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## SCIENTIFIC RESPONSIBILITY AND THE LAW

Harold P. Green\*

During the past decade, the scientific community has been perturbed by a series of revelations of scientific misconduct. some including apparent outright fraud or falsification in the conduct or reporting of research. The inferences to be drawn from these revelations are matters of disagreement.<sup>1</sup> Some scientists believe that publicity about these affairs has been "grossly exaggerated," conveying the erroneous impression that fraud in science is widespread, thereby damaging the image of science. and that the mistakes and misinterpretations that do occur are inevitably detected and corrected.<sup>2</sup> Others worry that the recent disclosures signify that fraud in science is widespread, and that these instances of misconduct may represent only the tip of the iceberg. One study found thirty-four cases of "known or suspected cases of scientific fraud" from Hipparchus in ancient Greece to the immunologist Arthur Hale in 1981. Even more disturbing, fifteen of these cases are post-1970.<sup>3</sup>

The two views of scientific misconduct can be capsulized in the comments of Dr. Phillip Handler, former President of the National Academy of Sciences, and the book by Nicholas Wade and William Broad, two journalists who have investigated scientific fraud. Dr. Handler, speaking before a House Subcommittee, argued that, because exposure of scientific fraud is inevitable, only "psychopathic behavior" or "minds which . . . may be considered deranged" will produce fraud.<sup>4</sup> On the other hand, Broad and Wade assert that Handler's "conventional ideology of science" cannot explain the phenomenon of fraud. In their view,

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<sup>1.</sup> See Sigma XI, The Scientific Research Soc'y, Honor In Science 1-2 (1984) [here-inafter Sigma XI].

<sup>2.</sup> See Fraud in Biomedical Research: Hearings on Fraud in Biomedical Research Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology, 97th Cong., 1st Sess. 10-39 (1981) [hereinafter Hearings on Fraud] (statements of Dr. Philip Handler, President, National Academy of Sciences, and Dr. Donald Frederickson, Director, National Insts. of Health).

<sup>3.</sup> W. BROAD & N. WADE, BETRAYERS OF THE TRUTH 225-32 (1982).

<sup>4.</sup> Hearings on Fraud, supra note 2, at 20-21.

scientists have a dual motivation: to understand the world and to obtain personal recognition. Fraud, they say, is a phenomenon that has occurred throughout the history of science, and many of those who committed fraud—including such luminaries as Newton, Mendel, and Millikan—did so to persuade their colleagues of a theory they knew to be correct even though their experiments did not turn out exactly as expected.<sup>5</sup> Accordingly, "history has been kind to scientists such as these . . . because the theories turned out to be correct."<sup>6</sup> Whatever the reason, although in the past "[t]he occasional instances of misconduct were thought to be unique . . ., [m]ore recent experience suggests that, at the very least, the incidence of reported misconduct has increased."<sup>7</sup>

The scientific community has been sufficiently shaken by recent experiences that many associations, universities, and research institutions have moved to establish procedures for dealing with misconduct in science. The underlying rationale is succinctly stated in a report published by the Association of American Medical Colleges (AAMC):<sup>8</sup>

The responsibility of the scientific community to the public is acknowledged. The maintenance of public trust in this pursuit is vital to the continuing vigor of the biomedical research enterprise. Loss of this trust because of isolated instances of dishonest behavior on the part of a few researchers could cause great harm by calling into question in the mind of the public the validity of all new knowledge and the integrity of the scientific community at large. In short, it is in the best interest of the public and of academic medicine to prevent misconduct in research and to deal effectively and responsibly with instances where misconduct is suspected.<sup>9</sup>

Although Dr. Handler's view was that "falsification of data . . . need not be a matter of general societal concern,"<sup>10</sup> the AAMC's rationale compels recognition that scientific fraud is indeed a matter of societal concern. The responsibility of the scientific

<sup>5.</sup> W. BROAD & N. WADE, supra note 3, at 212-13.

<sup>6.</sup> Id. at 213.

<sup>7.</sup> Special Issue—Policies and Procedures For Dealing with Possible Misconduct in Science, 15 NIH GUIDE, July 18, 1986, at 1 [hereinafter Special Issue].

<sup>8.</sup> Association of Am. Medical Colleges, The Maintenance of High Ethical Standards in the Conduct of Research (1982) [hereinafter AAMC Report].

<sup>9.</sup> Id. at 1.

<sup>10.</sup> Hearings on Fraud, supra note 2, at 10.

community to the public flows from the fact that scientific research, at least in the nonprofit sector, is funded largely by the federal government. Indeed, the reaction to Dr. Handler's point of view at a hearing before a House Subcommittee ranged from astonishment to outrage.<sup>11</sup>

Because public policy is implicated by scientific misconduct, the legal profession should be interested in overcoming this problem. This Article studies the scientific misconduct problem and provides a personal view of the legal dilemmas that confront those who report misconduct. Part I describes how the scientific community currently deals with alleged fraud. Scientists primarily rely on the peer review system and toothless guidelines. Part II illustrates the problems in the present system through a case study of an allegation of misconduct. The author represented a man who reported scientific misconduct; the National Institutes of Health (NIH) investigation took five and one-half years. This Article concludes that lawyers should become more involved in the investigation and adjudication of scientific fraud to assist the scientific community in preserving the due process rights of the accused, maintaining the integrity of the scientific community, and encouraging exposure of misconduct.

