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Scientific Misconduct

New Definition, Procedures, and Office—Perhaps a New Leaf

The good behavior of scientists might seem remote from the concerns of the physician. But the practice of medicine is based on science, which means that it is grounded on the integrity of the biomedical research community. For that reason alone, the matter would deserve our attention, but in addition, many scientists have medical degrees. We expect those scientist-physicians to share the high standards of the medical profession, and when they do not, the profession is damaged in the eyes of the public. Finally, if medical editors unwittingly publish fraudulent work in journals, as happens from time to time, reputations are tarnished. It is for these reasons that we are all involved in the debate over what has come to be called "scientific misconduct," and why *JAMA* is publishing the article by Dresser in this issue.[1]

Few medical articles are so uniquely important that patients would suffer were the articles to be fraudulent. Yet when misconduct occurs, the consequences extend far beyond the reputation of the perpetrator, and the consequences are particularly severe when the deed goes unpunished. Misconduct arouses passions and saps morale in research institutions and undermines the confidence we have in each other and in our science. So, it is in all our best interests to acknowledge its existence, define it, and frame a just response.

See also p 895.

The modern era of what we now call scientific misconduct began at Sloan-Kettering with Summerlin and his painted mouse in 1974.[2] Other, equally spectacular cases followed in doleful succession: Soman and his imaginary patients at Yale, Darsee and his fictitious patients and papers at Harvard, and Slutsky and his multiple fabrications at the University of California, San Diego, to name just a few, all dutifully reported by the media. Scientists, however, seem to have been less able to accept the revelations than the general public, and a great deal less than members of Congress. Perhaps the difference can be explained by the fact that the Congress is composed largely of lawyers, who are not taught to trust easily. Our representatives correctly view themselves as custodians of the public purse and see plenty of evidence to counter the notion, seemingly prevalent among researchers, that scientific degrees endow their holders with the attributes of rectitude and honesty.

Perhaps it was because the whole culture of science is one of trust. Scientists were outraged to hear that a few of their number had abused this trust and were vocal in insisting, on the basis of no evidence whatsoever, that scientific fraud almost never occurred[3] and, conversely, that when it did, the cases were extreme aberrations committed by people who were sick or driven to their misdeeds by a publish-or-perish imperative (a popular explanation that one of their number went out of his way to deny).[4] Few scientists were able to acknowledge openly what common sense dictated: namely, that some percentage of their colleagues were likely to be fraudulent.

Perhaps it was simply that the practices of science grew up in an era of closeness and clubbiness, where everyone knew everyone else and what they were doing. With the post–World War II explosion in funding, perhaps the inculcation of good scientific behavior became a casualty along with intimate apprenticeships.

In some dozen congressional hearings (the first, in 1981, chaired by then Congressman Albert Gore),[4] delinquent scientists were called on the carpet, and whistle-blowers came forward to show how they had been abused for their courage and persistence. Distinguished administrators and institutional pooh-bahs insisted, sometimes in manifest defiance of the facts, that existing controls were sufficient to prevent misconduct,[5] or that the problem was vanishingly rare,[6] or that large sums of money could not bias their researchers.[7]

The institutional denial and inertia widely exhibited were depressing, especially at a time when research institutions—those with the duty and the power to ensure the integrity of their scientific output—could have seized the high ground and the lead. Yet, case after embarrassing case showed them unwilling or unable to grasp this nettle. In 1985, the Congress said "enough" and ordered the first federal regulations on scientific misconduct. The National Institutes of Health (NIH) were slow to implement the legislation, and universities were even slower. Congress became restive, and in 1989, the Department of Health and Human Services, trying to prevent

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more drastic action by the Congress, set up the investigatory Office of Scientific Integrity (OSI), within the NIH, and a second, adjudicatory, Office of Scientific Integrity Review (OSIR), within the office of the assistant secretary in charge of the Public Health Service (PHS). The regulations gave a name to the crime, scientific misconduct, and defined it as:

> 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.[8]

The National Science Foundation promulgated a similar definition. Since the punishment for institutions that did not toe the line was withdrawal of all federal funds, the government's definition and procedures stuck.

