) (1988).

old FCA,<sup>180</sup> is not required.<sup>181</sup> The term "claim" is broadly defined to include "any request or demand . . . for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion [thereof]."<sup>182</sup> Thus, similar to a criminal case under false claims,<sup>183</sup> a scientist who knowingly presents or uses false data or a statement in support of a grant application for research monies to the NIH/PHS, as a grantee of federal funds, is in violation of the FCA. Likewise, proof of damages is not required for application of the FCA penalty.<sup>184</sup> Unlike false claims, however, actual damages caused by the violation must be proven before the full measure of FCA damages is awarded.<sup>185</sup> Where the prosecution can meet its burden of proof on this element, a defendant convicted and punished on the basis of the same conduct in a prior criminal false claims proceeding can be liable for a second sanction proportionate to the penalties and damages assessed in a civil FCA proceeding.<sup>186</sup>

The amended FCA lowers the jurisdictional requirements for the

180. See *United States v. Aerodex, Inc.*, 469 F.2d 1003, 1007 (5th Cir. 1972); *United States v. Mead*, 426 F.2d 118, 122-23 (9th Cir. 1970). *But see* *United States v. Hughes*, 585 F.2d 284, 287-88 (7th Cir. 1978) (government need not prove intent to defraud); *United States v. Ekelman & Associates, Inc.*, 532 F.2d at 548 (proof of actual knowledge required); *United States v. Cooperative Grain and Supply Co.*, 476 F.2d 47, 56 (8th Cir. 1973) (knowing submission of false claim sufficient).

181. "[N]o proof of specific intent to defraud is required." 31 U.S.C. § 3729(b) (1988).

182. 31 U.S.C. § 3729(c) (1988).

183. See *supra* notes 153-62 and accompanying text.

184. *United States v. Killough*, 848 F.2d 1523, 1533-34 (11th Cir. 1988); *United States ex rel. Luther v. Consolidated Industries*, 720 F. Supp. 919, 922 (N.D. Ala. 1989); *United States v. Board of Educ. of Union City*, 697 F. Supp. 167, 177 (D.N.J. 1988); *Blusal Meats, Inc. v. United States*, 638 F. Supp. 824, 827 (S.D.N.Y. 1986), *aff'd*, 817 F.2d 1007 (2d Cir. 1987); *United States v. Silver*, 384 F. Supp. 617, 620 (E.D.N.Y. 1974), *aff'd mem.*, 515 F.2d 505 (2d Cir. 1975).

185. *United States ex rel. Luther v. Consolidated Industries*, 720 F. Supp. at 923; see also *United States v. Hill*, 676 F. Supp. 1158, 1180 (N.D. Fla. 1987).

186. See *United States v. Pani*, 717 F. Supp. 1013, 1017-19 (S.D.N.Y. 1989); *United States v. Diamond*, 657 F. Supp. 1204, 1205-06 (S.D.N.Y. 1987). However, the Supreme Court recently indicated that the application of FCA penalties subsequent to criminal false claims penalties may constitute multiple punishment violative of the Double Jeopardy Clause of the Fifth Amendment to the U.S. Constitution. *United States v. Halper*, 109 S. Ct. 1892 (1989). In *Halper*, the Court held that in the rare case where a prolific but small-gauge offender previously has sustained a criminal penalty and the civil penalty sought in the subsequent proceeding bears no rational relation to the goal of compensating the government for its loss, but rather appears to qualify as "punishment," the defendant is entitled to an accounting of the government's damages so that the trial court may determine whether the penalty sought amounts to a second punishment violative of the Clause and set the size of the civil sanction without crossing the line between remedy and punishment. *Id.* at 1902.

private initiation of FCA lawsuits. Under the old FCA, a private person could not bring an action based on evidence or information the government already knew.<sup>187</sup> This jurisdictional bar is eliminated in the amended FCA. Instead, the amended statute precludes a private *qui tam* suit if it is based on information publicly disclosed in: (1) a criminal, civil, or administrative hearing; (2) a Government Accounting Office report or investigation; or (3) a news media report.<sup>188</sup> Furthermore, even when the allegations are based on publicly disclosed information, an action can still be maintained if the person bringing suit qualifies as an "original source."<sup>189</sup> An original source is an individual who has direct and independent knowledge of the information and has provided it voluntarily to the government before filing suit.<sup>190</sup> Thus, a whistleblower, who is an original source of information concerning a case of scientific misconduct, could still bring suit based on that information if the government failed to take action.

The amended FCA also offers strong incentives for individuals to exercise a private right of action under the statute. When a private *qui tam* plaintiff files an action, the complaint is served on the United States and remains under seal for sixty days while the government determines whether to intervene and direct the action.<sup>191</sup> If the government elects to proceed, "it shall have the primary responsibility for prosecuting the action,"<sup>192</sup> and the *qui tam* plaintiff continues as a party to the action.<sup>193</sup> Alternatively, if the government elects not to proceed, the *qui tam* plaintiff may conduct the action.<sup>194</sup> In a successful action, the *qui tam* plaintiff receives reasona-

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187. 31 U.S.C. § 3730(b)(4) (1982) (amended 1986); *see also* United States *ex rel.* Wis. v. Dean, 729 F.2d at 1103 (jurisdictional bar of the FCA applies when the government has prior knowledge of the information on which the suit is based, even if the plaintiff is the source of that information).

