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THEME ISSUE

on

SCIENTIFIC MISCONDUCT

Guest Editor:
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Canada

Journal Editor:
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International Center for Health,
Law and Ethics, University of
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The Editor’s Page

In her role as Guest Editor, Professor Lorraine Ferris has assembled fourteen original papers and organised them into a significant edition of our Journal. For this I am most appreciative. Over the past several months, we have enjoyed a very close collaboration, in spite of the physical distance between us. In her introductory review, Professor Ferris outlines the many problems involved in Scientific Misconduct and demonstrated by the scholarly and well-researched papers to be found in this volume.

The occurrence and inevitable outcome of scientific misconduct, and the ethical aspects of both research and publication must be addressed positively. Every prospective researcher should be required to learn, at the outset of his career, about the relevant pitfalls he may encounter and how to avoid them. Professors and their colleagues have the responsibility of helping their younger research staff and students to resolve difficulties. My limited inquiries have shown that this part of the research education process is still not a regular or frequent part of the training of researchers. A course of instruction at least for Master’s degree students should be mandatory in every university and academic institution which offers any kind of research program.

The consequences of not doing this or similar are serious and will continue to threaten the trust currently invested in research integrity.

One of our contributors to this theme issue, Mary D. Sheetz describes the Teaching Scholars Program. This is an attempt to integrate an educational program at the author’s university with the Federal Office of Research Integrity. Although the model illustrated appears complex, it is comprehensive and may provide the conceptual basis for similar schemes in the wider world.

Professor Ferris has, through her interest in ‘Medicine and Law’ and by the work she has done in connection with this theme issue brought credit to herself and to the authors involved. I am personally indebted to them all.

David Nachshon
Scientific Misconduct and International Communities

By devoting an entire issue of *Medicine and Law* to the theme of scientific misconduct, the Journal makes a strong statement about the international importance of the topic. No jurisdiction is exempt from having to address scientific misconduct – making this a domestic issue needing attention – and no jurisdiction in our global environment can ignore the international relevance.

Each paper in this Theme Issue recognizes the complexity of the subject, but rather than being caught in a web of hopelessness, each explores practical issues and possible solutions. The papers are organized into four (albeit overlapping) sections – Concepts in Scientific Misconduct, Investigating Scientific Misconduct, Journals and Scientific Misconduct, and Creating Ethical Environments.

Scientific misconduct erodes two of the major foundations of research: truth and trust. Corrupting truth and trust can, for example, negatively impact on patient volunteers, patient care, population health, public policy, judicial decisions, future research, reputations of collaborators and institutions, and advancement of informational globalization. Scientific misconduct breaches the public trust casting a wide net of public suspicion around the entire research enterprise; not only on a particular study, researcher, or institution. This breach can impede the public’s use and uptake of valid scientific information and deter the public from supporting governmental expenditures on research.

Although truth and trust are internationally understood concepts, Momen & Gollogly illustrate the complexity in defining scientific misconduct when cultural perspectives come into play. They believe we need an international research forum to agree on principles, benchmarks, and norms as to what constitutes scientific integrity and what constitutes scientific misconduct (and do so without creating unnecessary research obstacles). No doubt such an international research forum would need to consider how financial conflict of interest situations may lead to scientific misconduct; a topic addressed by Lexchin, Cohen-Kohler & Esmail and Krimskey. Both Lexchin and Cohen-Kohler & Esmail examine how the for-profit corporate culture clashes with a government’s role to protect and promote the public interest in regulating drugs and devices. Lexchin focuses on the culture of corporate secrecy – which can lead to ethical violations and to allegations of scientific misconduct – and discusses how it impacts on what is (and is not) disclosed. He effectively argues that this culture of corporate secrecy is not challenged by governments, those conducting research and those
involved in the research dissemination process because of conflict of interest situations. Cohen-Kohler & Esmail examine legislative and regulatory models and how corporate profit seeking can impact on research and on dissemination of scientific findings. Cohen-Kohler & Esmail call on governments to critically evaluate their regulatory policies and procedures and on the pharmaceutical industry to make further commitments to corporate social responsibility. There is synergy between these papers and Krimsky’s writing. In his paper, Krimsky provides evidence of ghost writing, fabricating credentials and failure to disclose conflicts of interest and effectively argues these activities should constitute scientific misconduct as they bias the outcome of research and its reportage. Krimsky reinforces the need to have more transparency about conflicts of interest.

It is in the public interest that we investigate activities that, if found to have occurred, will constitute scientific misconduct. Arguments founded on public interest often result in action. However, action is necessary, but insufficient. Procedures for investigating allegations of scientific misconduct must be based on the principles of natural justice. Catano & Turk argue that we must have a strong commitment to “root out” scientific misconduct – and they helpfully define academic fraud and misconduct – but that we must do so in a fair, impartial, and rational manner. They outline academic procedures that are acceptable to a national university faculty association. The two papers by Spece & Bernstein examine government regulation of scientific misconduct investigations involving publicly funded studies arguing that regulatory definitions (or lack thereof) interfere with principles of natural justice, among other things. Taken together, the papers in this section provide insightful cautions for those establishing or revising their rules or practices for investigating allegations of scientific misconduct. Arguments that we have fallen short in this arena are as concerning as arguments that we have failed to address scientific misconduct.

The articles relating to journals and their role in addressing scientific misconduct remind us that journals and editors are gatekeepers of the scientific record. Fletcher & Black argue that the presentation of scientific data can be influenced by complex social forces and the legal milieu. They provide concrete recommendations to journals as to how to remedy these issues during peer review and publication. Journals and editors, by the nature of their role and their resources, rely on others to investigate allegations of scientific misconduct that are closer to the research environment and with the appropriate jurisdiction to act. The paper by Daroff provides valuable insight into what it is like for
editors to be responsible for the accuracy of the scientific record while working in an uncoordinated system. Wager, and Marusic, Katavic & Marusic highlight the fact that while many need to address allegations of scientific misconduct, many fail to do so. Is it a case of diffusion of responsibility (people or institutions believe others are acting), inertia, or ignorance? The papers by Wager, and by Marusic, Katavic & Marusic not only describe the current practices of journals and editors, but also skilfully describe a complex interplay between journals, editors, researchers, and academic/research institutions (and likely research funders). Both papers provide insightful recommendations about what is needed for journals and editors to effectively oversee the accuracy of the scientific record.

We can get nowhere in addressing scientific misconduct – or preventing it from occurring – unless we find ways to create ethical environments. Faunce & Jefferys highlight the importance of whistle-blowing as a mechanism to achieve accountability and transparency. They capably argue that we need to provide appropriate policy and legal environments to facilitate whistle-blowing and to protect whistle-blowers who act in good faith. The papers by Scheetz and by Lind & Swenson-Lepper address research integrity by examining ways to sensitize researchers and to promote ethical environments. Just as research tends to span the globe, so should our efforts to strengthen research integrity.

This Theme Issue highlights the fact that we have domestic and international challenges in how we define, investigate, sanction, and correct scientific misconduct. We clearly need to strengthen our ethical research environments; however, this is not enough. We need to articulate – and debate – various models and strategies for a legally supported global scheme that will create principles for how we will work together to address these challenges and what needs to be accomplished within specific timeframes.

Lorraine E. Ferris, Ph.D., C.Psych., LL.M.

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Defining Scientific Misconduct

CROSS-CULTURAL PERSPECTIVES OF SCIENTIFIC MISCONDUCT

Hooman Momen* and Laragh Gollogly**

Abstract: The increasing globalization of scientific research lends urgency to the need for international agreement on the concepts of scientific misconduct. Universal spiritual and moral principles on which ethical standards are generally based indicate that it is possible to reach international agreement on the ethical principles underlying good scientific practice. Concordance on an operational definition of scientific misconduct that would allow independent observers to agree which behaviour constitutes misconduct is more problematic. Defining scientific misconduct to be universally recognized and universally sanctioned means addressing the broader question of ensuring that research is not only well-designed – and addresses a real need for better evidence – but that it is ethically conducted in different cultures. An instrument is needed to ensure that uneven ethical standards do not create unnecessary obstacles to research, particularly in developing countries.

Keywords: Ethical review; informed consent; plagiarism; research misconduct; ethical standards

The proportion of scientific research performed outside the academic centres of Europe and North America has been increasing in recent years1. This increase

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has been accompanied by some high profile cases of research misconduct\(^2,3\). With the increasing globalization of scientific research the question arises of whether there can be an international agreement on the concepts of scientific misconduct.

Standard ethics texts instruct researchers in their duty to recognize the “importance of national and local cultures and social systems, values and beliefs”\(^4\). Does this mean conducting the research elsewhere when those local cultures do not ascribe to the basic principles of ethical conduct: justice, beneficence, non-maleficence and autonomy? A host of scenarios can be imagined, but it may be more helpful to query the legitimate limits of, and alternatives to, the uncritical export\(^5\) of ethical review committee procedures as designed by a handful of developed countries.

The first consideration is the legal environment of a given country. While universal rights are held to exist regardless of legal jurisdiction or other localizing factors, such as ethnicity and nationality, the right of participants to ethically conducted research are not universal, and therefore subject to local factors. For example, obtaining informed consent from women and children in countries where neither have legal autonomy is clearly problematic; does this mean that they should be excluded from participation?

The composition and tasks of local ethical review committees vary widely, and in situations of scarce human resources, can be difficult to establish and maintain. We suggest that developing countries should be surveyed explicitly on their positions regarding the more contentious operational issues of medical research; parallel duty of care, confidentiality, untreated controls, inducements, storage of samples and reporting. In this way, the substantive gap between the theory and practice of ethical oversight can be bridged by concrete examples rather than hypothetical concerns.

These issues have been discussed in international forums, such as the World Congress on Bioethics, held in Beijing in 2006, but published guidelines give them uneven treatment. For example, guidelines on the parallel duty of care address the researchers’ obligations to provide medical care for participants beyond that directly indicated by the research protocol, usually for other diseases beyond the focus of the research. There is no clear guidance on how to design, fund and conduct studies in order to have ethically acceptable answers to the following questions. What happens to the participants when the trial is over, and the drugs under study are withdrawn? If the trial has been successful, who ensures that the participants have access to the drug that they have helped to bring to market? What are the researchers’ obligations towards participants who were enrolled as an untreated control group? What are appropriate rewards for participation, and how can these be set to benefit the participants, while allaying concerns about undue inducement? Countries with low institutional capacity for data and specimen storage are particularly vulnerable to compromising confidentiality, but there is no consensus on how to manage the ownership of data generated by a trial, or who has the responsibility to ensure that it is properly reported and disseminated; including reporting back to the participants themselves.

The National Institutes of Health (NIH) have created an initiative on International Research Governance which supports the advanced training of developing country officials who will assume the responsibility of ethical review or clinical trial design. The initiative also provides grants that enable institutions in these countries to develop or expand graduate curricula and training opportunities in ethics. In addition, Emmanuel et al. from the NIH have provided a comprehensive overview of the issues surrounding ethical conduct of clinical research in developing countries and developed benchmarks for the conduct of research carried out by developed countries in these settings. These authors have suggested that many of these issues might be resolved by collaborative partnerships between investigators, sponsors and the local community.

The Nuffield Council’s *The ethics of research related to healthcare in*

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developing countries identifies the following six factors as worthy of consideration: research-associated harms in the absence of potential benefit, parallel care, applicability and relevance of existing guidelines, appropriate standards of care, capacity to consent, effective ethics review and nationally-determined research agendas.

The Medical Research Council’s *Human tissue and biological samples for use in research: operational and ethical guidelines* states that “Researchers should ensure that they are aware of cultural or religious differences in the meaning and significance attached to the body or specific parts of it before approaching potential donors.”

Many concerns about the exploitation of vulnerable groups, and the restaging of clinical trials to the developing world can be ascribed to opacity surrounding “Who wants to know what, and to what ends will they apply this knowledge?” WHO is constantly solicited by its member states to provide answers to dilemmas of distributional equity (the most resources being spent on the health problems responsible for the least of the global burden of disease), persisting inequalities, and the lack of progress in terms of population health. Communities in which the desire to know more about the diseases that afflict them outstrips their capacity for bureaucratic procedure are disadvantaged by universally equating the highest ethical standard with the most complex procedures.

What constitutes scientific misconduct can lead to argument even in relatively homogeneous academic organizations within Europe, so is a universal definition of scientific misconduct possible? The Universal Declaration of Human Rights endorsed – if not practiced – by nearly all the countries of the world, is predicated upon universally agreed ethical standards. The major world religions, even if they disagree in other spheres, share common spiritual and moral principles on which these ethical standards are generally based. Member states of international organizations have shown through many international conventions and codes of practice that it is possible to reach international agreement on the ethical principles underlying good scientific practice.

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However, reaching concordance on an operational definition of scientific misconduct that would allow independent observers to agree which behaviour constitutes misconduct is much more problematic. Scientific misconduct covers a range of activities, with minor to serious implications. It is much easier to obtain international agreement on the condemnation of blatant misconduct such as fabrication of data, or falsification of results, where these activities clearly violate universal moral principles such as truthfulness and trustworthiness.

