FRAUD AND MISCONDUCT IN BIOMEDICAL RESEARCH

THIRD EDITION

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2: Regulations on scientific misconduct: lessons from the US experience

DRUMMOND RENNIE, C KRISTINA GUNSAUS

In November 2000, a conference was held in Bethesda, MD, to present research into scientific integrity. The research presented was modest, but the importance of this conference was not in the quality of the research. It lay in the fact that the conference was being held at all. In 1988, one of the authors (DR) had proposed, at a meeting of the National Academy of Sciences (NAS) in Washington, DC, some modest experiments to determine the prevalence of major scientific misconduct. The reasoning behind this idea was that any response should be geared to the prevalence of the problem. The plan was to find out by confidential audit of the data behind published papers the prevalence of the grossest forms of fraud.

The suggestion met with a storm of abuse. The presenter was told that the experiment – which would be confidential and the results never presented except in aggregate, so no individual misdeeds would ever be revealed – would tear the very fabric of science and destroy the delicate web of trust that held scientists together. Yet in 1995, the US Government Commission on Research Integrity made the support of such research one of its key recommendations, and only 12 years after the initial suggestion, this conference took place a few miles from the NAS, co-sponsored by the two great governmental supporters of research, the National Institutes of Health (NIH) and the National Science Foundation (NSF), as well as by the prestigious Association of American Medical Colleges and the American Association for the Advancement of Science. Numerous studies were presented.

The conference was not only oversubscribed, but it passed off without incident and has left science, in the US at least, not merely unscathed, but looking good to the public. Its sponsorship and its reception were powerful indications that, with the passage of time, the US scientific establishment has become less defensive in its attitudes. A month later, in December 2000, the US Government issued a set of revised, government-wide policies on research misconduct, policies that apply equally to all research and researchers, from
anthropologists to mathematicians to biologists. Unless you were looking very closely, you would not have noticed this event – an indication of how routine the handling of allegations of research misconduct has already become on this side of the Atlantic.

Contrast this picture with what is happening in the UK. There it is clear that everything is almost exactly 15 years behind the US. As case after case of misconduct blows up in the media, institutional officials scurry around trying to reinvent the wheel in coming up with a response to scientific misconduct, or to cover up the problem.

A memorable meeting, held in Edinburgh in November 1999, at the instigation of medical journal editors, and attended by representatives of important professional societies and journal editors, drew up a consensus statement. To some, action seemed imminent. Yet a year later, three of the editors, in an editorial made up in equal parts of anger, despair, and disgust, pointed out that no official action has occurred and the situation has only become worse. Meanwhile, coverage in the media becomes steadily more intense and the public more disillusioned. Our experience in the US tells us that failure to move in a year is to be expected. What concerns us here is failure to move in 20 years at a time when the happenings in the US over the previous 25 years have scarcely been kept secret from the UK.

When the first cases arose in the US, it was often stated in the UK that this must be a peculiarly American disease, a consequence of the competitive nature of science in the US. However, for years it has been clear that this attitude, which never had evidence to support it, was nonsensical and that scientific misconduct knows no national boundaries. The cases occurring in the UK have not been trivial. Despite that, the paths being followed in the two countries seem to be diverging. In the US, relative calm means relative consensus and, most importantly, reflects effective handling of cases, yet the increasing storminess in the UK could, we believe, have been avoided if the UK had been more able or willing to listen to, and learn from, the massive, well-documented experience gained across the Atlantic.

What happened in the US in the intervening years to bring about the current state of affairs where a new definition can be introduced without controversy? What are the new US Governmental Regulations? How good are they? What lessons do they and this story have for the rest of the world, particularly the UK?

The US experience

A rancorous tone

In the US, the tone that characterised the struggle between scientists and the Federal Government on the issue of scientific misconduct was evident from the start. In 1981, during testimony in the first of over a dozen Congressional hearings, the opening witness, the President of the National Academy of Sciences, asserted that problems were rare – the product
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of "psychopathic behavior" originating in "temporarily deranged" minds – and called for Congress to focus its attention on increasing the funding for science rather than on these aberrant acts. The Chairman, then-Congressman Albert Gore, Jr, thanked him for this "soothing and reassuring testimony". At the conclusion of the hearing, however, Gore could not "avoid the conclusion that one reason for the persistence of this type of problem is the reluctance of people high in the science field to take these matters very seriously."

This edgy tone characterised practically every step of the process until the first Federal Regulations were issued eight years later, in 1989. It is worth noting that though the regulations were federal, in that they applied equally to researchers and their institutions in every state, until the end of 2000, they still applied officially only to research performed under grants from the Public Health Service (which includes the NIH) and the NSF, which funds much biomedical research. This was presumably because the cases of research misconduct that grip the imagination of the media, the public, and their elected representatives were those involving physicians and clinical research. However, as it was hard for research institutions to operate with more than one set of rules governing misconduct, these early, restricted regulations had a widespread effect. Even later, as general consensus as to handling of cases, standards, and a common, government-wide definition (which de facto covers all research conducted at US universities and hospitals) emerged, the process was marked by continuing rancour and heated – and often unsupportable – rhetoric. This aspect of the American experience seems worth understanding, as it may well be impeding progress elsewhere.