### I. EXISTING APPROACHES TO DEALING WITH MISCONDUCT

Only five years ago, very few institutions had given any significant thought to the problem of dealing with scientific misconduct. As Dr. Handler testified, "I will admit . . . the absence of any sense of what due process should be when some suspicion is aroused."<sup>12</sup> To be sure, the problems of due process are daunting. First, the substantive content of "misconduct" has never been defined in a generally accepted manner. A significant question is whether the elements of misconduct should be codified, or whether they should evolve, like the common law, on a caseby-case basis. Second, an allegation of scientific fraud can impact substantially on several important interests that warrant protection.

Obviously an allegation of fraud, regardless of how it is resolved, can have a profound effect on the career of the alleged wrongdoer. It may also impact his or her supervisors and coau-

<sup>11.</sup> Hearings on Fraud, supra note 2.

<sup>12.</sup> Id. at 43.

thors.<sup>13</sup> as well as those who "refereed" the reports of the research prior to publication. The employing institution is in a potential "catch-22" situation. A confirmation that fraud has taken place suggests that the institution has employed less than adequate supervisory, review, and quality control procedures, and this cannot help but be damaging to the institution. On the other hand, failure to seek out the truth could be equally damaging. If the research has been publicly funded, particularly if it is in some way politically sensitive, allegations of fraud could produce substantial political fallout. If the suggestion or accusation of fraud comes from a "whistle-blower" colleague, that colleague has an interest in how the matter is handled. Whistleblowers are subject to retaliatory action by the institution, by colleagues, and by the accused. They, however, should be held accountable if it turns out that the allegations were clearly unfounded, irresponsible, or viciously motivated.

It is understandable that scientists would have some difficulty in coping unassisted with due process implications of such issues. If, however, these issues raise public policy questions requiring changed procedures and reform of long-accepted principles, the legal profession has a great deal to offer science in a serious and constructive effort to cope with these new, or newly perceived, problems.

#### A. The Peer Review System

Science is a vast enterprise embracing many diverse disciplines. These disciplines are frequently broken down into subdisciplines. The disciplines, and often the subdisciplines, may have little in common with each other except that they are all concerned with the acquisition of knowledge and the pursuit of truth. Although it has been asserted that "the principles governing the way that research is carried out and reported are the same in geography as in physics, in medicine as in archaeology," it must also be recognized that "habits and conventions" differ from one field to another.<sup>14</sup>

Science is not a profession like medicine and law. One does not need a license to practice science; and, although those scien-

<sup>13.</sup> It was reported in February 1987 that a respected NIH scientist committed suicide as a result of pressures resulting from an investigation he helped initiate of alleged scientific fraud by a member of his staff. NIH Scientist a Suicide Amid Probe of Paper, Wash. Post, Feb. 14, 1987, at A1, col. 4.

<sup>14.</sup> SIGMA XI, supra note 1, at 23.

tists concerned with a particular discipline or subdiscipline organize associations or societies, these are generally concerned only with advancing the state of knowledge within their sphere and not with determining the qualifications or establishing standards of conduct for their members.

For these reasons, science has no formal mechanism for selfregulation and no formalized ethical codes. This is not to say, however, that science is a refuge for villains and charlatans. There are *informal* but regularized ways in which candidates are admitted to, and advance within, science. These center upon the process of "peer review."<sup>15</sup>

Recognition of scientific scholarship is a function of the scientist's research accomplishments. These accomplishments become known when scientific journals publish descriptions of a scientist's research and its results. Scientific journals are, however, "refereed." The journal will send the manuscript to scientists regarded as the author's peers for critical comment, suggestions for improvement, and a recommendation whether the paper warrants publication. The peers who act as referees are, therefore, the gatekeepers who, in conjunction with the editors, control access to, and advancement in, the world of science. If the research and results described in the article are sound, other scientists should be able to repeat the research and obtain the same results. It is in this sense that it can be said that "[s]cientists may be fallible, but science is self-correcting,"<sup>16</sup> since inability to replicate the reported results signals that there has been error on the part of the author of the paper.

There are, however, some potential problems with the peer review system. Peers naturally tend to relate the quality of a paper to the manner in which it builds on existing knowledge. Peer review is therefore a force for conservatism that tends to discourage large steps forward and unorthodoxy generally.<sup>17</sup> Moreover, at the same time peer review operates as a defense against scientific error or misconduct, it provides splendid opportunity for the referees to engage in misconduct of their own. Peers are, after all, at least potential competitors of the scientist whose manuscript they are reviewing, and they can attempt to turn their function to personal advantage by the suggestions and rec-

<sup>15.</sup> Id.

<sup>16.</sup> Id. at 2.