For other types of misconduct, judging what is serious and what is minor misconduct is very dependent on culture and context. Plagiarism, the copying of ideas, data or text without permission or acknowledgement, is a good example of where a spectrum of misconduct occurs, from the wholesale copying of articles to the unattributed quotation of sentences or phrases. There is also a range of opinions regarding the seriousness of the offences. In many news organizations plagiarism by a journalist would by itself be sufficient grounds for summary dismissal. This is not a sanction that is usually applied in scientific research. A recent discussion on the World Association of Medical Editors’ listserve\(^\text{11}\) illustrated large differences of opinion between editors on whether self-plagiarism constitutes scientific misconduct. Self-plagiarism occurs when an author reuses portions of their previous writings in subsequent research papers. This is considered unethical by some as the reader assumes that what is being read is new and original unless there is a specific reference to the contrary.

A different cultural view on plagiarism was expressed in a recent letter to the *Lancet*\(^\text{12}\). Current guidelines on avoiding plagiarism\(^\text{13}\) in scientific writing recommend that even for the methods and results section where procedures and analyses are similar to those carried out and reported previously, authors should paraphrase these and not repeat the wording. In the letter the authors explain the difficulty non-native English speaking authors have in writing articles for the international English journals and ask for leniency in the copying of texts (not data). Paraphrasing is a particularly difficult skill for authors who are

\(^{11}\) World Association of Medical Editors (WAME) [http://www.wame.org/wame-by-topic#plagiarism](http://www.wame.org/wame-by-topic#plagiarism)


not confident in their use of English tenses, prepositions and pronouns. Increased use of attributed quotations would resolve this problem, but this is not the current practice in scientific publications\textsuperscript{14}. Just as legal texts use formulaic language in order to express the conventions of the profession, the scientific community could recognize that such use is a necessary part of reporting standard materials and methods.

In terms of minor misconduct, there are also differences of opinion on how such conduct should be sanctioned. Some cultures are lenient, while others take a harsh stance analogous to the differences in how countries define and punish misdemeanours, such as recreational drug use or graffiti. These differences may be founded on implicit assumptions about the tendency for minor infringements to evolve to serious misconduct.

In medical research the failure to get consent from an ethics review committee or an institutional review board for research on human participants would be considered scientific misconduct in many countries. In other countries where there are few practicing clinical researchers, such committees where they exist tend to be mainly composed of people whose only knowledge of the issues is theoretical at best\textsuperscript{15}. For the practising researcher who has obtained, or will obtain, informed consent from the participants, the approval of the ethics committee can represent a bureaucratic hurdle that adds nothing tangible to good ethical practice.

Informed consent is also subject to different cultural perceptions. Some societies are more paternalistic. The medical profession is generally trusted and people are more willing to assume that physicians are motivated to act in the best interests of their patients. Defensive medicine and class actions are non issues. Women and children may not be legally autonomous and are unable or unwilling to give consent. Conducting trials in such settings would be considered uncontroversial by some – particularly by those who have always practiced in such a setting. Others complain that doing research in such contexts is deliberate exploitation of patients’ naivety, and constitutes serious scientific misconduct.

Defining scientific misconduct to be universally recognized, and universally

\textsuperscript{14} Roig M. Ethical writing should be taught. \textit{BMJ}. 2006 Sep 16;333(7568):596-7.

sanctioned means addressing the broader question of ensuring that research is not only well-designed, and addresses a real need for better evidence, but that it is ethically conducted in different cultures. Prevention of scientific misconduct in the developed world has been predominantly tackled by the proliferation of research guidelines, and by increasing the burden of proof on researchers and the scope of research ethics committees. Several highly-publicized cases of scientific misconduct have probably increased the anticipation of ignominy as a result of misconduct, and may have an unquantifiable, but significant impact as a deterrent to the research community as a whole.

Complete trial registration is not only a mechanism to ensure public accountability and the reporting of pre-specified endpoints. It also has the potential to address the current uncertainty surrounding estimates of global research spending, its relative focus, and the corresponding likelihood of addressing issues of proportionate public health impact. This transparency can be realized by including trial costs as part of the minimum data set for registration purposes.

Notwithstanding the important precedent set by requirements for complete trial registration, developing countries are not necessarily equipped to address the issues of ethical research conduct in a manner that is to the advantage of their populations. The existing international guidelines for good clinical practice do not in themselves address this lack of capacity, or the feasibility of doing research at all in these settings.16, 17

The World Trade Organization administers the Technical Barriers to Trade (TBT) Agreement, which seeks “to ensure that technical negotiations and standards, as well as testing and certification procedures, do not create unnecessary obstacles to trade”18. While recognizing countries’ rights to set their own standards, the WTO provides a negotiating forum, a set of rules, and a process for settling disputes arising from the interpretation of those rules. These needs arose with increasing trade liberalization; scientific research is undergoing the same international expansion. As with trade between countries, research collaboration between countries has a similar need for reference to


international standards when possible, a way to report and resolve disputes - particularly those surrounding research misconduct. Like the TBT, the international research community needs a forum in which to reach agreement on principles and benchmarks for ethical research practice. It also needs a set of rules to ensure that ethical norms are met, and that the interpretation of how to achieve these norms does not create unnecessary obstacles to research, particularly in developing countries.
THE SECRET THINGS BELONG UNTO THE LORD OUR GOD: SECRECY IN THE PHARMACEUTICAL ARENA†

Joel Lexchin *

Abstract: Secrecy in the pharmaceutical arena has taken on more importance in the recent past as the pharmaceutical industry has assumed greater prominence in the funding of clinical research and has also become a funder of the agencies that are charged with regulating it. Governments have adopted a neo-liberal agenda that prioritizes private profit over public health and are therefore willing to let industry set the research agenda. As a result, secrecy, to protect intellectual property rights, is a major feature of clinical research. Secrecy also leads to biases in the published literature that conceal significant safety problems. Because regulators are now partially dependent on the pharmaceutical industry for their existence regulators are unwilling to challenge industry. By treating data on efficacy and safety as commercially confidential information they effectively collude with industry in denying health professionals and the public access to essential information to be able to use drugs appropriately.

Keywords: Clinical research; conflict-of-interest; funding; ghostwriting; government; medical journals; pharmaceutical industry; regulation, secrecy

INTRODUCTION

Over the past decade the funding of medical research has gradually been swinging in favour of the pharmaceutical industry, especially when it comes to

† An edited version of this paper appeared in the May 2007 issue of the Canadian Centre for Policy Alternatives (CCPA) Monitor.

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clinical research. In 1995 domestic research funding in the United States (U.S.) was almost evenly divided between the National Institutes of Health (NIH) ($11.3 billion)\(^1\) and the brand-name pharmaceutical industry ($11.9 billion)\(^2\) but 10 years later the industry was spending $31.4 billion\(^2\) versus $28.5 billion for the NIH.\(^1\) Clinical research in the U.S. is heavily funded by the biopharmaceutical industry with 70% coming from that source and an additional 20% originating with the makers of medical devices.\(^3\) There is no similar Canadian data but the entire budget of the Canadian Institutes for Health Research is about equal to the amount spent by the brand-name pharmaceutical companies on clinical research.\(^4, 5\) The trend is similar in other developed countries like the United Kingdom where funding from non-industry sources for randomized clinical trials has dropped precipitously since 1998.\(^6\)

Who funds the research has implications with respect to whether or not the results of that research are shared and with whom. If research is publicly paid for, then the assumption is that it will be openly available but if the funding is coming from a private entity like a pharmaceutical company, then the results are treated as a commodity. Commodities are by their nature sold or traded for profit so that the companies can realize the maximum value out of their investment.

Of course, governments could increase the amount of money that they devote to medical research to keep pace with growth from the private sector in order to ensure that there is a substantial body of publicly available research. However,
there has been a paradigm shift in the thinking of the Canadian and American
governments with respect to the balance between the public and private roles
in this area. In Canada, about half the cost of paying for the branch of Health
Canada that approves new drugs, the Therapeutic Products Directorate (TPD),
comes from user fees collected from the pharmaceutical companies. Since
user fees started a little over a decade ago, the federal government has placed
much more emphasis on the priorities of the industry especially with respect to
the industry’s concern for more rapid drug approvals. The reorientation of the TPD to reflect the interests of the industry is reflected
in its Business Transformation Strategy (BTS). The BTS was introduced in
early 2003 and “builds on the commitments made by the Government of Canada
to ‘speed up the regulatory process for drug approvals,’ to move forward with
a smart regulations strategy to accelerate reforms in key areas to promote
health and sustainability, to contribute to innovation and economic growth, and
to reduce the administrative burden on business.”

One of the key concepts in the BTS is “smart regulation.” This means that
Canada should “regulate in a way that enhances the climate for investment
and trust in the markets.” Smart regulation does not ignore health interests
but the emphasis in the BTS is clearly on creating a business-friendly
environment. There is a subtle but unmistakable shift in thinking from the
precautionary principle to risk management. Precaution means assuming that
a new product is potentially harmful until proven otherwise whereas the principles
of smart regulation and risk management are based on the premise that there
would have to be a threat of serious or irreversible damage from a product
before a regulatory body would step in.

The situation in the U.S. with respect to increasing industry influence over the
regulatory apparatus mirrors what has happened in Canada. In 1992, in response

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to industry complaints about slow approval times the U.S. Congress passed the Prescription Drug User Fee Act (PDUFA). Under PDUFA companies began paying user fees to the FDA, however these fees were specifically earmarked to hire new reviewers to speed up the approval of applications. The fees were contingent on the FDA meeting specific goals on timelines and until the reauthorization of PDUFA in 2002 none of the funds could be used to fund any other FDA activities, including those involving safety issues. User fees from companies now account for more than 50% of the money that is available to the agency for reviewing new drug applications.\(^{11}\) As in Canada, there were dramatic effects from the injection of industry money. From 1993 to 2003, approval times for priority review drugs (drugs judged to have a significant therapeutic advantage over existing medications) dropped from 14.9 months to 6.7 months and over the same period, times for standard reviews declined from 27.2 months to 23.1 months.\(^{11}\)

In addition to the influence of funding on the direction of the FDA, the Bush Administration has eased up on enforcement activities for violations of federal requirements\(^{12}\) and appointed a series of industry friendly people to high posts within the organization. Prior to his August 2001 appointment as Chief Counsel for the FDA, Daniel Troy had represented the tobacco industry in its fight against FDA regulation and had opposed FDA efforts to restrict the promotion of drugs for unapproved uses.\(^{11}\) Former FDA Commissioner Mark McClellan was hailed as industry friendly both by friends and foes\(^{13}\) and the former Associate Commissioner, Scott Gottlieb believed in faster drug approvals and fewer warnings to the public about potential safety issues.\(^{14}\)

These changes in the funding of both clinical research and the regulatory approval process make it even more important that there is transparency in all areas involving pharmaceuticals to ensure that the public interest continues to be the first priority. This article will use information primarily from the U.S. and


\(^{13}\) Rowland C. FDA’s economist in chief Mark McClellan’s views on healthcare make him popular with the drug industry. Boston Globe 2004 January 18.

\(^{14}\) Mundy A. Wall Street biotech insider gets no. 2 job at the FDA. Seattle Times 2005 August 24:A1.
Canada but also other developed countries to examine how the increasing influence of industry and the inevitable increase in secrecy affects how the results of clinical research are being privatized, how unwanted findings are being suppressed, how the relationship between researchers and industry is concealed and finally how bias is creeping into the published literature. A lack of transparency can interfere with journals’ editorial processes and determine what does and does not appear in print and this question will be examined in the penultimate section. Finally, I will examine how secrecy within regulatory agencies interferes with work that people within the organization do and how the interests of health professionals and consumers are damaged.

Secrecy and sharing of information

Companies conducting or sponsoring research in academic institutions often keep information confidential well beyond the time needed to file for a patent. In one survey of life science companies, 56% reported that they sometimes or often kept the results confidential for more than 6 months. On the opposite side of the relationship, faculty members with industry support were almost twice as likely as those without such support (11.1% versus 5.8%) to report that they had refused requests from other academic scientists to share research results or biomaterials. The observation that receipt of industry funding constrains the discussion of research results extends to graduate students and post-doctoral fellows. Suppressing communications among researchers for prolonged periods can harm scientific interests in a variety of ways including forcing the unnecessary repetition of research that uses up valuable resources and perhaps even causing projects to be terminated because necessary information or biomaterials are not available.

