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SCIENTIFIC RESEARCH, LAW, AND PENALTIES FOR SCIENTIFIC MISCONDUCT

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INTRODUCTION

Individual scientists and their research institutions (academic, nonprofit, or industrial) risk a variety of penalties if they engage in scientific misconduct. Penalties may be imposed administratively by the federal agency (if any) that supported the research or by the Food and Drug Administration (FDA) which must approve each new drug, biologic, or device before it may be marketed. Additional penalties may follow criminal prosecution or civil claims pursued through the courts.

Potential penalties range from increased supervision of research to sizable fines and imprisonment. The scientists and their institution may also be excluded from further participation in government funded or federally regulated research for a period of years (or sometimes, permanently). In addition, if the discredited research was supported by a federal grant or contract, the funding agency may demand that the full amount be returned. The agency invariably insists that articles or reports found to be the result of misconduct be formally withdrawn, and the publicity surrounding findings of scientific misconduct can tarnish the reputation of the research institution and destroy the career of the scientists involved. When the research institution is a commercial entity, the misconduct findings and penalties also may affect sales of its products and the value of its stock or its ability to make an initial public offering.

ADMINISTRATIVE SANCTIONS

The two government agencies that provide most of the funding for biomedical research in the United States are the National Institutes of Health (NIH) and the National Science Foundation (NSF). Each has regulations requiring investigation of alleged research misconduct and appropriate action if the allegations are confirmed (1). (Table 2) The FDA has similar authority to impose sanctions for violations of rules governing the development and evaluation of new drugs and medical devices. The actions taken by the agencies supplement any disciplinary action imposed by the research institution.

The NIH and NSF developed their scientific misconduct procedures following a series of congressional hearings in the 1980s which criticized the responses of government agencies and the recipients of federal grants to allegations of fraud in science. The hearings and related press accounts publicized several incidents in which data were fabricated or falsified, and others in which papers submitted to a journal were found to have been plagiarized.

The federal definition of research misconduct has been controversial. Whatever the definition, confirmation that one or more scientists engaged in such misconduct will lead NIH or NSF to impose administrative actions and civil or criminal penalties appropriate to the nature and seriousness of the misconduct that occurred.

The Public Health Service and National Science Foundation

The Public Health Service, of which NIH is a part, and the NSF may take one or more of a range of administrative actions at the conclusion of a scientific misconduct investigation, unless an appeal is filed. In addition the research institution or the funding agency, or both, may impose "interim administrative actions" even before an investigation has been concluded, if necessary to protect human or animal subjects, prevent improper use of federal funds, or safeguard the public interest (2). Although described as administrative actions rather than penalties, the distinction may make little difference to the scientist or institution subjected to the action.

Interim Administrative Actions. The stated government purpose of interim administrative action is to ensure the

proper use of public funds, the protection of research subjects, and the fitness of the principal investigator to continue to direct the research project. Although research institutions are expected to take interim administrative actions as appropriate, the funding agency may take one or more actions in addition, to protect the federal interests. Administrative actions once taken are reviewed periodically and may be modified as necessary in light of new information. The possible interim actions that may be taken by a federal agency are as follows:

- Total or partial suspension of ongoing research
- Total or partial suspension of the accused researchers from eligibility to receive additional federal grants or contracts
- Prohibition or restriction of certain research activities (e.g., research involving human subjects or animals)
- Requirements for supervision and prior approvals to ensure/ compliance with federal law and to protect public health and safety
- Delaying the award of pending grants or contracts
- Revoking agency approval of key research personnel to direct or perform research activities

Administrative Sanctions for Scientific Misconduct (Table 1). If allegations of scientific misconduct are confirmed by an investigation, the funding agency may impose one or more of the following sanctions:

- Send letter of reprimand to the scientist's institution
- Require increased supervision of the scientist's research and publications
- Require that a supervisor certify the accuracy and integrity of information submitted to the agency in grant applications and progress reports
- Restrict the use of agency funds to certain activities
- Conduct special reviews of all grant applications from the guilty scientists or their institutions
- Prohibit the scientists from serving on agency advisory committees
- Suspend or terminate ongoing research support
- Debar the scientists or their institution from eligibility for federal research support for a given period of time

