Criminal Liability for Misconduct in Scientific Research

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In April 1988, Stephen Breuning, formerly a research psychologist with the University of Pittsburgh, was indicted in federal district court in Baltimore for falsifying his research results. The National Institute of Mental Health (NIMH) had provided Breuning with grants of more than $150,000 to investigate the effects of treating hyperactive retarded children with Ritalin and Dexedrine. Breuning's research was well-known in the field. Nevertheless, he was accused of not performing the studies that he claimed to have performed. His plea of guilty in September 1988 supports the truth of the allegation.

Breuning's prosecution raised the disquieting issue of misconduct by scientific researchers and the questions of whether and how a person conducting scientific research should be criminally prosecuted for misconduct related to that research. Although interest in the problem of scientific misconduct has been sporadic, in recent years there has been a swell of concern about and attention to the subject. In the past decade the media has reported on a number of distressing incidents of scientific misconduct. Congressional hearings, professional rules of conduct, and Breuning's criminal prosecution have marked recent efforts to confront this difficult problem.

Unpleasant and unsettling as it is to contemplate, criminal prosecution can serve a valuable role in deterring and condemning some forms of scientific misconduct and therefore should not be rejected in favor of internal controls. At the same time, investigation and prosecution of scientific misconduct raise the special issues of the competence of prosecutor
and jury, the chilling effect of government oversight on the conduct of scientific research, and the possible entangling of government and science.

This Article will explore our society’s attitude to prosecuting scientific misconduct, the need to consider prosecution in such cases, and the utility of current statutes available for prosecution. To assist the reader in understanding the issues, this Article will provide some background information about misconduct in scientific research and will include a discussion of some specific incidents. These background materials provide a context for my argument that criminal sanctions should be available to punish scientific misconduct. Finally, I propose a federal criminal statute designed specifically for prosecuting scientific misconduct.

I. HISTORICAL REVIEW OF MISCONDUCT IN SCIENTIFIC RESEARCH

Scientific misconduct is not a recent phenomenon, nor has it been limited to a few deranged and obscure individuals. Some well-known and ingenious scientists are believed to have been involved in scientific misconduct. Ptolemy, Galileo,

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3. For two detailed explorations of the problems raised by scientific misconduct, see WILLIAM BROAD & NICHOLAS WADE, BETRAYERS OF THE TRUTH (1982) and ALEXANDER KOHN, FALSE PROPHETS (1986). The examples described in this Article are largely drawn from these sources. For further information see Patricia K. Woolf, Deception in Scientific Research, in AAAS-ABA National Conference of Lawyers and Scientists, PROJECT ON SCIENTIFIC FRAUD AND MISCONDUCT, Report on Workshop Number One 37, 42-65 (1988) [hereinafter PROJECT ON SCIENTIFIC FRAUD].

4. The view of Claudius Ptolemy, the great astronomer of second century Alexandria, Egypt, that the planetary system was centered by the earth, dominated scientific thought until it was successfully challenged by Copernicus in the 1500s. An astronomer in the modern era, however, has reexamined Ptolemy’s data and has questioned whether he actually observed what he reported. This astronomer points to the inaccuracy of Ptolemy’s reported observations as evidence that he actually relied on observations made by Hipparchus of Rhodes nearly 300 years earlier. BROAD & WADE, supra note 3, at 24–25. For more detailed descriptions of Ptolemy’s work, see ROBERT R. NEWTON, THE CRIME OF CLAUDIUS PTOLEMY (1977). At least one modern scholar has defended Ptolemy’s reputation. BROAD & WADE, supra note 3, at 25–26.

5. Galileo has been faulted in modern times for generating experimental data that are too good to be true:

With Galileo, the desire to make his ideas prevail apparently led him to report experiments that could not have been performed exactly as described. Thus
Newton,\textsuperscript{6} and Mendel\textsuperscript{7} are among the scientific greats whose achievements have been scrutinized in modern times because of suspicions that some of those achievements were obtained in less than honest ways.\textsuperscript{8} These and other examples are useful in defining the elusive problem of scientific misconduct and in evaluating both its potential for harm and the extent to which internal controls prevent such misconduct or expose it after it occurs.

Several modern incidents illustrate how scientific misconduct can occur and how it is treated in the post-World War II era. One of the more notorious incidents of wrongdoing is an ambiguous attitude toward data was present from the very beginning of Western experimental science. On the one hand, experimental data was upheld as the ultimate arbiter of truth; on the other hand, fact was subordinated to theory when necessary and even, if it didn't fit, distorted. The Renaissance saw the flowering of Western experimental science, but in Galileo, the propensity to manipulate fact was the worm in the bud.

BROAD & WADE, \textit{supra} note 3, at 27.

6. Sir Isaac Newton, whose theories formed the basis for the study of physics, is faulted for having introduced a "fudge factor" in the reporting of his research results in order to obtain greater acceptance for his theories. Richard S. Westfall, \textit{Newton and the Fudge Factor}, 179 SCI. 751, 751–52 (1973). Later editions of Newton's \textit{Principia} contained measurements that supported his theories more than those he had initially reported. This enhanced accuracy, it is claimed, was no small part of the reason for the acceptance of Newton's work. See BROAD & WADE, \textit{supra} note 3, at 27–29. "Not the least part of the \textit{Principia}'s persuasiveness was its deliberate pretense to a degree of precision quite beyond its legitimate claim." Westfall, \textit{supra}, at 751–52.

7. The data generated by Gregor Mendel, the father of modern genetics, also have been scrutinized in modern times. The great degree of the conformity of his observations to his theory has been criticized as unlikely to match the results of actual experimentation. Whether this apparent misreporting of results was intentional or not, or even done by Mendel himself, is the subject of some debate, but the consensus seems to be that the data reported were too good to be true. BROAD & WADE, \textit{supra} note 3, at 31–33.

8. At least one commentator has defended these scientists:

Because standards of scientific honesty vary with concepts of method, one should be highly suspicious of any person who accuses scientists from centuries past of fraud: the person making the charge is probably guilty of methodological anachronism. For example, the accusations leveled against Ptolemy, Galileo, Newton, Dalton, Mendel, and Millikan by William Broad and Nicholas Wade . . . should be taken with a grain of salt. In the case of Mendel, they simply repeat Ronald A. Fisher's charges against him without even mentioning the literature defending Mendel against Fisher.

Warren Schmaus, \textit{An Analysis of Fraud and Misconduct in Science}, in \textit{Project on Scientific Fraud}, \textit{supra} note 3, at 114 n.19. Broad and Wade, however, include references to authorities other than Fisher, including some whose views are more favorable to Mendel. BROAD & WADE, \textit{supra} note 3, at 32–33.
involved John Darsee, a doctor engaged in cardiovascular research at Emory and then at Harvard.\(^9\) Darsee, then working as an instructor at the Harvard Medical School and on a National Institutes of Health (NIH) fellowship, was caught fabricating raw data for an experiment.\(^10\) Darsee was removed from the faculty appointment and the fellowship, but was allowed to remain as a researcher. Subsequent research data collected by Darsee were questioned, leading to investigations both by the Medical School and by the NIH. The investigation uncovered various irregularities in the research results Darsee had reached at Harvard. A later investigation by Emory confirmed the validity of only two of the ten papers and two of the forty-five abstracts that Darsee had published at Emory.\(^11\) One of the unusual aspects of Darsee's research reports was the reported assistance of three persons whose existence the investigating committees were unable to substantiate.\(^12\)

Equally notorious is the case of William Summerlin,\(^13\) a dermatologist who was engaged as a researcher in the field of immunology at the prestigious Sloan-Kettering Institute for Cancer Research in New York. Summerlin was studying the rejection of tissue grafts. Working with skin grafts among genetically unrelated mice and corneal grafts from humans to rabbits, Summerlin claimed to have developed a method for ensuring that grafts were not rejected.\(^14\) Summerlin’s reported findings were significant because he appeared to have found a way to suppress the immune reaction that could

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9. The Darsee incident is described in greater detail in BROAD & WADE, supra note 3, at 13–15, and in Kohn, supra note 3, at 84–88.
10. BROAD & WADE, supra note 3, at 14; Kohn, supra note 3, at 84–85. Darsee claimed that he was reproducing data from an earlier experiment that had been lost. Id. at 85.
11. See Kohn, supra note 3, at 87.
12. Id. at 88.
14. BROAD & WADE, supra note 3, at 154; Kohn, supra note 3, at 76.
solve an important problem in transplant surgery and also might help evaluate the theory that cancer is related to malfunctioning of the immune system.¹⁵

Other researchers, including researchers working under Summerlin, were unable to duplicate Summerlin’s work. Skepticism about Summerlin’s work led to a request by Summerlin’s boss (and director of the Institute), Dr. Robert A. Good, for a conference about Summerlin’s research. Summerlin brought to the conference white mice with dark patches of skin that supposedly had been transplanted from genetically unrelated dark mice. Good was satisfied by the demonstration, but a lab technician afterward noticed a peculiar thing about the dark patch on a white mouse—it rubbed off with alcohol. This discovery led to Summerlin’s confession that he had darkened the area on the animal with a felt tip pen.¹⁶ Further inquiry determined that Summerlin’s dark mice and white mice were actually genetically related to one another, making it less, if at all, surprising that the grafts were not rejected. Investigators detected other irregularities in Summerlin’s operating procedures, including the fact that most of his claimed successful grafts could be neither confirmed nor disproved because the animals on which the grafts were performed had been destroyed.¹⁷

¹⁵. HIXSON, supra note 13, at 6.
¹⁶. BROAD & WADE, supra note 3, at 155; SUMMERLIN PEER REVIEW REPORT, supra note 13, at 202–03. A similar case of painting a test animal occurred in 1926 in connection with studies done by Paul Kammerer, a biologist in Vienna. Kammerer was studying Lamarck’s theory that acquired characteristics could be genetically transmitted to offspring. One of Kammerer’s test animals was the midwife toad. This toad mates on land rather than in water, and so the male lacks the dark colored “nuptial pads” on its feet that water-mating toads use to grip the slippery skin of the female toads with which they mate. Kammerer reported that after forcing the midwife toads to mate in water rather than on land, the males developed nuptial pads and their male offspring were thereafter born with pads.

Another scientist, however, discovered that the dark pad on one of Kammerer’s male toads was actually the result of a subcutaneous injection of ink. Kammerer acknowledged that the scientist’s observation was true, but denied knowledge of how the ink came to be injected. The next day Kammerer committed suicide. For a general account of the incident, see BROAD & WADE, supra note 3, at 182–85; KOHN, supra note 3, at 45–48. It is a matter of debate whether Kammerer was responsible for the forgery. BROAD & WADE, supra note 3, at 184–85; KOHN, supra note 3, at 46. See generally ARTHUR KOESTLER, THE CASE OF THE MIDWIFE TOAD (1971) (presenting a strong defense of Kammerer).

¹⁷. See KOHN, supra note 3, at 78–79; SUMMERLIN PEER REVIEW REPORT, supra note 13, at 205. Summerlin claimed that the mice were destroyed to obtain serum for later antibody tests. The investigating committee that looked into Summerlin’s
With respect to Summerlin's corneal transplants on rabbits, Summerlin's plan was to have each rabbit receive two human corneal transplants, with one cornea left untreated and the other treated according to Summerlin's procedure for preventing rejection. If the experiment worked, each rabbit would have one cloudy eye, in which the untreated corneal transplant had been rejected, and one clear eye, in which the treated corneal transplant was accepted. In fact, only one eye of each rabbit received a transplant, thereby leaving each test animal with one clear eye and one cloudy eye, not because the clear eye contained a treated cornea, but because it had not been operated upon at all. Summerlin, however, claimed that both eyes of each rabbit received corneal transplants, and continued in this claim even after assistants brought the problem to his attention. Summerlin maintained that the problem was attributable to a misunderstanding between him and the ophthalmologists who actually performed the surgery.

misconduct found Summerlin's explanation "astonishing," and found it "scarcely conceivable that Dr. Summerlin could have believed, in such immunologically sophisticated surroundings as Dr. Good's group at Minnesota, that it is necessary to kill a mouse to obtain serum." Id.


19. See id. at 80; Summerlin Peer Review Report, supra note 13, at 213. The Peer Review Committee that investigated Summerlin rejected Summerlin's explanation:

Before the Committee, Dr. Summerlin gave no rational explanation of how anyone could conclude that any particular rabbit had been doubly grafted. . . . The only possible conclusion is that Dr. Summerlin was responsible for initiating and perpetuating a profound and serious misrepresentation about the results of transplanting cultured human corneas to rabbits.

Id.

The remarks of Nobel Prize-winner Peter Medawar, who was shown Summerlin's rabbits, provide valuable insight about how Summerlin could have pulled off his misrepresentation:

Through a perfectly transparent eye this rabbit looked at the board with the candid and unwavering gaze of which only a rabbit with an absolutely clear conscience is capable.

I could not believe that this rabbit had received a graft of any kind, not so much because of the perfect transparency of the cornea as because the pattern of blood vessels in the ring around the cornea was in no way disturbed. Nevertheless, I simply lacked the moral courage to say at the time that I thought we were the victims of a hoax or confidence trick. It is easy in theory to say these things, but in practice very senior scientists do not like trampling on their juniors in public.

Summerlin's relationship with the institution was severed, but he was placed on medical leave for one year before he was terminated. The event did not end his career in medicine, however; according to information provided at a congressional hearing in 1981, Summerlin was practicing medicine as a dermatologist.

Another rather remarkable instance of scientific misconduct, involving a researcher named Elias Alsabti, reveals how even detection of wrongdoing might not put an end to it. Alsabti

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21. Testimony before the House Subcommittee on Investigations and Oversight of the Committee on Science and Technology disclosed that although Summerlin did not continue as a researcher, he was able to continue practicing medicine:

MR. [Albert] GORE[, Jr., Chairman]. . . . Your testimony states and I quote:

The disincentives for wrongdoing are powerful and in most instances the individual is unable to establish himself or herself as a respected scientist and seek other means of livelihood.

Isn't it true that in the most recent and celebrated cases of falsification of data the individuals involved are still in medicine, although not doing research?

Dr. Summerlin continues work as a dermatologist . . . . How much of a penalty is that?

DR. [William F.] RAUB[, Associate Director for Extramural Research and Training, NIH, Public Health Service, Department of Health and Human Services (HHS)]. My statement was concerned specifically with a career in research. Those who enter research rarely do it for any motivation other than the excitement of a research career and perhaps the desire to achieve immortality in what one discovers.

The inability to practice that livelihood for whatever circumstances for one genuinely motivated to work at a career in research is a severe penalty and most indeed don't achieve that re-entry. Having been trained in areas related to research, such as the practice of medicine, they are able to find employment in some circumstances.

Fraud in Biomedical Research: Hearings Before the House Subcomm. on Investigations and Oversight of the Comm. on Science and Technology, 97th Cong., 1st Sess. 286 (1981) [hereinafter Fraud in Biomedical Research]; see also infra note 42 (noting that another researcher found work as a surgical pathologist after discovery that he had fabricated his data).

Instances of alleged wrongdoing within the medical research community continue to surface. In 1986 problems with data were discovered in connection with the claimed discovery of a molecule called interleukin-4A. Published and submitted papers relating to the alleged discovery were retracted in 1986. See Robert Steinbrock, Fraud on Rise: Faking It in Biomedical Research, L.A. TIMES, Apr. 29, 1987, § 1, at 1. One year later, the NIH censured Dr. Charles Glueck, a researcher who studied cholesterol in children, for errors in the presentation of his data. Laurence K. Altman, Cholesterol Researcher Is Censured for Misrepresenting Data in Article, N.Y. TIMES, July 18, 1987, § 1, at 8; see also Credit and Credibility in Science, N.Y. TIMES, July 26, 1987, at E26; Charles J. Glueck, No Fraud Was Found in Cholesterol Report, N.Y. TIMES, Aug. 19, 1987, at A22 (letter to the editor).
managed to carry out a successful career as a researcher in oncology for three years by misrepresenting his credentials and plagiarizing the articles of other scientists.\textsuperscript{22} According to one study of Alsabti's ventures:

The exploits of Alsabti could never have occurred in a community of scientists where rigorous self-policing was the rule and instant expulsion was the automatic penalty for any form of dishonesty. Even when his methods eventually came to light, fellow researchers were reluctant to make a public issue of his cheating. Alsabti would be allowed to leave quietly, and would find a job in another laboratory where the same process would start over again. It was only after Alsabti's methods were described in a handful of international journals that the career of this . . . plagiarist came to a halt.\textsuperscript{23}

Even when a researcher's study is questioned, the researcher's intent may be impossible to ascertain. Investigators have raised questions about the data of Cyril Burt,\textsuperscript{24} the British psychologist whose research into whether IQ and heredity are linked was influential in England and the United States.\textsuperscript{25} Burt claimed to have conducted several studies that traced the intellectual development of a number of twins who were separated and raised apart, as well as twins who were raised together. Several years after Burt's death, however, other psychologists questioned the validity of Burt's data, partly because of an exact coincidence of statistical correlations from one study to another that could not plausibly be

\begin{itemize}
  \item \textsuperscript{22} See BROAD & WADE, supra note 3, at 38–55. The flagrancy of Alsabti's conduct is difficult to capture in a summary, but is epitomized by the following account of Alsabti's plagiarism:
  \begin{quote}
    Each passing month saw another group of Alsabti articles appear in various journals around the world. His method was simplicity itself. He would retype an already published paper, remove the author's name, substitute his own, and send the manuscript off to an obscure journal for publication. His tactics deceived the editors of dozens of scientific journals around the world.
  \end{quote}
  \textit{Id.} at 45.
  \item \textsuperscript{23} \textit{Id.} at 38.
  \item \textsuperscript{24} The story of the debate over Burt's research can be found in BROAD & WADE, supra note 3, at 203–11, and Kohn, supra note 3, at 52–57.
  \item \textsuperscript{25} BROAD & WADE, supra note 3, at 203–06; Kohn, supra note 3, at 52.
\end{itemize}
explained by chance. In addition, Burt claimed to have collected data through two colleagues; the fact that a reporter was unable to trace or locate these colleagues led some to speculate either that Burt had fabricated their existence or that at least they did not perform the research Burt attributed to them. Scientists disagree about whether Burt’s data were deliberately fabricated, merely fudged, or even inadvertently misreported.