Evidence of the extent of the culture of secrecy that industry funding generates comes from a recent survey of 107 U.S. medical schools.\(^{19}\) While some of the results are reassuring, for instance 93% do not allow the sponsor to decide about publication, other findings lead to considerable disquiet: 62% permit the sponsor to alter the study design after an agreement has been executed and 80% allow the sponsor to own the data. In the wake of recent controversies, some universities have strengthened their policies about suppression of publication. The University of Toronto modified agreements with its affiliated teaching hospitals to state that clinical trial agreements between hospitals and sponsors should not allow sponsors to suppress research results and that investigators should be allowed to submit work for publication within 6 months of revealing the results to sponsors.\(^{20}\)

While the results within the academic community are generally disturbing, even if more universities strengthen their policies, information sharing may not substantially improve as research funding is moving out of academia into the community setting where there is no tradition of academic freedom. The majority of the research dollars from corporations used to go to the academic community but in the U.S. between 1994 and 2004 the proportion going to that sector declined from 63% to 26%.\(^{21}\) Canadian figures show that the percent of trials being done in a community setting went from 47% to 60% over the period 1997 to 2004.\(^{22}\)

**Secrecy and suppressing publication of research results**

Faculty who have their research funded by commercial sources are much more likely to have the results of their research either suppressed or the publication delayed. When asked the question “Have you personally conducted any research at your university the results of which are the property of the sponsor and cannot be published without their consent?” 24% of those who

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were involved in university-industry research relationships responded positively versus only 5% who were not involved in such relationships.\(^{23}\)

Trade secrets, defined as information kept secret to protect its proprietary value, might be one reason for the nonpublication of results. More than three times as many faculty members with industrial support compared to those without such support reported that trade secrets had resulted from their research (14.5% versus 4.7%).\(^{16}\) Twenty-seven percent of faculty who participated in relationships with industry delayed publication for longer than 6 months, compared to 17% of faculty without such relationships.\(^{24}\) Graduate students and post-doctoral fellows also report that industry funding leads to delays in publication.\(^{17}\) The results of meta-analyses can be biased to make a product look more beneficial if the publication of negative results is either withheld or delayed. One illustration of this bias is seen in an analysis of trials on the effectiveness of using selective serotonin reuptake inhibitors (SSRIs) in treating childhood depression. The meta-analysis based on just the published trials suggested a favourable risk-benefit profile for most SSRIs but when data from unpublished trials was included, then only a single drug out of the class continued to have a positive harm-benefit ratio.\(^{25}\)

Despite knowing that paroxetine (Paxil®) was ineffective for the treatment of childhood and adolescent depression, GlaxoSmithKline did not publish these results because, according to an internal company memo, “It would be commercially unacceptable to include a statement that efficacy had not been demonstrated, as this would undermine the profile of paroxetine.”\(^{26}\) The Wall Street Journal claims that “internal Merck e-mails and marketing materials as well as interviews with outside scientists show that the company fought forcefully

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for years to keep safety concerns from destroying the drug’s [Vioxx’s] commercial prospects.”

Close to one-third of academic scientists who were recipients of gifts from companies in the form of biomaterials, discretionary funds, research equipment, trips to meetings, support for students and other research-related items, reported that in return the companies wanted prepublication review of any manuscripts or reports that resulted from the use of these gifts. Requesting prepublication review may have a benign outcome if investigators have full control over data analysis and publication decisions, but where this is not the case, significant changes may result. An article in the *New England Journal of Medicine* presents six cases, based on interviews with researchers, where publication was denied or the content of articles was changed by the company funding the research.

**Secrecy and the relationship between researchers and industry**

Financial relationships between industry and journal authors are unlikely to be reported by the authors in their publications. A series of articles on calcium channel blockers had 70 authors in total, of whom 26 had received funding from the companies making these products. However, only 2 out of the 26 reported any type of potential conflict of interest when their articles were published.

Despite recent improvements in the reporting of conflicts of interest, only 8 out of 100 industry sponsored randomized controlled trials in five major medical journals reported the role of the sponsor and 8% (13 of 163) of original articles published from December 2003 to February 2004 in four major journals failed.

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to declare conflicts. Failure by authors to declare their conflicts in a string of articles published in *JAMA* lead to the editors not only strengthening the journal’s policy in this area in 2006, but also publishing public apologies to its readers. Authors of clinical practice guidelines (CPGs) are in a similar situation. *Nature* examined more than 200 sets of CPGs. Details about individual authors’ conflicts of interest were declared in just 90 cases and in only one-third of these were the authors free of industry influence. Ten percent of the panels developing the CPGs had a member who owned stock in a company whose products were being considered and more than a third of the panels included at least one member who gave presentations on behalf of a company whose products were recommended in the CPGs.

**Secrecy and published research**

Concern about the lack of disclosure of industry funding is not merely theoretical. Authors’ conclusions in randomized clinical trials published from 1997 to 2001 in the BMJ were statistically significantly more likely to favor the experimental treatment if financial competing interests were declared.

A 2000 issue of *JAMA* carried the results of the CLASS study which appeared to demonstrate the superior gastrointestinal safety of celecoxib (Celebrex®) over traditional nonsteroidal anti-inflammatory (NSAID) medications. However, material on the FDA’s web site revealed a number of discrepancies between the data that had been submitted to the FDA and the data that was reported in JAMA. Most importantly, originally there had been two trials running for 12 and 16 months. The *JAMA* article combined these two studies into one and only published the results after 6 months. When the trials actually ended at


12 and 16 months, there was no difference in gastrointestinal adverse effects between the celecoxib and traditional NSAID groups.37, 38

Drug companies are also frequently accused of ghostwriting, the practice of writing an article favourable to one of their products and then seeking a well-known clinician to sign the article.39 In the summer of 2004, Fugh-Berman was asked by a medical communications company, representing a drug firm, to write an article about interactions between herbal preparations and a blood thinner known as warfarin.40 Before agreeing, she queried the communications company about further details and a few months later received a draft of an article listing her as the author. The drug company funding this entire project was planning on releasing its own blood thinner in the near future and, in order to enhance the marketing prospects for its new medication, wanted the medical community to be alerted to the dangers of existing products. To make sure that these dangers received sufficient publicity it had hired the communications company to write the article. Fugh-Berman’s job was to sign off on the piece if she agreed with its contents.

Dr. David Healy documents how another medical communications company, Current Medical Directions, produced manuscripts favourable to the antidepressant sertraline (Zoloft®) made by Pfizer, and then hunted for well-regarded academics who would consent to being the authors of the pieces.41 In a third example, the Hartford Courant describes how Wyeth-Ayerst altered ghost-written manuscripts to remove unfavourable data about its diet medication fenfluramine (Pondimin™).42

Secrecy and medical journals

Since journal editors overwhelmingly report having a great deal of control over the editorial contents of their journals, their susceptibility to commercial (and other types of) biases due to their own conflict-of-interest will determine what appears in print. The first study to investigate this issue chose 30 peer reviewed general and internal medical journals, including the top 4 by impact factor. Only 30% stated that they had an explicit policy for dealing with editors’ financial conflict-of-interest. Reasons for nondisclosure included statements that it is unnecessary, that editors do not have conflicts and that the question has never been raised. A second, larger survey used a convenience sample of 135 editors of biomedical journals that publish original research including an international selection of general and specialty medical journals. Out of 91 journals that responded, only 40% had a policy on editor conflict-of-interest and out of these, 31% said that they required editors to recuse themselves if they reported a conflict-of-interest. Finally, only 12% publish the editors’ disclosures. The contribution that undisclosed editors’ conflict-of-interest makes to biases in journal contents is at present unknown.

Secrecy in drug regulation

Evidence is lacking to demonstrate that confidentiality around clinical trial data concerned with safety and efficacy is necessary to foster research and innovation in the pharmaceutical industry. On-the-other hand, keeping this type of information secret has serious negative consequences for regulatory agencies, health professionals and the public. Currently, information submitted to regulatory authorities is not subject to the normal scientific peer review.


process unless it later is sent for publication. Keeping safety and efficacy data from being scrutinized by independent scientists means that drug reviewers are deprived of a second opinion about the accuracy of their evaluations and this lack of oversight may mean that any misjudgements they make about the data will not come to light. In addition, this isolation may impede the professional growth of the staff in the regulatory agency. In the absence of other independent evaluations, healthcare professionals have to rely on the reviewers’ assessments regarding the safety and efficacy of these new medications. In situations where there is limited experience with these products this lack of a second opinion is problematic.47, 48

The European Medicines Agency (EMEA) produces European Public Assessment Reports (EPARs) after a drug has been approved. These are supposed to reflect the assessment file submitted by the manufacturer, its analysis by the EMEA’s scientific advisory body, and the reasons underlying that body’s opinion.49 An analysis of 9 EPARs issued between September 1996 and August 1997 found that there was no standardized method of presenting information in these documents. Examples of the problems included a lack of consistency in whether or not the Scientific Discussion section contained an introduction and epidemiological data and in whether or not the mechanism of action of the drug was fully described. Clear reporting of clinical trials was sometimes absent and references to published trials were missing in all 9 EPARs.50 A subsequent analysis that covered all EPARs published in 1999 and 2000 revealed that the EPARs were not harmonized, reliable, or correctly updated.49

Some progress has recently been made in transparency in EMEA. Under new European legislation, financial interests of EMEA experts and members of the EMEA management board must be declared on an annual basis and at each meeting, declarations must be made of “specific interests which could be considered prejudicial to their independence with respect to the items on the agenda. These declarations shall be made available to the public.” Also, under


the same legislation, if the EMEA rejects a product for marketing, it must make the reasons for doing so publicly available.\textsuperscript{51}

There is a significant lack of transparency in the Canadian drug regulatory process. All of the data that the industry submits, including clinical trial results dealing with safety and efficacy is secret including even the names of the products in the approval process. The TPD will not release any of this information even through an Access to Information request, unless the company owning the data agrees.

In response to repeated criticism about being overly secretive, in early 2004, the TPD announced a new initiative termed the Summary Basis of Decision (SBD). The SBD is modeled closely on the EPARs and is issued after a new drug or medical device is approved and explains scientific and benefit/risk information that the TPD considered in making its decision.

As far as prescribers and consumers are concerned, the most important section of the SBD is the presentation of the clinical information on the product’s safety and efficacy. Do the SBDs contain enough information to allow for the rational prescribing and use of new medications? This question is crucial because within the past few years there have been a number of instances where data held by regulatory agencies was significant in identifying problems with medications that were not apparent by just consulting the published literature. Examples of these problems include cardiovascular risks associated with hormone replace therapy, safety issues with antidepressants in children and adolescents and the gastrointestinal safety of celecoxib versus traditional NSAIDs that was referred to above.

The absence of key information in the SBDs would have made all of these discoveries impossible. The SBDs lack information about the study protocol, the baseline characteristics of trial participants, the number of participants who withdrew and reasons for their withdrawal, primary and secondary efficacy outcomes and fatal and non-fatal serious adverse events by treatment arm.\textsuperscript{52}


CONCLUSION

The pharmaceutical industry is the largest single source of funding for medical research in developed countries and it uses that position to impose its agenda of commercial secrecy on the research that it pays for. As a result, communication between researchers is becoming more difficult, potentially jeopardizing one of the fundamental tenets of science. Scientific advances do not occur in isolation, they rely on open channels of discourse within the scientific community. Negative research results are either buried or not submitted for publication in order to protect sales. The legitimacy of questionable research is not threatened because the conflict-of-interest between industry and researchers and authors is kept hidden. Companies hire ghost writers to ensure that the most favourable slant is put on the research that is published or research findings are presented in ways that conceal key information. Editors’ own conflict-of-interest, commercial or otherwise, are not revealed to the readership in the majority of journals and as a result how these conflicts may threaten the objectivity of the contents of the journals is unknown.

Finally, regulatory authorities which are supposed to protect the public interest are increasingly relying on money that they receive from the pharmaceutical industry in order to be able to function. As a consequence, they are adopting the values of the industry and prizing private profit ahead of public health. This shifting of allegiances is shown in the speeding up of drug approvals while drug safety is ignored and in the willingness to keep key information about safety and efficacy secret. Keeping this information confidential not only damages the public credibility of drug regulators, but it also lays the groundwork for the misprescribing and misuse of drugs to the detriment of doctors, other health care workers and the people who take the medications.

The pharmaceutical industry despite its wealth does not have divine powers and should not be allowed to impose its values ahead of those of the public that uses its products. In order to assert public health interests, it will be necessary to challenge the corporate ethic that has permeated the thinking of government in general and the drug regulators in particular.

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Environments and Scientific Misconduct

SCIENTIFIC MISCONDUCT, THE PHARMACEUTICAL INDUSTRY, AND THE TRAGEDY OF INSTITUTIONS

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Abstract: This paper examines how current legislative and regulatory models do not adequately govern the pharmaceutical industry towards ethical scientific conduct. In the context of a highly profit-driven industry, governments need to ensure ethical and legal standards are not only in place for companies but that they are enforceable. We demonstrate with examples from both industrialized and developing countries how without sufficient controls, there is a risk that corporate behaviour will transgress ethical boundaries. We submit that there is a critical need for urgent drug regulatory reform. There must be robust regulatory structures in place which enforce corporate governance mechanisms to ensure that pharmaceutical companies maintain ethical standards in drug research and development and the marketing of pharmaceuticals. What is also needed is for the pharmaceutical industry to adopt authentic “corporate social responsibility” policies as current policies and practices are insufficient.

Keywords: Pharmaceuticals; ethics; drug industry; pharmaceutical ethics; business ethics; scientific misconduct.