Most informed observers agree that serious scientific misconduct is probably quite rare in what is a large and successful scientific enterprise. If that is so, why does the debate about the definition and handling of misconduct arouse so much antagonism? Part of the reason is that hardworking and honest scientists resent the disproportionate attention the media give to occasional spectacular cases of malfeasance, but even those who are resigned to the media's emphasis upon flashy bad news at the expense of workaday good news seem to have felt personal jeopardy from the original proposal to implement rules governing misconduct, and then later from any, and every, proposed change to those rules. A common element seemed to be apprehension that rules would be unfairly applied to one's own solid science. Had the scientific community been deeply divided at any point as to definition and response, this visceral fear would be easier to understand. What is so confusing is that the divisions have been only at the margins, and careful examination of the issues shows a consistent, remarkably high level of general and fundamental agreement throughout the implementation process.

**History**

In early 1993, we gave a brief account of the turbulent history of scientific misconduct in the US. Until 1989, universities and the Federal Government
relied upon ad hoc efforts to respond to allegations of malfeasance, much as now seems to be the case in the UK. We described the widespread publicity that accompanied numerous cases in the 1980s and the consequent public perception that fraud was rife. We noted the reaction of the US Congress, which asserted that there was a major problem; and that of research institutions and scientists who, without providing evidence, countered that it was uncommon, and should be left to them to handle. Finally, we noted how the massive publicity and the mishandling of aggrieved whistleblowers caused Congress to conclude that the institutions’ track record was too spotty to maintain the public trust. Despite continuing resistance from scientists and their institutions, Congress insisted on some accountability and governmental oversight, predicated on the government’s responsibility to oversee the proper use of tax dollars. The result was the requirement that the main federal funding agencies promulgate regulations and establish offices to provide a more systematic and structured response to allegations of malfeasance.

Definition
The definition adopted in 1989, under Congressional pressure, was “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.”

This definition caused problems for many reasons. Everyone agreed that fabrication, falsification, and plagiarism were antithetical to good science. However, the phrase “...other practices that seriously deviate...” was immediately seized upon by the Federation of American Societies of Biology (FASEB), who argued that this clause could allow penalties to be applied to novel or breakthrough science, and mobilised its members to remove this phrase completely and limit the definition to “FF&P”. As we noted,

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.

Since the Office of Research Integrity (ORI) – the government office charged with oversight of scientific integrity within biomedicine, the research field controlled by the Public Health Service – never invoked the “other practices...” clause, but the other large scientific grant-awarding government
agency, the National Science Foundation (NSF), did, researchers funded by different government agencies effectively came to be covered by different definitions of research misconduct. In addition, ORI, in a move that was purely administrative, and made to reduce the number and complexity of their formidable backlog of cases, announced that it would not take cases of alleged plagiarism if the authors of a work had been coauthors together, not least because such cases proved singularly awkward to sort out. By definition, ORI asserted, all such cases fell into the category of authorship disputes and would not be examined for the elements of plagiarism. NSF never instituted such a policy, and continued to examine cases where students or co-workers alleged that their contributions had been appropriated by another without cause or attribution. A system in which some can have their complaints examined and others cannot, could not succeed for long.

**Intent**

Science is a risky enterprise, often requiring much trial and error. No one could possibly undertake scientific experiments if error was construed as misconduct. As Mishkin has pointed out, “Misconduct” in legal parlance means a “wilful” transgression of some definite rule. Its synonyms are “misdemeanour, misdeed, misbehaviour, delinquency, impropriety, mismanagement, offense, but not negligence or carelessness.”11 Distinguishing error from misconduct requires making a judgment about intent. Whilst scientists are often cowed by this necessity, citizens routinely make them in other settings, most notably in our established criminal justice systems.

It is our opinion that this assessment should be made only at the time of adjudication, after the facts of a case of scientific misconduct have been determined, for example, “words were copied” or “no primary data have been produced.” This sequential approach has two salutary effects: first, it reduces the potential that the factual determinations will be obscured by other considerations. The danger otherwise is that – as has frequently happened – a panel’s sympathy for the accused (“He’s too young, too old, meant well”, etc.) interferes with a rigorous analysis of events. Second, this approach introduces proportionality into the response: what, if any, consequence should there be, in light of all the relevant circumstances? This factor is important in the final sense of whether the process “worked” or not – both for participants and for observers.