Similar ambiguity surrounds the case of Mark Spector, a graduate student who worked on the transformation of normal cells into cancer cells. Spector claimed to have identified a chemical process by which this change occurred, a chemical process he said was documented with radiographs generated to test his theory. It turned out, however, that the radiographs were in fact the product of manipulation. Spector disclaimed responsibility for the misrepresentation, but later was asked to leave his position after he failed to recreate fully his claimed findings.

These examples give some inkling of the variety of misconduct that has occurred within the scientific community, and the technical complexity of the factual situations such misconduct might entail. These examples also demonstrate the relatively light sanctions some people engaged in wrongdoing have received.

II. TYPES OF MISCONDUCT

An initial difficulty in thinking about scientific misconduct is the definition of misconduct. One scientist’s mistake or oversight is another’s deliberate misrepresentation; two scientists may simply disagree about the interpretation of data. It is certainly legitimate to disagree about the proper

27.  Id. at 207–08.
28.  KOHN, supra note 3, at 54.
29.  See BROAD & WADE, supra note 3, at 60–73; KOHN, supra note 3, at 103. Spector was able to recreate enough of his results to make it difficult for scientists to reject all his work. BROAD & WADE, supra note 3, at 68–69; KOHN, supra note 3, at 103. A further inquiry also revealed that Spector had a criminal record for forgery. BROAD & WADE, supra note 3, at 69; KOHN, supra note 3, at 103.
30.  See, for example, the controversy generated by Walter W. Stewart & Ned Feder, The Integrity of Scientific Literature, 325 NATURE 207 (1987), as is reflected
definition of misconduct, but reported instances of misconduct carve out an area of behavior so indefensible that no one would consider it intellectual nickel-and-diming to refuse to dismiss such behavior as mere difference of opinion or honest mistake. The most obvious example would be the reporting of results for experiments that were never performed. 31 Done on a large enough scale, such misconduct can be defended as innocent only by assuming incompetence and sloppiness of the most egregious sort. For the purposes of the present discussion, then, the term "misconduct" will be used in its broadest sense to include all forms of deviation from standard practice that could be viewed as deliberate. Plausible innocent explanations for such conduct will be considered separately. 32

31. See United States v. Keplinger, 776 F.2d 678 (7th Cir. 1985) (upholding the convictions of scientists who underreported the number of deaths of test rats), cert. denied, 476 U.S. 1183 (1986), discussed infra notes 61–79 and accompanying text.

32. Compare, for example, the definitions employed in the Public Health Service’s regulations governing the responsibility of institutions that are awarded or apply for grants to deal with and report possible misconduct in science: “Misconduct or Misconduct in Science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.” 42 C.F.R. § 50.102 (1990).

Also instructive are the definitions used in a study of scientific misconduct conducted by Martin F. Shapiro and Robert D. Charrow:

In this study, scientific misconduct is operationally defined as (1) the execution of a study in a way that compromises the validity or reliability of the findings, or (2) violation of the rights of the subjects who participate in the study. Scientific misconduct by an investigator involves taking an action that a reasonably prudent investigator would not have taken or failing to take an action that a reasonably prudent investigator would have taken. This definition encompasses a broad spectrum of conduct, from negligence to fraud. Negligence in research may be a consequence of cutting corners in the conduct of the study or may be due to the incompetence of the investigator. Fraud, on the other hand, involves deliberate misrepresentation of the data, in the form of either “fudging” (altering the results) or “dry labbing” (generating data without performing the study).

Martin F. Shapiro & Robert D. Charrow, Special Report, Scientific Misconduct in Investigational Drug Trials, 312 New Eng. J. Med. 731, 731 (1985) [hereinafter Shapiro & Charrow I]. See also H.R. Rep. No. 101–688, 101st Cong., 2d Sess. 4 (1990) [hereinafter CONFLICTS REPORT] (“Scientific fraud has been defined in a variety of ways, that have differing legal and practical implications. Virtually all definitions share the tenet that scientific fraud is the ‘deliberate misrepresentation of something as a fact by someone who knows that it is not.’” (footnote omitted)).
One genre of possible scientific wrongdoing involves the misrepresentation of research results, which may take a number of forms. Perhaps the most blatant, as noted above, is the reporting of results for experiments or tests that in fact were never performed.\textsuperscript{33} Such fabrication of data may be entire or partial; either no experiments were performed to test the hypothesis, or some experiments were performed, but fewer than the number reported. For example, Robert Slutsky, an associate professor at the Medical School of the University of California at San Diego and a prodigious author (turning out a paper every ten days), was investigated in 1985. The investigation concluded that twelve of his 137 articles were fraudulent, and forty-eight were "questionable."\textsuperscript{34} Among the misrepresentations that Slutsky made were reports of experiments that had never been performed.\textsuperscript{35}

Another well-known incident of data fabrication involved John Long, a researcher at the Massachusetts General Hospital who specialized in the study of Hodgkin's disease.\textsuperscript{36} Long achieved a degree of prestige in the field of medical research, and was awarded some $750,000 in grants to support his research.\textsuperscript{37} Long's assistant discovered that Long had fabricated data in order to rectify a perceived problem with a paper submitted for publication.\textsuperscript{38} The paper had been rejected initially because a particular measurement made by Long's assistant was unexpectedly low.\textsuperscript{39} Long supposedly made another measurement, while his assistant was on vacation, that conformed more closely to the expected measurement, and the paper was then accepted for publication. A challenge by Long's assistant to Long's data led to the

\textsuperscript{33} This is not to say that the hypothesis is necessarily inaccurate; it is just unproven. Fabrication, of course, is not an invention of the modern era. Charles Babbage refers to fabrication as "forging" in his 1830 book, \textit{CHARLES BABBAGE, REFLECTIONS ON THE DECLINE OF SCIENCE IN ENGLAND} (Augustus M. Kelley 1970) (1830). Babbage notes that "instances of the occurrence of forging are rare." \textit{Id.} at 177. \textit{See also infra} note 46.

\textsuperscript{34} \textit{CONFLICTS REPORT}, supra note 32, at 15.


\textsuperscript{36} A detailed discussion of the case of John Long is found in \textit{BROAD & WADE}, supra note 3, at 89–96; \textit{KOHN}, supra note 3, at 93–97.

\textsuperscript{37} \textit{BROAD & WADE}, supra note 3, at 90; \textit{KOHN}, supra note 3, at 95.

\textsuperscript{38} \textit{BROAD & WADE}, supra note 3, at 91; \textit{KOHN}, supra note 3, at 94–95.

\textsuperscript{39} \textit{BROAD & WADE}, supra note 3, at 90; \textit{KOHN}, supra note 3, at 94.
discovery that Long had fabricated not only his data but also (apparently after being challenged) his work papers in order to appear to have documentation of his data.\footnote{40}

Long resigned, and an investigation of his research efforts disclosed a number of other serious problems with Long's research. For example, three of the four lines of cells that Long was studying came not from unrelated human beings, as Long's research claimed, but from a monkey.\footnote{41} Investigators assumed that Long's human cells had become contaminated with monkey cells and that ultimately the human cells had died out, leaving only monkey cells. Long claimed that he was unaware of the problem.\footnote{42}

Another form of misrepresenting data is the practice of "cooking" data,\footnote{43} which might include selectively reporting data\footnote{44} or performing numerous, originally unplanned, statistical analyses on data to make the numbers come out right.

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40. BROAD & WADE, supra note 3, at 92–93; Kohn, supra note 3, at 95.
41. BROAD & WADE, supra note 3, at 92–93; Kohn, supra note 3, at 95.
42. According to Long's testimony before the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology in 1981, he was a practicing surgical pathologist and was hired by people "with full awareness" of his problems in research. Fraud in Biomedical Research, supra note 21, at 62.

The rather unusual but nonetheless documented instances involving the deliberate creation of a hoax, such as the infamous Piltdown Man, also fall within this category of scientific wrongdoing. The Piltdown Man was an archeological find in the early 1900s that supposedly represented parts of the skull of a prehistoric man. In fact, the parts included nonhuman bones and human bones altered to make them appear old. It took more than thirty years for the forgery to be discovered. See STEVEN JAY GOULD, THE PANDA'S THUMB 108–24 (1980); BROAD & WADE, supra note 3, at 119–22; Kohn, supra note 3, at 133–41.

43. See BABBAGE, supra note 33, at 178–83.
44. Selective reporting of data appears to have been a problem of Nobel Prize-winner Robert Millikan. A physicist, Millikan was involved in efforts to measure the electrical charge of electrons. Millikan believed that electrons had a single charge, but his competitor, Austrian physicist Franz Ehrenhaft, believed there were fractional charges carried by subelectrons. Variability in the measurements of charges, then, tended to support Ehrenhaft's rather than Millikan's theory. In a 1913 article Millikan claimed to have reported the results from all his experiments, but subsequent examination of his notebooks revealed that he had omitted a significant percentage of his data from the report. BROAD & WADE, supra note 3, at 33–35; Kohn, supra note 3, at 57–62; Steinbrock, supra note 21, at 1 ("In recent years physicists—using more accurate equipment than was available to either Millikan or Ehrenhaft—have accumulated evidence suggesting that Ehrenhaft may have been correct after all. Most scientists now believe that electrons, like other subatomic particles, are made from smaller units called quarks.").

Theodore X. Barber describes a similar problem: the failure to report that the experimental data did not support the original hypothesis. THEODORE X. BARBER, PITFALLS IN HUMAN RESEARCH 20–21 (1976). Instead, the experimenter, after studying the data, derives a new hypothesis that is supported by the data. Id. at 21. The experimenter then verifies the new hypothesis by performing statistical analysis on the old data rather than testing the new hypothesis through a new study. Id.
A related form of misrepresentation of data is "trimming," whereby the researcher evens out data by "clipping off little bits here and there from those observations which differ most in excess from the mean, and in sticking them on to those which are too small; a species of 'equitable adjustment.'"\textsuperscript{45} Clearly, aberrant data may be just that, but the uninformed public is unable to draw or to test that conclusion with independent consideration of whether the data are truly aberrant or instead indicate a flaw in the hypothesis.\textsuperscript{46}

Other lapses include the failure to report lack of adherence to the planned procedure, or "protocol," for conducting the experiment.\textsuperscript{47} Such failures to report mislead the public into believing that all tests were conducted in a particular way. Thus, another scientist might be unable to duplicate the experiment because the experiment was conducted in a manner different from what was reported. Moreover, if another scientist knew about the departures from protocol, she might conclude that the results were influenced by, and thus must be interpreted in light of, the different protocol actually used.

Clearly, failures of this sort may be inadvertent, or a result of the failure to appreciate the existence or significance of the lack of adherence to protocol. Likewise, a researcher may not recognize or consider significant the failure to specify a precise protocol for an experiment. A loose protocol may allow a

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\item[45.] \textbf{Babbage, supra} note 33, at 178. In Babbage's view, "This fraud is not perhaps so injurious \ldots as cooking \ldots [because] the average given by the observations of the trimmer is the same, whether they are trimmed or untrimmed." \textit{Id.}
\item[46.] Data manipulation in the context of research in the behavioral sciences is discussed in \textbf{Barber, supra} note 44. Barber calls this manipulation "fudging," and describes it as follows:

\begin{quote}
Although outright fraud (fudging of all or most of the data) is probably very rare in the behavioral sciences, "pushing the data", or letting desires and biases influence the way the data are analyzed or reported, may not be too rare. \ldots For instance, after discussing instances of outright fraud in science, [R.K.] Merton \ldots noted that probably much more common are instances of "trimming" or "cooking" the data which are probably due to excessive concern with success in scientific work.
\end{quote}


Babbage likewise attributes "trimming" to an objective on the part of the "trimmer" to "gain a reputation for extreme accuracy in making observations." \textbf{Babbage, supra} note 33, at 178. Babbage goes on to state, however, that "from respect for truth, or from a prudent foresight, he [the 'trimmer'] does not distort the position of the fact he gets from nature, and it is usually difficult to detect him. He has more sense or less adventure than the Cook." \textit{Id.}
\item[47.] \textbf{Barber, supra} note 44, at 16.
\end{itemize}
researcher to change the outcome of a particular phase of an experiment by varying the way in which the experiment is carried out each time it is run.48

Another type of misconduct is the failure to record data. A nonscientist might find it hard to accept that a scientist would not record the results of tests or experiments and might instead suppose that a failure to record data is in fact a failure to do the experiments or tests at all.49 Skepticism about this possibility is no doubt enhanced by the fact that on occasion, when faced with allegations that particular experiments or tests had not been performed at all, the implicated researchers argued that they had done the experiments, but did not record the results, or that they did record the results but did not retain the data after a particular period of time.50

48. Barber, after discussing the "rather rare instances" in which an experimenter has no formal protocol, describes the problem of loose protocol:

In a somewhat more common case than the one described above, the experimental protocol has more precise specifications as to how the experiment is to be conducted, but there is still much missing and there is room for the experimenter to vary the procedure from subject to subject. . . . This failure to plan for contingencies is also found in loose protocols that do not state what the experimenter is to do at various steps in the procedure. . . . The data from experiments that are based on loose experimental procedures are often reported very precisely. However, since the precise data are based on loose procedures that leave much room for bias, they can be misleading.

BARBER, supra note 44, at 17.

49. Unless, perhaps, the results were not favorable to the scientist's theory. In the case against employees of Industrial Bio-Test, for example, described infra notes 61-79, deaths of rats used as test animals were not recorded; in that case, excessive rat mortality might indicate that the product being tested was unsafe. United States v. Keplinger, 776 F.2d 678 (7th Cir. 1985).

In connection with the investigation of research supervised by David Baltimore, however, discussed infra note 153, the researcher whose work was questioned, Dr. Thereza Imanishi-Kari, told Congress that data from print-out tapes sometimes were not transcribed to lab notebooks until months after an experiment was performed. Larry Thompson, Science Under Fire, WASH. POST, May 9, 1989, at Z12, Z15.

50. John Darsee raised this type of defense when he was the focus of an investigation, described supra notes 9-11, and the employees of Industrial Bio-Test made a similar argument during their prosecution, described infra notes 61-79.

Similarly, the EPA in 1983 had to review its standard for carbon monoxide emissions when questions regarding the validity of a study conducted to assess health effects on heart patients could not be resolved, in part because of the loss or destruction of data and failure to maintain adequate records by the physician who conducted the study. Cass Peterson, EPA Probe Criticizes a Study Used in Air-Quality Standard, WASH. POST, June 7, 1983, at A17.

An extreme example of a claim of document loss is described in the New York Times:

In 1978, medical officers from the F.D.A.'s Clinical Investigation branch of the Division of Scientific Investigations within the Bureau of Drugs, decided to check the doctor's records of patients involved in studies against data that had been
genre of misconduct is plagiarism, which can take the form of lifting another's words or ideas, or even of stealing research proposals.\textsuperscript{51}

submitted to the agency. On April 25, the day of the inspection, Dr. Scheiner told investigators that his office had been vandalized the night before and that all the records relating to the studies that were to have been inspected had been dumped into a whirlpool bath. Dr. Michael J. Hensley, a medical officer for the F.D.A., later told Senate investigators that furniture had been slashed but that, "it appeared that the [medical] certificates and diplomas had been removed from the walls before the swastikas were painted. The outlines were clearly visible where they had hung."

At hearings held in October 1979 by the Senate Subcommittee on Health and Scientific Research, Dr. Hensley said that, before the next inspection, the doctor—referred to in the hearings as "Dr. 3"—reported that there had been a fire in his office. And the night before the rescheduled inspection, said Dr. Hensley, "The doctor was allegedly mugged in his office and struck on the head with a steel paperweight. It is worth noting, I guess, that the only prints on the paperweight were the doctor's own."


\textsuperscript{51} An incident involving a claim of plagiarism occurred at the Yale Medical School. \textit{See Broad \& Wade, supra} note 3, at 161–80; \textit{Kohn, supra} note 3, at 88–93; \textit{Fraud in Biomedical Research, supra} note 21, at 80–104. An NIH researcher, Helena Wachslicht-Rodbard, accused Philip Felig and Vijay Soman, then both faculty members at the Yale School of Medicine, of plagiarizing passages from a manuscript that she had authored. The paper had been submitted to a journal for publication, and was sent for peer review to Felig, who passed it on to Soman. Soman had undertaken earlier to study the same problem that was the subject of Wachslicht-Rodbard's paper. Felig recommended that Wachslicht-Rodbard's paper not be published. \textit{Broad \& Wade, supra} note 3, at 163–64.