<sup>17.</sup> See W. BROAD & N. WADE, supra note 3, at 100-02.

ommendations they make or, indeed, by appropriation of ideas or information in the manuscript.<sup>18</sup>

Peer review has not uncovered major pieces of outright scientific fraud that have been published in major journals and garnered honors for their authors. For example, belated inquiry into the research of Dr. John Darsee at Emory and Harvard Universities led to the retraction of numerous articles he had published in refereed medical journals because of apparent falsification of research and research results. These phenomena may be attributable to the lethargy, ineptness, or negligence of the referees or to the cleverness of the culprit. On the other hand, it has been asserted that a referee "is not a cop and should not be expected to determine whether a research report has been honestly produced," but rather is expected only to advise whether the reported results are sufficiently important to merit publication.<sup>19</sup>

An article published in *Nature* in January 1987 used the Darsee case to explore the prevalence of apparent misconduct notwithstanding peer review.<sup>20</sup> From 1978 to 1981, Darsee was author or coauthor of eighteen full-length research papers published in major journals and of about one hundred abstracts. book chapters, reviews, and short papers. A total of forty-seven scientists had coauthored one or more of these publications with him. The Nature article, by two NIH scientists, Walter W. Stewart and Ned Feder, reviewed these papers, which they conceded were a "sample of convenience,"<sup>21</sup> and not necessarily representative, to explore the vigilance of referees, editors of the journals, and Darsee's coauthors in "meeting the standards conventionally accepted as necessary in the scientific literature."22 Recognizing that the finding of "errors" was in part subjective and that many of the errors and discrepancies they found were "minor," they nevertheless reported that most of the papers contained "errors or discrepancies that can be recognized simply by examining them carefully,"<sup>23</sup> and that some errors were "so

23. Id.

<sup>18.</sup> Dr. Handler pointed out that "perhaps fifty knowledgeable individuals . . . have such an opportunity" to misappropriate an idea contained in a research proposal they referee, and reported with gratification that accounts of "transgressions" are "very, very rare indeed." *Hearings on Fraud, supra* note 2, at 21.

<sup>19.</sup> SIGMA XI, supra note 1, at 6.

<sup>20.</sup> Stewart & Feder, The Integrity of the Scientific Literature, 325 NATURE 207 (1987).

<sup>21.</sup> Id. at 207.

<sup>22.</sup> Id.

glaring as to offend common sense."<sup>24</sup> As an example of the latter, they cited a paper depicting a family with a high incidence of an unusual form of heart disease. The family pedigree, as described in the Darsee paper, indicated that a seventeen-year-old male had four children ranging in age from four to eight; his sister, brother, and first cousin had their first children at ages sixteen, fifteen, and fifteen respectively; and three women in the family had their last children at ages forty-one, forty-five, and fifty-two.<sup>25</sup>

Stewart and Feder reported that among the eighteen research papers there were as many as thirty-nine errors or discrepancies in a single paper, with an average of about twelve per paper.<sup>26</sup> Of the twenty-two scientists who were coauthors of a research paper, nineteen were coauthors of at least one paper with ten or more errors or discrepancies.<sup>27</sup> In addition, Stewart and Feder found that in numerous cases the coauthors had not retained the data on which the publications were based;<sup>28</sup> that in many cases the coauthors were merely "honorary authors" with no direct involvement in the research;<sup>29</sup> that some papers embodied statements and data that impeded the reader's ability to reconstruct the manner in which the research was conducted;<sup>30</sup> and that a number of the papers had previously been published in a different journal without attribution in the subsequent paper.<sup>31</sup>

26. Stewart & Feder, supra note 20, at 209.

28. Id.

31. Id. at 211. The Stewart-Feder article was first submitted to Nature in 1983, which declined to publish it in its original form because of threats of libel suits. Editorial, supra note 25, at 181. After considerable give and take, a revised version was finally published. Still, the article carries a bold type legend stating that "[s]ome editorial changes have been made in this manuscript without the consent of the authors." Stewart & Feder, supra note 20, at 214. The article is preceded in the same issue by an editorial critical of the authors, skeptical of their methodology, but concluding "for all this, what Stewart and Feder have written deserves close attention." Fraud, Libel and the Literature, supra, at 182. In addition, immediately following the Stewart and Feder article was a "reply" by Dr. Eugene Braunwald, who was Darsee's supervisor at Harvard and who reportedly was among those who threatened a libel suit. Braunwald, On Analysing Scientific Fraud, 325 NATURE 215 (1987).

According to an article by Philip M. Boffey in April 1986, based on an earlier (probably the original) version of the manuscript, Stewart and Feder concluded that many of the Darsee coauthors had engaged in "misconduct" with the potential to undermine the accuracy of science," and "that they 'knew or should have known'" that some of the

<sup>24.</sup> Id. at 208.

<sup>25.</sup> An editorial in *Nature* lamely suggests that the "bizarre pedigree" would be less puzzling "if the ages given in the original paper were intended to mean something other than chronological age." Editorial, *Fraud*, *Libel and The Literature*, 325 NATURE 181, 182 (1987); see infra note 31.

<sup>27.</sup> Id.

<sup>29.</sup> Id. at 210.

<sup>30.</sup> Id.

## B. Guidelines for Scientific Conduct

1. The Edsall Report— The beginnings, although indirect, of the scientific community's efforts to deal with scientific misconduct came with the establishment by the American Association for the Advancement of Science (AAAS) of a Committee on Scientific Freedom and Responsibility. The impetus, in part, for its establishment was the concern that two scientists were retaliated against by the Atomic Energy Commission (AEC) because they had vigorously and publicly argued that the AEC's standards for protection against ionizing radiation were too lax. The committee was initially established in response to Senator Edmund Muskie's request that the AAAS look into the allegations of administrative harassment of the scientists, but the AAAS soon thereafter decided to broaden the inquiry.