**The scientific dialogue model**

Originally, the ORI tried to keep misconduct proceedings in the hands of scientists rather than lawyers. The “scientific dialogue model” they advanced soon came under criticism for being unfair and flawed.9 Changes were made, and the standards for responding to allegations gradually became more structured and legalistic so that results could withstand scrutiny from administrative tribunals. Defendants, faced by the loss of
their livelihoods, hired lawyers to insist on their basic right to fundamental fairness and due process. Most fundamental among these rights are the rights to know and to respond to all evidence to be used against an accused. Unfortunately, these rights were all too easy to overlook while collegiality prevailed (“the scientific dialogue”), and where hard issues were not always faced directly or even-handedly.

The early 1990s: the heat increases
Despite these problems, and the heat they engendered, in February 1993, we concluded on a note of cautious optimism:

...practically everything to do with scientific misconduct is changing rapidly: the definition, the procedures, the law and our attitudes... 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.9

Our optimism was premature. In 1994, despite more than 20 years of widely publicised cases of misconduct, more than a dozen congressional hearings, years of regulations as a result of congressional impatience with science (and layers of modifications to them), and, first, an Office of Scientific Integrity and then of Research Integrity, there remained widespread division and dismay. The definition was still hotly debated, as was the process owed an accused scientist, the extent of federal oversight, how to protect whistleblowers, and how to prevent misconduct. At the same time, in the early 1990s, several high-profile cases were decided against government science agencies and their ways of proceeding.12

The Commission on Research Integrity (Ryan Commission) (Figure. 2.1)

In 1993, as part of the Act that continued funding for the National Institutes of Health (NIH), the US Congress mandated the formation of a Commission, charged with considering the whole field, from the definition of misconduct, through the process of handling cases, to whistleblower protection. The Commission, of which the two of us were members, held 15 open meetings in five different cities across the US, and heard hundreds of witnesses “including scientists, whistleblowers, attorneys, institutions, scientific organizations, the press, interested citizens and government officials.”12 The number and severity of the cases presented to the Commission was impressive.

At the end of 1995, asserting that the US Federal Government had an interest in professional misconduct involving the use of federal funds in research and which could affect the public health, the Commission recommended that the definition of research misconduct (Figure 2.1) should be “based on the premise that research misconduct is a serious
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1. Commission on Research Integrity's Definition12
Research misconduct is significant misbehavior that improperly appropriates
the intellectual property or contributions of others, that intentionally impedes
the progress of research, or that risks corrupting the scientific record or
compromising the integrity of scientific practices. Such behaviors are
unethical and unacceptable in proposing, conducting, or reporting research
or in reviewing the proposals or research reports of others.

Examples of research misconduct include but are not limited to the following:
Misappropriation: An investigator or reviewer shall not intentionally or
recklessly a. plagiarize, which shall be understood to mean the presentation
of the documented words or ideas of another as his or her own, without
attribute appropriate for the medium of presentation; or b. make use of any
information in breach of any duty of confidentiality associated with the
review of any manuscript or grant application.

Interference: An investigator or reviewer shall not intentionally and without
authorization take or sequester or materially damage any research-related
property of another, including without limitation the apparatus, reagents, bio-
logical materials, writings, data, hardware, software, or any other substance or
device used or produced in the conduct of research.

Misrepresentation: An investigator or reviewer shall not with intent to
deceive, or in reckless disregard for the truth, a. state or present a material or
significant falsehood; or b. omit a fact so that what is stated or presented as a
whole states or presents a material or significant falsehood.

2. Other Forms of Professional Misconduct
a. Obstruction of Investigations of Research Misconduct
The Federal Government has an important interest in protecting the integrity
of investigations in reported incidents of research misconduct. Accordingly,
obstruction of investigations of research misconduct related to federal funding
constitutes a form of professional misconduct in that it undermines the
interests of the public, the scientific community, and the Federal Government.

Obstruction of investigations of research misconduct consists of
intentionally withholding or destroying evidence in violation of a duty to
 disclose or preserve; falsifying evidence; encouraging, soliciting or giving false
testimony; and attempting to intimidate or retaliate against witnesses,
potential witnesses, or potential leads to witnesses or evidence before, during,
or after the commencement of any formal or informal proceeding.

b. Noncompliance with Research Regulations
Responsible conduct in research includes compliance with applicable federal
research regulations. Such regulations include (but are not limited to) those
governing the use of biohazardous materials and human and animal subjects
in research.

Serious noncompliance with such regulations after notice of their existence
undermines the interests of the public, the scientific community, and the
Federal Government, and constitutes another form of professional misconduct.

Figure 2.1 The US Commission on Research Integrity's definition of research
misconduct.

violation of the fundamental principle that scientists be truthful and fair in
the conduct of research and the dissemination of its results.12 The
Commission, which we will hereafter in this section call “we”, strongly
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recommended the development of a common federal definition of research misconduct and other forms of professional misconduct related to research. With its definitions, we put forward examples within the report (Figure 2.1).