Shortly thereafter, a paper by Soman, in which Felig was listed as coauthor, was circulated to Wachslicht-Rodbard's supervisor for peer review. When Wachslicht-Rodbard's supervisor passed the paper on to her, she noticed passages that mirrored passages from her own paper, but a full investigation began only after Wachslicht-Rodbard invested an enormous amount of time and effort to convince her colleagues that her complaint was valid. The investigation ultimately disclosed fabrication or "fudging" of data by Soman on a number of papers. \textit{Id.} at 165–80; \textit{Kohn, supra} note 3, at 89–92. Other examples of this conduct include the case of Elias Alsabti, \textit{see supra} notes 22–23 and accompanying text, and the case of Shervert Frazier, the head of McClean Hospital, Harvard University's psychiatric teaching facility, who resigned his position after allegations were made that he had plagiarized papers between 1966 and 1975. John Crewdson, \textit{Cheating in the Lab}, \textit{Chi. Trib.}, March 19, 1989, at 1; Peter G. Gosselin et al., \textit{Scientists Grapple with Increase in Fraud}, \textit{Boston Globe}, Dec. 4, 1988, \textsection 4, at 1. \textit{See generally Broad \& Wade, supra} note 3, at 57–59. For other examples of scientific plagiarism, see \textit{Kohn, supra} note 3, at 146–60. Broad and Wade conclude the following about the subject of plagiarism:

The rewards in science are supposed to go strictly and exclusively for originality. That is why scientists strive so desperately to establish priority for their discoveries. It is also why, to judge from the frequency and bitterness of complaints, researchers sometimes fail to make fair acknowledgment of the work of their colleagues and competitors. The failure to make due acknowledgment of another researcher is, in a minor way, a theft of his work.
The possibility of financial conflicts of interest has recently commanded attention.\(^5\) An example of this is when

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Plagiary is an interesting phenomenon because it carries this common sin of scientific reporting to extremes. Plagiary, the wholesale theft of another's work, is so outrageous and obvious a crime that an outsider might predict scientists would never commit it. The evidence shows that, to the contrary, plagiary in the scientific community is not rare, that it probably often escapes detection, that it takes time for even the most blatant cases of plagiary to come to light, and that even those discovered committing plagiary are often able to continue their careers unaffected. If plagiary, the grossest offense against intellectual property, merits just knuckle-rap treatment from the scientific community, what degree of indulgence must be accorded to lesser crimes?


52. See generally Federal Response to Misconduct in Science: Are Conflicts of Interest Hazardous to Our Health?: Hearings Before a Subcomm. of the House Comm. on Government Operations, 100th Cong., 2d Sess. (1988) [hereinafter Conflicts Hearings] (examining the effects financial conflicts of interest have on scientific research). Leonard Minsky, Ph.D., Executive Director of the National Association of Universities in the Public Interest, describes an example of such a financial conflict of interest:

[We have a case at the University of Florida in Gainesville . . . where there is a for profit firm occupying space in a research park. The dean of the college of pharmacy had stock in the firm. Most of the principal researchers of the college of pharmacy had stock or were consultants to the firm. Most of the work done in the college of pharmacy was work done on the subject of interest to the firm and when one colleague, a scientist in the college of pharmacy, urged the firm to consider that the work they were doing was dangerous to the workers and that the tests they were using were perhaps inappropriate for the drug, he was fired as a consultant to the firm.

The way we put it, the college of pharmacy in this particular instance becomes a wholly owned subsidiary of a private for profit firm because of the nature of the relationships between the professors and the college of pharmacy, and between the dean, the college of pharmacy and the firm.

Id. at 48–49.

Conflicts of interest in research were also explored in Is Science for Sale? Conflicts of Interest vs. The Public Interest: Hearing Before the Human Resources and Intergovernmental Relations Subcomm. of the Comm. on Government Operations, House of Representatives, 101st Cong., 1st Sess. (1989). The recent prosecutions of Food and Drug Administration (FDA) employees for accepting gifts from three representatives of drug companies seeking approval of generic drugs raise a related problem. While no evidence indicated that the FDA had approved unsafe drugs, it appeared that the approval procedures were manipulated to the benefit of certain companies. See FDA's Generic Drug Approval Process (Part 1): Hearings Before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce, House of Representatives, 101st Cong., 1st Sess. 2 (1989) [hereinafter Generic Drug Hearings].
a researcher owns stock in the company whose product he is testing or otherwise has a financial stake in the particular research result. Financial conflicts raise not only the possibility of research-related misconduct but also the possibility that a researcher will use research results inappropriately. For example, a researcher, privy to significant research results that could affect the value of the company’s stock, might have the opportunity to speculate in the stock on the basis of information not generally available to the public.\(^{53}\)

Failing to obtain informed consent from human research subjects\(^{54}\) or otherwise failing to follow regulations governing

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53. The case of Scheffer Tseng, a researcher at the Massachusetts Eye and Ear Infirmary, demonstrates the potential for a link between research and the market value of a company:

In October, medical school officials acknowledged that a junior researcher at the Harvard-affiliated Massachusetts Eye and Ear Infirmary, Scheffer C. G. Tseng, had tested an experimental eye drug on hundreds of patients while helping organize a company to make it. The drug later proved largely ineffective.

Tseng’s experiments, conducted between 1984 and mid-1986, raised questions about whether he failed to report negative effects of the drug to help the company, Spectra Pharmaceutical Services Inc. of Hanover. Tseng and his family made at least $1 million from stock sales and other payments from the firm.


54. This species of misconduct is sufficiently distinct as to be beyond the scope of this Article. The most well-known example of criminal prosecution for this type of misconduct is the Nuremberg trials, in which the defendants were charged with war crimes and crimes against humanity for carrying out nonconsensual experimental medical procedures. See HEINZ SCHULER, ETHICAL PROBLEMS IN PSYCHOLOGICAL RESEARCH 169–72 (Margaret S. Woodruff & Robert A. Wicklund trans., 1982).

Rules governing the conduct of medical experiments on human subjects were formulated after World War II and became known as the “Nuremberg code.” The HHS has adopted regulations governing the use of human subjects in experiments. 45 C.F.R. §§ 46.101–.409 (1990).

In recent legal development relating to the problem of patient consent, the California Supreme Court recognized civil causes of action for a physician's breach of a fiduciary duty to disclose facts material to the patient's consent, and for the performance of medical procedures without first having obtained the patient’s informed consent. Moore v. Regents of the Univ. of Cal., 793 P.2d 485 (Cal. 1990) (en banc), cert. denied, 111 S.Ct. 1388 (1991). The court held, however, that a leukemia
the conduct of particular sorts of experiments are other potential forms of scientific misconduct. Finally, garden-variety property crimes such as embezzlement or misapplication of research funds also could be included as examples of misconduct related to research.

III. PUNISHING SCIENTIFIC MISCONDUCT WITH CRIMINAL SANCTIONS

Setting aside the scientific context of the problems discussed above, the familiar ring of problems that arise in virtually every walk of life can be heard: lying and cheating, with a healthy dose of mistake and negligence. Generally mistake and negligence do not present criminal law concerns, so the discussion will be confined to the first group of evils. Of course not every dishonorable act is a crime (and fewer are federal crimes), but some types of scientific misconduct raise the same criminal law concerns that similar misconduct raises outside the scientific arena. Indeed, some forms of misconduct described earlier are clearly punishable under existing federal statutes; in such cases, the federal interest in and ability to prosecute does not depend on the scientific context.

55. For example, the FDA provides regulations dealing with “Good Laboratory Practice for Nonclinical Laboratory Studies.” 21 C.F.R. §§ 58.1–219 (1991). These regulations set forth standards for “conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration” such as drugs and food additives. Id. at § 58.1. They cover a range of topics including personnel, equipment, protocol, reporting, and record retention. Id. at §§ 58.1–219.

56. Recent media accounts have raised the possibility of misuse of grant funds at various universities. See, e.g., Turning Labs into Cedar Chests: Alchemy, Stanford Style, NEWSWEEK, Feb. 4, 1991, at 70.

57. See, e.g., MODEL PENAL CODE § 2.02(3) cmt. 5 (Official Draft and Revised Comments 1985) (“Since negligence is an exceptional basis of liability, it should be excluded as a basis unless explicitly prescribed.”). Scientific misconduct involving negligence or quality-control issues, rather than the kind of deliberate or venal misconduct with a high potential for harm that one associates with criminal conduct is not an appropriate target of criminal law. Thus, failure to adhere to protocol is hardly of criminal law interest and is the sort of misconduct that could be addressed through internal controls.


59. Stephen Breuning’s submissions of false information to the HHS were punishable under 18 U.S.C. § 1001 (1988), which prohibits using or making false
Nor should the scientific context obscure or insulate from scrutiny the fact that the actual or potential harm of particular conduct is characteristic of other conduct that is treated criminally. Acts that wrongfully allow one to obtain money or property, as well as acts that compromise the integrity of a public process are no less wrong or harmful if they are done in the context of scientific research. Misrepresenting research results in order to obtain federal grant money is essentially theft by false pretenses. It corrupts the governmental process of awarding grant money. Misrepresentation of research results also can corrupt other governmental decision-making processes, such as a decision to allow the marketing of a food additive.

The misrepresentation of research results, either in connection with efforts to obtain government funding of research or in connection with other governmental decisions, has attracted the attention of federal prosecutors because of its potential financial impact and its tendency to undermine governmental decision-making. In the applied research arena, prosecutions have been brought for making false statements to a federal agency, such as the Food and Drug Administration (FDA), in connection with the testing of drugs and food additives.\(^{60}\)

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For example, Shapiro and Charrow describe the results of FDA investigations that led to action being taken against an investigator involved in testing new drugs for safety and efficacy in order to obtain approval for marketing. Shapiro & Charrow I, supra note 32, at 732. Their analysis covers the period from January 1975 to February 1983:

Audits are initiated by the FDA if the data in a study appear to be too “clean” or if the FDA observes that a clinician has enrolled a larger number of subjects from his or her practice than seems realistically attainable. Still other audits are triggered by problems in a previous FDA audit of the investigator. For-cause audits may result in an action against the investigator ranging from disqualification to restriction of his or her access to new drugs. Some cases are referred to the U.S. Department of Justice for criminal prosecution.

\(^{60}\)Id. A follow-up study by Shapiro and Charrow concluded that serious problems with research declined after the FDA instituted an auditing program. Martin F. Shapiro & Robert D. Charrow, The Role of Data Audits in Detecting Scientific Misconduct, 261 JAMA 2505 (1989). The article is discussed in Susan Okie, FDA Audits Apparently Reduce Fraud in Drug Tests, WASH. POST, May 7, 1989, at A4.
A good example is the criminal prosecution of the officers of Industrial Bio-Test Laboratories, Inc. Based in Northbrook, Illinois, Industrial Bio-Test (IBT) was one of the largest laboratories to engage in contract research in the 1970s. IBT's

In their first study, Shapiro and Charrow cite the case of an obstetrician-gynecologist who was paid $140,000 between 1975 and 1979 to test analgesics for five drug companies:

In 1983, he was indicted and pleaded guilty to making false statements that he had properly administered the medications to over 900 patients; failing to give any of the medications to some patients whom he reported had received them; including incorrect listings of surgical procedures for patients purportedly being treated for postoperative pain; and failing to note when other medications, including other analgesics, were given to the patients. His attorney acknowledged that he did not have accurate data but had filled in the blanks and submitted data to the manufacturers "as if the drugs had been administered and then proceeded to get paid for it." The physician also concealed the falsified laboratory testing from his practice partners, put the funds that he received for this purpose to his own use, and falsified the records of an institutional review committee.


Other references to criminal prosecutions of doctors for fabrication of research results can be found. See, e.g., Generic Drug Hearings, supra note 52, at 115 (describing the case of a doctor who was sentenced to four years' imprisonment and $4 million in fines and restitution when he contracted with pharmaceutical companies to perform tests but submitted false Medicare claims and falsely stated that he had performed trial tests he never performed); Jersey Doctor Accused of Fraud in Drug Tests, N.Y. TIMES, Feb. 21, 1988, at A32 (describing the indictment of Robert A. Fogari, a New Jersey doctor, for conspiracy to defraud the FDA and for making false statements to hinder an FDA investigation).

According to congressional hearing testimony, there is a prosecutorial bias toward offenses under Title 18 (the federal criminal code) rather than offenses under Title 21 (the federal drug code, which contains a number of criminal statutes). Fraud in Biomedical Research, supra note 21, at 309 (describing the testimony of Dr. Alan Lisook, Chief of Clinical Investigation Branch, Division of Scientific Investigations, Bureau of Drugs, FDA). This bias may be due to greater familiarity with Title 18 offenses, or greater potential sentences under Title 18.

61. United States v. Keplinger, 776 F.2d 678 (7th Cir. 1985), cert. denied, 476 U.S. 1183 (1986). Another example is the 1978 indictment of six former and then current officers of Velsicol Chemical Corporation for concealing from the Environmental Protection Agency (EPA) laboratory data about two pesticides, chlordane and heptachlor. The indictment was dismissed due to prosecutorial misconduct before the grand jury. United States v. Gold, 470 F. Supp. 1336 (N.D. Ill. 1979). See also In re November 1979 Grand Jury, 616 F.2d 1021 (7th Cir. 1980) (denying Velsicol's efforts to terminate a new grand jury proceeding). Certain registrations for chlordane and heptachlor were later cancelled pursuant to a memorandum of understanding between the EPA and Velsicol. Chlordane and Heptachlor Termiticides, 52 Fed. Reg. 42,145 (1987) (cancellation order).
role in the world of contract research was to conduct animal toxicity studies on various products subject to government regulation, such as drugs and pesticides, in order to provide factual support for submissions to regulatory agencies that the products tested were safe and effective. In the mid- and late-1970s, the FDA raised questions about the validity of IBT's laboratory studies and findings. The lab closed in 1978.

In June 1981, a federal grand jury returned an indictment in Chicago against the former Manager of Toxicology of IBT, the Section Head of Rat and Dog Toxicology, the Group Leader of the Rat and Dog Toxicology Department, and the former president of IBT. The charges alleged violations of the false statement statute and the mail fraud statute relating to three studies that had been performed by IBT.

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62. Apparently the FDA first discovered the problem purely by chance and went on to document serious defects in the data that IBT had reported. The EPA also became involved because of the submission of data generated by IBT to support applications for approval of various pesticides. Indeed, IBT had performed more than 4,000 studies upon which the registration of 123 pesticides and the establishment of 160 tolerance levels for pesticide residue had been based. Congress conducted hearings into the problems with IBT and several other contract research companies that were also under investigation because of irregularities in their reported research data. Preclinical and Clinical Testing by the Pharmaceutical Industry, 1977: Hearing Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources, 95th Cong., 1st Sess. (1977) (Part IV); Linda Garmon, Since the Giant Fell, SCI. NEWS, July 4, 1981, at 11.


64. Keplinger, 776 F.2d at 683–84; Garmon, supra note 62, at 11.

65. Keplinger, 776 F.2d at 684 n.2.
defendants\textsuperscript{66} were convicted on charges relating to two of those studies.\textsuperscript{67} Misconduct included failure to disclose information,\textsuperscript{68} or false reporting and underreporting of data to the FDA or Monsanto or Syntex Corporation, the chemical companies for which the studies had been done.\textsuperscript{69}

A synopsis of some of the false reports will illuminate the kind of wrongdoing at issue. One study related to the chemical trichlorocarbanilide (TCC), which was used in deodorant soaps, and the other related to an anti-inflammatory drug called Naprosyn, which was used to treat arthritis.\textsuperscript{70} A key problem with the TCC study was alleged underreporting of the rat mortality rate.\textsuperscript{71} The rats used in the TCC study had the unfortunate tendency to die at a rate high enough to call into question the validity of the study and any product safety evaluations based on the study.\textsuperscript{72} According to the government, IBT therefore sought to mask the high death rate by substituting new animals for dead ones, and inaccurately recording the number of deaths of rats.\textsuperscript{73} This “procedure”

\textsuperscript{66.} A mistrial was granted as to one defendant due to health problems. \textit{Illinois Case Mistrial Declared}, N.Y. TIMES, July 12, 1983, at A15.

\textsuperscript{67.} \textit{Keplinger}, 776 F.2d at 684 n.2.

\textsuperscript{68.} \textit{Id.} at 684. These omissions comprised part of the basis for the fraud charges, but liability for omissions can arise under the first clause of the false statement statute, which punishes one who, in a matter within the jurisdiction of a department or agency of the United States, “knowingly and willfully . . . conceals or covers up by any trick, scheme, or device a material fact.” 18 U.S.C. § 1001 (1988).

\textsuperscript{69.} \textit{Keplinger}, 776 F.2d at 684. With respect to the false statement counts, the false reports that were made to Monsanto were then submitted by Monsanto to the FDA. \textit{Id.}

\textsuperscript{70.} \textit{Id.}

\textsuperscript{71.} Regarding the significance of rat mortality, the court of appeals noted: “Accurate mortality data is important because it provides evidence of a substance’s impact on test animals and also because it can provide evidence of environmental problems which might compromise the validity of a study.” \textit{Id.}

\textsuperscript{72.} \textit{Id.} at 685.

\textsuperscript{73.} \textit{Id.} at 685–86. To prove that substitution had occurred, the Government called as witnesses two laboratory technicians who had observed rat deaths that had not been accurately recorded and also produced both a draft report and an internal IBT document that showed higher rat mortality rates than IBT eventually reported to Monsanto. Testimony was also adduced that lab technicians filled empty rat cages with new rats at several points in the study. Moreover, the evidence showed that at the termination of the study, when all the animals were sacrificed, exactly the correct number of male rats needed to ensure the validity of the study was found in each group. Such a perfect statistical correlation was urged to be an unlikely coincidence, suggesting that male rats had been added as needed to make the numbers come out right. Finally, the total number of rats that died or were killed during the study was greater than the total number of rats that had started the study. \textit{Id.}
clearly would result in an inaccurate picture of how many rats had died in the course of the study, a fact of critical importance in evaluating the safety of the chemical used.\textsuperscript{74}

The Naprosyn study, performed for the Syntex Corporation, also formed the basis of criminal charges. The government

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Newspaper accounts describing the testimony of the lab technicians paint a grim picture of lab conditions and procedures:

The witness, Philip Smith, said rats died in tests of the substance, Trichlorocarbanilide, but he was told to write a report showing no deaths in the first six months of the study.\ldots

\ldots

While Mr. Smith said that the cause of the rat deaths was often not determined, they were caused in part by a frequently malfunctioning water sprinkler designed to provide drinking water and to clean cages.