Accordingly, the committee was charged (1) to study and report on the general conditions required for scientific freedom and responsibility, (2) to develop suitable criteria and procedures for the objective and impartial study of these problems, and (3) to recommend review mechanisms for instances where scientific freedom is alleged to have been abridged or otherwise endangered, or where responsible scientific conduct is alleged to have been violated.<sup>32</sup> The committee had a blue-chip membership, including former Chief Justice Earl Warren.<sup>33</sup>

The committee was constituted in December 1970, and its final report, prepared for the committee by Dr. John T. Edsall, Professor Emeritus of Biochemistry at Harvard University, was submitted in 1975.<sup>34</sup> Because at that time concerns about widespread scientific fraud had not yet begun to emerge, it is not surprising that the Edsall Report did not deal with the subject directly. Rather, the Report concentrated on the responsibilities of scientists with respect to, first, the conduct of scientific activities that might be harmful to society and, second, the failure of scientists to conduct and support activities that might be benefi-

statements in their publications were false. Boffey, Major Study Points to Faulty Research at Two Universities, N.Y. Times, Apr. 22, 1986, at C1, col. 4.

<sup>32.</sup> The third charge originally called upon the committee to study and report on specific instances rather than to develop mechanisms to enable such review. The charge seems to have been modified because of doubts that the AAAS should enter the thicket of passing judgment on specific cases.

<sup>33.</sup> The history encapsulated in this and the preceding paragraph is based on a review of documents on file at the AAAS offices in Washington, D.C.

<sup>34.</sup> J. EDSALL, SCIENTIFIC FREEDOM AND RESPONSIBILITY (1975) (report of AAAS Comm. on Scientific Freedom & Responsibility).

cial. Accordingly, the Report's main thrust related to issues of the kind raised by the AEC's alleged harrassment of scientists for speaking out contrary to the "party line" and to "whistleblowing" generally.

Issues of scientific freedom and scientific responsibility were regarded as "basically inseparable."<sup>35</sup> In the committee's view, scientific freedom is not in any sense unique, but is granted by society as necessary for the advancement of beneficial knowledge.<sup>36</sup> Scientific freedom is therefore dependent upon the exercise of the responsibilities that arise from the possession of special knowledge. When scientists become aware of action or inaction in the realm of science that they believe will be harmful to the public interest, they have both the right and the responsibility to blow the whistle, but "the responsibilities are primary."<sup>37</sup> In other words, the Edsall Report takes the position that scientists should be encouraged to be whistle-blowers when serious issues are involved and that they should have assurance of some form of due process in passing judgment on the questions they raise.<sup>38</sup>

Although the Edsall Report did not explicitly address scientific misconduct, it laid down a principle that is clearly relevant: "One of the basic responsibilities of scientists is to maintain the quality and integrity of the work of the scientific community."<sup>39</sup> Scientists, therefore, have a duty to blow the whistle when they have reason to believe there is scientific fraud. Moreover, the Edsall Report explicitly condemns other forms of misconduct inherent in the peer review system—opportunities for misappropriation and the taking of unfair advantage.<sup>40</sup>

2. The Sigma Xi statement— The principle that scientists have an affirmative responsibility to expose dishonest or unacceptable practices in science received further support in 1984 with the publication of a statement by Sigma Xi, the honor society of science, that was intended as "practical advice" to those entering careers in science.<sup>41</sup> The statement views whistle-blowing as necessary to maintain the integrity of scientific research, and tells young scientists they cannot turn their backs on scientific misconduct. At the same time, the honor society cautions

<sup>35.</sup> Id. at 5.

<sup>36.</sup> Id.

<sup>37.</sup> Id.

<sup>38.</sup> Id.

<sup>39.</sup> Id. at 8.

<sup>40.</sup> Id. at 8-10.

<sup>41.</sup> SIGMA XI, supra note 1, at preface.

young scientists that one who blows the whistle faces "problems and dangers" including the hostility of colleagues, academic censure, dismissal, professional ostracism, and lawsuits.<sup>42</sup>

The AAMC recommendation- In 1984, the Association of 3. American Medical Colleges (AAMC) recommended to its members that they should adopt procedures to investigate and resolve allegations of fraud in an expeditious, thoughtful, fair, and judicious manner.<sup>43</sup> Guidelines for such procedures were also suggested. According to the AAMC, a principal consideration in such procedures should be protection of the rights and reputations of all parties involved, including those who reported the perceived misconduct in good faith.<sup>44</sup> The guidelines contemplate an initial review by the dean or the institution head to screen out "blatantly frivolous" allegations, followed by an "initial review" by a committee to determine whether further investigation is required. If the committee recommends further action, the researcher involved is to be notified along with any collaborators and an investigation is to be conducted.<sup>45</sup> If the allegations are not substantiated by a thorough investigation. "appropriate action" should be taken against the whistle-blower if his or her "involvement in leveling unfounded charges was demonstrated to have been malicious or intentionally dishonest."46

