SECTION I

Introduction to the Study of Ethics in the Biological and Health Sciences

The Ethics Movement in the Biological and Health Sciences

A New Voyage of Discovery

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The modern voyage to chart the ethical bases of the biological and health sciences (biohealth sciences) is an important episode in their history and also in the annals of society. Its purpose has been to identify, for scientists from different disciplines who probe human function and for the surrounding society, principles for setting the goals of this research, creating the resultant knowledge, and influencing its subsequent use. This essay traces seminal events of this journey, which began near the midpoint of the twentieth century, and seeks to identify directions the journey may take as it continues on a course into the future. This passage has occurred in four phases, in each of which biohealth scientists have altered a fundamental relationship: in the first phase with the individual research subject, in the second with society, in the third with their research procedures, and in the fourth with their institutions of learning.

Phase I 1945–1966: Fathoming the Human Subject

Revelations emerging from the Nuremberg War Crimes Trials at the end of World War II disclosed the forced induction of prisoners of war and civilians into experiments that injured and killed many. These activities were officially sanctioned and promoted by government authorities of the Nazi regime and conducted by scientists and physicians. To prevent future harm to subjects of human studies, instruct investigators about the ethical precepts needed to protect subjects, and delineate the responsibilities of investigators to carry out these goals, a set of ten principles was developed by the war crimes staff. It came to be called the Nuremberg Code.

The code focused on giving the potential subject of an experiment the opportunity to decide whether to participate. It enumerated the conditions necessary to assure the freedom and capacity of individuals to make this choice. This included the absence of a coercive environment that would hinder choice, the presence of a mental capability and adequate data about harms and benefits that would facilitate choice, and the freedom of the subject to withdraw at any time from the experiment. The code made investigators responsible for assuring the adequacy of the consent process, the scientific credibility and safety of the experiment, the qualifications of those conducting the experiment, and the ending of an experiment when the likelihood of injury or death to subjects emerged.[1]

With the code in hand, and the consequences of moral insensitivity to the possibilities of harm in human studies so starkly taught, scientists believed that major ethical problems now could be avoided or adequately handled if they occurred. As researchers entered the 1950s they were also caught up in the excitement of a period of unsurpassed growth in biomedical research. This was a time when the public accepted scientists as benevolent experts whom

they trusted to select the projects and determine the goals of science. Research into health and illness was a good of which the public wanted more, and they were willing to give considerable sums of money for this purpose. The National Institutes of Health (NIH) became a major scientific funder in the postwar period, its grants rising from $75 million in 1948 to $150 million in 1954.[2] Understandably, the research community wished to focus on scientific questions. Hence the 1950s produced little commentary about the ethical issues of human studies or the relation of the biohealth sciences to society.

However, in the 1950s a small group of lawyers was interested in strengthening legal protections for human subjects. They attempted to encourage research organizations in the United States to build on the ideas in the Nuremberg Code. They urged scientists to seek ways to refine scientific practices used in human studies and to develop innovative principles to guide the research. But as one of these lawyers, William Curran, who became Professor of Legal Medicine at Harvard, wrote of his efforts in the 1950s to gain attention to research ethics: "We had only very limited success in this ambitious undertaking. We were working at a time somewhat before the researchers were ready to believe such action was necessary."[3]

Attitudes changed in the 1960s. The catalysts were the discovery of particular cases in which investigators disregarded the canons of the Nuremberg Code, the burgeoning civil rights movement that heightened social sensitivity to the needs of vulnerable groups, and legislative and regulatory actions that changed the procedure of research on human subjects.

A case that drew wide attention occurred in 1963, when three physicians experimentally injected live cancer cells into twenty-two elderly and debilitated in-patients at the Jewish Chronic Disease Hospital in Brooklyn to determine whether such patients would reject such cells. Several physicians opposing this experiment and particularly concerned that the subjects never consented to participate brought the matter to the hospital's board of trustees. One of these physicians took the hospital to court to see the records of involved patients. In the complicated proceedings that followed, several of the study's investigators contended that a doctor could rightfully withhold data that patients might find threatening. This position was not upheld when the Board of Regents of the State University of New York reviewed the case. It asserted that the investigators had an experimental, not a therapeutic, relationship with subjects. Thus no basis existed for the exercise of the "usual professional judgment applicable to patient care."[4] As the story unfolded in the media, however, there was public and professional surprise and consternation that existing ethical principles of scientific research had not prevented the occurrence of such an experiment.