The mortality rate of rats in the room was two to three times higher than normal, Mr. Smith said, adding, “Some rats would get no water; some had constant water falling on them.”

“Drain hoses would come unattached from racks and spray food and feces on the floor and plug the drain,” he said. Mr. Smith said he repeatedly reported this.

\textit{Ex-Aide in Laboratory Says Data on Soap Ingredient Were Falsified, N.Y. TIMES, May 9, 1983, at A17 [hereinafter Soap Ingredient Falsified]; see also Trial Ending, supra note 63, at A21 (noting that the “animal feeding room [was] known as ‘the swamp’”).}

Similar testimony was recounted about other tests:

In separate research on the toxicity of Naprosyn, an arthritis drug, Mr. Smith said Mr. Plank supplied results of blood and urine tests that were never performed. He said that though he could not find the final test reports, Mr. Plank told him “it would save time” if he wrote that the tests were negative.

Mr. Smith also said animals that died in this study often were not examined for cause of death and were listed by Mr. Plank as succumbing to diseases such as pneumonia that were unrelated to the substances being tested.

\ldots

[In research performed for another company,] “[s]ome animals were listed as dying natural deaths, but I didn’t know how they died,” Mr. Smith said.

\textit{Soap Ingredient Falsified, supra.}

\textsuperscript{74} Although the mere fact that rats died does not mean that the chemical was unsafe, that is scarcely mitigating. Governmental action is predicated upon the assumption that the data submitted to it are accurately reported. Without accurate data, the government, and therefore the public, is forced to bear the risk that accurate data would not substantiate the claim that the chemical is safe. As the prosecutor in the IBT case said in closing argument, “What these defendants were doing was gambling, rolling the dice, playing Russian roulette. Fortunately, the chamber came up blank. But they didn’t know what the results would be. There is no room in science for gambling.” 3 Ex-Officials of Major Laboratory Convicted of Falsifying Drug Tests, N.Y. TIMES, Oct. 22, 1983, § 1, at 13.
contended, among other things, that blood and urine data for rats used in the study were fabricated and that gross pathology data were largely fabricated.\textsuperscript{75} As part of the government's proof, there was testimony that the gross pathology findings included animals whose bodies in fact had not been examined but instead had been thrown away because they were too badly decomposed to allow for autopsies.\textsuperscript{76}

The effects of IBT's actions were felt long after the case ended because so many governmental decisions rested upon IBT studies. The EPA, in the wake of questions raised about the validity of IBT's data, was forced to review the validity of more than a thousand IBT studies; in the interim, products marketed on the basis of IBT studies remained on the market.\textsuperscript{77} In 1986, dinoseb, a chemical marketed at one point on the basis of studies performed by IBT, was the subject of an emergency order by the EPA banning its use or sale because new safety tests had shown it to be an imminent hazard to human health;\textsuperscript{78} a final cancellation was issued in mid-1988.\textsuperscript{79}

While prosecution for this type of conduct may not seem problematic, one's intuition may be different when the context shifts from applied to basic research. Perhaps the business context or the perception of profit motive makes the harm seem more tangible or the conduct more venal in situations like that presented by the IBT case. When consideration is given to prosecuting a university professor for misrepresenting research results, however, some would find the criminal aspect of the

\textsuperscript{75} United States v. Keplinger, 776 F.2d 678, 689 (7th Cir. 1985).
\textsuperscript{76} Id. at 689–90.
\textsuperscript{79} The history of EPA's action on dinoseb is recounted in Dinoseb Pesticide Products, 54 Fed. Reg. 7,372, 7,373 (1989) (amended and final notice). The final cancellation order was issued on June 9, 1988. Id. See also Schneider, supra note 63, at E5.

scientists have played and continue to play an important role in the evolution of our culture. Over the years, scientists

A. The Need for Prosecution: Conditions for and
Nonpenal Controls of Misconduct

80. See Fraud in Biomedical Research, supra note 21, at 10–11 (testimony of Dr. Philip Handler, President, National Academy of Sciences).

81. See infra notes 103–04 and accompanying text. A general description of this view, termed "the conventional ideology of science," is found in BROAD & WADE, supra note 3, at 15–18. The tenor of the disparity in views on this point was reflected in a number of statements made before the Senate Subcommittee on Health and Scientific Research. In discussing what, if any, political controls should be exerted over science, Gerard Piel, the publisher of Scientific American, spoke about the self-policing nature of science, including among his remarks the following:

It [the control of science] comes out of the self-governing democracy of the scientific community, which no matter how fallible and error-prone and ridden with clique and fashion and nonsense it is, provides a kind of knowledge that is verifiable and objective. Nobody can be a crook, to quote a recent national leader. Murder will out.

Biomedical Research and the Public: Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources, 95th Cong., 1st Sess. 42 (1977) [herein-after Biomedical Research].

Piel contended that the ideal, of which the peer review system was an outgrowth, must be a "self-governing community of independent sovereigns who are citizens and scientists." Id. at 43. Piel's views were referred to later in the discussion as a "kind of glorification and romanticization of the arrogation of special privileges to the scientific community," id. (statement of Jonathan King, Associate Professor of Biology, Massachusetts Institute of Technology; Member, Genetics and Society Group, Science for the People), and "a relic from the 18th and 19th centuries." Id. at 54 (statement of Harold P. Green, Professor of Law, The National Law Center, George Washington University).
have enjoyed a high degree of public acceptance and respect because of the important contributions they have made, particularly in areas such as the prevention and treatment of disease and the exploration of space.\(^2\)

The public image of scientists has tended to be a positive one; each of us no doubt can conjure up an image, formed or fostered by television or film depiction, of the white-coated and slightly distracted scientist squirreled away in a musty university laboratory thinking great thoughts, quite unaffected by the mundane passions of the real world. Given that image, it is shocking to contemplate acts like the fabrication of research results and plagiarism.

Yet, one by one our cultural heroes have become tarnished in the public eye. From Watergate to Wall Street, formerly esteemed segments of professional life in this country have suffered a precipitous decline in reputation and public confidence.\(^3\) Professions we might have viewed in the years gone by as of unassailable integrity have come to be viewed in a more jaded, and some would say more realistic, light. Scientists, however, to a large extent have escaped this degree of cynicism, perhaps because of the relatively lesser incidence of misconduct by scientists, or perhaps because of the relatively greater obscurity of such misconduct. Whatever the cause, our favorable impression of scientists has tended to prevail despite significant instances of misconduct.

While reasonable persons might differ about the frequency of abuse, it would be unreasonable to conclude that the potential for abuse is inconsequential or that the seriousness of the possible consequences of scientific misconduct does not merit concern. Although scientific research may be a profession that tends to attract people committed to truth-finding, scientists are subject to the same day-to-day pressures of the work world as anyone else, even in academic settings.\(^4\)

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82. See id. at 21 (statement of Ruth S. Hanif, Senior Research Associate and Study Director, Institute of Medicine, National Academy of Sciences) ("The Sputnik era reinforced the trends toward increased research and technology and the prestige that accrued to the scientist-researcher.").

83. For example, Oliver North was fined for his participation in the Iran-Contra Affair, David Johnston, North, Spared Prison, Gets $150,000 Fine and Probation for His Iran-Contra Crimes, N.Y. TIMES, July 6, 1989, at A1, and Michael Milken received a prison sentence for his crimes related to securities trading. Kurt Eichenwald, Milken Gets 10 Years for Wall Street Crimes, N.Y. TIMES, Nov. 22, 1990, at A1.

84. As William S. Beck noted:

Likewise, science cannot be regarded as a thing apart, to be studied, admired, or ignored. It is a vital part of our culture, our culture is part of it, it
For example, the notion is sometimes advanced that the scientific profession by its nature attracts (and keeps) persons who by nature are truth-seekers, skeptical and critical in their thinking. There are, however, a number of forces that might work against this hypothesized self-selection for honesty. For example, even if the hypothesis is true, the explosion of the number of scientists in the past fifty years may have had some diluting effect on the general qualifications of scientists. Additionally, just like the attraction of truth-finding, the attractions of attention, of accolade, and even of monetary reward for discovery, are also forces at work in the self-selection process.

permeates our thinking, and its continued separateness from what is fondly called “the humanities” is a preposterous practical joke on all thinking men.

In the pages that follow, we will speak of the nature of science, of the scientist, of ideas, and of life. It is my intention to connect science with the rest of our experience by interweaving the notions of biological thought with aspects of history and the philosophical and cultural climate of each age and by showing the scientist to be a human being, not a wizard, demon, or lovable white-haired old man. He is not a caricature or a stereotype but a man who faces difficult problems (for a variety of personal reasons), who succeeds and fails, and who behaves as nobly or erratically as his neighbor—sometimes more so, sometimes less so.


85. Some have argued to the contrary, that is, that there is a powerful potential for self-deception and gullibility among scientists:

Expectancy leads to self-deception, and self-deception leads to the propensity to be deceived by others. The great scientific hoaxes, such as the Beringer case and the Piltdown man demonstrate the extremes of gullibility to which some scientists may be led by their desire to believe. Indeed, professional magicians claim that scientists, because of their confidence in their own objectivity, are easier to deceive than other people.

BROAD & WADE, supra note 3, at 108.

86. As the New York Times reported, “The National Science Foundation notes that from 1976 to 1986, the number of scientists in the United States more than doubled, rising from 969,500 to 2,186,300.” William J. Broad, Science Can’t Keep Up With Flood of New Journals, N.Y. TIMES, Feb. 16, 1988, at C1.

87. As Lawrence S. Kubie notes:

Pure research and the more abstract forms of art and literature . . . dissect the units of experience, rearrange the pieces, juggle them around, and juxtapose them out of context. The outcome of this process cannot fail to bear the imprint of multiple projections of buried and often predominantly unconscious aspects of the personality of the abstract artist, or of the basic scientist.

. . . In applied research external pressures predominate among the sources of distortion. These are manifested in the influence of the pursuit of money, status, and fame, in the immediate alleviation of anxiety, in the urgent demand to satisfy immediate practical, commercial, military, or humanistic
Scientists suffer the same "publish-or-perish" tenure process as other academics.88 This pressure also exists in the grant process, in which awards are based in part on the "productivity" of the researcher,89 and is exacerbated by the pressure to generate research funds, which increasingly are available only for directed research. Those involved in this endeavor professionally say that many hours of their time are spent applying for research grants and "papering the file" for the grants they already have, rather than conducting studies and experiments and analyzing the results of those studies.90

purposes, etc. For example, in the entire field of applied scientific research I know of no external source of distortion greater than is the eagerness of the physician to find a cure, an eagerness which derives simultaneously from social pressures, from humanitarian impulses, and from more deeply egocentric needs. (Freud commented long since on the unconscious sadistic purposes which may at times masquerade in this disguise.)

In pure research, on the other hand (as in abstract art), the major sources of distortion are internal; and the products of the creative processes bear to a more unique degree the imprint of buried and unresolved neurotic problems.

LAWRENCE S. KUBIE, NEUROTIC DISTORTION OF THE CREATIVE PROCESS 94–95 (1958); see also Lawrence S. Kubie, Some Unsolved Problems of the Scientific Career, 41 AM. SCIENTIST 596–613 (1953) (discussing neurotic and socio-economic forces which influence the scientist's emotional life and intellectual career).

88. Patricia K. Woolf disagrees, arguing that, while there is pressure to publish, "supporting evidence for the allegation that only quantity counts is almost always anecdotal," and the few studies "that do exist show that unduly prolific publishing is in fact not widespread." Patricia K. Woolf, "Pressure to Publish" Is a Lame Excuse for Scientific Fraud, CHRON. OF HIGHER EDUC. A52 (Sept. 23, 1987). Woolf maintains that "'[p]ressure to publish' is a mechanical metaphor" and that "'[t]he excuse of 'pressure' is offered in the belief that it somehow softens the charge, and to a certain extent exonerates the malefactor by picturing him as a victim of a difficult situation rather than as the perpetrator of an offense." Id.


90. Dr. Suzanne Oparil described the grant application process:

I would like to emphasize one thing, if I could, that no one has really touched on yet. That is how exhausting the grant preparation process per se is and how expensive it is. As director of this program, I have spent most of my time since November 1983 first getting our people together for our competitive renewal, which was submitted in May 1984, and getting them ready for the site visit, which was held in November 1984. This entailed numerous rehearsals, paring down of projects, budgetary negotiations, and so on.

The actual grant application was about 1,200 pages long, single-spaced. The estimated cost for its preparation is of the order of $100,000.

Another problem with the research environment is the enlargement and depersonalization of research facilities, with a corresponding dilution of the responsibility of any one person for any particular phase of the research project. The role of the person awarded a research grant thus can take on the aura of a manager rather than a researcher, a rainmaker rather than a scientist, a promoter rather than a scholar. As research facilities and staffs get bigger, a lead researcher spends less time directly supervising the personnel, the direction of the research, and the interpretation of the investigative results.

More generally, the increase in directed research may have a negative impact. Although scientific research historically has been conducted for the general growth of scientific knowledge and understanding of the way the world operates, more and more research in the modern era is directed;

91. This problem is a by-product of the infusion of large amounts of federal funds into scientific research. As Dr. Ernest Borek, a microbiology professor at the University of Colorado Medical Center, notes: "Ambitious young scientists in large laboratories become especially tempted because often they are not properly supervised. As large grants for medical research become available, entrepreneurial ability in some cases was added to scientific ability in securing funds, laboratories and research associates. The researcher became an employer." HIXSON, supra note 13, at 160–61.

92. Heinz Schuler offers the following observation:

One could also view the development of guidelines as a consequence of the rapid growth of the institution of science. Its size and complexity have now reached a stage at which it no longer seems adequate or even feasible to rely on informal regulation or to expect implicit standards to be accepted as obvious. The growth of the institution called science makes it harder to survey and regulate by means of informal agreement, and perhaps the mechanisms of socialization are no longer as definite and coherent as they once were.

SCHULER, supra note 54, at 167.

93. Basic research generally refers to research about the validity of any given scientific hypothesis posed by the researcher, regardless of whether the research has any immediate practical application. For example, see the definitions of basic research included in the regulations for the Department of Defense, 32 C.F.R. § 272.2 (1991) ("Basic research is that type of research which is directed toward increase of knowledge in science. It is research where the primary aim of the investigator is a fuller understanding of the subject under study.")., and the National Aeronautics and Space Administration, 14 C.F.R. § 1260.107(c) (1992) ("Systematic, intensive study directed toward greater knowledge or understanding of the subject studied."). Such information, of course, provides the building blocks for applied or directed research. The field of biomedical research exemplifies the blurring of the distinction between basic and applied research. The research often is directed toward solving the mystery of a particular disease, and so may be viewed as applied rather than basic because the ultimate product could well be a marketable prevention, treatment, or cure.
that is, modern research is targeted ultimately at the achievement of a particular scientific goal, such as the eradication of a particular disease. In the modern era of scientific research, a great deal of research is paid for with federal dollars—$21 billion in fiscal year 1990 alone. Thus, the federal government has subsidized extensively the war on cancer. Recently, the federal effort to conquer the AIDS virus has occupied national attention.

Some scientists argue that the process of directing scientific research is inherently unscientific, because it is impossible to channel and compel discovery and knowledge in this fashion. Directing scientific research is also unscientific, some argue, because it ignores the benefits of increasing general understanding and knowledge on many different fronts. Directed research funnels many dollars and scientists into narrow areas of research, creating vacuums in other areas and a generally uneven distribution of scientific resources.

94. In fiscal year 1990, the federal government planned to spend approximately $21 billion in basic and applied research. More than $7 billion was planned for NIH research, and approximately 62 percent of those funds was to go to colleges and universities. See Conflicts Hearings, supra note 52, at 132.

95. See HIXSON, supra note 13, at 157–82 (setting forth a critical evaluation of the government's policies on spending for cancer research).

96. See Conflicts Hearings, supra note 52, at 107 (testimony of Richard Kusserow, Inspector General, Department of Health and Human Services) ("For AIDS research alone, funding has reached $1 billion a year and is expected to reach $4 billion by 1990."). Other examples of directed or applied research include research conducted to support applications to the federal government for approval of the marketing of certain commercial products.

97. Dr. Howard H. Hiatt, referring to Bruce Ames, who developed an effective and inexpensive test for the mutagenic and carcinogenic power of a substance, notes:

Perhaps the most important development in our attempts to identify environmental carcinogens in the last couple of decades, as everybody in this room knows, is the test Bruce Ames came upon as a result of his research in Salmonella, where he was looking at the genetics and biochemistry of the synthesis of amino acids. I don't know who funded that project. I suspect it wasn't the Cancer Institute. It had no apparent relevance to cancer at the time, and surely he had no interest in that project as a means of helping solve the problem of cancer. There would have been no way to predict the ultimate usefulness of that information. All one knew was that here was a first-rate scientist undertaking a study of a serious problem. The dilemma to which I was referring is that if we insist, as I think we increasingly do, that research spin off immediate developments, we risk a lessened emphasis on this kind of work, at a time when our knowledge of fundamental life processes is extremely limited.

Biomedical Research, supra note 81, at 30 (statement of Howard H. Hiatt, M.D., Dean, School of Public Health, Harvard Medical School).
Directing research also can generate considerable pressure to produce tangible and marketable results in a relatively short period of time. 98

Another characteristic of modern research is the great commercial value of some research. The uproar over cold fusion emphasizes the potential monetary value of scientific research. 99 Who would not want the patent rights to a drug that is effective against the symptoms of AIDS? The possibility of receiving patent rights and royalties 100 may create a potential profit motive in what used to be a "purely academic" endeavor.