Table 1. Penalties for Scientific Misconduct: Federal Regulations

FDA regulations	Citation
Administrative actions for noncompliance	21 CFR, pt. 56, Subpart E
Civil money penalties	21 CFR, pt. 17
Disqualification of clinical investigators	21 CFR, §312.70
Disqualification of testing facilities	21 CFR, §§58.200-58.219
HHS regulations	
Government-wide debarment and suspension (nonprocurement)	45 CFR, pt. 76
Responsibility of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science	42 CFR, pt. 50, Subpart A
NSF regulations	
Government-wide debarment and suspension (nonprocurement)	45 CFR, pt. 620
Misconduct in science and engineering	45 CFR, pt. 689

The U.S. Food and Drug Administration

Under the Food, Drug, and Cosmetic Act, new drugs, biologics, and devices must be approved by FDA before they may be marketed. Approval is based on data collected in clinical trials demonstrating that the product is safe and effective for its intended use. Sponsors of new products must first apply to FDA for permission to conduct the clinical trials. Sponsors (usually drug or device manufacturers) or the clinical investigators who repeatedly or deliberately fail to follow FDA rules for the conduct of the research, or who fabricate or falsify their data, may be disqualified from further participation in clinical or laboratory research involving investigational products (3). Such disqualification by FDA is similar to debarment, although FDA also may debar research entities, drug and device manufacturers, and individual scientists for serious research misconduct such as submitting false statements to the agency, conviction of a crime related to the development or approval of a drug or device, or involvement in a conspiracy to commit any such crime (4). Debarment is also authorized following conviction of a crime such as bribery, fraud, perjury, falsification or destruction of records, and similar acts related to product development. The period of debarment may be as short as one year or permanent, depending on such factors as the nature and seriousness of the offense, the extent to which management was involved (either in encouraging or participating in the criminal activity or in failing to report it), and the extent to which management tried to correct the causes of or mitigate the offense.

FDA also has authority to take administrative actions similar to those described above for PHS-funded research (e.g., immediate suspension of research in order to protect research subjects or public health and safety). In addition FDA may refuse to accept data from a clinical trial to support an application to market the product being evaluated and may even withdraw approvals previously granted (5).

Finally, FDA may seek criminal convictions or civil money penalties. When a person (individual or corporate) submits a false statement of a material fact to FDA, or knowingly fails to disclose information required to be submitted (e.g., the number and severity of adverse events observed in a clinical trial), that person may be liable for a civil penalty, under the Food, Drug, and Cosmetic Act (6). Individuals may be fined up to $250,000 for each violation, while fines against manufacturers may reach $1 million

per violation. Civil fines may be imposed in addition to other authorized civil, criminal, and administrative remedies. Criminal prosecutions are typically based on claims of wire fraud, mail fraud, or submission of false statements to a federal agency. These actions are described below.

Government-wide Debarment and Similar Exclusions

Debarment is an extended exclusion from government grants and contracts, while suspension is a temporary exclusion. Both are viewed by federal agencies as serious actions to be used only to protect the federal government's interests and are not considered to be punishment (7). The actions nevertheless have decidedly punitive effects.

In order to avoid providing government support to anyone found guilty of serious misconduct, President Reagan in 1986 ordered that the debarment of an individual or institution by one agency should have government-wide effect. The order applies as well to suspensions, disqualifications, and "voluntary exclusion agreements," which the agency negotiates with individuals or entities who are willing to settle misconduct charges to avoid the cost and disruption of hearings and appeals. Accordingly debarment of a scientist or technician for research misconduct prevents that individual from receiving research support from any federal agency for the period of debarment (8). The same restrictions apply to any research institution or corporate entity that has been suspended or debarred. As of September 1997, however, no institution had been debarred as a result of a finding by the Department of Health and Human Services (HHS) Office of Research Integrity (ORI) confirming scientific misconduct (9). A suspended, debarred, disqualified, or excluded scientist may not even participate in another scientist's federally funded research without special permission from the funding agency. Periods of debarment or exclusion for scientific misconduct typically range from 3 to 10 years but sometimes are permanent (10). A consolidated list of all agency suspensions, debarments, disqualifications, and voluntary exclusions is maintained by the General Services Administration (GSA) for enforcement purposes and is available to the public (11).