Federal interest in this subject had emerged a year earlier in 1962. A group of U.S. senators devoted to civil rights issues and led by New York Senator Jacob Javits added a requirement to the Food, Drug, and Cosmetic Act being amended that year. It mandated investigators of experimental drugs to obtain a formal consent from subjects in their trials. In 1965, more pressure for reform was introduced. In March of that year Harvard anesthesiologist Henry Beecher delivered a paper at a conference in which he cited cases in the published literature showing disregard of the consent process in human experiments. This speech, published in 1966 as an essay, received widespread coverage in the public media. In December 1965 The National Advisory Council to the NIH added its weight to the issue and went much further than had the food and drug legislation. It announced that guidelines would be developed requiring prior review of all research protocols on human subjects before a study could begin. A February 1966 memorandum from the U.S. Surgeon General spelled out what these guidelines would mean. Scientists now would be required to obtain an informed consent from all research subjects and provide an assessment of the possible harms and

benefits of the studies they proposed. Evaluation of this material would be given to a group of peers within the investigator's institution. In a July 1966 revision these institutions were made responsible for assuring that all research funded in them by the NIH met its review requirements.[3] The panels became known as Institutional Review Boards, or IRBs.

With the IRBs in place, the private world of the individual investigator was opened not only to peers but to social others as the membership on IRBs became enlarged to include community participants who were not scientists. The IRB requirement made investigators consider and discuss explicitly with subjects ethical questions connected with their research. This discourse, involving issues of consent and the risks and benefits of medical interventions, dovetailed with and further stimulated consideration of these matters in clinical medicine. Indeed the scientists whom such regulations involved often worked in the milieu of hospitals where human subjects could be recruited from among patients. Accordingly these events influenced investigators doing basic and applied research in the clinical community more than it did those working on biologic questions in laboratories removed from patient care.

In the 1940s and 1950s social authority was used to free both the individual scientist and the research subject. The NIH increasingly freed scientists from monetary constraints to pursue their research projects; the Nuremberg Code liberated research subjects from the authority of scientists to decide their own welfare. However, in the 1960s, the introduction of the IRB diminished the scientist's authority to determine the content of research procedures used on the human subject, while it enhanced the self-determination of the subject.

Phase II 1966–1974: The Social Engagement of Scientists

While the first part of this ethics movement focused on the danger of the scientist's work to particular individuals, the second part emphasized its threat to society at large. In the context of exploring potential social threats, a searching examination was conducted concerning the respective roles of the public, government, and investigators in deciding the course of scientific work that posed a possible threat to populations. This phase began in the mid-1960s and lasted about a decade.

The proximal antecedents of this phase were calls of alarm in the early 1960s by a number of prominent intellectuals such as Lewis Mumford, Jacques Ellul, and Raymond Aron. They and others were concerned about the growing hegemony of science in determining the course of civilization. Through innovations in transportation, communication, and warfare science was altering basic patterns of life, and scientists were becoming the quintessential experts of society. As the power over the way society lived flowed to the experts upon whose scientific knowledge social change was based, anxiety arose about the ability of the laity to question their authority. Raymond Aron wondered whether democracy could function in this situation. How, he asked, could legislators, politicians, or the electorate evaluate the complex facets of social problems when the most basic knowledge about them increasingly fell into the domain of the scientific expert? He worried that democratic institutions were threatened by the emerging dominance of a scientific elite.[5]

Ironically, this problem stemmed in part from the retreat of scientists from political dialogue and not their entrance into it. Scientists, including those in the sphere of biology, generated these transforming innovations without a clear view of the changes their work produced. They largely were unprepared to discuss the social consequences of their innovations when called into public forums for this purpose. Scientists held the knowledge

to create transforming social change but lacked the understanding or will to evaluate its influence on social institutions or values. They exercised power but seemed unwilling and unable to take responsibility for its effects.