Finally, one needs to take account of the pressure for priority in discovery—the desire to be the first to learn something. 101 Little, if any, benefit accrues to the scientist who reinvents the wheel. Thus, there is pressure to achieve novelty in one's ideas and discoveries. While this pressure may always have been present, it is magnified by the surge in the number of scientists engaged in research in the modern era, the compression of timetables brought about by technological advances in research equipment, research techniques, and in reporting results of research, and the amounts of money at stake (both research dollars and the possible commercial value of the discovery).

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98. As Stanley Jones testified:

[People in general expect and believe that medical science can do something to relieve the terrible problems of their human condition. . . . A good deal of the correspondence [from constituents to Congress] also insists that if only there were more money, more time invested, then a cure would be found and medical science could in fact deliver us from such trials. That conviction is strong enough that the American public is willing and ready to invest enormous amounts of money in medical research.]

99. The news media reported that some scientists have concluded that the data supporting the claimed discovery of cold fusion were fabricated. William J. Broad, Cold-Fusion Claim Is Faulted On Ethics as Well as Science 'Invented,' Scientists Say, N.Y. TIMES, Mar. 17, 1991, § 1, at 1 (reporting the conclusions of Frank Close, FRANK CLOSE, TOO HOT TO HANDLE (1991), that the data were fabricated).

100. Exec. Order No. 10,096, 3 C.F.R. 292 (1949–53) created patent policies for federally funded research; 45 C.F.R. §§ 6.0–4; 8.0–8 (1990) provides current policies.

These aspects of scientific research may contribute both to the pressure to produce and a feeling of alienation from one's work and its implications. These pressures may in turn create an impetus to falsify research results or engage in other sorts of misconduct, or at least may detract from the restraints on engaging in such conduct that might otherwise adhere.102

While these conditions might be seen as a breeding ground for problems, the conventional wisdom is that any problems are addressed adequately by the profession itself. The claim is that the scientific community polices itself.103

A common form of internal control is the practice of obtaining a critical evaluation of research results submitted to scientific journals for publication. Scientific journals frequently

102. But see the statement of Dr. Ronald Lamont-Havers, Director of Research, Massachusetts General Hospital, in Fraud in Biomedical Research, supra note 21, at 66–67 (responding to a congressional inquiry into whether having experimental work done by proxy and competition for shrinking grant funds had altered the research environment). Dr. Lamont-Havers took the position that such factors were of great concern and contributed to tensions within the research community, but "in themselves . . . probably play little part in the perpetration of fraud in science." Id. at 66. He added:

I know of no evidence that competition for major awards in science has played a significant, if any part, in the deliberate distortion of research data . . . .

Certainly, the "publish or perish" pressures . . . are real. There is also no doubt that investigators may rush into print before experiments have been repeated or confirmed in order to establish priority. Such data hastily disseminated may prove to be wrong when subsequently checked and the experiments repeated. These types of publications are usually taken for what they are, as preliminary reports.

The reputation of the investigator is influenced by how often he resorts to this type of announcement. Error in such publications are [sic] not fraudulent, but misdirected enthusiasm, and such premature publication is generally frowned upon, although certainly practiced.

Id. at 67.

See also Schmaus, supra note 8, at 105–06, citing an instance of admitted fabrication of data on the part of Robert J. Gullis of the Max Planck Institute for Biochemistry in West Germany. Gullis' printed retraction indicates that his motivation in falsifying data "was that [he] was so convinced of [his] ideas that [he] simply put them down on paper; it was not because of the tremendous importance of published papers to the career of a scientist." Robert J. Gullis, Statement, 265 NATURE 764 (1977); see also supra note 88 and accompanying text (arguing publishing pressures are an unlikely reason for fraud). But see BROAD & WADE, supra note 3, at 151–52 (concluding that Gullis' misconduct was at least partially caused by pressures to publish).

103. See, e.g., Fraud in Biomedical Research, supra note 21, at 11–13 (testimony of Dr. Philip Handler, President, National Academy of Sciences); KÖHN, supra note 3, at 196–99.
submit manuscripts to a number of qualified scientists for their opinions about the soundness of the work. Once a piece is published, critical evaluation by the scientific community at large is at least possible. Another form of peer review is the practice that government agencies follow of submitting research proposals or research results to qualified scientists for evaluation of the soundness of the proposal or the work.

In theory, such review prevents researchers from publishing implausible research results. Evaluation by other researchers after publication also deters outright fabrication because validity of the research results will be questioned if the other researchers cannot replicate the author's results.

There are, however, problems with the theory. To the extent it is premised on replication, it has been argued both that replication of research is a hit-or-miss proposition and that it does not actually occur as often or as predictably as proponents of the theory might lead one to believe. Recent celebrated cases of scientific fraud were not uncovered because of efforts to duplicate research or through any other peer review process. In any case, detecting misconduct through peer review wastes time, scientific resources, and

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105. Id.
106. See BROAD & WADE, supra note 3, at 86–87; Engler et al., supra note 35, at 1385–86. Confirmation of the earlier research does not necessarily produce any immediate benefit for the second researcher; the inability to confirm the earlier research is not, in and of itself, sufficient enough to ensure publication of negative results, since such an inability may be the result of procedural errors by the second researcher. As Theodore X. Barber notes:

Failure to replicate results of a previous investigator, using the same method but a different sample, is generally of questionable value. A single failure may merely testify to sampling errors or to the conclusion that one of the two samples had unique characteristics responsible for the reported effect, or the lack of effect. An author can resolve the issue when he reports several failures with a range of samples. A single failure is too equivocal to justify publication on its merits alone.

BARBER, supra note 44, at 33 (footnotes omitted) (quoting PUBLICATION MANUAL OF THE ADA 21–22 (1974)).
107. It has been argued, however, that the definitions of “peer review” and “replication” used in this context are too narrow to capture accurately the efficacy of these processes as deterrents. PROJECT ON SCIENTIFIC FRAUD, supra note 3, at 61–65.
money to duplicate bad research. Thus, we must focus on deterring misconduct before it occurs, rather than catching it afterward.

Supporters of the internal review process argue that the system creates a deterrent because no researcher would risk losing credibility and position by fabricating or misreporting research results when she knows that she can or will be caught. Yet, significant instances of misconduct have occurred despite the existence of the review system. In addition, this view suggests that scientists who, oblivious of their interests, engage in wrongful conduct must be deranged because rational scientists would be deterred from wrongdoing by the threat of review.

108. Dr. Ronald Lamont-Havers supports this view:

The investigator is always well aware that if his work is found to be bad science with unreproducible data, then his career as a scientist is finished. The rational individual—and I stress rational individual—knows that the deliberate falsification of data to fit a given hypothesis will inevitably, sooner or later be found out by others who seek to repeat the findings or who can critically judge the experiment. Once the suspicion of lack of good science is raised, future endeavors are scrutinized with even greater care.

_Fraud in Biomedical Research, supra_ note 21, at 66 (statement of Dr. Ronald Lamont-Havers, Director of Research, Massachusetts General Hospital).

109. As Dr. Philip Handler states:

Accordingly, one can only judge the rare such acts that have come to light as psychopathic behavior originating in minds that made very bad judgments—ethics aside—minds which in at least this one regard may be considered as having been temporarily deranged.

_Id. at 12_ (statement of Dr. Philip Handler, President, National Academy of Sciences).

Broad and Wade, however, challenge this theory, at least as applied to the case of William Summerlin, discussed _supra_ notes 13–21 and accompanying text:

Why did Summerlin stoop to deceit? The explanation seized on by administrators at Sloan-Kettering was that the man had gone out of his mind. Lewis Thomas, president of the center, announced in a formal statement of May 24: “I have concluded that the most rational explanation for Dr. Summerlin's recent performance is that he has been suffering from an emotional disturbance of such a nature that he had not been fully responsible for the actions he has taken nor the representations he has made. Accordingly, it has been agreed that the Center will provide Dr. Summerlin with a period of medical leave on full salary [$40,000], beginning now, for up to 1 year, to enable him to obtain the rest and professional care which his condition may require.” It is a recurring theme. Episodes of deceit are often said to be caused by insanity, at least according to administrators where the deed was performed.

_BROAD & WADE, supra_ note 3, at 155–56.
Yet, the criminal law rejects this theory with respect to any other antisocial conduct that is treated criminally. Engaging in criminal conduct does not establish that one is legally insane or not culpable for one's conduct. While one might attempt to argue that a scientist's loss is greater than that of most criminals, the argument is unsound, both because it ignores the fact that individuals with a great deal to lose do engage in criminal conduct, and because it is hopelessly elitist.

Finally, the deterrence argument assumes that the honest scientist is willing (or at least is perceived by dishonest scientists as willing) to police other scientists, and will deem it in her best interest to expose any discovered misconduct. This assumption, however, ignores the personal aversion and discomfort people feel about making accusations against their colleagues. It also ignores the difficult situations in which "whistle-blowers" seem to find themselves after bringing to light the possibility of wrongdoing.

B. Penological Justification for Criminal Sanctions

Regardless of whether the internal mechanisms of science provide protection against wrongdoing, criminal sanctions

Similar discontent with this theory is reflected in a letter to the editor of *Science* regarding Summerlin:

As Thomas Szasz pointed out long ago, the label of mental illness or emotional disturbance is more and more frequently applied to explain behavior that is not normative. Yet, as Szasz has also argued, the reliance on such a label to explain behavior represents an abnegation of moral responsibility.... This raises the question of why Summerlin should be let off so easily, for he violated one of the principal mores of the profession. It seems to me that professional scientists are too quick to duck the real issue here. They seem too willing, on the most tenuous basis, to excuse the behavior of "a colleague"—even one who has broken their most sacred rule.


110. The Model Penal Code states that "the terms 'mental disease or defect' do not include an abnormality manifested only by repeated criminal or otherwise antisocial conduct." MODEL PENAL CODE § 4.01(2) (Proposed Official Draft 1962).

would provide additional deterrence. Criminal penalties, under traditional hypotheses, enhance deterrence, and operate to condemn the conduct in question as evil.\footnote{112} Many problems that are treated criminally are also the subject of other nonpenal deterrents and controls.\footnote{113} The same considerations of deterrence and condemnation apply to some forms of scientific misconduct, particularly the falsification of research results. The theory of deterrence is especially relevant to white-collar crime because it is characterized by actors who are well informed and less inclined to act on impulse. Particularly in a small community of actors, like the community of researchers, word can be expected to spread quickly when stringent repercussions follow wrongdoing.\footnote{114}

The initial reasons for considering criminal sanctions in the interest of deterrence and condemnation are the nature and degree of societal harm that can result when scientific misconduct, particularly the false reporting of research results, affects the integrity of the research process. Fraudulent research wastes grant funds and other resources,\footnote{115} including the time of researchers who make futile efforts to

\footnote{112. Model Penal Code § 1.02 (Proposed Official Draft 1962).}

\footnote{113. No one, for example, would argue seriously that drunk driving should not be treated as a criminal law problem because the possibility of getting in an accident is deterrent enough for this conduct and anyone who nonetheless engages in the conduct must be deranged. Drunk driving is a criminal offense because some may be deterred by the existence of criminal penalties and because the conduct is morally wrong and potentially hurtful.}

\footnote{114. See, e.g., United States v. Bergman, 416 F. Supp. 496, 500 (S.D.N.Y. 1976). The court addressed the defendant's argument that he should not be incarcerated for the purpose of general deterrence:}

But the whole business, defendant argues further, is guesswork; we are by no means certain that deterrence "works." The position is somewhat overstated; there is, in fact, some reasonably "scientific" evidence for the efficacy of criminal sanctions as deterrents, at least as against some kinds of crimes. Moreover, the time is not yet here when all we can "know" must be quantifiable and digestible by computers. The shared wisdom of generations teaches meaningfully, if somewhat amorphously, that the utilitarians have a point; we do, indeed, lapse often into rationality and act to seek pleasure and avoid pain. It would be better, to be sure, if we had more certainty and precision. Lacking these comforts, we continue to include among our working hypotheses a belief (with some concrete evidence in its support) that crimes like those in this case—deliberate, purposeful, continuing, non-impulsive, and committed for profit—are among those most likely to be generally deterrable by sanctions most shunned by those exposed to temptation.

\footnote{Id. (footnotes omitted).}

\footnote{115. See supra notes 106–07 and accompanying text.}
duplicate fraudulent research. In addition, future research efforts may be misdirected because others may rely upon the falsified data either to pursue a line of research that otherwise would not be warranted, or forego a particular line of research that may be fruitful. Immeasurable, of course, is the human suffering that attends either incorrect treatment premised on false research results, or absence of treatment because research efforts have been diverted.

A terrible cost associated with this type of misbehavior is that the hypothesis supported by fraudulent research may be true, but it becomes virtually taboo because of the notoriety that a researcher’s use of false data brings to it. Future scientific endeavor into a fruitful area of research may thus be slowed or even stopped for some period of time out of fear of being associated with a tainted research subject.

116. In the prosecution of Stephen Breuning, the government observed in its memorandum on sentencing that “a number of people have had their careers severely disrupted because they had relied upon the representations [in publications] of Stephen E. Breuning.” Gov’t Memorandum on Sentencing at 9, United States v. Breuning, No. K-88-0135 (D. Md. Nov. 8, 1988). By being associated with a wrongdoer, coauthors of a researcher who falsified data may also suffer a decline in reputation. In some cases, the coauthors might be seen as having some culpability for failing to detect the falsification, even if they did not directly participate in the acts of deception. See Engler et al., supra note 35, at 1386.

117. It is sometimes argued that scientific fraud exists only on the fringes of science, in areas of little interest or significance, and that this accounts for its success. That is, the more significant or controversial the claimed findings, the less likely that fraud will occur or go undetected; conversely, the more likely that fraud will go undetected, the less likely it is that the fraud relates to a matter of true scientific significance. See Engler et al., supra note 35, at 1388. “‘Does it really matter,’ the cynic asks, ‘if a cunning faker gets away with producing hundreds of papers that nobody reads?’” Id. Thus, some instances, such as the misconduct of Stephen Breuning, discussed supra notes 1–2 and accompanying text and infra notes 136–42 and accompanying text, involve extensions or confirmations of existing research and others, such as that of Elias Alsabti, discussed supra notes 22–23 and accompanying text, involve obscure publications of little interest. See, e.g., Fraud in Biomedical Research, supra note 21, at 66 (statement of Dr. Ronald Lamont-Havers) (noting that research that is considered relatively unimportant may not be investigated for a long time).

Even if this claim were true (and the Summerlin case gives some reason to doubt it, since his research related to an important and controversial area), it is not inevitably mitigating. Certainly, if a project is significant enough to fund, it is significant enough to police. Moreover, since the development of scientific knowledge takes an unpredictable path, it is impossible to state with certainty the importance certain research ultimately would have.

118. Interestingly, this possibility seems to have been true of the work of William Summerlin, supra notes 13–21. As Lois Wingerson commented:

Although Summerlin admits “touching up” a skin graft on a mouse to make it look healthy when it was being rejected, he had in fact stumbled on a
Reporting false research also spews useless information into an already daunting body of scientific literature that must be searched and absorbed by scientists attempting to keep up with current developments. Until recently the scientific community has not had any sustained method for notifying its members that a particular article has been discredited or withdrawn. Either the volume of problem articles or the attention drawn to the subject apparently has resulted in the creation of several ways to learn about discredited or withdrawn literature. The lag time between discovery of and dissemination of information about the problems with reported research, however, still may permit harm to occur.

Phenomenon—something so unexpected and simple that it seemed ludicrous at the time—which turns out to be valid after all. It is now supported by considerable research from reputable scientists, and has sparked a theory that has helped to transform our understanding of rejection.

Not surprisingly, both [Paul Lacy and Kevin Lafferty, researchers following up on Summerlin's work] made the discovery accidentally, while doing something else. After 1974, who would have asked for grant money for the express purpose of studying the organ transplantability of skin taken from culture?

Even now, such an offer [of a grant to follow up on Summerlin's work] is a fantasy. Most of the researchers in Summerlin's wake have not even dared to dream of asking for grant money for this work, let alone being asked to do it. Sometimes they have had to put up with a good bit of twitting for doing it on the side. "It was an extremely unpopular area, so we told no one what we were doing," Lacy recalls. "We already had a grant from a foundation, and we informed them we wanted to try this, and luckily they said OK. Otherwise, if we had applied for the funds before we had done any work we wouldn't have gotten past base one."

As a staff member at the Australian National University, Lafferty was lucky to be able to pursue his theory without asking for grants; he agrees there would have been trouble getting one. However, he did have problems getting published. "I sent the first paper to Nature, and they wrote back saying they were fascinated with the work," he remembers. "They had no scientific criticisms, but said they didn't see how they could persuade people to believe it."

Lois Wingerson, William Summerlin: Was He Right All Along?, 89 NEW SCI 527, 527 (1981); see also HIXSON, supra note 13, at 66-68.

119. There are more than 40,000 scientific journals worldwide, publishing in excess of one million articles per year. Broad, supra note 86, at C1, C11 ("Experts estimate that the scientific literature now doubles every 10 to 15 years."). See BROAD & WADE, supra note 3, at 53-54, 56, 57. Self-interest prevents me from waxing too poetic on the evils of useless publication.

120. Retraction policies of scientific journals are discussed in Fraud in Biomedical Research, supra note 21, at 346-47 (statement of Dr. Patricia Woolf, Science and Technology Project, Princeton University), and in PROJECT ON SCIENTIFIC FRAUD, supra note 3, at 76-78. In addition, a new publication, ACCOUNTABILITY IN RESEARCH, has been started. CONFLICTS REPORT, supra note 32, at 6.
Perhaps the most truly damaging aspect of scientific misconduct is its potential for undermining trust. Researchers not only rely upon each other's reported results, but the willingness to fund research may depend on the perceived integrity of the scientific profession. When trust is a necessary feature of a system, it is especially important to discover and condemn those whose behavior casts doubt upon the integrity of the operation. Thus, conduct such as product tampering is punished (and heavily so) even if no injury results.