4. The government approach to fraud— The problem of scientific misconduct is one that should be dealt with in the first instance by the employing institution, but federal funding agencies obviously have a strong interest in the integrity of science at institutions that are their grantees. These agencies have begun to consider adopting rules to ensure that cases of alleged or suspected misconduct are adequately and fairly investigated and resolved.<sup>47</sup> The adequate and fair resolution of these cases involves a number of issues that must be clarified. First, scientific misconduct must be defined. Second, the duty of enforcement must be placed on the research institutions so that concern for repu-

<sup>42.</sup> Id. at 29 (quoting Oakes, Protecting the Rights of Whistleblowers and the Accused in Federally Supported Biomedical Research, in WHISTLEBLOWING IN BIOMEDICAL RESEARCH 111, 111 (J. Swazey & S. Scher eds. 1982)).

<sup>43.</sup> AAMC REPORT, supra note 8, at 3.

<sup>44.</sup> Id. at 4.

<sup>45.</sup> Id. at 4-5.

<sup>46.</sup> Id. at 6.

<sup>47.</sup> On July 18, 1986, the National Institutes of Health (NIH) published Policies and Procedures for Dealing with Possible Misconduct in Science. Special Issue, supra note 7.

tation does not preempt thorough investigations. Third, the degree of protection accorded whistle-blowers must be determined.

A threshold question is the definition of scientific fraud, and whether this definition should be codified. There are some kinds of conduct that all scientists would condemn. No one would argue that it is justifiable for scientists to fabricate or deliberately misrepresent research results or to use their participation in the peer review process for advancement of personal objectives. Bevond these obvious cases, however, there are murky differences between fraud, on the one hand, and error, carelessness, or poor practices on the other; the ambiguities are compounded when one gets into the traditions, courtesies, and practices associated with scientific publications and journals. Moreover, the standards, or at least the relevant "habits and conventions"<sup>48</sup> for determining misconduct may vary from one scientific discipline to another. For example, one would expect that judgment would be at least somewhat different for astronomy than for medical science: and even within medical science, the standards might vary depending upon whether the researcher was a scientist, a physician, or both, in connection with the particular conduct.

These difficulties make it unlikely that a substantive code of scientific probity could be formulated easily. One is tempted to suggest, assuming the investigation is adequate and in good faith, that, like hard-core pornography, one knows scientific misconduct when one sees it. The questions whether codification should be attempted and, if so, how the effort should be implemented, are ones that could usefully be considered in the context of constructive collaboration between scientists and lawyers. The legal profession, after all, has had generations of experience in attempting to codify some very difficult concepts.

In July 1986, the Public Health Service (PHS) published policies and procedures for handling scientific misconduct in which it undertook to define "scientific misconduct" in the context of the use of PHS research funds and direct transactions with the PHS.<sup>49</sup> The definition embraces

(1) serious deviation, such as fabrication, falsification, or plagiarism, from accepted practices in carrying out research or in reporting the results of research; or (2) material failure to comply with Federal requirements affecting specific aspects of the conduct of research—e.g., the pro-

<sup>48.</sup> See supra text accompanying note 14.

<sup>49.</sup> Special Issue, supra note 7.

tection of human subjects and the welfare of laboratory animals.<sup>50</sup>

Excluded from the definition are deviations from policies that may result from a "weakness in institutional controls or disagreements between an awardee institution and a PHS component."<sup>51</sup> More significantly, the definition does not encompass "certain types of possibly inappropriate practices that should be of concern to scientists everywhere but do not necessarily call for Federal action. . . . [These include] coauthorship practices, recognition of collaborators, and multiple publication."<sup>52</sup> Although such practices are not within the scope of the policies and procedures, the PHS "encourages institutions, professional societies and individual scientists to address [such] broad questions of scientific conduct."<sup>53</sup> Essentially similar guidelines have been promulgated by the National Science Foundation (NSF) for dealing with misconduct under NSF grants.<sup>54</sup>

Once the definition of scientific misconduct has been ascertained, the research institutions must enforce it. It is imperative that institutions employing scientists clearly understand that scientific misconduct will not be tolerated, and that the burden of policing scientific conduct rests squarely upon them. They must be convinced that even though a determination that one of their scientists engaged in misconduct may cost them "points" with granting agencies and others, by indicating that their supervision of research may not have been adequate, whitewashing scientific misconduct will cost them even more. Although it is important that investigations proceed with due regard for protection of the reputation and interests of those who are "accused," the primary purpose of the investigation is to reach a just conclusion, not to protect reputations.<sup>55</sup> These are messages that must be delivered by the federal granting agencies, and it is important that these agencies be more than pious preachers. Indeed, there should probably be some kind of appeal/review

<sup>50.</sup> Id. at 2.

<sup>51.</sup> Id.

<sup>52.</sup> Id.

<sup>53.</sup> Id.

<sup>54. 52</sup> Fed. Reg. 4158 (1987) (to be codified at 45 C.F.R. pt. 689) (proposed Feb. 10, 1987).