Publication of Misconduct Findings

The PHS, FDA, and NSF policies differ in their approach to publicizing misconduct findings. The PHS publishes the names of the scientists and their research institution, together with a brief summary of their misconduct and the sanctions imposed. These notices appear in both hard copy and Internet versions of the *Federal Register*, the *NIH Guide to Grants and Contracts*, and the *ORI Newsletter*. The PHS also may notify state licensing boards (if the scientist involved is a licensed health practitioner), professional associations, and journals in which the scientist has published reports of past research. FDA publishes notices of disqualifications and debarment in the *Federal Register* and also may notify sponsors of products being tested and collaborating institutions. The list of investigators who are ineligible to receive investigational drugs, or whose use of investigational products is limited, is available to the public. By contrast, NSF publishes summaries of misconduct findings and sanctions, but it does not identify either the scientists or the institutions involved (12). The summaries of NSF cases are included in semiannual reports to Congress from the NSF Inspector General.

Retraction or Correction of Publications

Both PHS and NSF require a formal correction or retraction of journal articles found to contain fabricated, falsified, or plagiarized material. Although previously these notices were submitted as letters to the editor, most biomedical journal editors now agree that retractions should be labeled as such and appear independently on a numbered page of the journal, in order to include references to the retraction or correction in standard bibliographies (13). The National Library of Medicine, for example, annotates in its computerized databases (e.g., MEDLINE) articles that have been corrected or retracted, and provides a citation to the withdrawal or correction notice (14). This practice was challenged in 1994 by a scientist who was then under investigation for scientific misconduct as a result of patients improperly enrolled, by a collaborating researcher, in a multicenter breast cancer clinical trial. The principal investigator challenged the Library of Medicine's annotations of numerous articles from the collaborative trials but was rebuffed by a federal district judge, who ruled that the entries in the Library's databases pertained to publications, not to their authors (15). The district court's ruling was affirmed by a federal appellate court and motions for reconsideration were denied. In a letter to the editor in *Science*, the acting ORI director emphasized that the annotations had not been added to the Library's databases until after there had been a formal finding that the collaborating researcher had committed scientific misconduct. He added: "Scientists should not be concerned that annotations have been in the past or will be in the future placed in databases before a misconduct investigation is completed. They have not and will not be" (16).

Recoupment of Government Funds

Federal agencies have authority to require that institutions return any public funds that have been misused. In the context of research grants, this is typically accomplished by asserting that the funds in question were used improperly, and therefore the institution was not entitled to them and must refund the money (17). When ORI closes a case with a finding of scientific misconduct, it reports its findings to the institute at NIH that awarded the grant or contract. NIH in turn may seek recoupment of the research funds involved. In 1995, for example, NIH recovered $296,478 from an institution after ORI found that a principal investigator had submitted progress reports for three years describing research he had not performed. In 1994 NIH recovered over $1 million from three institutions involved in two scientific misconduct cases. NIH recoveries of research funds are actions independent of ORI's and are not routinely reported in the *ORI Newsletter*.

In late 1996 the Department of Justice sued for restitution of over $100 million from the University of Minnesota which allegedly obtained research grants fraudulently from NIH and illegally sold an antirejection drug that FDA had not approved for marketing (18). In July 1997 a U.S. district judge reduced the amount at stake from $109 million to $60 million by dismissing the False Claims Act portions of the suit (19). That ruling was reversed on appeal (20), and the university ultimately paid $32 million to settle the case (21).