By defining the central terms used in the definition of misconduct, we obviated the problem endemic in institutional proceedings in which every investigative panel secured a dictionary and defined for itself key elements upon which its findings depended. This common and understandable impulse all too frequently compromised the integrity of individual misconduct proceedings, as the resulting ad hoc definitions did not pass the "laugh", let alone the "red-face", test. In addition to providing a fuller internal definition of plagiarism, our proposed definition explicitly addressed other issues upon which faculty review panels repeatedly stumbled. For example, we incorporated misconduct in reviewing manuscripts or grant applications into the definition of offenses outside acceptable professional conduct.

We also researched and then recorded the legal reality in the US that the "standard of proof" required in civil proceedings is the "preponderance of the evidence", not the higher standards of "clear and convincing" or "beyond a reasonable doubt". These issues had derailed many an institutional proceeding and prevented them from reaching a finding. Another very important component of the Ryan Commission's work was the declaration that, whilst intent should be a necessary requirement for a finding of fabrication or falsification, a finding of carelessness suffices to support a finding of plagiarism.

We broadened the definition beyond the then-prevailing standard of "fabrication, falsification and plagiarism" to include other forms of unethical behaviour not then governed by any specific regulations (Figure 2.1). Guided by actual cases, we defined research misconduct as:

1. misappropriation (including plagiarism);
2. interference (for example, tampering with someone else's research), and
3. misrepresentation.

In addition, we included categories of lesser misconduct that, whilst not "scientific misconduct", still warranted response. These included:

• obstruction of misconduct investigations;
• retaliation against those participating in investigations, and
• non-compliance with research regulations.

We recognised that, although research institutions might make their own rules, the governmental definition had, after 1989, become de facto the one in general use.

In our report, we did not merely list bad acts, but laid out the rights and responsibilities of scientists. We recommended that educational programmes on research integrity should be required in institutions receiving federal money. We wanted:

• to assure that information about good professional conduct be provided as a fundamental element of education;
• to make discussion of these matters more common and less threatening;
federal definition of research misconduct related to research. In the report (Figure 2.1), we found that every key element of misconduct—monetary and intangible—was implicitly or explicitly addressed. For example, in grants or contracts, misconduct often involves professional standards.

In reality, the US has a system in which the so-called “preponderance of evidence” and “beyond a reasonable doubt” are used in institutional proceedings. Another very important declaration is that, whilst a finding of fabrication or plagiarism is so serious as to justify the then-prevailing standard of to include other forms of misconduct as:

- someone else's research), and
- misconduct that, whilst not
  - investigations, and
- acts, but laid out the rights
  - professional conduct be provided
  - common and less threatening;

- to make it possible for the powerless to ask questions, and
- to make it harder for the clever sociopath to slide by.

We recommended that there be “Funding for scholarship, teaching, and research in science ethics. Such funded research should include an experimental audit of the prevalence of data misrepresentation.” We also recommended that “professional societies adopt a code of ethics in research” and initiate “activities that will further promote the ethical conduct of research and professionalism in science.”

Recognising that whistleblowers provide an important quality control mechanism in science, and mindful of the numerous examples of abuse of whistleblowers who have brought forward well-founded allegations, we set forth a detailed appendix to the report Responsible whistleblowing: a whistleblower's bill of rights (Figure 2.2). We spelled out the rights and responsibilities of whistleblowers, of the accused and of their institutions. Institutions should deal with “retribution against whistleblowers as rigorously at the inquiry, investigation, and adjudication stages as they do in cases with research and other technological misconduct”; and that institutions that performed competent investigations should be protected from adverse use of their findings in litigation.12

Our Commission made a number of recommendations, based upon our collective experience, the testimony presented at our meetings, our research, and information presented by commissioned papers, about how misconduct proceedings should be conducted. For example, we advised that investigation and subsequent adjudication should always be separated organisationally; that “legal, law-enforcement, and investigator staff participate in each federally conducted investigation and ensure that scientists participate in hearings and appeal procedures”; that “those conducting investigations have subpoena power over persons and documents”; and that “authorship or collaborative” disputes (those previously dismissed by the Office of Research Integrity, for administrative reasons) should be addressed by institutions and by federal funding agencies.

While our proposals protected institutional decisions from second-guessing, if properly conducted, they recognised the built-in conflicts that institutions can face when investigating their own scientists, some of whom might be influential and bring in large amounts of money. We proposed “widespread, systematic public disclosure of all outcomes of federal research and research-related professional misconduct cases, with detailed, specific statements of their rationale, in view of the strong public interest in the disclosure of information underlying such cases.”12

We articulated the elements required for fair process, by articulating the various interests at stake in these proceedings—including those of the accused, whistleblowers, witnesses, and funding agencies. We recommended internal checks and balances throughout, even for the federal agencies providing the funding for research. We suggested approaches for streamlining processes, made numerous recommendations to improve the
a. **Communication:** Whistleblowers are free to disclose lawfully whatever information supports a reasonable belief of research misconduct as it is defined by PHS policy. An individual or institution that retaliates against any person making protected disclosures engages in prohibited obstruction of investigations of research misconduct as defined by the Commission on Research Integrity. Whistleblowers must respect the confidentiality of sensitive information and give legitimate institutional structures an opportunity to function. Should a whistleblower elect to make a lawful disclosure that violates institutional rules of confidentiality, the institution may thereafter legitimately limit the whistleblower’s access to further information about the case.