The main exceptions in this period were found in the community of atomic scientists. During the late 1940s and 1950s J. Robert Oppenheimer, Leo Szilard, and other leading physicists urged scientists to participate in discussing the use of their innovations. But the example of the physicists was not widely followed in other scientific disciplines. Scientists for the most part stayed out of social controversies for several important reasons. Too much involvement would take time away from the reading, reflection, and experimental work that made them "expert" in the first place: an excessive public profile threatened their scientific status. Public discourse required oversimplification of complex issues, and too much public exposure could turn scientists into celebrities. These effects could taint their image as detached analysts. Further, their training did not prepare them intellectually or emotionally for the social and political forums of public debate. Some worried, rightly, that when they entered into social debate, they descended from the platform of the expert to the ground of the layperson.[6]

However, by the mid-1960s a small number of biologists and medical scientists began actively to embark on an involvement in social issues. They were joined by a public grown increasingly interested in, and perturbed about, the power of the biological sciences to alter human life. The trust that the public had imposed on the scientist to decide alone what research to pursue was fading. In no aspect of biology and medicine was this concern deeper than in genetics.

The modern scientific transformation of this field had occurred in 1953 when James D. Watson and Francis H. C. Crick described the structure of DNA. This development made possible dramatic advances in understanding the architecture and function of human genes. During the 1960s, particularly the latter half of the decade, discussions were held in growing numbers on the ethical, social, and medical consequences of this research. Concerns grew that a second eugenics movement would emerge as more was learned about genetic functions. Worry began to compete with exhilaration about what the knowledge might bring. One of the earliest efforts to study these issues began in 1966. A small research group at the newly created Harvard Program on Technology and Society was formed to explore the social implications of advances in the biomedical sciences. The group convened conferences that brought together scientists, humanists, and policy experts. A book describing its early work noted that the issues being addressed had "to do specifically with the social control of the new biomedical technologies. . . . They relate to how science and technology can be used to social advantage. . . . It is evident that what were once considered exclusively professional decisions are increasingly coming to be regarded as decisions that need to be made by the larger society."[7]

As the 1960s came to an end, popular books began to appear that portrayed the threatening sides of the emerging understanding of biological function. A typical one, by the journalist Gordon Rattay Taylor, was called, ominously, *The Biological Time Bomb*. The titles of its eight chapters tell its story: "Where Are Biologists Taking Us?" (a chapter describing how biological knowledge is outpacing society's ability to control it), "Is Sex Necessary?" (a view of test-tube babies), "The Modified Man" (a look at transplantation), "Is Death Necessary?" (prolonging life through hibernation and freezing), "New Minds for Old" (manipulating emotions, memory, and intelligence), "The Genetic Engineers" (the possibilities of genetic surgery and eugenics), "Can We Create Life?" (making cells and

viruses), "The Future, If Any" (social discord as the aforementioned innovations mature). In this and in similar publications, analogies were made between the possible destructive force of biological discoveries and the problems caused by the knowledge of atomic energy. The book's cover included a quote from Arthur Koestler from which its title apparently was taken: "Biology is just reaching the critical point of sudden acceleration which physics reached a generation ago . . . the biological time bomb is about to explode in our face."[8]

These concerns extended into the 1970s. In 1971, ethicist Joseph Fletcher made a comment about genetic research that mirrored an emerging social fear that biological knowledge could be used to harm or control society: "Even though its medical aim were only to gain control over the basic "stuff" of our human constitution it could no doubt also be turned into an instrument of political power."[9]

It was against this background of rising anxiety that in 1971, a member of the research staff of the Cold Spring Harbor Laboratory, Robert Pollack, telephoned Stanford biochemist Paul Berg. He called to discuss his concern with Berg's research to determine if the simian virus 40 could be used to transfer a foreign gene into bacteria. Because it had been shown that this virus produced tumors in hamsters, Pollack worried about the consequences of placing it into a strain of bacteria that grew in the human intestine, such as the widely used *Escherichia coli*, the one that Berg had intended to employ. Given the possibility that the virus could cause tumors in the human population, Pollack asked whether more knowledge was needed before conducting such an experiment. After much consultation Berg decided two things: He would postpone the experiment, and he would seek to convene a conference on the hazards of using tumor viruses. The conference was held in January 1973, at Asilomar, California, with about 100 scientists attending and Berg as chair. The meeting concluded that firm evidence of hazards of laboratory viruses inducing cancer was not available but that caution should be used in work with these viruses.