At NSF, recoupments of research support are regularly reported in the Inspector General's Semiannual Reports to Congress and commonly result from findings of scientific misconduct. Restitution often results from criminal or civil litigation but may also result from internal agency determinations.

CIVIL MONEY PENALTIES

In addition to the administrative actions described above, scientists and their employers may be subject to civil money penalties and recoupment of publicly funded research support for offenses related to the development and testing of new drugs and devices. Other agencies have similar authority.

Program Fraud Civil Remedies. The Program Fraud Civil Remedies Act of 1986 was designed to deal with the submission of false statements to the government involving claims of less than $150,000. Under that Act, anyone submitting a claim or statement to a government agency, with knowledge that the claim or statement is false, fictitious, or fraudulent (or acting in deliberate ignorance or reckless disregard of the truth or falsity of the claim), is subject to a civil penalty of up to $5,000 for each such claim and twice the amount of each claim (22).

False Claims Act. If more than $150,000 is involved, the government may proceed under the False Claims Act, 31 U.S.C. §§3729–3730, which authorizes civil fines up to $10,000 plus recoupment of three times the amount of damages suffered by the agency as a result of the false claims. Alternatively, if the person who submitted the false claim cooperates with the government's investigation, the amount assessed may be reduced to two times the amount of damages. Under this provision universities and other research entities have been induced to cooperate and plea bargain, to avoid the treble damages.

In 1994, for example, the University of Utah and the University of California agreed to repay NIH more that $1.5 million in grants allegedly obtained through false data submitted in the grant applications. The universities' alternative to settlement was to risk treble damages (totaling $3.6 million) under the False Claims Act for knowingly presenting a false or fraudulent claim for payment to a government agency (23). Federal research grants are within the Act's definition of a "claim."

Qui Tam Actions. The "qui tam" provisions of the False Claims Act permit private citizens to bring suit in the name of the United States to recover funds paid out by the government of the basis of fraudulent claims. "Qui Tam" means "who as well ..." and denotes actions initiated by private citizens or informers who sue on behalf of the government as well as for themselves. In return for prosecuting the case, or at least alerting the government to the false claims, the informer (called a "relator") is entitled to a significant portion of the amount recovered. If the government successfully prosecutes the case, the relator may receive between 15 and 25 percent of the damages recovered. If the government declines to participate in the litigation, the relator who litigates in the name of the United States—and wins—is entitled to receive up to 30 percent of the damages awarded, in addition to costs and reasonable attorney fees. With damages trebled and potentially reaching millions of dollars, the informer's share can be sizable. Critics of the qui tam provisions say that the process offers an opportunity to settle personal scores while, at the same time, collecting a windfall and posing as a public citizen.

The qui tam provisions were enacted during the Civil War in response to sales of defective supplies to the Union Army. Amendments to the law in 1986 strengthened the role of relators and resulted in a surge of qui tam cases over the next decade. In fact, recoveries under the False Claims Act increased from $2 million in 1988 to over $200 million in fiscal 1995 (24). At the same time the portion of qui tam cases involving fraud related to HHS has surpassed those at the Department of Defense, which dominated the field in the past. HHS fraud cases involve primarily Medicare, Medicaid, and similar third parties who pay for health care services and supplies (24). A growing segment, however, relates to allegations of scientific misconduct in NIH-supported research activities.

A recent case illustrates how the qui tam law operates. In 1994 a former graduate student from Cornell, Pamela Berge, filed a qui tam suit against the University of Alabama, Birmingham, and four of its faculty members for allegedly submitting false statements in grant applications to NIH. A jury returned a verdict favorable to the informer/relator, which resulted in a judgment of just under $2 million (plus costs and attorney fees). Berge's claims were based on allegations of plagiarism, or misappropriation of intellectual property, which had been investigated and found to be meritless by a series of academic, scientific, and administrative reviewers. She therefore transformed her plagiarism charges into a qui tam action on behalf of the United States, asserting that a series of annual reports and grant applications submitted to NIH by the university incorporated plagiarized material and therefore constituted multiple false claims. Following the jury verdict, a federal district court judge awarded Berge 30 percent of the $1.6 million judgment, plus costs and attorney fees. The judgment subsequently was overturned by the Fourth Circuit Court of Appeals (25), which found no evidence on which a reasonable jury could have concluded that the challenged statements were even false, much less the basis for any NIH-funding decisions. The appellate court also ruled that there was no plagiarism and that Berge's claim for misappropriation of intellectual property was preempted