<sup>55.</sup> The emphasis on protecting reputations probably reflects a predisposition within the scientific community to regard scientific fraud as a rare event and a presumption that allegations of fraud will turn out not to have substance. Interestingly, there seems to be little concern about the reputation of the whistle-blower. See supra text accompanying notes 42, 44; see also Special Issue, supra note 7, at 11, 34.

mechanism for monitoring decisions reached and actions taken by grantee institutions with respect to alleged scientific misconduct. Here again, lawyers can be helpful in developing such procedures.

Lastly, even if institutions shrink from actively encouraging whistle-blowing "snitches," those who have the courage to blow the whistle should be protected and given some measure of presumption of having acted in good faith. As noted above, both Sigma Xi and AAAS encourage scientists to take the initiative in bringing reasonably founded suspicions that a colleague's research involves misconduct to the attention of the appropriate authorities.<sup>56</sup> Indeed, whistle-blowing may be the single most important means for discouraging and exposing scientific misconduct. A belief that colleagues will lack the stomach or the will to blow the whistle undoubtedly encourages some scientists to seek personal gain from misconduct. On the other hand, it is probably true that most whistle-blowers' allegations will ultimately prove baseless and motivated by animosity, personal grievances, personality problems, and the like.<sup>57</sup>

The treatment of whistle-blowers therefore presents important and difficult issues in formulating procedures for dealing with scientific misconduct. Existing procedures do not contemplate a role for the whistle-blower in the inquiry, but usually drop the whistle-blower from the cast of relevant characters. Once the whistle is blown, the institution's organs for inquiry and investigation take over. If the whistle-blower is involved at all, it is likely to be only as a witness. Provision is not made for keeping whistle-blowers apprised of the progress of the investigation, and they are not given the opportunity to comment on preliminary findings of fact and conclusions.

In other words, the position of the whistle-blower is analogous to that of the individual who witnesses the commission of a felony by an acquaintance and calls the police. The matter is then in the hands of the police and the prosecutors, and the complainant is regarded as one with no special interest, beyond that of any citizen, in seeing that justice is done. An inquiry into scientific fraud that has been initiated by a whistle-blower is, how-

<sup>56.</sup> See supra notes 37-42 and accompanying text.

<sup>57.</sup> The author was an original member of the AAAS Committee on Scientific Freedom and Responsibility established pursuant to the recommendations in the Edsall Report. See J. EDSALL, supra note 34. During the term of his membership, the committee actively solicited whistle-blowers to bring their allegations to the committee for consideration. In the author's opinion, a substantial majority of the cases presented to the committee were without merit.

ever, very much different. To begin with, there is no prosecution and no prosecutor, but only an investigation to uncover the facts. Moreover, as noted above, there may be strong motivations for the institution to reach the conclusion that there has been no misconduct. Finally, the whistle-blower *does* have a strong personal interest in the outcome, because she is subject to criticism and hostility from the scientific community if the charges are determined to be without foundation, and to disciplinary action if, beyond this, it is determined that she acted with improper intent.

#### II. WHISTLEBLOWING—A CASE STUDY

The centrality of the whistle-blower's role, as well as the tendency to give him relatively short shrift, is vividly illustrated in a case in which the writer was actively involved for the past six years.<sup>58</sup>

In October 1981, Dr. Jerome Jacobstein, a nuclear medicine specialist, had reason to believe that one of his colleagues at Cornell University Medical College (CUMC), Dr. Jeffrey Borer, a cardiologist, had misrepresented research methodology so as to make his research results look better; and that in so doing Dr. Borer had, in at least one instance, led a medical student who was working on research supervised by Dr. Borer to believe that it was not improper to mischaracterize methodology so long as the research results as reported were sound. At the time, Dr. Jacobstein's concerns did not involve a published paper, but rather a draft "talking paper" prepared by the student and a draft manuscript of an article that was subsequently published.<sup>59</sup> After several weeks of agonizing soul-searching, and after writing to Dr. Borer to state his concerns and request an explanation (Dr. Borer did not respond). Dr. Jacobstein discussed the matter with the Medical School Dean on December 14, 1981.

The Dean hastily organized a committee of three medical school faculty members to conduct an inquiry to determine if the allegations warranted a full-fledged investigation and hear-

<sup>58.</sup> For news stories about this case, see Part I: Chronicle of a Scientific Misconduct Case, Sci. & Gov'T REP., Nov. 1, 1986, at 1; Part II: Chronicle of a Scientific Misconduct Case, Sci. & Gov'T REP., Nov. 15, 1986, at 1; Part III: Chronicle of a Scientific Misconduct Case, Sci. & Gov'T REP., Dec. 1, 1986, at 1; NIH Upholds Misconduct Charges in Cornell Case, Sci. & Gov'T REP., Oct. 1, 1987, at 5; Palca, Cornell Misconduct Case Grinds Slowly to its Conclusion, 326 NATURE 816 (1987).

<sup>59.</sup> See infra note 66 and accompanying text.

ing. The committee met for several hours in the afternoon and early evening of Friday, December 18, 1981, and heard from Dr. Jacobstein, Dr. Borer, and the medical student. Although Dr. Jacobstein informed the committee that his suspicions were supported by documentary evidence, including the research data books, the committee apparently did not deem it necessary to request or to examine any papers. Before the committee adjourned that evening, the chairman wrote in his own hand a three sentence note to the dean informing him that it was the unanimous view of the committee that no further action was warranted with respect to the allegations.