b. **Protection from retaliation:** Institutions have a duty not to tolerate or engage in retaliation against good-faith whistleblowers. This duty includes providing appropriate and timely relief to ameliorate the consequences of actual or threatened reprisals, and holding accountable those who retaliate. Whistleblowers and other witnesses to possible research misconduct have a responsibility to raise their concerns honorably and with foundation.

c. **Fair procedures:** Institutions have a duty to provide fair and objective procedures for examining and resolving complaints, disputes, and allegations of research misconduct. In cases of alleged retaliation that are not resolved through institutional intervention, whistleblowers should have an opportunity to defend themselves in a proceeding where they can present witnesses and confront those they charge with retaliation against them, except when they violate rules of confidentiality. Whistleblowers have a responsibility to participate honorably in such procedures by respecting the serious consequences for those they accuse of misconduct, and by using the same standards to correct their own errors that they apply to others.

d. **Procedures free from partiality:** Institutions have a duty to follow procedures that are not tainted by partiality arising from personal or institutional conflict of interest or other sources of bias. Whistleblowers have a responsibility to act within legitimate institutional channels when raising concerns about the integrity of research. They have the right to raise objections concerning the possible partiality of those selected to review their concerns without incurring retaliation.

e. **Information:** Institutions have a duty to elicit and evaluate fully and objectively information about concerns raised by whistleblowers. Whistleblowers may have unique knowledge needed to evaluate thoroughly responses from those whose actions are questioned. Consequently, a competent investigation may involve giving whistleblowers one or more opportunities to comment on the accuracy and completeness of information relevant to their concerns, except when they violate rules of confidentiality.

f. **Timely process:** Institutions have a duty to handle cases involving alleged research misconduct as expeditiously as is possible without compromising responsible resolutions. When cases drag on for years, the issue becomes the dispute rather than its resolution. Whistleblowers have a responsibility to facilitate expeditious resolution of cases by good faith participation in misconduct procedures.

g. **Vindication:** At the conclusion of proceedings, institutions have a responsibility to credit promptly – in public and/or in private as appropriate – those whose allegations are substantiated.

Every right carries with it a corresponding responsibility. In this context, the Whistleblower Bill of Rights carries the obligation to avoid false statements and unlawful behavior.

Figure 2.2  Responsible whistleblowing: a Whistleblower's Bill of Rights.\textsuperscript{12}  

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to disclose lawfully whatever arch misconduct as it is defined at retaliates against any person prohibited obstruction of fined by the Commission on the confidentiality of sensitive structures an opportunity to a lawful disclosure that violates may thereafter legitimated situation about the case. duty not to tolerate or engage. This duty includes providing the consequences of actual or not able those who retaliate. le research misconduct have a and with foundation. to provide fair and objective claims, disputes, and allegations retaliation that are not resolved should have an opportunity they can present witnesses and gain them, except when they v ers have a responsibility to by respecting the serious induct, and by using the same apply to others. a duty to follow procedures that oral or institutional conflict of save a responsibility to act within concerns about the integrity of concerning the possible partiality incurring retaliation. elicit and evaluate fully and raised by whistleblowers, needed to evaluate thoroughly questioned. Consequently, a whistleblowers one or more d completeness of information olate rules of confidentiality. handle cases involving alleged possible without compromising x years, the issue becomes the have a responsibility to facilitate n participation in misconduct s endings, institutions have a d/or in private as appropriate – possibility. In this context, the on to avoid false statements and effective oversight of institutional performance, and broadened the array of sanctions that could be applied against those found guilty of misconduct, and against institutions failing to carry out investigations properly.

The Reaction
Although the Commission’s report was characterised by a disinterested observer, the editor of The Lancet, as “a superb piece of analysis”, many academics pronounced themselves content with the commission’s definition, it met with widespread condemnation by the scientific establishment. The Commission consisted largely of scientists (as well as ethicists, administrators, and lawyers), but the reaction from the scientific elite in the US was immediate, loud, defensive, dismissive, confused, and self-contradictory. Given that the reaction was in response to a careful report based on the articulated “fundamental principle that scientists should be truthful and fair in the conduct of research and the dissemination of research results,” this reaction seemed at times hysterical. The President of the Federation of American Societies for Experimental Biology (FASEB) wrote to the Secretary for Health and Human Services that the “Commission’s report is so seriously flawed that it is useless as a basis for policy making and should be disavowed...We find the definition to be unworkable, and therefore unacceptable.” He was quoted in the press as calling the report “an attack on American science”. The same letter objected to what was called an expansion of the definition of plagiarism, even though the Commission had been guided in its definition by the Academy’s own report, Responsible science, a report the latter strongly endorsed.