by the U.S. Copyright Act. The United States Supreme Court declined Berge's petition for review; thus the Fourth Circuit Court opinion stands as the last word in this case.

The likelihood that personal grievances will generate False Claims Act litigation is increased by the bounty-hunter (qui tam) provisions and the publicity attending successful cases. In addition a Washington-based group called Taxpayers Against Fraud actively solicits and supports potential qui tam plaintiffs, with a Web site on the Internet offering referrals to counsel, loans for litigation, help with legal research, and production of amicus (friend of the court) briefs. Supporters of qui tam view this as a public service, while opponents see disgruntled employees and students being encouraged to file multimillion dollar claims in the name of good citizenship (24). A similar support group has been established in Michigan to encourage and assist "whistleblowers" alleging scientific misconduct more generally. The likelihood is that agency actions and qui tam litigation both will increase in the foreseeable future.

CRIMINAL PROSECUTION

Statutory Penalties

Submitting false statements or information to the federal government, and similar offenses involving deceit, false statements, or fabrication, may result in criminal prosecution. It is a felony knowingly to submit a false statement or false claim to a government agency (26). A statement may be false either through omission (i.e., failure to disclose a material fact) or through submission of a false statement or representation. Conviction may result in incarceration for up to five years, debarment, imposition of fines, and recoupment of grant or contract monies.

When a scientist submits false statements in an application for a research grant, or in an annual report to the granting agency, that constitutes a false claim (request for money) and is punishable under the criminal False Claims Act by imprisonment for up to five years, a fine, or both (27). When the false claim is submitted by telephone or through the mail, the scientist and research institution may also be charged with wire fraud or mail

Table 2. Penalties for Scientific Misconduct: Federal Statutes

False claims and statements	**Penalties**
Administrative remedies for false claims and statements, 31 U.S.C. §§3801–3802 (applies to claims less than $150,000)	$5000 for each false claim, plus up to twice the amount of the claim
False Claims Act (civil actions), 31 U.S.C. §3729 (false claims exceeding $150,00)	$10,000 for each false claim, plus treble amount of each claim
False claims actions by private persons (qui tam), 31 U.S.C. §3730(d); Informer ("relator") may receive up to 30% of damages, plus attorneys' fees and costs	$10,000 for each false claim, plus treble the amount of each, plus costs and attorneys' fees
False, fictitious, or fraudulent claims (criminal), 18 U.S.C. §287	Fines and/or imprisonment up to 5 years
False statements or entries (criminal), 18 U.S.C. §1001	Fines up to $10,000 and/or imprisonment up to 5 years
Related crimes	**Penalties**
Conspiracy, 18 U.S.C. §371	Depends on underlying violation(s)
Mail fraud, 18 U.S.C. §1341 and Wire fraud, 18 U.S.C. §1343	Fines (up to $250,000, depending on amount of fraud), restitution, and/or imprisonment up to five years
Presidential order (Ronald Reagan)	**Penalties**
Debarment and suspension (government-wide effect), Executive Order No. 12549; *Fed. Regist.* **51**, 6370 (1986)	Individual or entity debarred or excluded by one federal agency may not receive grants or contracts from any federal agency
Food, Drug, and Cosmetic Act	**Penalties**
Withdraw approval of abbreviated drug applications, 21 U.S.C. §335c	Approval withdrawn; drug may not be marketed
Civil penalties (fines), 21 U.S.C. §335b; (informants may receive $250,000 or one-half of penalty, whichever is less)	Fine up to $250,000 for individuals; fine up to $1 million for corporate entities, partnerships, etc.
Debarment, and suspension; also, temporary denial of approval, 21 U.S.C. §335a	For corporation, partnership, etc., exclusion from research involving investigational products for 1–10 years; for individual convicted of felony related to product development, permanent exclusion
Public Health Service Act	**Penalties**
Office of Research Integrity, 42 U.S.C. §289b	Limitations on use of grant funds, supervision, suspension/termination of grant, debarment (exclusion) from future grants/contracts