At that point, Dr. Jacobstein retained me to represent him in his effort to obtain a fair inquiry into his allegations. He emphasized that he wished to pursue this, despite the fact that he had already accepted a new position at another institution, because of his strong sense of scientific and social responsibility. He was convinced that the committee's inquiry had not been fair, because he knew with certainty that the relevant documents supported his allegations. At the same time, he recognized the possibility that there might be a satisfactory explanation for Dr. Borer's apparent misconduct. Hence, his objective was to obtain a fair inquiry, not to convict Dr. Borer.

Over the next few months, Dr. Jacobstein paid several thousand dollars for my services. When I recognized that the matter would probably be drawn out over a long period of time and that fees for my services would impose enormous financial burdens on Dr. Jacobstein, I undertook to continue my representation pro bono publico.

Cornell's internal review procedures were inadequate. When we sought to interest the University President's Office in the matter, the Office referred the matter to the university's house counsel. An attorney in that office, after five months of fruitless discussion as to acceptable procedures for a satisfactory inquiry, candidly asserted that his function was to represent the interests of the medical school. This assertion caused me to break off the discussions. When I informed him that I intended to take the matter to the NIH, he threatened orally and in writing that Dr. Jacobstein and I would be held legally accountable for any damage that might result to the University and its personnel because of Dr. Jacobstein's allegations. It seems clear that the University's objective was to get rid of the problem as quickly as possible because Dr. Borer was a prominent researcher who attracted substantial funds to the University. Significantly, shortly after the matter was referred to the NIH, Dr. Borer was appointed to an endowed chair at Cornell.

The case was referred to the NIH on June 8, 1982, and the NIH initiated an inquiry that continued for five and one-half years. It appears from the history of the matter there that the NIH was more interested in developing facts that would exonerate Dr. Borer than it was in facts that would support the allegations against him. On the other hand, although the NIH had no procedures requiring this, Dr. Jacobstein was given access to the NIH reports at various stages of its inquiry, with a full opportunity to comment. It is not suggested, therefore, that the NIH sought to "whitewash" Dr. Borer; rather, its role seems more properly explicable as stemming from a reluctance to believe that a scientist of Dr. Borer's stature (and an NIH alumnus) would be guilty of misconduct.

On September 18, 1987, the Director of the NIH made a final decision on the Cornell affair based on the NIH Committee's investigation. The NIH concluded that the subject of the Cornell committee's inquiry of December 18, 1981, based on the issues Dr. Jacobstein originally raised, "could not be adjudicated."<sup>60</sup> Nevertheless, the NIH Committee found significant departures from the acceptable standard of "record-keeping, of collecting and recording data, and of reporting results" of research in two subsequently published papers Dr. Jacobstein brought to the attention of the NIH.<sup>61</sup> It also concluded that there was "no evidence of intentional misconduct in the part of Dr. Borer."<sup>62</sup> Moreover, Cornell's inquiry into the matter was faulted.

In reaching these conclusions, the NIH obviously made findings against Dr. Borer only when they were clearly documented beyond doubt. It was unwilling to balance the conflicting contentions in light of their plausibility and how they fit within the overall pattern of conduct revealed in the investigation. For example, Dr. Jacobstein's original charges were totally consistent

<sup>60.</sup> Memorandum from Associate Director for Extramural Affairs, Office of Extramural Research, to Director of the National Institutes of Health 5 (Sept. 17, 1987) [hereinafter Decision Memorandum] (decision regarding the NIH investigation of alleged misconduct at Cornell University Medical College and proposed actions) (copy on file with U. MICH. J.L. REF.). The basis for this conclusion was that there were "wide discrepancies between the account of Dr. Jacobstein and the accounts of Dr. Borer and the other participants in the research" that could not be evaluated in the absence of a published paper. Office of Extramural Research, National Insts. of Health, Review of Alleged Misrepresentations on the Part of Jeffrey S. Borer, M.D., Cornell University Medical College 8 (1987) (copy on file with U. MICH. J.L. REF.).

<sup>61.</sup> Decision Memorandum, supra note 60, at 2. 62. Id.

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with the conduct of Dr. Borer that the NIH found not to meet accepted standards. Despite this fact, the NIH gave no weight to Dr. Jacobstein's original charges. Similarly, the NIH did not infer "intentional misconduct" from the careless research and reporting practices that all made Dr. Borer's research results look better and more credible.