Later in 1973, the ability to splice and recombine different DNAs became possible. On first learning of this possibility at a Gordon research conference in New Hampshire, several scientists became alarmed. As Donald Frederickson writes, they reacted "to this hint that biology was approaching something akin to the nuclear physicists' chilling arrival at 'critical mass.'" Maxine Singer of the NIH and Dieter Söll of Yale drafted a letter, with the backing of others attending the meeting, to the National Academy of Sciences. It asked the academy to convene a committee to study the consequences of making biological alterations such as joining DNA from animal viruses with DNA from bacteria. "In this way," they wrote, "new kinds of hybrid plasmids or viruses, with biological activity of unpredictable nature, may eventually be created."[10]

The letter, and a general societal concern that this work posed a potential threat, produced a second Asilomar Conference held in September 1974, chaired again by Paul Berg. Its explicitly announced purposes were threefold: to review progress on research on recombinant DNA molecules; to discuss whether what were called "the biohazards of the work" still required a "pause" in certain of its aspects; and to decide how to conduct this research with minimal risk to laboratory workers, the public, and plants and animals.[11]

The conferees produced a set of guidelines for recombinant DNA research. It specified that the research should proceed but that biological and physical safeguards were to be used to contain the new organisms it generated. The biological barriers were bacterial hosts that could not survive in the material environment and vectors able to grow only in specified hosts. The physical barriers were containment technologies – for instance, gloves, hoods, and filters – applied in a strategy that matched the level of containment to the risk of

the experiment. However, experiments involving highly pathogenic organisms were to be deferred until more knowledge was gained. These guidelines were to be implemented by codes of practice in different countries. But until such codes were developed, scientists as individuals were to decide on how to comply. A clear statement also was made about the ethical duties of principal investigators to their staff: they were to inform the staff fully about the hazards of experiments before initiating research, assure they were properly trained in containment procedures, and monitor their health.

Like the events that led to the creation of the IRBs, Asilomar reflected a growing public need for a voice in shaping the research agenda of biological science. In this sense, as Dorothy Nelkin argues, Asilomar was a challenge to the autonomy of biological science.[12] But Asilomar also stood for the recognition by a small vanguard of biological scientists that consideration of effects of their work on society should be a factor in developing the scientific agenda. Perhaps most fundamental, concern over the social harms and benefits of biological science became appreciated more widely in the 1970s as a shared responsibility of scientists and the public. However, this phase is marked more by the public's growing interest in biological science than by scientists' concern with public issues. The large majority of scientists still were focused on performing their basic work in the laboratory.

Phase III 1975–2000 Challenges to the Process of Creating Knowledge

The third part of the ethics movement, which directed attention to the procedures within the biohealth sciences used to generate and transmit knowledge, had four distinct components. It began in 1975 with the publication of Peter Singer's book *Animal Liberation;* continued with the highly publicized events of 1981 when John Darsee, a scientist at Harvard Medical School, admitted to falsifying scientific data; kept on into mid-decade with the growth of large project grants for the biological sciences made possible by its new relation with industry, and the development of social interest in the human genome project; and concluded in 2000 when the U.S. Public Health Service proposed that required training in research integrity be given to all investigators and their staff working under its research grants. The growing density of events perceived as ethical issues by the biohealth sciences community marks this phase as one of greater openness of that community toward ethical discourse and reflection. By the end of Phase III the stage was set for the development of a collective self-consciousness among these scientists about the moral dimensions of their work and a greater understanding of why public accountability should be important to them.

In 1975, with a number of worldwide movements for human rights as background, Peter Singer published his book *Animal Liberation*. In it he disputed commonly held views about animals, such as the belief that they lack the capacity to suffer. He argued that the human claim to a right to life should be extended to animals, whom society should not cause to suffer regardless of particular characteristics (or lack of them) they might have. He urged us to "bring non-human animals within our sphere of moral concern and cease to treat their lives as expendable."[13]

This book, and the rights-conscious social environment fostered by the civil rights and medical ethics movements, were important catalysts of a re-examination of the ethical issues concerning animals in experimental work that occurred in the 1980s. Groups emerged such as the Animal Liberation Front, The International Society for Animal Rights, and the Coalition to End Animal Suffering in Experiments. By 1986, eighty bills dealing with the use of animals in research had been introduced in state legislatures around the United

States.[14] By the decade's end, federal legislation had extended to animals protections similar to those given human subjects in the mid-1960s. Institutional review boards to examine all experiments involving animals from the viewpoint of humane treatment now were required. However, the controversy over their appropriate use continued, marked by heated discussions and even violent entries by activists into laboratories to free animals being used in scientific experiments.