That was over 3 years ago. Since that time, we have seen a proliferation of cases; the spectacular development of the two most newsworthy cases (those associated with the names of Robert Gallo and David Baltimore); a gradual acceptance of the facts of life by the research institutions and by the scientific community; a movement on the part of those accused to fight their cases in court and to challenge the authority of the OSI[9]; and endless controversy over procedures and definitions. The Abbs case showed that the Department of Health and Human Services had failed to publish their procedures in the proper way. And, to the surprise of almost everyone, whistle-blowers began to use the False Claims Act, which qualified them to win a portion of grant monies recovered by pursuing their cases through the courts rather than through designated institutional routes.[10]

From the start, the OSI (and its less apparent oversight body, the OSIR) came under continuous heavy fire from scientists, from the new head of the NIH,[11] from accused persons and their attorneys,[12] from whistle-blowers, from the press, and from members of Congress. The OSI and OSIR were accused of having "no clearly established or well-articulated mission" and rules that were "amorphous" and "internally inconsistent"[13]; of having procedures that seemed to be biased against the defendant[14] or illegal[13,15]; and of being too aggressive and for not being aggressive enough.[16] They were faulted for being too thorough[17]; for being too quick and too slow, for being easily influenced politically[16]; for bungling[18]; for being secretive and for leaking[11,19,20]; and for being illegally set up.[9] Further, their basic approach, "the scientific dialogue model," intended to keep the process in the hands of scientists rather than lawyers, came in for a barrage of criticism as unfair and procedurally flawed.[17,21]

The director, virologist Jules Hallum, resigned in frustration on August 15, 1992.[22] The procedures have been revamped[23]; the OSI has transmogrified into a larger and more lawyer-heavy Office of Research Integrity within the PHS, but now outside the NIH. A more legalistic and adversarial process has been adopted. A year ago, we prophesied that the process would inevitably migrate to the harsher venue of the administrative courts, and this is what has happened.[24] We await to hear whether the open system, "heavy with legal safeguards and due-process protections for the rights of the accused," will turn out to be beneficial to, or to the liking of, the scientific community.[25,26]

THE DEFINITION DEBATES

As we move into an era of mandatory and formalistic approaches to allegations of scientific misconduct, its exact definition has become hotly debated.[1] The question has been confused by all sorts of side issues, including crimes that are not peculiar to the practice of science, such as sexual misconduct, fiscal fraud, and so on. Such malfeasance, though serious, should not be the focus of efforts to create a strict definition of scientific misconduct. What should worry us are acts that are seriously deceptive and that are destructive of science, but that are not already covered by other regulations.

Fabrication, falsification, and plagiarism are indisputably antithetical to good science. The most contentious problem lies in the final phrase in the definition, "other practices that seriously deviate." The Federation of American Societies of Biology has argued that this clause could allow penalties to be applied to novel or breakthrough science. At the first meeting of the Advisory Committee on Scientific Integrity to the PHS, Bernadine Healy, head of the NIH, also attacked the "other practices that seriously deviate," a phrase that, she said, could include as misconduct "tinkering, bold leaps, unthinkable experimental design, and even irritating challenges to accepted dogmatic standards."[11] The Federation of American Societies of Biology mobilized its members to demand that the definition be confined to falsification, fabrication, and plagiarism—"FF&P." We are not aware of examples where scientists engaged in novel, groundbreaking science have been prosecuted for so doing. We are therefore highly skeptical of the reality of this threat, which we regard as a bogeyman used to mobilize scientists in opposition to *any* regulation. This is particularly the case, as the definition could be modified to state specifically that innovative and unconventional science is not the target.

The National Academy of Sciences, after a 2-year, $800 000 study, proposed a new definition that omitted the phrase,[27] and the PHS Advisory Committee on Scientific Integrity followed suit. The latest definition of scientific misconduct from the Office of Research Integrity, which will probably be published shortly as a "Notice of Proposed Rulemaking," also omits this specific phrase. It reads:

> Research misconduct is plagiarism; fabrication or deliberate falsification of data, research procedures, or data analysis; or other deliberate misrepresentation in proposing, conducting, reporting, or reviewing research.