INTRODUCTION

The research-based pharmaceutical industry likes to emphasize it is in the business of health. This is desirable insofar as companies produce drug therapies that can help treat or prevent illness. But what is inherently problematic with the pharmaceutical industry is precisely the point that it is a business and by

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definition, a business seeks to maximize profits. This is what all for-profit industries do and it is not problematic if actions related to this are within the boundaries of ethical, legal, and responsible practice. But oftentimes, the drive for profit, particularly in an intensely competitive market, may foster unethical practices and even scientific misconduct unless tightly monitored. ¹

We argue that existing legislative and regulatory frameworks (both governmental and self-regulation) are not strong enough. We demonstrate this by illuminating examples where the pharmaceutical industry has exhibited blatant scientific misconduct in the following areas: the drug approval process, selective reporting of research results, protection of human research subjects, and marketing practices. We define scientific misconduct broadly as “.. an intentional or unintentional departure from the methodology or procedure of scientific enquiry, self-criticism, or data recording, verification, storage, interpretation, or presentation without an explanation consistent with such methodology or procedure.”¹ More narrowly, scientific misconduct is that which can be considered inconsistent with accepted scientific standards, which can range from undeclared conflicts of interest to falsification and fabrication of results.²

Under this definition, we include the unethical treatment of research subjects and we consider scientific misconduct as applied in the drug approval process and marketing practices. Based on our examples, we propose that governments need to critically examine whether regulations and legislation are robust enough to ensure pharmaceutical industry practices do not slip into the area of unethical behaviour. We also advocate for the pharmaceutical industry to earnestly apply the principles of corporate social responsibility. The combination of tighter governmental controls and a meaningful industry ethos of doing “good” are necessary for meaningful change to happen.

The Drug Approval Process

All governments rely on drug regulatory institutions to control products that are available in the market through the process of drug registration. Drug registration

¹. This is a definition provided to the authors by Professor Bernard Dickens, Faculty of Law, University of Toronto. We are grateful for his assistance here.


involves several processes, which are dependent upon and linked to the scientific integrity of research. This includes the evaluation of a product’s efficacy, safety, indications for use, and subsequently, ensuring appropriate labeling, warnings, and restrictions on marketing and prescribing. But globally, as the WHO notes, one-third of drug regulatory authorities have either limited or no capacity to regulate medicines.\(^3\) And even when drug regulatory agencies have the requisite institutional structures and human resources in place, institutions are tragically imperfect—if an oversight happens, public health can be compromised. Part of this is a result of the fact that regulatory agencies have imperfect information about the products, which they are regulating. This is discussed below. What is of equal concern is that drug regulatory agencies are not always impartial and can be captured by the pharmaceutical industry, which they are charged with regulating. While regulation itself may commence with the public’s interest in mind, it can evolve to become a mechanism through which industry promotes its private interests to the extent that the industry through seemingly benign interface effectively “capture” the regulator.

One well-known contemporary example of information asymmetry between the manufacturer and the regulator is the Vioxx (rofecoxib) case. This drug was withdrawn from the market in September 2004 after Merck reported that it doubled the risk of heart attack or stroke.\(^4\) Internal company communications reveal that Merck was well aware of rofecoxib’s cardiovascular risks yet encouraged representatives to downplay physicians’ concerns.\(^5,6\) Merck’s “obstacle handling guide” instructed company representatives to respond in an indirect manner to physicians’ concerns by stating that the drug “would not be expected to demonstrate reductions” in cardiovascular events and that it was “not a substitute for aspirin.”\(^5\)

However, the Vioxx debacle does not simply reveal internal problems within a corporation. The U.S. Food and Drug Administration (FDA) was also

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implicated in the widespread use and marketing of Vioxx. An FDA internal review showed a “clear cut excess” in the number of heart attacks associated with rofecoxib. The FDA failed to mandate that Merck conduct further clinical tests. The FDA finally ordered Merck to include warnings on package inserts in 2002. By the time that Merck “voluntarily” pulled the drug off the market, approximately 20 million people had used the medication for about 5 years. Whether this case was a clear-cut example of regulatory capture is still up for debate. Some claim that it is a question of political interference from Congress, pressuring the FDA regulators to speed up the drug review and approval process. Others point towards a combination of consistent under-funding and lack of resources. A report released by the Institute of Medicine in September 2006, criticized the FDA on a number of grounds among which included the lack of the FDA’s “clear authority” to ensure compliance with the regulations.

All of these criticisms emphasize the importance of having institutions in place that can manage the pharmaceutical industry effectively. The dangerous mixture of profit incentives, an increasingly competitive industry, and the inherent uncertainty in medical science and practice demand more careful regulation and attendant procedures. The pharmaceutical industry is a high-risk research industry and is largely opaque. Much of its conduct falls outside of the public domain due to restrictions on access to data and transparency of business practices. The level of disclosure required for adequate regulation can threaten the market price of their stocks, which is a disincentive for shareholders but it is in the public’s interest. There is a growing recognition that inappropriate scientific misconduct can affect share prices. This ideally may lead to more ethical corporate behavior – a phenomenon that we are now observing in our post-Vioxx world.

Selective Reporting of Research Results

The Merck-Vioxx case highlighted the problem of the suppression of research results and put the onus on medical journals for tougher standards and practices.


In December 2005, the editors of the *New England Journal of Medicine* stated that at least two of the authors of the VIGOR trial were aware of three deaths due to myocardial infarction in the rofecoxib group. Investigators argued that they did not include this information in the study analysis because they occurred after the trial’s cardiovascular event cut-off date.\(^\text{10}\) Recent reports implicate *The New England Journal of Medicine* as well. Emerging evidence suggests that the editors failed to respond to concerns about the validity of the study results and the safety profile of rofecoxib.\(^\text{11}\) This reservation was raised as early as 2001. The suppression of data on three serious adverse events is an example of the inherent risks of business incentives in the proper conduct of scientific research.

While the Vioxx case is a glaring example of scientific misconduct on the part of the pharmaceutical industry, it is not atypical. In June 2004, then New York State Attorney General Eliot Spitzer filed a lawsuit against GlaxoSmithKline (GSK). The lawsuit alleged that they withheld research results on their antidepressant drug, Paxil. He accused the company of “having engaged in repeated and persistent fraud by misrepresenting, concealing and otherwise failing to disclose to physicians information in its control concerning the safety and effectiveness of its antidepressant medication paroxetine HCL (“paroxetine”) in treating children and adolescents with Major Depressive Disorder (“MDD”).\(^\text{12}\) According to the allegations, GSK reported to the FDA the results of only one of the five studies conducted. The Attorney General’s office reports that the remaining four unreported studies suggest “a possible increased risk of suicidal thinking and acts.”\(^\text{13}\) An internal company memo advised sales representatives to avoid discussion of the clinical trial data that


suggested the increased suicide-related risk of Paxil/Seroxat with physicians.\textsuperscript{14} The FDA has since recommended against the use of Paxil in those under the age of 18.\textsuperscript{15} Shortly after, GSK settled the lawsuit for 2.5 million dollars and committed to the establishment of a clinical trials register to provide public online access to their clinical study summaries.\textsuperscript{16} Their full disclosure has led to increased scrutiny of their products, which recently led to claims questioning the safety of their popular anti-diabetic drug Avandia (rosiglitazone maleate).\textsuperscript{17}

Perhaps the primary reason for the prevalence of scientific misconduct is the growing commercialization of medical research. Commercialization has led to an industry “intertwined” with academe, regulatory bodies, government policies, and the protection of research subjects.\textsuperscript{18} While regulatory regimes have adjusted to accommodate pharmaceutical innovation and development, mechanisms aimed to protect patient safety and research subjects have not adequately recognized these changing relationships. As a result, existing regulatory standards are failing to serve their purpose.\textsuperscript{18} These new relationships need to be recognized, understood, and addressed with proper checks and balances. This should include implementing the Institute of Medicine’s recommendation to make the registration of all Phase 2-4 clinical trials mandatory if they are to be considered valid for drug approval.\textsuperscript{18} Accordingly, mechanisms to ensure the timely and comprehensive reporting of research


results must be applied vigilantly

Pharmaceutical industry critics have pointed out that questionable research practices such as improper study design result in the wastage of hundreds of millions of dollars (US) for healthcare expenditures and also have a negative impact on public health outcomes.19

Protection of Human Research Subjects

The protection of human research subjects is another area where the pharmaceutical industry goal of obtaining fast marketing approval can foster scientific misconduct, which obviously has an impact on patient safety. This problem is particularly acute in settings where governmental institutions are weak and where the outsourced clinical research industry is booming. In a 2004 survey of researchers in developing countries, Hyder and colleagues found 46 of 203 (25%) respondents reported that “their studies did not undergo an ethics review by an IRB, ethics board, or Ministry of Health in the country.”20 In countries lacking adequate regulatory and monitoring structures, the weakness in research ethics regulation has the potential to cause widespread and serious harm.

For-profit contract research organizations (CROs), which coordinate and run clinical research trials for pharmaceutical companies around the world, play an important role within the outsourced clinical research industry. Angell estimates that in 2001, approximately 1,000 CROs globally, accounted for revenues upwards of $7 billion.21 One example is Igate Clinical Research International (based in Pittsburgh and Mumbai). This company’s website describes the “India Advantage” as including a “huge patient base...drug naïve population...high enrollment rates...[and an] increasingly accommodating regulatory environment”.22 However, patients who do not have access to


health care may be more willing to join these clinical trials for the promise of free medical care. Because clinical trials provide a means of obtaining access to better health care, they can be easily recruited and quickly enrolled. Medical literacy and cultural and economic barriers can make informed consent a problem. Furthermore, these CROs pay local doctors and nurses well for recruitment. In developing countries, these payments can raise a physician’s salary considerably.\textsuperscript{21} Financial incentives could increase the likelihood of stretching eligibility criteria or deceiving patients and obtaining poorly informed consent. With the pressure that pharmaceutical companies face in achieving fast approval of a drug — industry claims that a one-day delay in getting a drug to market can cost them $1.3 million\textsuperscript{23} — the incentive exists for unethical practices.

In 2001, over 24 families from Nigeria filed a lawsuit in a US court against Pfizer (Abdullahi v. Pfizer, No. 01 Civ. 8118, 2002 WL 31082956). Their lawsuit concerned a clinical trial conducted in 1996 on Trovan (trovafloxacin). This drug is an antibiotic to treat bacterial meningitis.\textsuperscript{24} According to \textit{The Lancet}, the families claimed that Pfizer gave their children a “new, untested and unproven drug without first obtaining their informed consent” or without explaining that Trovan was an experimental drug which they could refuse and instead receive the proven effective treatment for meningitis at no cost. Pfizer claims that they had received ethics approval from Nigerian authorities and that informed consent was obtained from the families.\textsuperscript{24} A US federal judge dismissed the case in 2002 on the basis that the trial was not appropriate for the US courts.\textsuperscript{25} In May 2006, \textit{The Washington Post} described the contents of a leaked report by a panel of Nigerian medical experts. They concluded that Pfizer violated Nigerian law, the Declaration of Helsinki, and the UN Convention on the Rights of the Child.\textsuperscript{26} Among the allegations, the report states that Nigerian ethics approval was only obtained after the study was

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\item \textsuperscript{26} Stephens J. Panel faults Pfizer in ’96 clinical trial in Nigeria: unapproved drug tested on children. \textit{The Washington Post} 2006 May 7; Sect. A:01.
\end{itemize}
completed and that the approval was then backdated. Most recently, the Nigerian government filed another lawsuit against Pfizer demanding $7 billion in damages.\textsuperscript{27}

In 1997, Lurie and Wolfe alerted the international community of unethical placebo-controlled antiretroviral therapy trials in developing countries.\textsuperscript{28} Almost three years after the 1994 AIDS Clinical Trials Group Study 076 proved that zidovudine reduced vertical mother-to-child HIV transmission by two-thirds, Lurie and Wolfe identified 15 randomized controlled trials — either already underway or about to enroll patients — taking place in developing countries, where some or all of the patients were not provided with antiretroviral therapy. Some of these trials were sponsored by the National Institutes of Health and the Centers for Disease Control. Critics argued that the failure to provide the established standard of care violated the international Declaration of Helsinki, US Department of Health and Human Services regulations on foreign research, and WHO ethical guidelines.\textsuperscript{29} The NIH, CDC and UNAIDS, which oversaw the PETRA studies in Africa, defended their use of placebo-controlled trials primarily on scientific grounds.\textsuperscript{30, 31} No action was taken against the agencies or the researchers, however the controversy spurred a surge of debate over what constitutes ethical conduct in the design and implementation of clinical trials in developing countries.\textsuperscript{29-33} Since then, the Declaration of Helsinki has

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\end{thebibliography}
been amended three times(197,565),(275,577) and the Council for International Organizations of Medical Sciences (CIOMS) revised their ethical guidelines for biomedical research in 2002, in the attempt to be more responsive to the social, economic and political context of the host country, especially for multinational and transnational research. The interpretation and precise application of these principles continues to be an ongoing issue, including how to define what the standard of care should be in developing countries.