The second component of this phase arose at the turn of the 1980s as big business became interested in the biohealth sciences. Up to then, apart from the funding of drug research by pharmaceutical companies, key sources of revenue for the biohealth sciences were from the federal government (mainly through the NIH), private foundations, and universities. However, the possibilities to develop profitable innovations led industrial corporations to make significant investments in biohealth research. For example, in the 1980s the Massachusetts General Hospital received two major industrial grants: one of almost $50 million was from a German drug and chemical company for molecular biology research, and a second of $85 million was from a Japanese cosmetics company to study the skin. In this period, the founding of the Biogen Company by Nobel Laureate Walter Gilbert and colleagues marked another milestone – the emerging viewpoint among biohealth scientists that work in a business corporation is an appropriate extension of their lives in science. During that decade many scientists developed relationships with industry to produce commercial products. By 1984 industrial funds accounted for almost a quarter of the external support of university research in biotechnology, which included projects on genetically engineered drugs and genetically altered bacteria, cell and tissue cultures, DNA technology, monoclonal antibodies, and fermentation.[15,16]

The growing relationship between biohealth scientists and industry posed ethical issues for investigators, universities, science, and the public. With new interests in profit-making activities, would the scientific agenda of research shift from seeking basic knowledge to seeking profitable knowledge? Would openness of communication be damaged by the introduction of competition among scientists working under grants from different companies? Would industrial relationships undermine the obligations and allegiance of scientists to the universities in which they held appointments? What obligations did universities have to ensure timely dissemination of inventions developed within them that might significantly further the public's health? How could universities avoid compromising the education of students and fellows employed by faculty supervisors to work on industry-sponsored research? Studies indicated the existence of such problems.[16,17]

In addition to large grants from industry, a major effort that led government to invest, over time, several billion dollars in a single biological research project emerged in the second half of the 1980s, when proposals appeared to delineate the human genome. In 1984 Robert Sinsheimer and colleagues at the University of California at San Diego attempted to create a genome sequencing institute. "They likened the effort to the exploration of the moon, arguing it would provide insights into who we were, and serve as an integrative focus of all DNA cloning techniques," wrote R. M. Cook-Deegan.[18] The proposal failed to attract private or federal funding. But in 1984 the parallel efforts of Charles DeLise and David Smith at the U.S. Department of Energy to begin a human genome project did garner governmental and scientific support, ultimately with the NIH jointly sponsoring the project with the Department of Energy. In 1987 the NIH made an initial appropriation of $17 million, and in 1990 Congress allocated $87 million for human genome research.

The organizers of the genome program recognized the ethical implications of gaining a genetic portrait of human beings – particularly James Watson, named as head of the NIH genome office created in 1988 and then as director of the National Center for Human Genome Research initiated in 1989. As a result of this recognition, a working group was created and funds dedicated for social, ethical, and legal research as part of the project. This research brought up issues such as: How will knowledge of human propensity for genetically determined illness influence employment and insurance coverage? Will it lead to wholesale discrimination in both? What right to such information does government have? Can the confidentiality of genetic data be assured? This new project has promised to make biological scientists more sensitive to the social significance of their work. As Paul Berg put it, "Judging the ethical value of basic research prospectively and preemptively would be a considerable departure from current practice."[19]

While scientists in the 1980s debated aspects of discovery that affect society, another set of events pointed to problems within the research community itself. In 1981 John Darsee, a medical scientist working in clinical and experimental cardiology, admitted to falsifying data in one of his papers. Darsee had published 18 research papers in major biomedical journals and about 100 abstracts, book chapters, and other works. Investigations at institutions where he worked – Emory and Harvard Universities and the NIH, which funded some of his studies – revealed that his fabrication was more widespread.