The damage that can be caused by scientific misconduct certainly makes it a candidate for criminal sanctions. This harm is certainly no less serious from a penological point of view than shoplifting or forging a social security check. Yet, some may hesitate to prosecute the scientist on the theory that a person of this group who engages in misconduct related to research is simply not a "criminal." The misrepresentation of research results might be dismissed as mere "fudging," not unlike the kind of glossing and embellishing that attends much of life's activities. But fudging is just a softer word...


122. See 18 U.S.C. § 1365 (1988), which criminalizes various acts of product tampering. The statutorily authorized penalties vary depending upon the degree of harm caused by the conduct, but include a maximum sentence of ten years under § 1365(a) and three years under § 1365(b), even absent a showing of specific harm. In addition, the Federal Sentencing Guidelines impose rather stiff sentences even absent harm, although they authorize an increased sentence if death, extreme psychological injury, or substantial property damage or monetary loss results. Fed. Sentencing Guidelines §§ 2N1.1, 2N1.2, 2N1.3 (1987) (hereinafter Sentencing Guidelines).

123. See, e.g., United States v. Cavada, 821 F.2d 1046, 1047, 1049 (5th Cir.), cert. denied, 484 U.S. 932 (1987) (affirming a conviction under 18 U.S.C. § 495 for forging a social security check in the amount of $136.66; the maximum penalty for the felony was ten years incarceration and the defendant was sentenced to two years); United States v. Hill, 579 F.2d 480, 481 (8th Cir. 1978) (affirming a conviction under 18 U.S.C. § 495 for forging a social security check in the amount of $306.20; the defendant was sentenced to six months' incarceration).

124. As Dr. Patricia Woolf testified:

[T]hese events of falsification should not be interpreted to mean that scientists who falsify data are trying to fleece the public. Though it is clear to the academic research community, it may not be as clear to the general public that these events are different in kind from overt embezzlement or culpable mismanagement or misappropriation of research funds.

Fraud in Biomedical Research, supra note 21, at 344 (testimony of Dr. Patricia Woolf, Science and Technology Project, Princeton University).

125. A statutory recognition of the distinction between fraud and puffing is found in the Model Penal Code's approach to the crime of theft by deception, which provides
for lying; the quality of the conduct does not improve with the class of person engaging in it or the complexity of the context in which it is done. Moreover, many situations in which one might be tempted to engage in glossing and embellishing do not carry the price tag or societal implications of scientific misconduct.

Likewise, there may be an impetus, born of the reluctance to ruin the life of someone like a scientist, to look for excuses for the conduct—"The poor guy worked under such pressure to achieve results"; "There was such great publication pressure"; "The pressure to get grants was unbelievable"; "He must have just snapped." But when speculating about reasons for the conduct, one ought not fail to consider a reason that applies to many people who are prosecuted—the individual simply did not have the moral fiber to do the right thing when temptation was placed in her path or pressure was exerted upon her. Educated or not, middle class or low, engaging in misrepresentation to get what you want or spare yourself an unpleasantness is a basic feature of many criminal acts. For better or worse, we live in a society in which the pressures of poverty are not considered an acceptable reason to steal food or money, nor is the pressure of loneliness or neglect an acceptable

that "[t]he term 'deceive' does not . . . include falsity as to matters having no pecuniary significance, or puffing by statements unlikely to deceive ordinary persons in the group addressed." MODEL PENAL CODE § 223.3 (Proposed Official Draft 1962). Likewise, cases under the mail fraud statute have required that false statements in sales pitches go to the basis for the bargain before liability will attach. See, e.g., United States v. Regent Office Supply Co., 421 F.2d 1174, 1182 (2d Cir. 1970).

126. Similar views were expressed in a letter to the editor of Science regarding William Summerlin:

We know about deviance in almost every sphere of life; why should we assume, as we do, that such behavior does not occur among professional scientists? What makes the scientist immune from vulnerability to deviance? We seem to take it for granted that the efforts of scientists are so much more important, their motives so pure, that under these conditions, altering one's data cannot occur. . . . We are naive to believe that dishonesty in research in [sic] unique and aberrant. The rewards are just too tempting: prestige, ego enhancement, promotion, and, as in the case of Summerlin, a $40,000 salary and a home in Darien, Connecticut. Mighty tempting rewards for success. Not only are the rewards tempting but, while the process of socialization in graduate school may give credence to veracity, it nonetheless emphasizes success. The emphasis on scientific success creates a severe strain on the practicing researcher, who is torn between the norms established for the process of research and the penultimate rewards for success. Under these conditions deviance is likely to occur in any group, even among scientists.

Faber, supra note 109, at 734.
reason to engage in criminal acts to gain status or attention. This being the case, one may legitimately conclude that the pressures of a lucrative and prestigious job that a scientist voluntarily undertakes are not an acceptable reason to steal, in effect, the taxpayers’ money by obtaining it under false pretenses or to steal undeserved recognition by falsely claiming credit for research.\textsuperscript{127}

Taking this position, however, does not require that one deny that there may be certain obstacles to investigation and prosecution that might not be found in more mundane contexts. For example, one might question whether nonscientists are capable of understanding enough about scientific matters to make the factual determinations relevant to a criminal offense sanctioning scientific misconduct. Unlike the readily understandable facts relevant to resolving garden-variety crimes, scientific misconduct may involve some extremely complicated facts not within the understanding of the average person. This

\begin{flushright}
\textbf{127.} An interesting contrast is provided by the views, similar but expressed in a different context, of a court in response to a white-collar defendant's claim that his sentence constituted cruel and unusual punishment and denied him equal protection of the laws. \textit{See Browder v. United States,} 398 F. Supp. 1042, 1043 (D. Or. 1975), \textit{aff'd,} 544 F.2d 525 (9th Cir. 1976). The judge had sentenced the defendant to four ten-year terms and one five-year term, to run consecutively, upon the defendant's plea of guilty to charges of transporting and pledging stolen securities valued at more than \$500,000. The court remarked:

The basis for petitioner's claim is a study he conducted of 100 cases involving similar white collar crimes. If accurate, his study contains startling statistics. Of the 100 defendants studied, 20\% received fines, probation, or suspended sentences only for acts involving \$350,000,000 or more. The others studied received light sentences for a variety of swindles in which the public became victim to members of the Mafia, labor union officials, mayors, attorneys, stock brokers, business executives, bankers, a former state Attorney General, a governor, a federal judge, and others.

\ldots

I cannot reconcile a policy of sending poorly educated burglars from the ghetto to jail when men in the highest positions of public trust and authority receive judicial coddling when they are caught fleecing their constituencies. \ldots

If we are to justify imprisonment for the rest, it must be on the grounds of punishment or deterrence. And if this is our premise, the white collar criminal must come to expect equal or greater treatment than the common, non-violent thief. The consequences of a white collar property crime tend to reach a higher magnitude in direct proportion to the level of status and power held by the criminal involved.

Edward Browder was convicted of pledging over \$500,000 worth of stolen securities. He concedes his guilt for those crimes. The fact that they were accomplished by means of wit and charm rather than a burglar's tools does not minimize the damage done to the public.

\textit{Id.} at 1046-47.
concern, however, can be addressed through the exercise of prosecutorial discretion, for there will be cases in which the gist of the wrongdoing is comprehensible to nonscientists despite the fact that the misconduct arose in a complex scientific context. To operate on the assumption that no jury could understand facts related to scientific research would effectively create an a priori immunity for scientists who engage in misconduct in their research.

Another legitimate reason for caution is the recognition that scarce research dollars will be diverted from funding research to pay for the investigation of scientific misconduct. Thus, it might be argued that the reliance upon criminal sanctions will lead to the creation of an investigational bureaucracy that ultimately will decrease the amount of funds spent on research. The cost of vigorously investigating and prosecuting this type of misconduct is a legitimate factor to consider. Because grant funds are so scarce, however, a serious commitment is essential to ensure that no one abuses the grant process or the scientific process it supports. The existence of criminal sanctions that are taken seriously is most likely to deter future misconduct. Clearly, deterrence is taken seriously in the context of scientific research, as the reliance on the existence of peer review to prevent misconduct by researchers attests.

A word about morale, however, is appropriate. Morale suffers when people are forced to work in an atmosphere of suspicion and second-guessing. Morale may already be a problem among scientists because of the paucity of research funds available to fund research ideas, particularly the ideas of young scientists. If a sort of institutionalized mistrust of scientists is added to this problem, will the result be a restriction of the availability or intellectual freedom of persons who wish to engage in scientific research?

The question is certainly worth considering. It is particularly relevant to the question whether a criminal investigation of a given act of scientific misconduct should be initiated. In the long run, however, the possibility of criminal prosecution of a person for misconduct in a particular field or line of research should not deter honest and talented persons from pursuing


129. See, e.g., NIH Research Funding: Hearing Before the Intergovernmental Relations and Human Resources Subcomm. of the House Comm. on Government Operations, 99th Cong., 1st Sess. 5 (1985) (remarks of Dr. Charles A. McCallum, Sr. Vice-President for Health Affairs, University of Alabama at Birmingham).
that field or line. Indeed, failure to police a profession vigorously can lead to the general decline in reputation and public acceptance of that profession, which can also result, in the case of a governmentally funded profession, in a decline in monetary support. Such results could ultimately have an even more devastating impact on the scientific community's morale. Morale may actually be enhanced by demonstrating that only honest effort is rewarded and that those who obtain benefits through misconduct are severely punished for their acts.

On balance, the interests of deterrence and condemnation justify prosecution and outweigh the possible detriments of treating scientific misconduct as a criminal law problem. Potential impediments to and disadvantages of prosecuting are not unique to this sort of misconduct, and may be taken into account on a case-by-case basis, as they are for a number of other federal crimes.

IV. STATUTES AVAILABLE FOR PROSECUTION OF SCIENTIFIC MISCONDUCT

This section will examine the existing federal statutes that have been used to prosecute scientific misconduct.

A. State v. Federal Interest

Prosecution of scientific misconduct should occur under federal, not state statutes. The extent of federal funding of scientific research creates a federal interest in protecting the federal fisc. Separate federal interests, such as protection

130. Basic research is associated primarily with university laboratories and research institutes, which may be federally funded in whole or in part, or supported by private funding. Although private funding is a source of money for basic research, most financial support for such research comes from the federal government. Dr. Minsky's testimony before a subcommittee of the House Committee on Government Operations addressed this issue:

MR. LIGHTFOOT. Do we have research going on that wouldn't be occurring if we didn't have the private money in terms of carrying something further? This could be construed one of two different ways, I guess, and one of those ways being that the combination of public/private funding is a larger pool of money which takes research further down the road than what we could appropriate from public funds. Maybe research has gone another step; otherwise it would have stopped if we didn't have the private money to help fund it.
of the integrity of governmental decisionmaking, may be implicated as well when scientific misconduct is prosecuted under the false statement or the mail fraud statutes. The federal government also has an interest in the uniform treatment of persons working under federal grants, so that an investigator in one state is subject to the same working rules as an investigator in another state. Furthermore, given the federal government's experience with funding and overseeing scientific research, it has an expertise that individual states might lack. Thus, while a state might decide to apply state law sanctions, there is ample justification for a federal role in policing scientific misconduct.

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DR. [Leonard] MINSKY[Ph.D., executive director, National Association of Universities in the Public Interest]. . . . The corporate contribution to research funds in universities is relatively small overall. When we started in 1983, the corporate contribution was no more than 3 percent of the total of funds going to research in universities. . . . My own best guess would be that at present levels, it is 10 percent. That is, the corporate contribution to university-based research is no more than 10 percent, while the Federal Government pays, and therefore the public pays, for 90 percent of the research done in universities.

. . . . The total corporate investment is really small by comparison to the public investment.

. . . . However, corporate money is not the kind of money that finds its way to the truly experimental or frontier research situations.

Confl icts Hearings, supra note 52, at 53.


Sources of federal funding of scientific research include the grants awarded by the NIH and the NIMH, which are both part of the HHS. The Defense Department's policy on the administration and support of basic research is found at 32 C.F.R. § 272 (1991).

131. See infra notes 133-50 and accompanying text.

132. There would seem to be no impediment, however, to prosecution on a local level if the particular misconduct violated a state criminal statute. For example, the misappropriation of another scientist's research proposal might constitute a property crime. To the extent the misappropriation involves information or an idea rather than an object, an interesting issue regarding the coverage of theft or misappropriation statutes might arise. See, e.g., United States v. Lambert, 446 F. Supp. 890, 895 (D. Conn. 1978) (holding that it is a violation of 18 U.S.C. § 641 to sell information derived from government computer records), aff'd sub nom. United States v. Girard, 601 F.2d 69 (2d Cir. 1979), cert. denied, 444 U.S. 871 (1979).
B. False Statements and Fraud

There is no federal statute that specifically and discretely punishes misrepresentation of research results as "fraud in science" or "scientific misconduct." Instead, potentially applicable federal statutes focus on two areas: submitting false statements to the federal government and defrauding someone through the use of a federally controllable means (e.g., the mails or interstate wire communication facilities). Thus, if a scientific researcher falsely reported her findings to the federal government in an application for renewal of a research grant, that researcher might face criminal liability under the generally applicable false statement statute or the federal mail or wire fraud statutes.

133. To the extent that a particular researcher acted in concert with another person in submitting false statements to the government or in obtaining grant funds by fraud, liability might also lie under the federal conspiracy statute, 18 U.S.C. § 371 (1988), either for conspiring to commit an offense against the United States or for conspiring to defraud the United States.

134. The statute provides:

> 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). The maximum fine has been increased to the greater of $250,000 (for individuals) or twice the amount of pecuniary gain to the defendant or pecuniary loss to the victim. 18 U.S.C. § 3571 (1988).

135. The federal mail fraud statute provides in pertinent part:

> Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises, . . . for the purpose of executing such scheme or artifice or attempting so to do, places in any post office or authorized depository for mail matter, any matter or thing whatever to be sent or delivered by the Postal Service, or takes or receives therefrom, any such matter or thing, or knowingly causes to be delivered by mail according to the direction thereon, or at the place at which it is directed to be delivered by the person to whom it is addressed, any such matter or thing, shall be fined not more than $1,000 or imprisoned not more than five years, or both.


The wire fraud statute tracks the mail fraud statute, but substitutes for the mailing requirement the following: "transmits or causes to be transmitted by means
The prosecution of Stephen Breuning is a good example of how a criminal prosecution of scientific misconduct might be structured under the false statement statute. According to the indictment against him, Breuning conducted research at the Western Psychiatric Institute and Clinic, affiliated with the University of Pittsburgh's Medical School. From July 1, 1982 to April 1984, under grants from the National Institute of Mental Health (NIMH), Breuning was to study the effect of stimulants on the behavior of hyperactive retarded children. To obtain funding for the continuing phases of his proposed study, Breuning was required to submit to NIMH applications for continuation grants, in which he described the progress he had made in the initial phase of the study.

Counts One and Two of the indictment against Breuning alleged that several of the statements in each of the two applications for continuing funding misrepresented the numbers of persons included in the study and the results obtained. According to the government's sentencing memorandum, "[W]hat appears to have happened, is that . . . Stephen Breuning did not obtain the expected results. Rather than lose the grant money which was going to the Western Psychiatric Institute and Clinic he submitted false data to support the continuation of this study." The sentencing

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137 The first application was for continued funding from July 1, 1983 through June 30, 1984, the second year of a two-year study that had initially been proposed by Breuning and approved by NIMH. Indictment at 4, United States v. Breuning, No. K-88-0135 (D. Md. Apr. 15, 1988). The second application, termed a competing continuing application, was for approval of additional funding for a new study period from July 1, 1984 through June 30, 1988 to follow up on the original two-year study. Id. at 7–8.

138 Id. at 1–11. The story of the problems with Breuning's research is described in Scientific Fraud, supra note 111, at 2, 4–65 (1988) (statement of Robert L. Sprague, Ph.D., Professor, University of Illinois, Urbana-Champaign).