The NAS leadership also wrote a letter criticising the Commission report. Whilst acknowledging that the Commission “repeatedly states that the primary investigative responsibility rests with the research institutions”, it brushed these statements aside in raising the bogeyman of a vast expansion of an intrusive federal bureaucracy, if the Commission’s recommendations were to be implemented. The NAS nowhere acknowledged that it was the abject failure of many research institutions to respond appropriately to allegations of misconduct that led to the Commission’s original formation by the Congress. The NAS failed to say that the report called only for government agencies to investigate allegations in certain very limited circumstances: in cases involving more than one institution, or where the institution had not conducted a proper investigation. Nor did it note that the government already had such an oversight role, which would, if anything, be diminished if the commission’s recommendations were followed.

In hindsight, what was most threatening in the Commission Report was the Whistleblower’s Bill of Rights. The Commission was accused of failing to “protect adequately the rights of scientists who are accused of misconduct.” Yet what moved the Commission was not the rights of scientists who were accused, who already had excellent protections, but the plight of accusers,
who blew the whistle in good faith, and who were later proved right, but who suffered considerable harm, often from the guilty and their institution. The Commission had heard testimony from a great many in this position.

Perhaps the most persistent, extraordinary and revealing criticism of the report, and, indeed, of any proposed regulation, was the continuing allegation that regulation would impede scientific progress, because truly original science might easily be labelled misconduct. In hundreds, even thousands of cases, this has never happened.

Finally some scientists still claimed that, because science is “self-correcting”, no rules were necessary. The corollary of this position is that it doesn’t matter if the record is never put right. In the medical field alone, however, the truth is that much science is never replicated, and this assertion says nothing about the costs – institutional and human – imposed by gross fraud, nor the abuse of, and loss of morale among, co-workers, the anger on the part of the public and politicians, and the outrage of the media.

Our report grew out of the failures of the past, including the failure of the 1989 government definition to stand up to legal challenge and to work effectively when applied to real cases. The vehemence of the reaction to the report, which proposed that scientists should be truthful and fair, and which was crafted to make it work in the real world of research and of lawyers, was telling. So was its widespread misrepresentation. Upon reflection, we conclude that this must stem from the fact that few of the scientists who objected had much experience in dealing with allegations of misconduct. Together, they suggest that scientists continue to feel threatened by the spectre that malicious allegations might be brought against them. Above all, objecting scientists failed to grasp the fact that, in this real world, legal challenges dominate the field, and that, in response to these realities, the Ryan Commission introduced precision – which in turn provides protections for those involved in misconduct proceedings, most especially the accused scientist.

We have presented this aspect of the US response in some detail because these sorts of reaction to any regulation may be predicted in the UK, given the striking similarities between the Ryan Commission’s “fundamental principle” (above) and the Edinburgh Consensus definition of misconduct as “behaviour that... falls short of good ethical and scientific standards.” (see Figure 2.4)\(^5\)

While more than a year has passed since the Edinburgh meeting, it is also worth noting that five years passed from the delivery of the Ryan Commission report until the most recent – and non-controversial – US government regulations.

The US Government-wide Regulations of December 2000 (Figure 2.3)\(^3\)

During the ensuing five years, cases occurred and were reported in the media, and were summarised in regular reports from the ORI and the
Federal Policy on Research Misconduct

I. Research Misconduct Defined

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research misconduct does not include honest error or differences of opinion.

II. Findings of Research Misconduct

A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community; and
- The misconduct be committed intentionally, or knowingly, or recklessly; and
- The allegation be proven by a preponderance of evidence.

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Figure 2.3 Federal policy on research misconduct.

NSF. Gradually, as the media, the public and the profession realised that the system was working in a routine and reasonably efficient manner, the heat died down, meanwhile, the administration embarked on the lengthy process of making common regulations that would govern all types of research, and not just those in biomedicine.

On 6 December 2000, after a two-month public comment period, the Clinton administration issued the new, government-wide regulations defining research misconduct and laying down the rules for investigation and adjudication of allegations of misconduct concerning research done with US federal funds. Since all important universities and research institutions receive such funds, these regulations will become institutional
rules, although institutions are allowed to have their own additional rules if they wish to impose a higher internal standard.

We strongly believe they should, and we say this because the new definition, confining itself to “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results,” leaves out many actions that we find destructive of good science, and which are not covered by other laws. We were both involved in assessing one case in which a junior investigator had sequestered data and materials from her colleagues – an action that would not be judged to be scientific or research misconduct by the new regulations, though common sense would tell us that the investigator’s conduct in the performance of research was wrong. We are troubled, then, that by making the definition too narrow, other egregious behaviours might seem to be condoned. It would send the worst possible signal if the academic community were to think such behaviour – by default – to be acceptable.