Of great concern is the dearth of information on the behavior of local companies in developing countries. In the context of little regulation or enforcement, we cannot be sure that human research subjects are being treated ethically and according to internationally set standards. This can be compensated to some extent by strong regulatory structures in developed countries where the drugs are to be registered for approval. For example, the FDA requires disclosure of clinical trials that are conducted abroad but the resources dedicated to monitoring these trials is low. More resources must be dedicated to meet these ends. Participation of civil society becomes important in countries with little institutional capacity, as they can play a watchdog role. However, active scrutiny by human rights agencies and nongovernmental organizations, while important, is not sufficient in itself. Ultimately, developing country governments, with the assistance of extra-budgetary funding from the WHO, must commit the funds and resources to strengthen their IRB capacity and improve transparency.


Scientific Misconduct through Marketing Practices

The interface between the pharmaceutical industry and physicians is an area that is particularly laden with the potential for scientific misconduct partly due to the lack of regulation in this area. The information asymmetry between manufacturer and physician makes physicians vulnerable to the inaccurate presentation of research on manufacturers’ products. The industry may argue that physician-industry interaction is necessary to educate doctors about the therapeutic qualities of new drugs and advances made in disease treatment. However, there is compelling evidence suggesting that a powerful motivation of corporate-sponsored events is not health education but profit maximization.

For example, a study by Wazana in 2000 found that physician interaction with the pharmaceutical industry was associated with increased requests for additional drugs on hospital formularies and changes in prescribing practice. As Carl Elliot wrote in a thoughtful essay in the Atlantic Monthly: “Doctors’ belief in their own incorruptibility appears to be honestly held. It is rare to hear a doctor—even in private, off-the-record conversation—admit that industry gifts have made a difference in his or her prescribing.”

But, drug companies possess sophisticated marketing techniques. Estimates from 2001 suggest that “marketing and administration” accounted for as much as 35% of industry revenues. While this figure is contested, industry’s heavy reliance on marketing for the promotion of its drug products is widely recognized.

Elliott describes pharmaceutical marketing practices in the following way. “Many reps can tell stories about occasions when, in order to move their product, they pushed the envelope of what is ethically permissible. I have heard reps talk about scoring sports tickets for their favorite doctors, buying televisions for waiting rooms, and arranging junkets to tropical resorts.”

A high profile case of unethical marketing involved Warner-Lambert. In 2004, Warner-Lambert (now a subsidiary of Pfizer) agreed to a settlement and paid $430 million after flagrant off-label promotion of its anti-epileptic drug.

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Evidence demonstrated that Warner-Lambert “aggressively marketed” Neurontin to treat conditions ranging from bipolar mental disorder, Lou Gehrig’s disease, attention deficit disorder, migraine, and other off-label indications. Neurontin was even promoted as “monotherapy for epileptic seizures” despite the fact that the FDA specifically rejected the approval for this use. The company was charged with a “widespread, coordinated, national effort” which involved tactics including one-on-one sales pitches, payments for expensive events, dinners and trips to conferences, and allowing sales representatives to shadow physicians while seeing patients and at times, advising treatment.

Physician-industry interaction may be even more problematic in developing and transition countries where doctors make paltry salaries and sometimes rely heavily on gifts from the pharmaceutical industry to supplement their livelihood. Aggressive marketing is frequently cited, with the use of expensive gifts. Unethical promotion practices range from expanding indications for use, exaggerating therapeutic efficacy and underplaying risks and side effects.

An analysis of pharmaceutical industry drug information materials in India, published in the WHO Essential Drugs Monitor, showed “many discrepancies between claims made and independent scientific data.” The WHO issued Ethical Criteria for Medical Drug Promotion in 1988. However, almost a decade later, WHO acknowledged that inappropriate drug promotion remained a problem in developing and industrialized countries. More helpfully,


42. Bal A. Can the medical profession and the pharmaceutical industry work ethically for better health care? Indian Journal of Medical Ethics. 2004;1:17.


44. Menkes DB. Hazardous drugs in developing countries: the market may be healthier than the people. BMJ. 1997;315:1557-8.


the IOM has put forward recommendations to result in stronger regulations. Fines, injunctions and withdrawals of drug approval need to be implemented forcefully. However, fines must be severe enough to discourage these practices and not simply a trivial amount for the industry.

**Codes of Conduct and International Standards**

In view of the potential for undue influence on prescribing behaviour, a number of professional bodies have developed codes of conduct. The American Medical Association states that “Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value...cash payments should not be accepted”. However, all gifts, no matter their size, have expectations for reciprocal behavior. The acceptance of gifts risks undermining the professional objectivity of physicians. Changes in the standards of professional conduct are required. To be succinct, physicians simply should not accept gifts from pharmaceutical representatives.

The International Federation of Pharmaceutical Manufacturers (IFPMA) has its own Code of Pharmaceutical Marketing Practices. This Code requires its terms to apply to any company belonging to at least one member association. Unfortunately, self-regulatory codes of conduct may do no more than delay meaningful reform in the pharmaceutical industry, as imposed by external enforceable regulations. Current voluntary codes are not audited, enforced with meaningful penalties, or overseen by independent and objective observers.

In recent years, there have been advances made at the international policy level to place social responsibilities on business enterprises as a way to encourage ethical behavior. The United Nations Sub-commission on the Promotion and Protection of Human Rights in 2003 issued “Norms on the responsibilities of transnational corporations and other business enterprises with regard to human

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Another United Nations initiative is the Global Compact of 2000, a voluntary international corporate network, which seeks to advance responsible corporate citizenship. The principles proposed were worthy but vague. The United Nations called to “embrace, support and enact a set of values” defining a new era of corporate responsibility, without giving a clear view of how this proposal should be implemented. However, the Compact was updated in 2004 with Principle 10: “(t)he promotion and adoption of initiatives to counter all forms of corruption, including extortion and bribery.” While these international declarations have good intentions, they, like other guidelines lack the requisite “teeth” to ensure that corporations abide by the standards. In the context of increasing recognition of corporate misconduct, it is unlikely that voluntary self-regulation will do much more than distract governments for implementing the bold solutions that are needed.

Moving Forward: Mitigating the Risk for Scientific Misconduct in the Pharmaceutical Industry

Corporate ethics and scientifically responsible conduct can be left alone as a desirable and even wistful goal. More helpfully, it ought to be governed by a combination of meaningful self-regulation and government regulation, with sanctions that would matter. While international statements and professional guidelines on best practices of corporate behaviour and marketing practices have good intentions, the reality is that they have limited positive impact unless they are enforced with legislation and regulation with teeth. Governments need to do some critical evaluations of their regulatory policies and procedures and how effective they are in terms of managing the risk of scientific misconduct. If assessments suggest that institutions are weak, then reform needs to happen on an urgent basis to avoid unnecessary tragedies as a result of institutional


failure. The problems of regulatory capture or political inference may require the establishment of an independent, arms-length institution to actively register and monitor the conduct of clinical trials. To be sure forceful regulations and other policies, while arguably necessary in this area, can often be messy to implement.

While this idea is in its earliest stage, we suggest that potentially, an international agency could be established that is set up to act as an over-arching monitor of individual country governance related to scientific conduct in the pharmaceutical area. Like other international bodies, countries would apply for membership. Funding ideally could be derived from regulatory fees which pharmaceutical companies pay to an individual country. For this institution to have meaning, it would need to ensure that countries would be sanctioned heavily if standards were not enforced sufficiently. It should ensure public notice of pending or past actions (likely through an institutional website) and assume an active role in communicating its actions to its member countries to demonstrate its value and ideally act as a deterrent by demonstrating that scientific misconduct is costly for governments that do not act against it and for companies that engage in it.

But the onus should not be lodged solely on the government or an international agency. The pharmaceutical industry that is so often the subject of public scorn and mistrust, partially as a result of its scientific misconduct practices, needs to examine its corporate culture and rethink how it does business. Corporate commitment to the concept of corporate social responsibility, which would severely limit scientific misconduct, should not be a meaningless tool to appease detractors but an integral part of company culture and practice. This is surely no easy task but change never is.

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Defining Scientific Misconduct

WHEN CONFLICT-OF-INTEREST IS A FACTOR IN SCIENTIFIC MISCONDUCT

Sheldon Krimsky*

ABSTRACT: Under the guidelines adopted by the United States (U.S.) Office of Research Integrity (ORI), scientific misconduct is defined by one or more of three activities: fabrication of data, falsification of results, and plagiarism or the improper appropriation of other people’s ideas or written work. This paper discusses whether three other breaches in scientific ethics, namely ghost writing, fabricating credentials, and failure to disclose conflicts of interest, rise to the level of scientific misconduct. After discussing the funding effect in science, the paper argues that, like ghost writing and fabricated credentials, conflicts of interest can bias the outcome of research. Thus, lack of transparency to reviewers, journals and readers for conflicts of interest should be considered a form of scientific misconduct.

Keywords: Conflict of interest; ghostwriting; office of research integrity (USA); vigor study.

INTRODUCTION

According to the Office of Research Integrity (ORI) of the United States (U.S.) Department of Health and Human Services, scientific misconduct is defined by three terms: fabrication, falsification and plagiarism. Scientists found guilty of fabricating, or making up data or results and reporting them, who falsify or consciously manipulate research results, or who appropriate other people’s ideas, processes or results without giving them credit could, under ORI’s definition, be found guilty of scientific misconduct. These breaches in scientific ethics, however, are not the only ones. Among others are fabricating one’s credentials, taking credit in a publication without personal contribution, and failure to disclose a conflict of interest. Should the other transgressions rise to the level of scientific misconduct?

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Conflict of interest has been defined as “a set of conditions in which professional judgment concerning a primary interest . . . tends to be unduly influenced by a secondary interest (such as financial gain).”¹ I would modify the definition to be more consistent with current usage by adding the term “or could be perceived to be” after “tends to be.” The definition of conflict of interest does not depend on whether a person’s affiliations are in fact conflictual, rather only that they be perceived to be conflictual. You are in a “conflict of interest” when you have two interests that could be perceived to be in conflict in a way that could impact your professional judgment. Tereskerz and Moreno (2005) propose a similar definition: conflict of interest is any financial arrangement that compromises, has the capacity to compromise, or has the appearance of compromising trust.”² This definition of conflict of interest does not meet any of ORI’s criteria for scientific misconduct. Most observers treat conflict of interest and scientific misconduct as independent behaviors. There are no credible studies that link conflict of interest with scientific misconduct. In other words, we do not know whether conflicts of interest are positively, negatively or simply uncorrelated with practices defined by ORI as scientific misconduct.

According to conventional wisdom, scientists who are charged and found guilty of misconduct are no more likely than not to have a conflict of interest. Of course if we include all sorts of potential conflicts in defining conflicts of interest in science such as the desire to succeed, or get a grant or be the first to publish in a new area, we may not be able to disaggregate science from other interests. Not all scientists have financial conflicts of interests, but probably all scientists have interests in succeeding, getting promoted and receiving grants. But through its laws and traditions, our society distinguishes financial interests from the other types of interests that are not separable from the research enterprise.³ I therefore focus on financial conflicts of interest for which there are clearly defined boundaries. Is there a relationship between “having a financial conflict of interest” and “scientific misconduct.” This is a researchable question

although it has not been empirically investigated. In this essay I shall examine the unexplored links between financial conflicts of interest (COI) and scientific misconduct. Also, I shall discuss the advisability of including non-disclosure of conflicts of interest, ghost writing, and fabricating credentials within the category of scientific misconduct.

**Investigating a link between COI and Scientific Misconduct.**

After a thorough search in the scientific literature I did not find any studies that showed an association between COI behavior and scientific fraud or misconduct. But I also could not find a study which framed a hypothesis that such an association exists. The connection between COI and scientific misconduct can be framed as a testable hypothesis. In one such experiment, one might look at all cases of demonstrated scientific misconduct, as determined by ORI, and ascertain what percentage of these cases had a component of financial conflict of interest. It certainly would mean something if there were a strong commercial affiliation of people found to have violated scientific norms in only 5-10 percent of the cases of misconduct; however it would mean something quite different if the great majority of the cases had a financial COI component. To be conclusive, such a study would also require a control, a matching group where the researchers possess a much lower COI activity.

All the ORI cases involve funding from the Public Health Service (PHS). But these cases are not coded or investigated by conflict of interest categories. It is quite possible that the driving force behind “scientific misconduct” is not financial interests but rather involves other motives such as building a resume for promotion or fierce competition in a fast moving field. However, a study of the association between COI and “scientific misconduct” might not be very fruitful unless there was a way to determine whether COI was involved in the misconduct and what its relevance was. Moreover, most of the research on conflict of interest has focused on cases where the funding came exclusively from private sources, and therefore do not fall under the aegis of the ORI even if there were allegations of scientific misconduct. Thus, there is a disjuncture between the cases we know about conflict of interest and the cases we know about scientific misconduct that make the study of their overlap problematic.

In ascertaining whether there are any connections between COI and misconduct we have to have clear definitions of both. The U.S. has adopted a narrow definition of misconduct in comparison to that adopted in the United Kingdom. The ORI’s definition derives from the 1996 U.S. Commission on Research
Integrity; improper appropriation of the intellectual property or contributions of others; intentionally impeding the progress of research; corrupting the scientific record or compromising the integrity of scientific practice. In contrast, a British consensus panel defined research misconduct in 1999 as “behaviour by a researcher, intentional or not, that falls short of good ethical or scientific standards.” The breadth of the British definition of misconduct can include many more categories, including ethical breaches, that would not qualify under the ORI trilogy of fabrication, falsification and plagiarism. My first point will be to look at “ghost writing” in science as a form of plagiarism.