According to a House Report, "Breuning's influence on the treatment of mentally retarded children was extensive; for example, several States changed their treatment
memorandum also refers to the government's investigation of allegations of other misrepresentations by Breuning about research he claimed to have completed.\footnote{Gov't Memorandum on Sentencing at 9, \textit{Breuning} (No. K-88-0135).} This investigation disclosed that "there [was] no evidence of data supporting most of the research published by Dr. Breuning. In fact, the research that was being done at the University of Pittsburgh was producing contradictory information to that which Dr. Breuning was officially reporting."\footnote{Id. at 9.}

Breuning received a sentence of two years' incarceration for each count, all but sixty days of which was suspended in favor of probation. Breuning also was ordered to pay restitution, perform community service, and refrain from employment as a research psychologist for the five-year probation period.\footnote{Judgment, United States v. Breuning No. K-88-0135 (D. Md. Nov. 10, 1988). Breuning was ordered to serve the sixty-day sentence on work release at a community treatment center or halfway house. The judge ordered that Breuning pay $11,352 in restitution, and perform 250 hours of community service. In his plea agreement, Breuning agreed not to be employed as a research psychologist for a period of ten years following sentencing, and the court's sentence indicates that Breuning would be subject to conviction for contempt if he violates that agreement. \textit{Id.}}

The federal government also used the false statement statute to prosecute employees of Industrial Bio-Test.\footnote{\textit{See supra} notes 61-69 and accompanying text.} Specifically, IBT reported, or caused to be reported, to the FDA false research data relevant to the assessment of the safety of various commercial products.\footnote{\textit{See supra} note 69 and accompanying text.} The falsified data included representations about the mortality rate and pathology of rats used in tests.\footnote{\textit{See supra} note 71 and accompanying text.} The IBT case also involved charges under the federal mail and wire fraud statutes.\footnote{\textit{See supra} note 65 and accompanying text.}

Given a jurisdictional predicate,\footnote{That is, a provable use of the mails or an interstate wire communication in furtherance of the scheme or artifice to defraud. 18 U.S.C. § 1341 (1988) (mail fraud statute); 18 U.S.C. § 1505 (1988) (wire fraud statute).} the mail or wire fraud statutes might offer some latitude and flexibility in shaping a charge because of the differences in the elements of the mail fraud and false statement offenses. The mail fraud statute policies to conform to Breuning's reported research results." \textit{Conflcits Report, supra} note 32, at 13 (footnote omitted).
contemplates victims other than the government\textsuperscript{148} and
encompasses more than the making of false statements.\textsuperscript{149}
Indeed, in the IBT prosecution, the defendants were convicted
under the mail fraud statute for omissions that could not form
the basis for liability under the false statement statute.\textsuperscript{150}

C. Impediments to Prosecution

In thinking about whether to apply the false statement and
mail and wire fraud statutes to acts of scientific misconduct,
a number of issues must be considered. Perhaps most
significant is the question of competence.\textsuperscript{151} Investigators
and prosecutors will struggle with the problems of understand-
ing what happened and making the difficult judgment about

\textsuperscript{149} Id.
\textsuperscript{150} The trial court had refused to permit jury consideration of a particular
omission in its deliberations on a false statement count because there was no legal
duty to disclose the omitted information. United States v. Keplinger, 776 F.2d 678,
697 n.8 (7th Cir. 1985). The court of appeals upheld the mail fraud conviction
premised upon this omission, however, because:

\textsuperscript{151} See supra text accompanying notes 127–28.
what should have happened, issues that to a large extent may turn on scientific judgments about what a particular researcher should or should not have done or known. No doubt there would be instances in which the primary disputed factual issue would not be what was done, but rather why it was done, which in turn may be relevant to the question whether the researcher acted with the requisite criminal intent. Therefore, the limitations on lay persons' (including investigators, prosecutors, judges, and juries) ability to understand and evaluate facts of a scientific nature are relevant. A scientist whose work is being questioned would be concerned that an investigator, prosecutor, judge, or jury, due to an inability to understand adequately the underlying scientific concepts, would conclude incorrectly that the scientist misrepresented research results and did so with the requisite mens rea.

Currently the legal system calls upon lawyers and juries to make a number of determinations that might be characterized as based primarily on scientific or technical evidence. For example, patent cases can involve very detailed scientific or technical issues, yet still may be tried before a jury. This hurdle, then, is not unique to a prosecution for scientific misconduct, though it may be more acute in this context. It might be contended, for example, that some of the basic research conducted in laboratories across the United States in fields such as molecular biology, genetics, and physics is more complex than the scientific or technical evidence involved in a patent case.

The legal requirements for prosecution under the false statement statute and the practical problems of convincing a jury to convict, however, will help minimize this problem. As a practical matter, criminal investigators and prosecutors will tend to gravitate toward cases that do not involve a detailed understanding or a resolution of difficult scientific issues. An investigator must understand a matter well enough to conclude and convince a prosecutor that proof beyond a reasonable doubt of a crime exists, and the prosecutor in turn must be able to convince a jury and a judge. The false

152. See, e.g., the discussion of Gregor Mendel's work, supra note 7, and that of Cyril Burt, supra text accompanying notes 24–28, raising the possibility of inadvertent misrecording of data. The case of William Summerlin, supra notes 13–21 and accompanying text, raises the possibility of misunderstanding research methods and results.
statement statute requires proof beyond a reasonable doubt that the statement in question is false and therefore, prosecutors will only be attracted to cases in which the falsity is clear and understandable.\(^{153}\)

Thus, there will be an inherent inclination to focus on relatively less complex questions of historical fact, such as whether certain experiments or tests were ever performed, rather than on questions more likely to involve an interpretation of scientific data and an understanding of the underlying

\(^{153}\) 18 U.S.C. § 1001 (1988). Perhaps a good example of the dangers of delving into an ambiguous fact pattern is the congressional investigation of Nobel Laureate David Baltimore. The House Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, chaired by Congressman Dingell, conducted hearings in the spring of 1989 focusing on the accuracy of a 1986 article in \textit{Cell} of which Baltimore was the lead author. \textit{Scientific Fraud: Hearings Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce}, 101st Cong., 1st Sess. (1989). The paper discussed research performed at the Massachusetts Institute of Technology on the genetic basis for the immune system. The allegations under investigation included claims that the paper reported about an experiment that was never performed and that work papers relating to the research had been back-dated. Larry Thompson, \textit{Science Under Fire: Behind the Clash Between Congress and Nobel Laureate David Baltimore}, WASH. POST, May 9, 1989, at Z12, Z14 (Health Section) [hereinafter \textit{Science Under Fire}]. One media account, describing the sharp exchanges between Baltimore and Dingell, highlighted the difficulties presented when a nonscientist challenges a noted researcher:

In the end, the hearing became a contest between two giants: Dingell from the Congress, Baltimore from the ivory towers of big-league science. Both men are smart; both are powerful. Neither wanted to lose.

But the day did not seem to go well for Dingell, who read from an unfamiliar script, filled with technical terms about the complexities of transgenic Mu products and bet 1 antibodies.

Dingell went on to say that the questions about integrity were still unanswered and that the inquiry would continue. . . .

As Dingell moved to gavel shut the session, Baltimore, shaking with adrenaline, asked: “Don’t I get a chance to respond?”

Yes, Dingell responded.

The subcommittee had publicly accused him of scientific fraud, Baltimore said, yet failed to produce any evidence.

\textit{Id.} at Z12.


It was later reported that Dr. Baltimore requested that the paper be retracted. Malcolm Gladwell, \textit{Scientist Retracts Paper Amid Allegations of Fraud}, WASH. POST, Mar. 21, 1991, at A1.
science, such as a claim that certain phenomena were observed when a particular experiment was conducted. The focus of the Breuning prosecution, for example, was the number of subjects evaluated in his research, an essentially historical fact that does not turn upon the resolution of a disputed scientific issue. The IBT prosecution also focused on historical facts like the number of rat deaths, which could be ascertained without debating a scientific theory.

Complexity may be problematic nonetheless in the determination of materiality or mens rea under the false statement statute. Inadequate understanding of underlying scientific principles might lead to an erroneous focus upon inconsequential or inadvertent misstatements.

Although the materiality standard is not stringent, the high mens rea requirement and perceptions of jury appeal will cause prosecutors to avoid fact patterns involving credible claims of mistake or disagreement about debatable scientific propositions. Once again, the more straightforward the false statement, the easier it will be for a judge or jury to appreciate what difference the false statement makes and why the scientist would have made it. A convincing showing is necessary particularly because the defendant scientist is a

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155. See supra notes 71–73. Nevertheless, some matters of a scientific nature did have to be considered in ascertaining the materiality of the false statements IBT made. See supra note 71.
157. The mens rea requirement for a violation of the false statement statute is “knowingly and willfully.” See supra note 134.
158. See, e.g., United States v. Whitaker, 848 F.2d 914, 916 (8th Cir. 1988) (“[M]ateriality involves only the capability of influencing an agency's governmental functions”) (citing United States v. Popov, 821 F.2d 483, 488 (8th Cir. 1987); United States v. Richmond, 700 F.2d 1183, 1188 (8th Cir. 1983)); Weinstock v. United States, 231 F.2d 699, 701 (D.C. Cir. 1956) (explaining that a statement is material if it has a “natural tendency to influence” an agency's decision).
159. Materiality under the false statement statute has been held to be a question of law, not of fact. United States v. Fern, 696 F.2d 1269, 1274 (11th Cir. 1983); United States v. Schaffer, 600 F.2d 1120, 1123 (5th Cir. 1979).
person whom a jury may be reluctant to see as a criminal. In any case, complexity is likely to generate momentum not to prosecute, particularly in weaker cases.

Serious consideration must be paid to whether prosecution presents a danger of chilling scientific endeavor by injecting the possibility that criminal investigators and prosecutors will second-guess a researcher's conclusions and reports. History demonstrates the dangers of excessive government involvement in the scientific process, and those dangers should not be overlooked because of the need to address scientific misconduct. The prospect for government manipulation of science already exists, however, because of the extent of government funding of scientific research.\(^{162}\)

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160. A notorious example is comes from the history of the Soviet Union and involves the agricultural theories of Trofim Lysenko:

Trofim D. Lysenko, a Soviet agronomist active during the period between 1929 and 1965, won the highest Communist Party support for an effort which, in essence, was based on the annihilation of the science of genetics. The Marxist ideology was founded on the concept of the malleability of human nature. In support of this theory Lysenko applied his energy and drive to show that the nature of plants can also be moulded by the environmental conditions, notwithstanding their genetic character.

Lysenko rebelled totally against modern-day science. His multi-faceted activities involving the top levels of Soviet agriculture stemmed from his arrogant belief that he knew better than the academic scientists how to increase the yields of agricultural products. This led to a situation where Soviet agriculture was abused for 35 years.

Kohn, supra note 3, at 63. Broad and Wade note the following lesson from the Lysenko affair:

The Lysenko affair is usually recounted, in simplified form, for the purpose of warning politicians never to jeopardize the autonomy of science. The moral is correctly drawn, but the full version of the complex history contains another, less obvious lesson: that scientists and their institutions do not always possess the inner strength to protect their deepest principles from political encroachment.

Broad & Wade, supra note 3, at 186.

161. See, for example, the concern that was voiced over even congressional inquiry about scientific practices when Congressman Dingell led an inquiry into research supervised by David Baltimore, discussed supra note 153. Media reports described the adverse reaction of some in the scientific community to the congressional inquiry. “Visions of 'science police' making unannounced laboratory visits, pawing through notebooks, auditing data and demanding explanations for every error are sending chills through the corridors of universities and research institutions nationwide.” Science Police, supra note 153, at E6.

162. As Harold P. Green noted:

My problem is that the fact of the matter is that science and scientists today are not autonomous. They are attached to an umbilical cord running from
history is not replete with instances of criminal prosecution for misconduct in the guise of promoting or suppressing certain academic endeavors.\(^{163}\)

Legitimate scientific effort may also be chilled by prosecution of scientists who deceive themselves about the results of their own work. Self-deception\(^{164}\) may result in the making and reporting of observations of phenomena that simply did not occur. If a scientist’s misunderstanding of or wishful thinking about experimental results could be interpreted as falsification of those results, concern may be raised about the possibility of prosecuting bad science rather than deliberate misrepresentation.

The *mens rea* requirement for the false statement statute should preclude imposing liability for misrepresentations that are not knowingly false.\(^{165}\) The free flow of ideas in the scientific community, arguably, still could be chilled because even under a high, subjective standard of *mens rea*, a jury inevitably will take into account whether it was possible for a reported phenomenon to have occurred and whether a
reasonable scientist under the circumstances would have observed it, both of which may involve resolution of the scientific merit of the scientist’s claim.

As a practical matter, these fact patterns present less attractive vehicles for prosecution because of their complexity and ambiguity. As a result, the possibility for prosecution in this context is more apparent than real. Moreover, one questions whether there are many cases in which legitimate scientific effort coexists with proof beyond a reasonable doubt that a scientist knowingly made a false statement regarding her research results. Finally, the possibility of erroneous conviction never can be totally eliminated for any offense, and does not present a convincing argument for foregoing criminal sanctions altogether.

As with any complex matter, a particular difficulty is gauging whether a particular investigation or prosecution is worth the resources expended. Simply investigating, let alone prosecuting, any claim of scientific misconduct would be time-consuming and expensive. As noted earlier, this problem is particularly acute if the money used to investigate comes indirectly from funds that otherwise would be spent on research itself. Given the broad range and large number of serious criminal law problems facing already overworked prosecutors, these crimes are arguably of low priority, particularly if the offenses are unlikely to lead to jail time.

166. The IBT case, for example, discussed supra notes 61–79 and accompanying text, produced “a trial that lasted more than six months[,] . . . more than 17,000 pages of transcript, . . . [and appellate] briefs totaling more than 500 pages.” United States v. Keplinger, 776 F.2d 678, 683 (7th Cir. 1985).

167. The potential for diverting research funds was demonstrated during the congressional investigation of research supervised by David Baltimore, discussed supra note 153. According to a media account, lawyers paid by the research institute Baltimore heads accompanied Baltimore to the congressional hearing. Science Under Fire, supra note 153, at Z13.

168. The Federal Sentencing Guidelines may to some extent obviate this problem since they embody a philosophy of a little jail time for everyone. SENTENCING GUIDELINES, supra note 122 § 1A4(d). For most crimes, the Sentencing Guidelines require at least a minimal period of alternative custody (such as intermittent or community confinement) even for first offenders. Id. Absent a departure, the Guidelines authorize straight probation only when the lower number of the sentencing range is zero. Id. § 5B1.1. For crimes like submitting a false statement to the government, the lower end of the sentencing range is zero for a first offender only for crimes involving amounts of less than $2,000. Id. ch. 5, pt. A (Sentencing Table). This assumes the offense level does not increase because of offense characteristics other than the amount involved, as with offenses involving “more than minimal planning.” Id. §§ 2F1.1(a), (b)(1)(A), (b)(2).
Scientific Misconduct

These are difficult arguments to discuss in part because they involve largely unproved and unprovable perceptions about the societal significance of certain types of criminal conduct. How would one rank the harm of the following crimes—the misrepresentation of research results in order to receive a grant, embezzlement of bank funds, cheating on welfare payments, and tax fraud—to society's sense of security? Unless one is prepared to impose a wide-ranging, a priori limitation, such as no non-violent crime should be prosecuted, the prosecutor's office should evaluate the investigative or prosecutorial merit of scientific fraud cases according to its standard policies. Prosecutorial guidelines may consider various factors, including the perceived problems and the need for deterrence, the prosecutorial and investigative resources available, the existence of meaningful administrative or civil sanctions, and the amount of money involved. But the decision should not be made in a vacuum, on the assumption that no case of this genre is "worth it."

Moreover, given that initial investigative powers are relegated to the institution with which the questioned research is associated, it is important that prosecutors and investigative agencies provide guidance to the institution. Currently, colleagues and associates of a person suspected of misconduct are responsible for the initial evaluation of the allegation, conducting the investigation (or deciding not to), and making recommendations for further action. Although this procedure stems from the legitimate interests of having the investigation conducted by people with sufficient expertise to understand the matter under investigation, avoiding undue disruption of research and negative impact on reputation, and avoiding unnecessary expense and delay, it creates conflicting interests for the investigative institution.

In the context of funded research, internal investigation may be problematic when the institution is the beneficiary of the research grant, because the institution or persons

172. Typically, the institution would be the named recipient of the grant, and the researcher designated the lead investigator. Anderson, supra note 128, at 132.
within it assigned to do the investigation may be faulted for failure to exercise adequate supervision of the questioned research if misconduct is found to have occurred. In-house investigations generate other sorts of psychological pressure; it may be difficult to criticize or jeopardize the career of a colleague. Conversely, someone seeking to reduce competition or "with an ax to grind" may be biased against the accused. Further, investigators may be influenced by the reputation or perceived power of the person accused.173

The institutional and personal conflicts that can occur in investigating claims of wrongdoing make it especially important that there be outside input into or review of the decision, whether or not a particular incident is a criminal matter. Congress has worked toward this goal by creating investigative units within the Public Health Service (PHS) to deal with matters relating to scientific fraud.174 These offices,

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173. Internal investigations have been characterized as slow, superficial, and reluctant to criticize senior personnel accused of wrongdoing. See, e.g., CONFLICTS REPORT, supra note 32, at 62–63. They also may fall victim to a desire to "sweep under the rug" matters that need to be pursued further:

When the allegations against Dr. Breuning were brought to the attention of the University of Pittsburgh Medical School by NIMH, the Medical School conducted a superficial investigation that convinced them that Dr. Breuning was guilty of scientific fraud. Rather than investigating Dr. Breuning's work in greater depth, in order to determine exactly which research was fraudulent, the Medical School urged Dr. Breuning to resign without any public criticism, enabling him to obtain a position as Chief of Psychological Services at Polk Center, a State institution for the mentally retarded. In that position, Dr. Breuning was responsible for treatment decisions for retarded children, who themselves were put at risk by his fraudulent research claims.

The Polk Center was not notified of any allegations against Breuning, and the letters of recommendation from the University of Pittsburgh did not mention them. Dr. Breuning continued to be considered an expert in the field, discussing his research at conferences all over the country.

Id. at 13 (footnotes omitted).

174. The two units are the Office of Scientific Integrity (OSI), which is part of the Office of the Director of NIH, and the Office of Scientific Integrity Review (OSIR), part of the Office of the Assistant Secretary for Health. 42 C.F.R. § 50.102 (1990). OSI "oversees the implementation of all PHS policies and procedures related to scientific misconduct; monitors the individual investigations into alleged or suspected scientific misconduct conducted by institutions that receive PHS funds for biomedical or behavioral research projects or programs; and conducts investigations as necessary." Id. OSIR

is responsible for establishing overall PHS policies and procedures for dealing with misconduct in science, overseeing the activities of PHS research agencies to ensure that these policies and procedures are implemented, and reviewing
although not completely independent, are at least functionally removed from the subject of the investigation. They can consult with prosecutors both to develop standardized criteria for declining to prosecute or declining to initiate a criminal investigation, and to obtain a decision to decline prosecution in individual cases. These criteria will reduce the influence an individual's reputation has on the ultimate decisions to investigate and prosecute. In addition, institutions will be under less pressure because they will not be making the final decision about a colleague's work. Standardized criteria will also enhance both the public perception that alleged wrongdoing is investigated without favor or animus and the perception that allegations about scientific misconduct are taken seriously.