This new definition is again appropriately silent on prolonged non-compliance with other research regulations, such as the unethical treatment of human research subjects or mistreatment of laboratory animals used in research, because there are already regulations governing these problems. Again, the new regulations do not supersede criminal or other civil laws that have nothing to do with the faithful reporting of good science (for example, laws on sexual harassment).

Like the Ryan Commission Report, from which the new rules drew extensively, from the incorporation of interior definitions of critical terms and of states of mind for offences, to articulation of necessary procedural safeguards, the new rules provide the rationale for all the proposals. We strongly recommend that anyone interested in the formulation of adequate institutional responses to allegations of research misconduct, read both the Ryan Commission Report and these new US Government Regulations of December 2000.

Lessons from the US experience

It took 20 years to achieve a set of widely accepted regulations in the US. In the hope that examination and understanding of this experience might prevent a great deal of reinvention of wheels, we will summarise what we believe are the essential elements. First, however, consider the catalysts:

- Repeated, dramatic incidents resulting in publicity showing that research institutions operated in ignorance, denial, and cover-up; and there was recurrent shaming of institutions in the media. (This is the present position in the UK.)
- A few powerful politicians, highly sceptical of the establishment’s reassurances that all was well, repeatedly exposing the thinness of these reassurances, pushing for regulation, and, finally, exasperated by the “do-nothing” approach of science, forcing regulation to be tied to the continuance of federal research funds. (This is not happening in the UK,
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is because the new definition, or plagiarism in proposing, ting research results," leaves good science, and which are bled in assessing one case in data and materials from her judged to be scientific or though commonsense would performance of research was g the definition too narrow, be condoned. It would send immunity were to think such ly silent on prolonged non- ns, such as the unethical mistreatment of laboratory already regulations governing do not supersede criminal or the faithful reporting of good ent).

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- Numerous meetings attended by representatives of science, lawyers, administrators, and legislators.
- The establishment of oversight offices predicated on the assumption that research misconduct was basically a clinical research problem. Followed by a gradual realisation that misconduct can occur in every branch of research, from mathematics to the humanities, and that administering its regulations would be much easier if all researchers were governed by the same rules.
- Learning from experiment and hard experience. The “scientific model” did not work when the unfairness and illegality of the process was exposed (usually by lawyers or journalists). Scientists had to learn that processes for appeal were necessary, and that investigation and adjudication should be separated. Gradually a case law built up, and the process was absorbed into those of administrative law.¹⁹–²¹
- Greater education all round. Everyone concerned came to realise that it is beneficial to assure that students – no matter who their mentor – receive certain baseline information about good practice, and that, because scientists were mortals, it made sense to have processes in place to deal efficiently and routinely with those who strayed.

Constantly retarding the process of reform are several factors. Many distinguished scientists cannot accept that scientific misconduct can occur until it happens near them and they have to deal with it. More generally, it seems to be a human trait to seek power without accountability, so scientific organisations can be expected to oppose all regulation, including any amendment to even previously-condemned regulations.

**Conditions/criteria necessary for any workable system**

It must:

- **Be universal.** Across all research disciplines and not confined to clinical research.
- **Be official and published.** The rules must be promulgated by some official and widely accepted body having the legal power to make them stick, and these rules must be published.
- **Have a clear and specific definition.** With internal descriptions of the critical elements.
- **Have a clear and fair process.** Essential elements include:
  - **Notice** to those accused of the charges against them.
• *Opportunity to respond to the charges* and to all evidence used to draw conclusions.
• *Opportunity to have an advocate or representative* accompany all those participating in official proceedings (including those accused, those serving as witnesses, and those bringing allegations).
• *Appropriate powers in those charged with performing investigations* to have access to all relevant evidence and witnesses. An investigation cannot stand if those charged with establishing relevant facts do not have full access to all relevant evidence and witnesses. This may require subpoena power.
• *Separation of investigation and adjudication* (that is, those who perform investigations and make findings of fact should be separated from those who judge the totality of the case and impose sanctions).\(^{12,19}\)
• *Meaningful consequences* for those who violate standards, institutions that countenance misconduct, and for any form of retaliation against those who, in good faith, raise questions about the propriety of scientific conduct.
• *Must allow appeals*. After a proceeding is complete, there must be one opportunity to seek review of the procedures and fundamental fairness employed in reaching the conclusions.

**The Joint Consensus Report of 1999 Statement**  
(Figure 2.4)\(^{5}\)

We have discussed the enormous importance of exact definition, if the process adopted is to be fair and acceptable, since it is obviously unfair for any scientist to be accused of misconduct if there is no clear statement of what constitutes misconduct. Indeed, a basic foundation of the rule of law is that the laws should be specific and published. The Edinburgh Consensus conference was a very important step in beginning to address the problem in the UK, but when we apply our criteria to the definition in the Consensus Statement (Figure 2.4) we find it wanting.