**Ghostwriting as Misconduct**

The role of ghost writing or ghost authorship in the biomedical sciences is well established. Ghost authorship occurs when the person whose name appears on the publication was not involved either in doing the research, framing the ideas behind the article, or in writing the article. Alternatively, it also occurs when an individual who has made substantial contributions to the manuscript was not named as an author or whose contributions were not cited in the acknowledgments. The incentives for participating in ghost-written publication are two-fold. For a company, let us say a drug company, the incentive to find a ghostwriter is to have a prominent scientist support the company’s product in a professional publication (medical journal), including a commentary or editorial. When a drug is being considered for off-label use, the manufacturer is prohibited from promoting such use before the drug has been approved by the Food and Drug Administration (FDA). But a scientist or physician can support its use without the same restriction. By orchestrating ghost-written papers, companies can get publicity for off-label uses of drugs without violating the law. They simply craft an article, hire a company to find a willing scientist, and find a journal that will publish it.

David Cullen, formerly Editor-in-Chief of the Journal of Clinical Anesthesiology, described the process in a journal commentary. He included a sample letter sent to his colleagues with redacted names.

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Dear Dr. ____:

Thank you for agreeing to review the enclosed article titled ___. As mentioned during our phone conversation, ___ is working with ___ on publishing this paper. We’d like to submit this article for publication as soon as possible. Please give the article a cursory review and let me know within a few days if you are interested in authoring this paper. If so, please send any revisions to me by Friday, September 6th. Please feel free to take complete editorial control, adding, changing, or deleting whatever you feel is necessary. (We’d like the neurosurgery section to be expanded (sic) a bit.) Indicate your changes on the enclosed copy. We will make these changes and return a manuscript, styled according to the journal’s guidelines, for you to submit. ___ will obtain permission from the publishers to use borrowed figures/graphics. If you prefer to work from a disk, please let us know. We’ve targeted Journal of Clinical Anesthesia as the journal for this article. If you have another journal in mind, please let me know. ___ will pay you $1000 for authoring this article. If you have any questions, please call. My direct line is ___. I’m looking forward to talking to you.

Thank you.
Sincerely yours,

Cullen described how this process corrupts scientific integrity.

“The potential for bias inherent in such an approach is obvious. The article may not have been written by an objective independent practitioner but by an unnamed source working for the drug company whose job it was to use this drug in a new setting, thereby enlarging the drug’s market. It is especially concerning that this was a review article because available negative data about the drug could be withheld, and only positive references to the use of the drug in this particular situation could be included.”

After an investigation into the practice of ghostwriting, the British newspaper The Observer reported “hundreds of articles in medical journals claiming to be written by academic doctors have been penned by ghostwriters in the pay of

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drug companies.” 7 Ghost writers, once used in journal supplement articles paid for by companies, have now become commonplace in mainstream journals. The signatories of the articles frequently do not even see the raw data about which they are writing. 8 Cullen explained how the process of soliciting ghost writers works in his field of anesthesiology where potential phantom writers are screened and sent letters asking them to sign a pre-written paper. 9

Flanagan et al. surveyed authors from randomly chosen list of 1,179 articles. Questionnaires were returned by 809 corresponding authors, of which 93 responses (11%) indicated that ghost authorship had occurred. 10 Another study published in PLOS Medicine reported a high prevalence of ghost authorship in industry-initiated clinical trials in Denmark. 11

If plagiarism is considered a condition for investigating scientific misconduct for recipients of funds within the U.S. Public Health Service, then why does biomedical science turn a blind eye to ghostwriting? Isn’t ghostwriting a form of plagiarism, namely, taking authorship credit for an article that one has not written? Conflict of interest is one of the drivers of ghost authorship. An editorial in the New Zealand Medical Journal raises the connections, among ghost authorship, research dishonesty, and conflict of interest. 12 The authors of ghost-written articles cannot meet the criteria for authorship as defined by the International Committee of Medical Journal Editors (ICMJE).

A substantial subset of biomedical scientists and physicians who agree to sign their name to an article written by another party do so for financial reasons and not simply to accrue another article on their resume. This is one of the cases

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where COI and scientific misconduct are co-dependent. According to Ngai et al (2005), “while most ghost authorship in medical research is ethically questionable, a potentially worrisome form aims to conceal conflicts of interest with industry.”13 Transparency in these cases would remove the incentive for paying for ghost authors and signatories because it would undercut the secrecy necessary to avoid penalties to drug companies for promoting off-label uses. While Ngai et al opine that “ghost authorship jeopardizes the integrity of academic publishing...masks conflicts of interest...and disconnects authorship from accountability”14 they do not classify it as “scientific misconduct.”

**Suppressing Unfavorable Results**

Few would deny that fabricating data or intentionally biasing one’s interpretation constitutes scientific misconduct. This might include throwing away data that does not conform to one’s expected hypothesis, ignoring outliers without declaring them, or tweaking the data so that they support a sponsor’s financial interests. For science to advance, it must display and address all the evidence. Selecting only the evidence that supports one’s prejudice or interests may be suitable to advocacy lawyers and ideologs, but such behavior is antithetical to responsible science. Should a conscious effort to suppress data be considered a form of scientific misconduct? Does conflict of interest impact this type of misconduct? There have been a number of highly visible cases in which negative findings have been suppressed? In the corporate community, data suppression is part of doing business. John Rengen, a former business executive for Eli Lilly in Sweden for eight years, in an interview reveals the policy of a leading drug company for distorting the scientific record.

“It is no secret that studies of medications, which have had bad outcomes, are often not published. They are also not presented to their authorities who decide about licensing of those medications…I made friends with so-called opinion makers or those who wanted to be; and I manipulated them into suppressing the side effects in their contributions and to submit positive votes.”15

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Studies have revealed that scientists also, at times, withhold results either because they have not been fully mined for their intellectual property or they do not support the desired ends of the scientist. A survey of 2,200 scientists found that more than 410 delayed publication more than 6 months (within the previous three years). Of the 410 who held back results, 28 percent indicated that it was to delay publication of undesired results.  

Because some drug companies did not publish unfavorable data, when their drugs were examined in the published literature, they appeared more effective and safer than they really were. For example, Bayer A.G., the German-based pharmaceutical company, withheld from federal drug officials the results of a large clinical study that indicated a widely used heart surgery drug increased the risks of death and stroke.

Whittington et al. examined the published and unpublished clinical trials of a class of drugs used to treat childhood depression. The unpublished clinical trials showed an unfavorable risk/benefit ratio compared to the published trials. The authors wrote: “Non-publication of trials, for whatever reason, or the omission of important data from published trials, can lead to erroneous recommendations for treatment.”

The revelation that clinical trial data are selectively published has prompted some observers to call for a centralized registration of all clinical trials. As a condition for publication in their member journals, the ICMJE requires relevant authors to register their trials in a public registry.

A study of the drug Celecoxib found a positive association with combined effects of lower incidence of gastric ulcers and ulcer complications. But the

authors only reported six months of their data when they had twelve months of data.\textsuperscript{22} The full data set reveals a different risk outcome. Another prominent and highly visible study in which results were withheld from \textit{NEJM} by investigators was the Vioxx Gastrointestinal Outcomes Research (Vigor) trial. According to the editors of the journal:

“The Vigor study was designed primarily to compare gastrointestinal events in patients with rheumatoid arthritis randomly assigned to treatment with refecoxib (Vioxx) or naproxen (Naprosyn), but data on cardiovascular events were also monitored. Three myocardial infarctions, all in the refecoxib group, were not included in the data submitted to the \textit{Journal} [NEJM]….Until the end of November 2005, we believed that these were late events that were not known to the authors in time to be included in the article published in the journal [NEJM] in November 23, 2000.”\textsuperscript{23}

The journal editors saw a memorandum that was obtained by subpoena in the Vioxx litigation indicating that at least two of the authors were aware of the three myocardial infarctions two weeks before the authors submitted revisions of the article. The withheld data resulted in misleading conclusions on the safety of the drug. While not rising to the level of scientific fraud, some observers recognize that both misrepresenting data in publication and selectively reporting results is a deviation from accepted scientific practices and qualifies as a form of scientific misconduct.\textsuperscript{24} Because there are very possibly so many examples of such practices and great difficulty in reaching consensus over whether they represent laziness, incompetence or unintentional honest mistakes, scientists have been hesitant to classify them as misconduct and incorporate them into a punitive structure. Few would deny from the record that financial conflict of interest represents one of the leading motives behind willful withholding of scientific data and distorting the evidentiary record behind a theory, hypothesis or causal claim.


There is no consensus among professional societies, journals, and universities over what constitutes a reasonable delay in publication of a study and the grounds for justifying any delay. For example, intellectual property is often used as a reason for delaying publication. However, doing so to hide data that may affect drug sales is considered unethical. The International Committee of Medical Journal Editors (ICMJE), which has set high ethical standards for publication, offers no explicit time standards for delaying publication in its guidelines, which state: “researchers should not enter into agreements that interfere with their access to the data and their ability to analyze it independently, to prepare manuscripts, and to publish them.”

A national survey of medical schools found that institutions rarely insure that investigators have the right to publish their findings and rarely comply with ICMJE guidelines.

Falsifying Credentials

Several years ago I was asked to serve as an expert witness for the plaintiff in a case involving two companies that manufactured latex gloves. The plaintiff alleged that the defendant made false and misleading advertising claims that impacted their market share of glove sales. The issue I was asked to address was the alleged false credentials of a chief company scientist.

The scientist in question was the Global Medical Affairs Director at Regent Hospital Products. In his opening remarks during the trial, the attorney for the plaintiff, Allegiance Healthcare Corporation, stated:

“Regent represented at one time or another to the public that Ms. Fay [Global Medical Affairs Director] had a bachelor’s degree from Columbia University in New York; that she had a Ph.D. from the University of Minnesota, Minneapolis, St. Paul, that she had done post doctoral studies in immunology at Cornell University, and at other universities, that she was a professor of surgery at the University of Virginia Medical School. Regent claims that Ms. Fay was a member of the National Science Foundation, and the National Academy of Science, and the American


Academy of Science. All of these claims are false…None of them are true."\textsuperscript{27}

After checks were made at the universities where Ms. Fay allegedly had received degrees and appointments, the plaintiff’s allegations of her falsified scientific credentials were confirmed. Regent executives and Ms. Fay admitted under oath that Ms. Fay had a nursing degree and all other claims were fabricated.

As chief scientist for the company’s glove division, Ms. Fay managed a $20 million budget to support research that would favor her division’s products. She dispensed this money to academic scientists at prestigious universities. They trusted Ms. Fay’s credentials and allowed her to edit and write papers under their name. During the trial her role in shaping academic science became more obvious. The head of Regents responded to questions by the plaintiff’s attorney about Ms. Fay’s collaboration with other scientists.

Q. Sir, you are aware that Ms. Fay during her employment with Regent was ghostwriting articles to be published under the researcher, other researchers’ names?
A. I was aware.
Q. You were aware, sir, as the highest officer of the defendant, in the United States, that not only was Ms. Fay ghost-writing articles…your public relations firm was ghost-writing articles for researchers?
A. I believe that is correct, yes.\textsuperscript{28}

Ms. Fay did not practice medicine without a license. She did practice science without credentials, but there is no law against falsifying your scientific credentials unless you perjure yourself or submit false documents to certain federal agencies, such as federal funding agencies. But is it a form of scientific misconduct to claim scientific credentials that you do not possess? So much of science involves a trust relationship among similarly trained individuals. Referees cannot observe scientists recording their data. Rarely, do referees or journal editors get to see the raw data from an experiment. Students of science


\textsuperscript{28}. Krimsky, 2003, p. 120.
internalize the norms of research integrity from years of mentorship. Without the training and mentoring there can be little confidence that someone has mastered the craft of science.  

Deborah Parrish, writing in the *Professional Ethics Report* asks whether falsification of credentials should be considered “scientific misconduct.” It is certainly possible for someone to do sound research with false credentials. Should scientific misconduct be focused exclusively on the research rather than on other peripheral issues such as false claims about one’s credentials? Parrish notes that both the ORI Office and the National Science Foundation treat false credentialing claims as a form of scientific misconduct. She reports that in 1994 four of ORI’s eleven scientific misconduct findings involved falsified credentials. Also, NSF reported that it had misconduct findings based on false credentialing claims.

ORI states that in certain circumstances fabrication or falsification of credentials can be considered research misconduct. “Falsification or fabrication of a researcher’s credentials in an application for HHS funds can result in a finding of research misconduct. A review of credentials and publications during the peer review process may be critical for determining if an individual is capable of performing the proposed research.” In one case reported by the ORI, an assistant professor was charged with falsifying his grant application to NIH for 11 years by claiming he had a Ph.D from Northwestern University. His institution investigated his credentials and learned he had a mail-order doctorate from a place called Northwestern College of Allied Sciences in Tulsa, Oklahoma, which was not accredited by the Oklahoma Regents of Higher Education. Even with this information, the ORI could not reach a conclusion by a preponderance of the evidence that the assistant professor was responsible for the submission of the false credentials.