fraud, and if more than one person is involved, a conspiracy charge may be added as well (28). Nothing in the law precludes prosecution under multiple federal statutes, and each grant application, status report, or request for payment constitutes a separate claim and, thus, an additional offense.

Examples of Cases

The first scientist to be indicted for research fraud was Stephen Breuning, a psychologist who fabricated data in federally supported studies on the use of stimulant drugs to treat hyperactivity in retarded children. Following indictment for fraud and making false statements to the National Institute of Mental Health, Breuning entered into a plea agreement which resulted in a conviction. Because of the potential impact of his fraud on treatment decisions for vulnerable individuals, Breuning was sentenced to incarceration for two years (suspended except for 60 days on work-release in a halfway house), five years' probation (during which he was required to perform 200 hours of community service), exclusion from federal research support for 10 years, and reimbursement of $11,352 to his university (29,30). He was also forbidden to work as a clinical psychologist for 10 years.

In a case that involved research submitted to FDA but did not involve federal research support, Dr. Robert Fogari, a physician who fabricated results over a period of eight years in a study of investigational anti-inflammatory drugs, was convicted of criminal fraud and obstruction of justice, sentenced to four years in jail, fined over $3.8 million, and ordered to make restitution (29).

Another case, that of Barry Garfinkle, demonstrates the multiple penalties that may be imposed for misconduct in clinical trials of new drugs (31). Dr. Garfinkle was convicted in 1993 of mail fraud and making false statements to the FDA while serving as principal investigator in studies of Anafranil. The drug was being tested as a treatment of obsessive-compulsive disorder in children and adolescents. The prosecution was triggered by complaints from the study coordinator that Garfinkle had ordered her to enter false data about weekly clinical evaluations that either never took place or were conducted by the coordinator rather than a physician. In addition the study coordinator alleged serious breaches of the research protocol. The indictment included charges under the Food, Drug, and Cosmetic Act, False Claims Act, and statutes prohibiting mail fraud.

Garfinkle was sentenced to six months in a halfway house, followed by six months of home detention, 400 hours of community service, and over $200,000 in fines. Based on his conviction of multiple felonies related to drug development, Garfinkle also was permanently debarred by FDA from serving in any capacity in connection with a new drug application. In addition the FDA served notice that it would not accept or review any abbreviated drug applications prepared by, or with the assistance of, Dr. Garfinkle, and that any person with a pending or approved drug application who knowingly used Dr. Garfinkle's services would be subject to a civil money penalty.

Such prosecutions are not limited to research involving NIH or FDA. In 1993, for example, a federal appellate court upheld the conviction of a scientist for conspiracy and fraud in connection with a grant, funded by the Agency for International Development, to create a diagnostic field test for malaria (32). Following a jury trial, the researcher was convicted and sentenced to eight months in prison (five of which were suspended), three years probation, and was ordered to make restitution in the amount of $75,000. The NSF also, together with the U.S. Attorney's Office, has successfully prosecuted individual scientists and biotech companies for fraud and false statements relating to Small Business Innovative Research (SBIR) grants. Within a six month period in 1996, these prosecutions resulted in criminal fines, civil penalties, restitutions, and other savings amounting to over $6 million (33).