**What is good about it?**

It recognises that every case of scientific misconduct weakens our trust in science. It also mentions that it goes beyond “FF&P”, which we believe to be important, and it recognises that changes may be necessary in the future.

**And what is bad?**

The Consensus Report is an early stage in an evolutionary process that will probably take years, so it is unfair to criticise it severely, but it is worthwhile to note its deficiencies because they help to tell us what needs to be done.

**Was it universal?**

The composition of the Consensus meeting, which was largely made up of people interested in clinical research, seemed to suggest a role for the
Consensus Statement (Preamble and Definition only)
Patients benefit not only from good quality care but also from good scientific research. We all expect high standards of scientific and medical research practice. The integrity, probity, skill and trustworthiness of scientific and medical researchers are essential if public confidence is to be assured. In the design and execution of biomedical and healthcare research, public participation is essential. The Joint Consensus Conference on Misconduct in Biomedical Research was convened in order to debate, address and offer guidance on key questions because “every single case [of fraud and misconduct] reduces public confidence, abuses the use of public and charitable funds, and causes insult and frustration to the vast majority of careful, honest workers”.¹

The definition of research misconduct

Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standards

No definition can or should attempt to be exhaustive. It should allow for change. The definition should not be read as being restricted to fabrication, falsification of data and plagiarism. It is intended to cover the whole range of research misconduct.


Figure 2.4 Joint Consensus Conference on Misconduct in Biomedical Research 28–29 October 1999.

General Medical Council. However, a proposal that the General Medical Council serve as the fulcrum of a UK system fails the test of universality. As in the US, concern first started when misconduct was found in clinical research, which, of course, seems rather too close to home for most people. But it is a widespread problem. An organisation established to discipline physicians cannot realistically police scientific misconduct when, even in clinical research, most projects involve numerous co-workers with different degrees and expertise, some of them completely outside medicine. Some mechanism must be found to broaden the scope of regulation and enforcement.

Was it official?
The Edinburgh Consensus Report, developed as it was in a closed meeting, even though a good start, and even though it was immediately published, was not issued by any body with the mandate and legal power to make its recommendations happen. Nor was it developed with a broadly-based enough input to build sufficient understanding to produce a result that will be widely accepted.

The definition of research misconduct proposed by the 1999 Joint Consensus Conference is neither specific nor does it provide clear guidance on the meaning of its critical terms. Indeed, it is so vague, non-specific, and all-encompassing, that it is unworkable. What are “good ethical
standards”? In which field? In what circumstances? By whose judgment? There are whole areas of research – for example, research on stem cells, or on aborted fetuses – where ethical scientists hold strongly divergent opinions about “good” standards. Worst of all, the definition includes unintentional behaviour that falls short of good scientific standards. To give an example, one of us (DR) used to conduct physiologic experiments at high altitude in Nepal. Once a whole batch of specimens was ruined because DR had not known that dry ice would be unavailable during a religious holiday. As a result, the results obtained were incomplete and the differences not statistically significant. I had not met the “good scientific standards” set out clearly in my protocol, devised with my colleagues in the US. If this sort of thing is misconduct, as it clearly would be under this strange definition, how could anyone ever dare to attempt science? In addition, the statement that the definition “is intended to cover the whole range of research misconduct” is circular.

As to “clear and fair process”, though the specifics of handling accusations of misconduct are essential ingredients of any successful system, the Consensus Report says little or nothing specific about procedures, so most of the elements necessary for a useful system are undefined or absent. The US experience illustrates that getting the process right matters as much as having the right definition. In fact, one could posit that the low-key acceptance of the new government definition in 2000 is rooted as much in the growing comfort that proceedings – if never pleasant – are not unfair or biased by design. Much can be learned from the American experience with process, both by those with institutional responsibilities, and those who are caught in a specific situation.19-21

Conclusion

Some bullfighters in Spain routinely shave the horns of the bulls they face – sometimes by as much as 2.5 cm – to reduce their risk of injury, as it impairs the weapons, vision, and balance of the bull. It is well known this occurs, and it is regarded as wrong, but when the Spanish government proposed a system of examinations to detect irregularities, the bullfighters went on strike, saying that they should be trusted to regulate themselves.22 We should all like our professions to behave in a way that to most of us would define professionalism, that is, to regulate ourselves effectively, but our experience with scientific misconduct in the US, and the experience with physicians in the UK, shows us that, as with bullfighters in Spain, there must be some higher body to force regulation upon them. We can expect that nothing much will happen in the UK until that fact is absorbed by all concerned, and this will not occur until the pain and shame of bad publicity becomes unbearable.

Meanwhile, no one can expect to draw up regulations in a couple of days, and full of holes as it is, the Edinburgh Statement is a start. Now, using the Ryan Report and the US Federal Regulations, and paying attention to the
long and carefully examined experience gathered in the US, as well as to the experience gleaned from other countries (for example, the Scandinavians), we would suggest that the UK begin the hard, contentious but necessary work of framing their own rules. We wish them luck.

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