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But in another case, Eric Poehlman was sentenced to a year in prison after he was convicted of submitting the results of falsified and fabricated reports in his grant applications to NIH. Compared to investigations on data manipulation and fabrication, it would seem that investigating a false credentialing claim is far less complex and unambiguous than investigating allegations of falsified data. Universities keep records that are usually fairly accurate of who attended and what degrees he or she was awarded. There have been cases in which a resume introduced with a grant application had false or inaccurate claims about schools attended. The only question is whether the applicant intentionally filed a false claim or that it was an inadvertent mistake possibly committed by another party. Scientists (and others in academia) who obtained their positions based on false credentials are likely to be terminated when discovered even if they have performed well because it is universally considered to be an egregious ethical violation. Those who use false credentials on grant applications can be punished severely. However, unlike false credentialing in academic job applications, which is believed to occur at a relatively low probability, conflict of interest among scientists is pervasive. In what respect, if any, is conflict of interest related to misconduct?

**Distortion of Research: The Funding Effect**

In a background paper prepared for a joint consensus conference on misconduct in biomedical research, Richard Smith, then editor of the *British Medical Journal*, developed what he termed “a preliminary taxonomy of research misconduct.” At the top of the 15 categories is “fabrication” (invention of data and cases) while the last is “failure to do an adequate search of existing research before beginning new research.” Thirteen from the top is “not disclosing a conflict of interest.” No one has argued that possessing a conflict of interest constitutes a breach of scientific integrity. But increasingly journal editors and bioethicists have held that failure to disclose such conflicts constitutes such a breach even rising to the level of scientific misconduct. The detractors of such a position have a different point of view.

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In a lengthy and acerbic letter to the journal *Environmental Science & Technology*, president and principal scientist of the company Applied Pharmacology & Toxicology, Inc. Christopher Borgert wrote that the demand by journals for disclosure of interests among scientists “erodes the epistemological basis of scientific reasoning because it focuses subjectivity on the participants in science rather than objectively on the scientific evidence.”

According to Borgert:

> “In science, the facts are asked to first speak for themselves in order to enhance objectivity. The method of science randomizes, double-blinds, measures, controls for biases and confounders, tests probabilities, and replicated in order to remove the participants as far as possible from the process of observation and interpretation... Scientists should advocate transparency of the scientific process and should insist that scientific journals, funding agencies, and peer-review bodies abandon demands of financial and political disclosure in favor of accessible and verifiable data and transparent methods as the *exclusive* determinants of scientific merit. To do otherwise is to accede to the invidious doctrine of antiscience interests bent on deciding issues by ad hominem arguments rather than by testable facts.”

In order to understand why the disclosure of conflicts of interest has become so important to research integrity, we must look at how these conflicts affect the quality of science. If science has numerous built in controls for reducing subjectivity and bias, then why should there be a “funding effect” in science? That is, why do we continue to produce studies that show that private funding of research is biased in support of the financial interests of the sponsor. If that bias is real and not an artifact of the studies, how serious is it in distorting the record of science and should the systematic bias of science resulting from or contributed by financial conflict of interest be considered a form of scientific misconduct?

Research into the relationship between the funding of science and the outcome of research findings were not undertaken prior to the mid-1980s. By the 1990s, because of a growing interest in conflict of interest, a number of published

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studies revealed the existence of the funding effect in biomedical research.\textsuperscript{37}

Let’s take a few examples. The best predictor of whether a review article came out positively or negatively on the hypothesis that there are health effects from passive smoking was whether the author had a conflict of interest. That factor weighed more heavily on the conclusion than the quality of the review.\textsuperscript{38}

In the field of nutrition, authors who studied the relationship between author association with food companies and their position on the fat substitute olestra found that 96 percent of the nutritionists who supported olestra, compared with 50 percent of neutral authors and 44 percent of critical authors, had financial relationships with at least one company in the food and beverage industry.\textsuperscript{39} In a study of studies in the biomedical sciences, Bekelman \textit{et al.} found that the outcome of scientific studies can be influenced by COI relationships. The authors concluded, “Evidence suggests that financial ties that intertwine industry, investigators, and academic institutions can influence the research process. Strong and consistent evidence shows that industry-sponsored research tends to draw pro-industry conclusions.”\textsuperscript{40} In another study illustrating the funding effect Stelfox \textit{et al} found “a strong association between authors’ published positions on the safety of calcium-channel antagonists and their financial relationship with pharmaceutical manufacturers.”\textsuperscript{41} Similar illustrations of the funding effect have been found in other drug efficacy and safety studies including randomized drug trials, as well as studies of addictive behavior, second-hand smoke, new-versus old therapies, metaanalyses, nutrition and climate change.


\textsuperscript{39} J. Levine, J.D. Gussow, D. Hastings, and A. Eccher. Authors’ financial relationships with the food and beverage industry and their published positions on the fat substitute Olestra. \textit{American Journal of Public Health} 93:664-669 (April 23).


CONCLUSION

Conflict of interest is an ethical problem for one or more of the following reasons. First, it can be a hidden factor of potential bias that may not be known to referees, journal editors, and readers of the study or publication. This can be addressed by the adoption of a universal disclosure policy for journals, advisory groups, clinical guidelines, books and book reviews.

Second, the funding effect demonstrates that research sponsored by for-profit companies tends to support the financial interests of those companies in comparison to similar research funded by government or not-for-profit sources. Universal disclosure will not resolve this issue, although it may raise the bar of constructive skepticism for reviewers and thus may result in improvements in the methodology, data analysis, and interpretation of studies.

Finally, conflicts of interest can affect the public’s confidence in scientific results. Specifically, scientists who have conflicts of interest are viewed by some as another stakeholder in an arena of multi-vested parties. With that comes the loss of disinterested arbiters of contested scientific claims. Some commentators have given up on “disinterested” as a norm in science. John Ziman wrote that in the modern “post-academic” university “disinterestedness” no longer operates. Nevertheless, he believed that science can still yield objective knowledge, particularly if the self-corrective nature of science functioned successfully through the norm of “organized skepticism” (high level of critical appraisal) held by the members of the scientific community persists and is not affected by commercial interests.42

If we take seriously the result that conflicts of interest can affect the quality of science, when there are multiple ways one can bias the results of a study, then it behooves us to accept any secrecy around disclosing one’s competing financial interests in the subject matter of one’s research. Some journals have considered taking punitive actions against authors who fail to report their competing interests. The American Association of Thoracic Surgery, which publishes the Journal of Thoracic and Cardiovascular Surgery, decided to issue tough sanctions against any author who does not disclose his or her conflicts of interest in a publication of the journal. The sanction may include barring an individual and their institution from publishing in the journal for some designated period of

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time. Catherine DeAngelis, editor-in-chief of the *Journal of the American Medical Association*, informed the institutions of several authors who failed to disclose their financial interests related to the subject matter of an article that appeared in the journal. DeAngelis noted: “Three times in the last 18 months, I have asked for investigations by deans, and all three times, appropriate sanctions were taken against the authors that were far more severe than anything I could have done.”

Scientists should accept full disclosure of conflicts of interest just as they should support full disclosure of data (rather than selective data reporting) or as they should accept reporting on the limitations of a study. There is precedent for legal claims against a clinical investigator who failed to disclose his conflicts to a patient who enrolled himself in a clinical trial. Withholding financial conflicts of interest can result in a published study that does not receive the full critical scrutiny it deserves. This might be viewed as a form of scientific misconduct because knowledge of conflict of interest has become relevant for evaluating the potential bias of the author, whether conscious or unconscious, in the published article.


Addressing Scientific Misconduct

FRAUD AND MISCONDUCT IN SCIENTIFIC RESEARCH: A DEFINITION AND PROCEDURES FOR INVESTIGATION†

Victor M. Catano,* and James Turk**

Abstract: Scientific fraud and misconduct appear to be on the rise throughout the scientific community. Whatever the reasons for fraud and whatever the number of cases, it is important that the academic research community consider this problem in a cool and rational manner, ensuring that allegations are dealt with through fair and impartial procedures. Increasingly, governments have either sought to regulate fraud and misconduct through legislation, or they have left it to universities and research institutions to deal with at the local level. The result has been less than uniform understanding of what constitutes scientific fraud and misconduct and a great deal of variance in procedures used to investigate such allegations. In this paper, we propose a standard definition of scientific fraud and misconduct and procedures for investigation based on natural justice and fairness. The issue of fraud and misconduct should not be left to government regulation by default. The standardized definition and procedures presented here should lead to more appropriate institutional responses in dealing with allegations of scientific fraud and misconduct.

† This paper is based on an earlier and more extensive discussion paper developed by Dr. Don Savage in 1992 for the Canadian Association of University Teachers (CAUT) and subsequently modified over time by CAUT’s Academic Freedom and Tenure (AF&T) Committee. Dr. Catano is currently the Chair of the AF&T Committee; Dr. Turk is the Executive Director of the CAUT and Dr. Savage, now retired, is the former Executive Director of the CAUT. We thank Dr. Savage and the many members of the AF&T Committee who have contributed to revisions of the original document over the years. The longer version may be found at www.caut.ca/en/policies/fraud.asp. A related document is a model clause developed by CAUT to integrate procedures for investigating allegations of fraud and misconduct into collective agreement language; the model clause is available at www.caut.ca/en/services/collectivebargaining/modelclauses/mc_fraud.asp

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Keywords: Scientific fraud, scientific misconduct, definition of scientific fraud, investigating fraud and misconduct.

Fraud and Misconduct in Scientific Research: A Definition and Procedures for Investigation

Dr. Steven Bruening, a member of the Department of Psychiatry at the University of Pittsburgh, was the first university research scientist in the United States to face charges arising from American statutes that made it a crime to make false statements in an application for federal research funds and made it a crime to conceal information from a federal agency investigating allegations of such fraud. Bruening was director of a medical school program involving evaluation and treatment of mentally retarded children on a short-term basis. He received federal funding to study the use of Ritalin and Dexedrine on hyperactive mentally retarded children. Bruening did not, in fact, study the number of patients he reported, did not conduct the research he claimed at the university, and invented the results of his non-existent or partial experiments. He tailored the false results to the then current wisdom in the profession that the drugs were overused. Bruening plea-bargained and pled guilty to two charges of false grant applications. He received two concurrent two-year sentences and was banned from working as a research psychologist for ten years.

We distinguish between academic and scientific fraud and misconduct in the following way. Academic fraud and misconduct pertains to all scholarship carried out in the academy while scientific fraud and misconduct is restricted to what is generally accepted as the natural and social sciences and that research need not be carried out in an institution of higher learning.

There is little doubt that scientific fraud and misconduct, particularly in medicine and the biomedical sciences is on a rapid increase despite the risks involved. The US Department of Health and Human Services’ Office of Research Integrity (ORI) reported in its December 2006 Newsletter that from 1992-2002, 529 institutions reported some allegation or form of scientific misconduct, with 281 of these institutions reporting incidents more than once over the 10-

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year period. There is a wide variety of incidents that constitute scientific misconduct. Several cases reported in the same issue of the ORI Newsletter involved falsifying and fabricating patient and scientific data. Other issues of the ORI Newsletter report even more serious cases. The March 2006 issue describes the case of a cancer research specialist who had been sentenced to 71 months in federal prison for the criminally negligent homicide of a research subject who died in a drug trial as a result of the specialist’s fraudulent manipulation of subject protocols to enroll a subject who did not meet the protocol guidelines. Scientific fraud and misconduct is not unique to North America; studies show its existence in both the UK and Scandinavia.  

Estimates of serious research misconduct vary; Steneck, a former senior consultant at the ORI, estimated from accumulated evidence that 1% of researchers engaged in serious misconduct. Questionable research practices that do not directly damage the integrity of the research process are estimated to occur at rates ranging from about 5% for publishing the same data twice to 28% for inadequate record keeping.  

Research and scholarship are core activities of the university. If they are allowed to be contaminated by fraud and misconduct, the widespread trust in the integrity and intellectual honesty of university research will be quickly lost.  

It is, however, one thing to state the principle; it is quite another to devise a fair, equitable and effective way of dealing with allegations of fraud and misconduct. Crusaders against research fraud in academe tend to think that such charges are self-evident and that the guilty parties should be cast instantly into outer darkness. They frequently like the sound of sweeping, vague and accusatory language. Or they devise unrealistic codes of ethics motivated by a puritanical

zeal that makes the results unworkable. Korn\textsuperscript{8} argues that it is not the role of government to define and proscribe ethical boundaries, but that of academia and professional societies.

One possible result of misguided zeal is over-regulation. We do not want to create within the universities an atmosphere that encourages only the blandest and safest research. A sense of proportion is required both in writing regulations and administering them. Academic energy should be directed to dealing with serious cases of falsification, fabrication, plagiarism or breach of the laws and governmental regulations concerning research conduct. Structures should not be created that serve to magnify minor offenses or to promote personal or intra-departmental vendettas. Universities must distinguish between the trivial and the serious. Failure to do this, whether in procedures or penalties, is apt to discredit the process. For example, administrators should not demand drastic penalties for trivial offenses, thereby provoking in all likelihood, long arbitrations which have serious cost implications for the university and for the faculty but not for the administrators personally. The distinction between minor or trivial offences and serious ones is subjective; however, we would characterize trivial offences as those which have no bearing on the safety of the participants or the outcome of the study. These could include such minor, technical offences as being late in making an annual report to the research ethics board.