What troubled many was not only that Darsee had been dishonest but that his coauthors had not detected the flaws in his work before it was published. This led to concern about whether the responsibilities of authorship are sufficiently clear to members of the scientific community. It cast doubt on what Walter W. Stewart and Ned Feder, NIH scientists at the forefront of this discussion, called "the integrity of the scientific literature." In a 1987 article in *Nature* that produced much comment and controversy, they claimed that Darsee's coauthors had not been adequately vigilant, that in some cases the contributions of coauthors were minimal and not entitling authorship. For instance, one coauthor's role had been to encourage Darsee and provide grant support.[20]

Sensitized by the Darsee case, the scientific and lay press publicized several other instances of alleged improper conduct in research during the decade. One of the most prominent of these cases involved a Nobel laureate, David Baltimore. In 1986 he was one of the authors of a published article concerning genetic influences on the immune system; the main investigator was a colleague, Thereza Imanishi-Kari of Tufts University. Baltimore's role was that of a senior advisor who reviewed the paper's data and research but did not personally participate in the laboratory work on it. Following publication of the article, Dr. Margot O'Toole, a junior researcher in molecular biology at Tufts who questioned the validity of some of its experimental data, lost her job. The ensuing controversy about the facts and meaning of these events brought the case to the NIH and to the U.S. Congress. As a result, Baltimore was called to testify before a Congressional committee about the issue, and the laboratory notebooks of the experiment were even subpoenaed by the Secret Service.[21] Responding to this case, *The New York Times* published a lead editorial headlined, "A Scientific Watergate?" The newspaper pointed out that Baltimore, who was never accused of fabrication, and several committees of scientists had investigated the affair and found no basic problems, yet a draft report by the federal investigators involved in the case did find problems. The *Times* faulted the scientific community's mechanisms for investigating such controversies.[22]

These events led, as had revelations of problems in human experiments in the 1960s, to a review of procedures of research. One of the earliest outcomes of this examination was

a careful look at the duties of scientific authorship. While the subject had been discussed before, it had never received the focused attention of investigators that it did in the mid-1980s. For example, in a 1986 article Edward J. Huth, editor of the *Annals of Internal Medicine*, defined what he called "unjustifiable authorship," a situation in which authors cited in a paper lack basic involvement in its generation: that is, the gaining and analysis of the evidence, and the writing and revision of the findings.[23] Such action appeared to be a leading cause of the burgeoning number of papers cited on the vitae of scientists. Some scientists and, more emphatically, members of the public believed that this behavior, like the highly publicized cases of fraud, represented a breakdown in the fidelity of scientists to truth in the oversight and reporting of their investigations and that it thus damaged the scientific community as a whole.

But within the scientific community these discussions were received with mixed feelings. Many believed that it remained appropriate, for instance, for the persons who obtained the funds for a project to be named as authors. They pointed out that the stream of help and obligations that flows through a laboratory and touches many of its staff in the course of a study makes rigid criteria for defining authorship too difficult to devise or implement. Many preferred to determine themselves, on an ad hoc basis and with less rigidity, who should be given the credit of assistance that the title of author conveys.

These events and discussions prompted a number of private and public institutions such as Harvard University, the University of Texas Health Science Center at Houston, and the NIH, and professional societies and journals to publish corrective guidelines delineating the responsibilities of authorship.[24] They led also to two developments in 1989, which demonstrated a social and governmental interest in areas that before were the private preserve of the biological scientist: the oversight of scientific misconduct, and the teaching of students.

An announcement in the *Federal Register* of March 16, 1989, told of the establishment at the NIH of an Office of Scientific Integrity. Its task was to delineate for investigators the responsibilities of handling and reporting possible scientific misconduct, and of investigating it. The office defined such misconduct "as fabrications, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research."[25] A parallel Office of Scientific Integrity Review was also established at this time in the Department of Health and Human Services (DHHS) under the purview of the Assistant Secretary of Health. These offices were created to carry out provisions of the 1985 Health Research Extension Act, which required all institutions receiving federal research grants to have an administrative process to examine reports of scientific fraud and to send details of serious cases to the Secretary of Health and Human Services.[26]

While some welcomed the introduction of a formal mechanism to deal with misconduct, others were concerned that because it came from government it was intimidating. An article by Bernard Davis, an emeritus professor at Harvard Medical School, titled "How Far Should Big Brother's Hand Reach?" expressed a widely held viewpoint within the scientific community. Davis was concerned that the office reached too deeply into the interstices of research and threatened its freedom. He thought that inadequate distinctions were being made between fraud and normal error and that the investigation of science by government authority could foster a repressive atmosphere that would cast a shadow over the environment of openness needed for creativity to thrive.[27]

Following this article, in December of 1989, a new administrative rule concerning teaching was placed in the NIH Guide for Contracts and Grants.[28] The rule stated that all institutions seeking National Research Service Award training grants were required to have