DAMAGE TO PERSONAL HEALTH AND PROFESSIONAL REPUTATION

Perhaps the most devastating penalties are the effects of scientific misconduct allegations on the personal and professional life of the accused. Researchers who have been accused and later exonerated report that the investigative process alone has had prolonged and significant adverse effects on their lives (34). Approximately three-fifths of the exonerated scientists who responded to a 1996 survey believed they were stigmatized by the accusations, and nearly 40 percent reported adverse effects on their professional careers, such as damage to their reputation, reduced job mobility, and diminished opportunities for presenting papers. Over three-quarters of the respondents reported negative effects on their mental health, and nearly half reported adverse effects on their physical health. Disruptions of family relationships are not unusual. These outcomes, reported by scientists who were ultimately exonerated, suggest that even more serious personal and professional consequences must follow confirmation of scientific misconduct. Scientists who are found guilty of scientific misconduct, however, have not been surveyed. In many instances, they seem simply to have left the scene.

A widely publicized example of a scientist accused and later cleared is the case of Thereza Imanishi-Kari, who coauthored a paper in 1986 with Nobel prize-winning scientist David Baltimore (35). Imanishi-Kari was accused by a coworker of faking her data. Baltimore was never accused of scientific misconduct, but his name was linked invariably with that of Imanishi-Kari in the scientific and lay press, as well as in congressional hearings. Both scientists suffered personally and professionally throughout a 10 year investigation, although neither ultimately was found to have committed scientific misconduct. Imanishi-Kari's faculty status was suspended and, with it, her eligibility for NIH grants. Baltimore was ultimately forced from his position as President of Rockefeller University and was ostracized for years by many members of the scientific community. In 1997, with his reputation in recovery, he was appointed President of California Institute of Technology. Other scientists, perhaps less conspicuously, have suffered

a similar damage to reputation, personal anguish, curtailed career, and diversion of significant emotional, intellectual, and financial resources to defend against the accusations.

Occasionally the accusation of research fraud has led to even worse tragedy. Paul Kammerer, for example, was an Austrian scientist who believed he had developed proof of the heritability of acquired characteristics. As described by Arthur Koestler in *The Case of the Midwife Toad*, Kammerer's controversial support of the Lamarckian theory of inheritance was challenged repeatedly by the followers of Darwin. One vigorous critic ultimately accused Kammerer of having faked his results. Although essential facts about the research remain murky, the effect of the accusation is clearly documented. Despairing of ever proving his innocence to the satisfaction of his critics, Kammerer went into the Vienna woods and shot himself. A note found in his pocket stated:

> Dr. Paul Kammerer requests not to be transported to his home, in order to spare his family the sight. Simplest and cheapest would perhaps be utilization in the dissecting room of one of the university institutes. I would actually prefer to render science at least this small service. Perhaps my worthy academic colleagues will discover in my brain a trace of the quality they found absent from the manifestations of my mental activities while I was alive (36, p. 13).

Kammerer's suicide occurred in 1926. Six decades later, a professor of neurology and neurosurgery at the Montreal Neurological Institute (affiliated with McGill University), together with her husband (a faculty member at another university), committed suicide following publication of anonymous allegations that she had committed research fraud (37). As her lawyer explained: "Given that her work was her life, and she felt that her ability to continue was being seriously undermined, it was obviously more than she could live with" (38).

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See other entries SCIENTIFIC RESEARCH, ETHICS, SCIENTIFIC MISCONDUCT; SCIENTIFIC RESEARCH, ETHICS, VALUES IN SCIENCE.

SCIENTIFIC RESEARCH, POLICY, TAX TREATMENT OF RESEARCH AND DEVELOPMENT

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INTRODUCTION

Research and development (R&D) in the field of biotechnology typically requires a significant investment before any marketable products may be produced. In an effort to encourage greater private sector investment in research and development activities, Congress has enacted several provisions under the Internal Revenue Code, including Sections 174, 41, and 45C, that authorize tax benefits for certain types of expenditures incurred in connection with R&D activities. Specifically, Section 174 provides a current tax deduction for research or experimental expenditures while Section 41 permits a tax credit for increases in research expenditures from one tax year to another.