Underlying the objections to the "other practices that seriously deviate . . ." clause is the fear that the vague language will result in application of a vague and misty standard of misconduct that cannot be known in advance. It seems fundamentally unfair to stigmatize someone for behavior they had no way of knowing was "wrong."

Unhappily, consideration of cases shows that some of the most egregious behaviors, abuse of confidentiality, for example, are not covered by the FF&P label. We cannot have a definition that implies that this sort of behavior is not wrong. Moreover, since we cannot possibly imagine every scenario in advance, the definition must ensure that perpetrators of acts that are deceptive and destructive to science are not exonerated. If they are, the public and our legislators, applying the standards of common sense, will rightly deride the outcome as nonsensical.[28,29]

We can continue to fuss about the theoretical shortcomings in a definition that includes "other practices that seriously deviate," but which seems to have served us fairly well so far. But we think it would be more constructive for our community—scientists, their institutions, professional soci-

eties, and journals—to focus on the task of articulating and defining precisely what constitutes good scientific practices and desirable behavior in specific areas. These should include data recording and retention, authorship practices, and student mentoring. Once we have done so, we can use those standards for assessing deviation. The Association of American Medical Colleges,[30] the Institute of Medicine,[31] the American Association for the Advancement of Science with the American Bar Association,[2] and the National Academy of Sciences[27] have made a good start. Whether we continue to build on these foundations voluntarily or are forced to do so by embarrassment from the Congress and by governmental fiat is up to us.

INTENT

Another harder problem is distinguishing misconduct from error. As Mishkin has pointed out, "misconduct" in legal parlance means a "willful" transgression of some definite rule. Its synonyms are "misdemeanor, misdeed, misbehavior, delinquency, impropriety, mismanagement, offense, but *not negligence or carelessness.*"[12] The first principle to grasp is that error, without which science could never be practiced, must never be construed as misconduct. Distinguishing the two necessarily means reaching a judgment about intent at some point in the process.

We believe that, contrary to the argument of Dresser,[1] intent should not be rolled into the central core of the definition of scientific misconduct, or if it is, an explicit two-stage process must be developed in which intent should be considered only after a finding of facts in the case has been reached. Once the finding has been made (eg, the data were misreported, words were copied without citation), then, and only then, at the time of adjudication, should intent be considered. After all, if words were in fact copied and published without attribution, that occurred. The fact that this was due to carelessness or was deliberate and malicious does not remove this finding, but is highly relevant to whether there is need for sanctions. Unfortunately, cases are accumulating in which institutions have attempted to negate the existence of facts by finding there was no "intent" to do the bad act.

The legal system assesses intent in criminal procedures all the time. But we think it is to society's advantage that these cases be assessed by working scientists. This is especially so for proceedings inside research institutions, which should be academic and scientific in nature, rather than legal. The definitions the government requires (on which those procedures are based) should help panels of scientists reach fair outcomes without legal sophistication.[28] To provide that help, we must recognize the shortcomings that have been exposed to date and address them directly; adding more legal formalities is not the answer. One problem seems to be that panels—seeing a colleague in trouble—tend to buy into an explanation (the colleague was too young, too old, too pressured, too distinguished, meant well, didn't mean it, and the like) rather than stating the facts and facing the conclusions that flow from them. In this way, they tend to dispose of the facts and, without intending to, achieve a whitewash. It is for this reason that it would be particularly helpful to set up and emphasize a two-stage process, separating fact-finding from the assessment of intent and final adjudication.

At this moment, practically everything to do with scientific misconduct is changing rapidly: the definition, the procedures, the law, and our attitudes. Further, our system allows institutions operating under the same federal regulations to implement them in different ways. While these changing circumstances and varied implementations can lead to problems, they also provide an opportunity for the scientific community to learn from a multiplicity of simultaneous experiments. It will take time to accumulate a body of experience (a case law, as it were) and to get it right. The challenge is to seize the opportunity, to capitalize on the wealth of accumulating information, and to focus on the long-term goals of strengthening science and the society that depends on it.

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