All final reports of investigations to assure that any findings and recommendations are sufficiently documented. The OSIR also makes final recommendations to the Assistant Secretary for Health on whether any sanctions should be imposed and, if so, what they should be in any case where scientific misconduct has been established.

*Id.*

175. As a document submitted to the House Subcommittee on Investigations and Oversight of the Committee on Science and Technology noted:

During this same 11-year period [from 1970 to 1981], DMSR [Division of Management Survey and Review, NIH], has worked on a total of 375 surveys, reviews or projects, and investigated 33 "hotline" referrals from the Office of the Inspector General. Few of these 408 cases involved scientific issues; rather, they mostly involved financial or managerial matters. In each instance where DMSR found even a hint of suspected criminal activity, the case was referred to the appropriate investigatory organization [i.e., to the Office of Inspector General which then refers it to the FBI or the United States Attorney's office].

*Fraud in Biomedical Research, supra* note 21, at 48 (Response of the Director, NIH, to questions from Congressman Albert Gore, Jr.).


Some might be concerned about the possibility of a scientist trying to gain an advantage by making false accusations against another scientist, thus tying up the competitor's time and reputation with allegations and investigations of wrongdoing. To some extent, however, this problem exists regardless of the type of criminal conduct involved. Moreover, criminal investigators and prosecutors are unlikely to initiate criminal investigations without a substantial showing of criminality. Finally, falsely reporting a crime can itself be a crime. See United States v. Rodgers, 466 U.S. 475, 481–84 (1984) (interpreting 18 U.S.C. § 1001 (1988) (false statement statute) to include a false report of a crime to the FBI).
V. A STATUTORY PROPOSAL

A federal criminal statute directed explicitly at scientific misconduct should be enacted in order to expressly indicate public intolerance of scientific misconduct.\(^{177}\) Although statutes such as the false statement statute currently provide general coverage for certain forms of misbehavior, a specific statute for scientific misconduct offers several advantages.\(^{178}\)

As procedures for dealing with allegations of scientific misconduct have developed, the scientific community has discussed safeguards for researchers who are accused of wrongdoing. Among the issues of concern are: the due process rights of an accused researcher if a state or federal institution is involved in taking adverse action such as the termination of a grant or employment; the extent to which allegations can or should be made known to the scientific community, a funding agency, prospective employers, or the public; the potential liability of institutions and professional journals for libel, defamation, wrongful discharge, or other injury to a researcher accused of wrongdoing; and the protection of "whistleblowers." See, e.g., PROJECT ON SCIENTIFIC FRAUD, supra note 3, at 3–23, 28–30.

177. In addition, some steps that could be taken to close loopholes under existing statutes include imposing criminal liability for deliberate failure to maintain records relating to the conduct of scientific research funded with federal monies. Currently it is a crime to destroy government records. 18 U.S.C. § 2071 (1988). This approach would assert a public interest in the records generated by government-funded research, and recognize omissions liability both by creating a duty to act and by punishing the deliberate failure to act. See, e.g., 21 U.S.C. §§ 331(e), 333 (1988) (making the failure to establish or maintain certain records relating to food or drugs a misdemeanor). A chief benefit of such a statute would be to preclude a scientist from arguing during an investigation of the soundness of his work that his data cannot be substantiated because no data were kept. The deliberate failure to keep records hardly can be said to contribute anything positive to science or to be part and parcel of intellectual freedom. While one can argue that misbehavior simply could shift from false claims of nonrecordation to the fabrication of records or to false claims of loss of records, it is still worthwhile to close the "I didn't write it down" loophole. One might infer that the more elaborate the falsification, the less likely someone would be to undertake it. In any event, it is conceivable that active falsification, will be easier to detect.

178. Congress has raised the possibility of criminalizing the intentional misreporting of scientific studies to an unreceptive scientific audience:

Dr. [Jerome] JACOBSTEIN, M. D., Director of Nuclear Medicine, Graduate Hospital, University of Pennsylvania. My own opinion is that's going too far. I don't think we need to make this a criminal matter in order to bring it under control. We have to devise some sort of oversight mechanism, and although, of course, that would be one option, it seems to me there ought to be others that do not bring it into that realm.

Dr. [Robert L.] SPRAGUE, Ph.D., Professor, University of Illinois, Urbana-Champaign. I would agree, I think it is going too far. I would be very concerned about the meaning of intentional here. This is such a complex area that I can see a great deal of difficulty in trying to define that appropriately. So I think that's going too far, at least at this point.
First, it permits a specific delineation of the actus reus and mens rea appropriate in this context. In a number of other contexts, Congress has supplemented a general criminal statute with more specific criminal statutes tailored to particular facets of the conduct involved. Targeting particular problem areas helps to focus public and investigative attention upon certain types of conduct. It further permits some more meaningful description of specific categories of proscribed behavior, taking into account any considerations unique to that area.

Second, a specific statute proscribing scientific misconduct permits consideration of permissible defenses such as a recantation defense. Third, it offers the possibility of tailoring the punishment for this type of conduct. Individual treatment would permit consideration of an aggravated and unaggravated form of the crime (spanning the felony/misdemeanor distinction) and also would permit some much needed latitude in prosecuting false statement offenses. A specific statute could make clear a court's power to impose restitution of grant funds. In addition, because of the complexity of these sorts of cases and the perceived desirability in the scientific community of having allegations initially reviewed by the affected institutions, I would urge that the statute of limitations for this offense be extended to at least six years.

But we—just as the previous panel had some reservations about the criminal side of the thing, we almost—I would almost go in the other direction. I think one of the things that inhibits people from simply correcting errors—I am now backing off the question of scientific fraud and addressing the question of scientific error—is the possibility they may be judged to have engaged in misconduct in some way . . . And I think one of the problems with addressing this via the criminal system is simply that it might increase the level of fear.

Id. at 134.


180. Although 18 U.S.C. §§ 3663, 3664 (1988) provide for restitution as a penalty for title 18 offenses, in the context of a false statement offense the concepts of victim and of loss attributable to the offense can be incongruous or perhaps inadequate to express the requirement that the defendant pay restitution, at least in the amount of any benefit she received as a result of the false statement.
I propose a two-tier statute that embraces both a felony and a misdemeanor provision. The base offense, to be treated as a misdemeanor, would penalize one for knowingly making a material false statement or representation about research results or about the method by which they were obtained. The aggravated form of the crime would provide enhanced penalties if particularly egregious behavior were proved, such as acting with intent to defraud, engaging in multiple and discrete acts of misrepresentation, or causing harm by inducing reliance on the falsified research.

The federal jurisdictional basis could be a finding by Congress that research embraces a class of activities that affect commerce. Alternatively, Congress could consider a more narrowly drawn statute that focuses only upon federally funded research; the existence of some percentage or amount of federal funding could be deemed a sufficient federal interest to justify intervention.

A triggering mechanism under the broader approach would need to be selected in order to fix the point at which criminal consequences would flow—the locus penitentiae, one might say. This point should be fixed late in the process of formulating and reporting research results, so that a fair degree of formality attends the making of the statement. This will give the wrongdoer notice of the act’s solemnity and the need for truthful reporting. Publication to the government or to the

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181. An example of a false representation might be knowingly mislabeling photographs that accompanied a description of research results.
182. Cf. 21 U.S.C. §§ 333(a), (b) (1988) (elevating misdemeanor to felony upon proof of “intent to defraud or mislead”). Although permitting misdemeanor treatment may result in more lenient disposition for this sort of misconduct than is currently permitted under the general false statement statute, it is justified by several considerations. First, it may reduce reluctance to prosecute. Second, it distinguishes more serious from less serious conduct. Third, it allows flexibility in plea bargaining that is currently unavailable under the false statement statute.
183. See, e.g., Perez v. United States, 402 U.S. 146, 153–54 (1971) (holding that Congress can believe that even intra-state and extortionate credit transactions can affect interstate commerce). But see Anderson, supra note 128, at 124 (indicating that federal intervention is warranted only when federal funds are involved).
184. An example of such a statute is 18 U.S.C. § 666 (1988), which criminalizes bribery and theft in certain federally funded projects.
185. A certification requirement, either in making statements to the government, or in publishing research results, would help to fix the point in time at which a scientist is vouching for the truthfulness of the information reported.
scientific community, knowing that the reported results will be considered truthful reflections of data and results actually obtained by the scientist, would represent such an occasion.\(^{186}\)

For a narrowly drawn statute, embracing only federally funded research, one model upon which to draw is the "in connection with" language found in the securities context.\(^{187}\) Thus, one formulation might proscribe "knowingly making a material false statement in connection with federally funded scientific research." This formulation conceivably could embrace more than the submission of a statement directly to the government,\(^{188}\) but again it is desirable to trigger liability only when a scientist makes formal representations about her research.

The \textit{mens rea} for the base offense should be "knowingly." This requirement comports with the more recent federal perjury statute\(^{189}\) and avoids the pitfalls of the term "willfully," now found in the false statement statute.\(^{190}\) In addition, it is a

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186. The argument has been raised that premising prosecution on the publication of information chills constitutionally protected speech. \textit{See In re Grand Jury Matter (Gronowicz), 764 F.2d 983, 987–89 (3d Cir. 1985), cert. denied, 474 U.S. 1055 (1986)} (rejecting the argument that the First Amendment protects authors from prosecution on the contents of a publication); \textit{Note, Mail Fraud and Free Speech, 61 N.Y.U. L. REV. 942 (1986)} (criticizing the \textit{Gronowicz} decision and urging that use of the mail fraud statute to punish criminal libel be limited to cases where the government can establish a compelling interest). The high \textit{mens rea} requirement of the proposed approach, coupled with the strong governmental interest in regulating, should satisfy the requirements of \textit{Garrison v. Louisiana, 379 U.S. 64, 78 (1964)} (holding that a Louisiana defamation law was unconstitutional because it punished even true statements made with actual malice and false statements about public officials regardless of the speaker's reasonable beliefs at the time of the statement).


188. The general false statement statute, 18 U.S.C. § 1001 (1988), has been held to embrace false statements not made directly to the U.S. government, so long as "it was contemplated that the statement was to be utilized in a manner which was within the jurisdiction of [a] department or agency." \textit{United States v. Candella, 487 F.2d 1223, 1227 (2d Cir. 1973), cert. denied, 415 U.S. 977 (1974)}). Moreover, false statements in documents subject to federal inspection have been held to fall within 18 U.S.C. § 1001. \textit{United States v. Diaz, 690 F.2d 1352, 1357 (11th Cir. 1982); Coil v. United States, 343 F.2d 573, 575–76 (8th Cir.), cert. denied, 382 U.S. 821 (1965)}.


190. Judge Learned Hand's comments about the word "wilful," made during formulation of the Model Penal Code, bear repeating on this point: "It's an awful word! It is one of the most troublesome words in a statute that I know. If I were to have the index purged, 'wilful' would lead all the rest in spite of its being at the end of the alphabet." \textit{MODEL PENAL CODE § 2.02 commentary on § 2.02(8), at 249 n.47}.
sufficiently high *mens rea* requirement to avoid any concern about prosecuting scientists for mistake or for negligence.\(^{191}\)

To avoid the inevitable confusion about the extent to which "knowingly" modifies other components of the proposed statute, I would make clear that "knowingly" applies to both the act of making the statement or representation and the fact that the statement or misrepresentation is false. If Congress selects a narrower jurisdictional base of federally funded research, the *mens rea* for the federal connection should be no higher than "knows or should know."\(^{192}\)

The proposed standard is simple to articulate and apply, incorporates behavior that is unquestionably wrong and that has significant potential for harm (economic or otherwise), and does not inject an appreciable possibility of second-guessing legitimate scientific debate in interpreting data. Nonetheless, a recantation defense, comparable to that recognized under the newer federal perjury statute,\(^{193}\) could be included to encourage scientists to correct the record if error is detected, rather than remaining silent when new data contradicting old data or conclusions are generated. Such a provision would help ensure a perception that inadvertent or good faith mistakes in reporting or interpreting research data would not be punished.

Discrete treatment in federal criminal law for scientific misconduct would dovetail with the current impetus toward enhanced efforts at self-policing.\(^{194}\) The scientific community has developed a number of procedures, including investigative procedures for dealing with allegations of scientific misconduct, to address practices that have been criticized as improper or

\(^{191}\) The term "knowingly" in federal criminal statutes has been interpreted to include deliberate ignorance. *E.g.*, United States v. Jewell, 532 F.2d 697, 700 (9th Cir. 1976). This interpretation, however, still embraces a highly culpable state of mind.


\(^{193}\) The statute provides:

> Where, in the same continuous court or grand jury proceeding in which a declaration is made, the person making the declaration admits such declaration to be false, such admission shall bar prosecution under this section if, at the time the admission is made, the declaration has not substantially affected the proceeding, or it has not become manifest that such falsity has been or will be exposed.


Scientific Misconduct

conducive to improper conduct both by private institutions and by the federal government. Watchdog units have been created within the PHS. In addition, under the PHS's guidelines, institutions receiving grants for biomedical and behavioral research are required to submit annual assurances that they have an administrative procedure to review reports of scientific misconduct and will report to the Office of Scientific Integrity whether any investigation is warranted as a result of that initial review.

A number of steps have been taken to tighten up laboratory practices, such as the federal government's adoption of rules regarding laboratory practices. In addition, private institutions have adopted rules regarding possible conflicts of interest, and some scientific journals have adopted policies requiring disclosure of an author's financial interests in the research about which he is publishing. Other journals' publication policies have been changed to deal with perceived abuses. For example, several journals have instituted certification requirements to enhance the personal responsibility of listed coauthors for the content of an article. This practice includes requiring authors to sign a form attesting to the authenticity of the data and committing them to produce data upon request or requiring authors to certify that they made a significant contribution to the work and have taken care to ensure its scientific integrity.

These reforms are certainly noteworthy efforts to address problems within the scientific community on a broad level;

195. Grantees have been criticized as slow to develop and abide by these procedures. See, e.g., Conflicts Hearings, supra note 52, at 105–61. A description of the procedures adopted by some universities is found in PROJECT ON SCIENTIFIC FRAUD, supra note 3, at 12–17.
196. See supra note 174 and accompanying text.
198. See supra note 55.
199. See, e.g., Bernadine Healy et al., Special Report, Conflict-of-Interest Guidelines for a Multicenter Clinical Trial of Treatment After Coronary-Artery Bypass-Graft Surgery, 320 NEW ENG. J. MED. 949, 951 (1989). Efforts to deal with conflicts of interest at the federal and private levels are discussed and in part criticized in CONFLICTS REPORT, supra note 32, at 52–59, 64–68; see also Booth, supra note 53, at 1496 (discussing how Harvard's Dr. Scheffer C.G. Tseng tested an eye ointment in which he had a significant financial interest).
201. See CONFLICTS REPORT, supra note 32, at 57–58.
implementing institutional reform is a significant step toward control of the problem of scientific misconduct. Yet the deterrent force of the criminal law should not be overlooked. Indeed, additional scrutiny may lead to the discovery of information about the nature and frequency of scientific misconduct, and the extent to which new statutes are needed to address conduct deserving of prosecution. Thus, to assure the most rational consideration of further development of criminal sanctions, the problems of misconduct in science and the impact of oversight of scientific research should be studied in light of recently developed internal controls.

Whether it be through the enactment of new statutes or through current criminal statutes, an effective deterrent can be generated by creating a credible threat of prosecution. Enhanced law enforcement efforts to consider and initiate prosecution in appropriate cases will go far toward the achievement of that goal.

CONCLUSION

Meaningful oversight of scientific research is a valuable tool for deterring misconduct that endangers the integrity of the process of scientific research, even if some risk of chilling

202. There are at least two obstacles one must confront in considering more open-ended federal criminal coverage for scientific misconduct. First, there is the problem of drafting a statute that is even reasonably specific about what is prohibited. Scientists need to know, clearly and in advance, what types of conduct on their part would likely lead to criminal investigation—of course, the Constitution compels fair notice as well if the prosecution stage is reached. Connally v. General Constr. Co., 269 U.S. 385, 391 (1926) ("a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law"). Terms like "misconduct," even if qualified by stringent mens rea requirements, may be too amorphous to both provide meaningful guidance and avoid intrusion upon legitimate scientific debate.

Second, there is the concern of injecting issues of the scientific merit of a researcher's work, issues that are not particularly conducive to resolution in a criminal law forum and that may pose the risk of chilling legitimate scientific endeavor. Certainly, an effective prosecutive effort requires statutes with enough flexibility to address the myriad of factual situations that cannot be anticipated at the outset, but the more broad the definition of the offense, the more likely it is that questions of scientific merit will become relevant.
scientific thought results. The lack of oversight appears to create an elite class of persons who are exempt from punishment for cheating. On balance, the lesser of the two evils is supervision, trusting common sense to observe reasonable limitations. In the long run, the more corrosive force is the undermining of public confidence in an important public institution and the engendering of a cynical perception that the reporting and the funding of scientific research is a rigged game. Criminal prosecution plays a valuable role in demonstrating a commitment to absolute integrity in this important arena.

When considering criminal prosecution, the prospect of discouraging legitimate effort cannot be overlooked. Complete protection from scientific misconduct, indeed if achievable at all, is achievable at a cost we should not want to pay. Our objective must be to have a serious commitment to prosecuting cheaters when found and to have sufficiently satisfactory tools to do so. Careful consideration should be given to the enactment of a new federal criminal statute tailored specifically to meet the goals of deterrence and condemnation. Vigilant but judicious use of such a statute or of the currently available federal statutes will achieve these goals without impairing the legitimate processes of scientific endeavor.