188. 31 U.S.C. § 3730(e)(4)(A) (1988). Other *qui tam* actions that are barred under the statute include: (1) actions brought by members of the armed forces against members of the armed forces arising out of such persons' service in the armed forces; (2) actions brought against a member of Congress, the judiciary, or a senior executive branch official if the action is based on information already known to the government; (3) actions based on information which is the subject of a civil suit or an administrative civil money penalty proceeding in which the government is already a party. 31 U.S.C. § 3730(e)(1)-(3).

189. 31 U.S.C. § 3730(e)(4)(A) (1988); Houck *ex rel.* United States v. Folding Carton Admin. Comm., 881 F.2d 494, 504 (7th Cir. 1989), *cert. denied*, 110 S. Ct. 1471 (1990); *see also* United States *ex rel.* Stinson v. Provident Life, 721 F.Supp. 1247, 1257-58 (S.D. Fla. 1989) (even though some information forming the basis of suit was obtained during prior state civil litigation, law firm was a proper *qui tam* plaintiff because it qualified as an original source).

190. 31 U.S.C. § 3730(e)(4)(B) (1988).

191. 31 U.S.C. § 3730(b)(2) (1988).

192. 31 U.S.C. § 3730(c)(1) (1988).

193. *Id.*

194. 31 U.S.C. § 3730(c)(3) (1988).

ble expenses and attorney fees plus a percentage of the proceeds: a maximum of 25% if the government directs the case<sup>195</sup> and a maximum of 30% if the *qui tam* plaintiff conducts the action.<sup>196</sup> These percentages are higher than those in the old FCA, which provided for maximums of 10% and 25%, respectively.<sup>197</sup> Moreover, the amended FCA imposes liability on employers who discharge or discriminate against employees because they bring or assist in an FCA proceeding, authorizing double back pay, damages, and attorney fees.<sup>198</sup> Thus, in addition to increased awards, FCA plaintiffs and informers enjoy employment protections not available under the old FCA. To the extent that whistleblowers informing on suspected scientific misconduct have experienced employment sanctions in the past,<sup>199</sup> they stand to benefit from these protections as FCA plaintiffs or informants.

## V. CONCLUSION

Scientific misconduct in academia is a multifaceted, potentially widespread problem with significant legal implications. Factors including the nature of medical education, the academic promotions system, and the apparent shortcomings in institutional self-regulation and editorial peer review all promote an environment that fosters this problem. Current federal efforts to regulate misconduct in science place the burden of responsibility for investigation of cases upon awardee institutions. They further allow flexibility in the adoption of procedures consistent with due process, attempt to ensure confidentiality of participants and provide for review of investigations at the federal agency level. Sanctions for those guilty of scientific misconduct range from debarment from federal programs supporting research to the imposition of substantial fines and imprisonment under federal statutes prohibiting false statements and

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195. 31 U.S.C. § 3730(d)(1) (1988).

196. 31 U.S.C. § 3730(d)(2) (1988). However, the amended FCA also offers some benefits to a defendant who prevails against a bad faith claimant. Section 3730(d)(4) provides:

If the [g]overnment does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

31 U.S.C. § 3730(d)(4) (1988).

197. 31 U.S.C. § 3730(c) (1982) (amended 1986).

198. 31 U.S.C. § 3730(h) (1988).

199. See *supra* note 68 and accompanying text.

false claims. One such sanction, the amended FCA, could have broad application to the prosecution of serious misconduct because of the lowered requirements and increased potential benefits accorded private individuals qualifying for a right of action under the statute.

A comprehensive program designed to deal with scientific misconduct requires that effective prevention and detection measures be implemented. While the current federal provisions help fulfill a need for deterrence and ensure timely, responsible institutional reviews of misconduct cases, they address the problem in an ex post facto fashion. Efforts targeted toward changing the environment that promotes misconduct and the dissemination of tainted research results should be made. This will require individual academic institutions to adopt self-policing activities to ensure quality research and valid reporting of results. Comprehensive standards of ethical conduct for researchers must also be developed and applied. The solution should include minimizing the pressure to publish for promotion, developing institutional policies that ensure discipline in the conduct of research, and increasing editorial oversight and verification by scientific journals.

The current regulations structuring the response of the academic community to the problem of scientific misconduct are fairly recent. There has not been sufficient time since the application of increased federal oversight to assess the efficacy of existing regulations. Together with more rigorous application of the FCA and other statutory sanctions, current federal efforts may be sufficient to deter future misconduct in science. If it is not, and the scientific community fails to adequately respond to the need for prevention and detection, increased federal regulatory measures may be necessary to control and correct scientific misconduct. The risk will be the end of self-regulation in science.

C. BETH SISE