Nevertheless, the NIH imposed fairly stiff sanctions against Dr. Borer. The principal sanction requires, for the next three years, that a copy of the NIH findings be provided to any NIH official who is considering appointing Dr. Borer to a committee or awarding a grant in which he would be the principal investigator or project leader.<sup>63</sup>

With respect to the adequacy of Cornell's internal investigation in December 1981, the NIH observed that "[b]ecause Dr. Jacobstein's original allegations related to a talking paper and a draft manuscript, CUMC's conclusion not to pursue the matter may have been appropriate at the time," but that its "hasty conduct of the inquiry, and the failure to document the findings until later, created understandable doubts about the institution's willingness to deal with a potential problem."<sup>64</sup> The bottom line was that the NIH officially expressed concern over Cornell's review of Dr. Jacobstein's allegations of misconduct.<sup>65</sup>

The NIH let Cornell off too gently. This is evidenced by the NIH investigation of a 1983 article by Dr. Borer that Dr. Jacobstein alleged contained inaccurate and unsupported statements.<sup>66</sup> The most egregious of the article's misstatements was that certain medications were withheld from the test subjects before the experiment. In its draft final decision of February 1987, the NIH concluded that this statement was not accurate. Thereupon Cornell, which had previously assured the NIH that its own investigation showed that Dr. Jacobstein's allegations were without merit, issued a press release. The press release acknowledged that there had indeed been "an error" in the article, and that Dr. Borer had written a letter to the American Journal of Cardiology about this inaccuracy.<sup>67</sup> The NIH ultimately con-

<sup>63.</sup> Id.

<sup>64.</sup> Id. at 9.

<sup>65.</sup> Id. at 3.

<sup>66.</sup> Jordan, Borer, Zullo, Hayes, Kubo, Moses & Carter, Exercise Versus Cold Temperature Stimulation During Radionuclide Cineangiography: Diagnostic Accuracy in Coronary Artery Disease, 51 J. A.M.A. 1091 (1983). It was a draft of this paper that was one of the bases for Dr. Jacobstein's original allegations against Dr. Borer.

<sup>67.</sup> Dr. Borer originally reported that only 4 of 54 patients had received the medication within 24 hours of the study. *See* New York Hospital-Cornell Medical Center, Press Release (Apr. 17, 1987) (copy on file with U. MICH. J.L. REF.).

cluded in its final decision that a "quarter to a third" of the patients received the medication within twenty-four hours of the testing, and that Dr. Borer and Cornell failed to reveal in their previous disclosures the full extent of the erroneous statement in the published article.<sup>68</sup>

The NIH's final decision served to vindicate Dr. Jacobstein even though it was based on matters other than those originally raised by him. On the other hand, the NIH's handling of the case, aside from taking more than five years to complete, appears to be less than adequate from the standpoint of the public interest. Indeed, the final decision raises almost as many policy questions as it answers.

NIH policy places primary responsibility on universities and other research institutions to deal with alleged scientific fraud and misconduct. Its excessively gentle treatment of Dr. Borer's culpability and Cornell's role raises considerable questions as to the extent to which the NIH is prepared to go to ensure that the institutions discharge their responsibility appropriately.

#### CONCLUSION

The Cornell case is unusual, probably unique, in a number of respects. The whistle-blower was exceptionally motivated by his sense of scientific and social responsibility, and persisted in his campaign with tenacity over a six year period. Moreover, he had the unusual assistance of legal counsel in his efforts. A less dedicated scientist, and one who did not have the resources to pay for a lawyer or the good fortune to find one who would represent him pro bono, would probably retreat from the cause, discredited and with a tarnished reputation. Those, like Dr. Jacobstein, who uphold and defend principles of scientific responsibility and integrity deserve better of the system. For these reasons, and because legitimate whistle-blowing requires considerable principle and courage, the whistle-blower is entitled to more consideration in an investigation initiated by his or her charges. At the very least, there should be an opportunity to participate in the proceedings, or in portions of them, as more than a witness: a right to be represented by counsel and perhaps to play a role analogous to that of prosecutor. Certainly, there should be the same opportunity that is afforded to the alleged wrongdoer to comment on preliminary findings of fact and conclusions.

<sup>68.</sup> Decision Memorandum, supra note 60, at 8.

Finally, in one way or another, concern about possible liability or expense arising out of defamation actions should be eliminated from, or at least greatly minimized in, situations involving possible scientific misconduct. This is another area in which the scientific community could benefit from legal inputs. One way to accomplish this would be to require—as a condition of employment as a research scientist—the execution of an instrument releasing from defamation liability any person who in the future makes any statements to officials of any scientific, educational, or governmental entity to the effect that the employee has engaged in scientific misconduct, unless the statements made are determined to be untrue, without any reasonable basis, and to have been made with malice. Another approach would be for institutions to indemnify a whistle-blower for litigation expenses and judgments in defamation actions growing out of his or her allegations that another scientist has engaged in scientific misconduct, unless, of course, it is determined that the allegations were untrue, without a reasonable basis, and made with malice.

In a society such as the United States, committed to scientific advance, much of which is supported by the government, it is particularly important that the integrity of science be maintained. Major reforms are needed, both in the way institutions deal internally with alleged scientific misconduct and in governmental procedures for ensuring the integrity of science. Although the legal profession to date has sat on the sidelines, and the scientific community may look upon its entering the game as superfluous, or perhaps even undesirable, much can be gained, and nothing lost, from an open and candid discussion of the issues by the two disciplines.<sup>69</sup>

<sup>69.</sup> Such a dialogue is now underway under the auspices of the National Conference of Lawyers and Scientists, which is a joint undertaking of the American Association for the Advancement of Science and the American Bar Association. The writer is the ABA cochairman of the National Conference. See Zurer, Workshop Airs Research Ethics and Monitoring of Scientific Misconduct, CHEMICAL & ENGINEERING NEWS, Oct. 5, 1987, at 44, 46.

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