One might argue that fraud in medicine is a special case, given the possible impact on human lives. The same possibility, of course, exists in a number of other scientific and engineering disciplines within the university. But above and beyond the consequences of particular fraudulent experiments, there is a more general matter of public policy. Such a scandal taints the whole university and all those working in it. It undermines public trust in the research enterprise. If the university tolerates one fraudulent scientist, how can anyone be sure that the remainder is not fraudulent as well? Moreover most university research is funded by the federal or provincial governments. They are only going to continue this funding if they think that such research is in the public interest. They are more likely to believe this if they think that university researchers are willing to address the issue of fraud and to root it out. Failure to do so will undermine the autonomy of universities and provide an excuse for governments to intervene in their affairs.

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Under Canadian granting policies, if universities wish to receive research funds for their staff, they are expected to investigate allegations of fraud and to establish impartial and accountable procedures to deal with allegations of misconduct. The procedures that are developed must be acceptable to the university community. Ideally they must be part of negotiated collective agreements, but, if not that, they must be presented in written form as institutional policies. Established procedures are a basic principle of due process. It is unacceptable to be developing policies and procedures on the fly as cases are being investigated. In such circumstances hysteria and panic frequently replace reason. Procedures should focus on legitimate areas of concern; be as simple, clear and straightforward as possible; and not improperly interfere with the privacy rights of academic staff. University policies should not undermine a researcher’s academic freedom to investigate controversial topics that may be upsetting to individuals, the broader community, or government and business leaders. Neither should those policies infringe on a researcher’s right to make fair comment on events or individuals.

Even the best arrangements can be corrupted. It is, for example, possible for large and wealthy corporations to use legal or administrative complaints to undermine researchers who question the claims of corporate products. Corporations can simply manufacture repeated allegations of misconduct, thus forcing the researchers to spend large amounts of money and time defending themselves, or give up the research. Universities and research institutes must vigorously defend their researchers in such circumstances.

As allegations of fraud and misconduct can destroy careers, it is imperative that universities and research institutes have procedures to determine the prima facie validity of claims to minimize publication of false accusations. Where there appears to be a valid claim, the university should ensure that there is a fair and independent way of adjudicating the matter. The first step is to have a clear understanding of what constitutes scientific fraud and misconduct.

**Definition of Academic Fraud and Misconduct**

Nylena *et al.* note that the diversity of definitions of scientific dishonesty makes a definition elusive. More recently, Steneck 6 has tried to resolve the

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issue of definition by focusing on irresponsible behaviours in scientific research, but that begs the question of what does constitute scientific fraud. Fraud has both a legal and a popular connotation. In law it means conscious deceit leading to profit or unfair advantage. Because of the stringency of that legal definition, federal government departments and other organizations in the United States such as the National Science Foundation (NSF) and the Public Health Service (PHS) have suggested using the word “misconduct” rather than fraud. The cases cited above are examples of fraud and/or misconduct. However, it is important to understand not only what academic research fraud or misconduct is, but what it is not.

A scientific experiment that leads nowhere is not fraudulent, nor is it misconduct if a scientist makes deductions from a particular piece of evidence which a reasonable person could make, even if the deduction turns out to be wrong. For it to be misconduct, there must be an element of calculated deception. Honest errors, which can occur in any enterprise, are not misconduct, nor are debatable scientific judgments about experimental design. The pursuit of a particular approach that may prove wrong can, nevertheless, lead to important, unanticipated discoveries, despite the lack of validity of the original conception.

While sloppiness in the conduct of research is undesirable, it is not necessarily research misconduct. Questionable scientific practices may be a cause for discipline by the sponsoring institution, but such practices are only misconduct if they lead to false results or cause harm to research subjects. Another form of misconduct is the bias introduced into studies by apparent conflicts of interest. Prominent among these concerns in recent years is the relationship of study outcomes that are favorable to companies or organizations that fund the research; 15.5% of respondents (N=3247) in a recent survey reported, “Changing the design, methodology or results of a study in response to pressure from a funding source.”

The Canadian Association of University Teachers (CAUT) developed a definition of fraud and misconduct, along with procedures for their investigation\textsuperscript{14,15}. CAUT had hoped that the definition and procedures would be used by all universities and granting agencies, rather than institutions establishing a hodge-podge of definitions and procedures that varied across the country. The CAUT definition has evolved over time and now incorporates five major points into its definition. The first is a statement of what does not constitute fraud or misconduct, followed by statements on fraud, misconduct, conflict of interest and financial fraud:

1. **Factors not Constituting Fraud:**
   \begin{itemize}
   \item[(a)] Factors intrinsic to the process of academic research and scholarly activity such as honest error, conflicting data, or differences in interpretation or assessment of data or of experimental design or practice do not constitute fraud or misconduct.
   \end{itemize}

2. **Fraud is:**
   \begin{itemize}
   \item[(a)] fabrication, falsification, or plagiarism
   \item[(b)] failure to obtain the permission of the author before using new information, concepts or data obtained through access to confidential manuscripts or applications for funds for research or training that may have been seen as a result of processes such as peer review.
   \item[(c)] failure to recognize by due acknowledgement the substantive contributions of others, including students, or the use of unpublished material of others without permission, or the use of archival materials in violation of the rules of the archival source.
   \end{itemize}

3. **Misconduct is:**
   \begin{itemize}
   \item[(a)] material failure to comply with relevant federal or provincial statutes or regulations for the protection of researchers, human subjects, or
   \end{itemize}


\textsuperscript{15} CAUT. Discussion paper on fraud and misconduct in academic research and scholarship. 1994 [cited 2007 March 4]; Available from URL: www.caut.ca/en/policies/fraud.asp
for the health and safety of the public or for the welfare of laboratory animals; or

(b) material failure to meet other reasonable legal or contractual requirements that relate to the conduct of research, including those related to the conduct or reporting of research activity and the retention of research data

(c) material failure to follow fair and reasonable rules on authorship including the attribution of authorship to persons other than those who have participated sufficiently in the work to take public responsibility for its intellectual content.

(d) submission for publication of articles originally published elsewhere except where it is clearly indicated in the published work that the publication is intended to be a republication.

4. Conflict of interest is:

(a) failure to reveal to sponsors, universities, journals or funding agencies, any material conflict of interest, financial or other, that might influence their decisions on whether the individual should be asked to review manuscripts or applications, test products or should undertake work sponsored from outside sources.

(b) failure to reveal to the university any material financial interest in a company that contracts with the university to undertake research, particularly research involving that company’s products. Material financial interest would include ownership, substantial stock holding, a directorship, significant honoraria or consulting fees but would not include routine stock holding in a large publicly traded company.

5. Financial fraud is:

(a) Fraudulent diversion of the research funds of the university, federal or provincial granting councils or other sponsors of research.

Procedures for Investigating Allegations of Fraud and Misconduct
A reasonable policy on fraud and misconduct should set out a clear and sensible definition of fraud and misconduct as noted above. That policy should establish fair and reasonable procedures for the investigation of any allegations of fraud.
or misconduct. If, in the opinion of the administration, a case has been made, it should move to discipline the academic staff member concerned who should have the right to challenge the merits of the administration’s position through the process of grievance and arbitration. Allegations of fraud can ruin the career of an academic. They should not be made lightly, and they should be judged according to the highest standards of procedural justice. Everyone so accused has a right to have their case heard by an independent third-party adjudicator or arbitrator.

As part of its policy, the university should designate a senior official to be responsible for the handling of allegations of research fraud and misconduct. The existence of the office should be widely publicized. Allegations of wrongdoing should be made to the designated officer. The senior official in charge of the office should have a sense of fairness and should be able to distinguish between misconduct, differences of opinion, and incompetence. The senior official should be able to refuse cases, which are vexatious or frivolous.

The faculty member, against whom the complaint has been made, should be informed immediately of that complaint and of any investigation that may be conducted into the allegation. The faculty member should be informed of his or her rights, including the right to be accompanied by a legal representative. The institution’s policy should clearly indicate whether any initial discussions with the faculty member are “without prejudice” or if they will be quoted in subsequent proceedings.

The senior official should determine through reasonable, confidential and thorough inquiries whether a prima facie case exists with respect to the allegation. This process may well require expert advice from outside the university rather than only internal sources who may be biased in their opinions as the allegations may touch upon their own reputations. If outside experts are used, the senior official should put the case to them in a fair and unbiased way without leading questions and assumptions of guilt. Outside experts and their reports should be available at any future hearing for examination. Experts who were approached for an opinion should not then be asked to sit as a member of any subsequent tribunal that may hear the case.

If the senior official believes that there is a prima facie case with respect to the allegation of fraud or misconduct, that opinion should be conveyed to the appropriate institutional authority. It is then the decision of that authority to determine whether to initiate disciplinary proceedings against the member of
the academic staff in question. Such proceedings must be carried out in accordance with any collective agreement that applies to the faculty member or, in the absence of relevant collective agreement provisions, with prevailing institutional policies. Generally, these procedures will refer the case directly to an independent arbitration panel where the faculty member should have all the normal rights inherent in an arbitration including formal notification, a clear and precise statement of the issues, the right to legal counsel, the right to examine and cross-examine all witnesses and to see all documentation including the authorship of any allegations, opinions or other statements. If there has been some form of administrative hearing prior to the arbitration, the arbitrators should nevertheless hear all testimony de novo. In other words, the administrative hearing should not in any way preempt the arbitration procedures.

Institutional policies should specify the timelines for any investigation and mandate adherence to those deadlines. It is imperative that charges of fraud and misconduct be investigated quickly. The case of Dr. Gabrielle Horne illustrates this point. Dr. Horne holds appointments at both the Capitol District Health Authority and Dalhousie University in Halifax, Nova Scotia. She has both a PhD and MD and is an eminent researcher in adult cardiology. In October 2002, Dr. Horne was told that her hospital privileges were being varied because her research conduct had threatened the safety of patients and that she had breached research ethics in handling patient charts. The charges effectively shut down Dr. Horne’s research and her laboratory. Under the terms of the Capitol Health Authority’s By-laws, the charges were to have been investigated within a two-week period from the initial variance. It was not until September 11, 2006, almost four years after it took action against her, that the Capital District Health Authority concluded that it should not have used the emergency privileges variation procedure in the By-laws against Dr. Horne. But it still suggested that corrective action was justified. Although the CDHA Board determined that Dr. Horne’s status should revert back to what it was before her privileges were varied, it left a shadow over her career and left her research in shambles.

The institutional policy should also establish procedures for the protection of those individuals who brought forward the allegations and any witnesses, should they subsequently be sued by the accused. They should be given independent counsel as their interests and those of the university may diverge at some point. For example, Dr. Horne was not provided independent counsel by the Capital District Health Authority, and she subsequently sued the authority for breach of contract and loss of earnings. She was ultimately awarded $1.5 million in damages.

point. The institution should make it clear that it will not protect those who provide false information, if they knew or ought to have known that it was false at the time of the accusation. The regulations should also allow the institution to take disciplinary action where accusations prove to be false, reckless and malicious, and to pay the legal costs of the victim.

Furthermore the institution should be required to take all reasonable steps to restore the reputations of those falsely accused. In today’s world, people are convicted in the court of public opinion once charged with an offence even before any evidence is brought forth. Institutions should bear the responsibility of acting quickly to re-establish the good name and reputation of the falsely accused. This can be done by the institution (1) informing all agencies, publishers or individuals who were aware of the charges of the results of its investigation clearing the individual(s); (2) providing legal counsel to any witnesses who in good faith participated in the investigation from any lawsuits arising out of their participation; and (3) ensuring that any disruption to research, teaching and service resulting from the allegations of fraud and misconduct do not adversely affect the future careers who have been cleared of such charges.

CONCLUSION

There is much speculation as to why fraud takes place. In certain circumstances the cause may be a psychological disorder similar to kleptomania. There are certainly cases where it would appear that the perpetrator kept committing and escalating the fraud in a manner that suggested to subsequent inquirers that the person desired to be caught.

Other researchers are so driven by their commitment to their original hypothesis that they blind themselves to any conflicting evidence and seriously distort or invent the data to justify their original inspiration. An example from the nineteenth century was Samuel G. Morton, one of the leading practitioners of the science of craniology. He firmly believed that the volume of the skull dictated intelligence, and that volume varied by race. He conducted experiments on more than 1,000 human skulls to prove his point. In 1978 Stephen Jay Gould of Harvard University recalculated Morton’s data and showed that Morton had misused that data to achieve the result that he wished, namely that blacks were inferior to whites17.

In other circumstances it is greed or the search for fame or both that motivated

fraud or misconduct. Given the large sums of money that can be involved in university research, it is not surprising that some have been tempted. Also, the increasingly single-minded productivity-driven research culture of science can lead some to justify bending the rules to produce results that will be published in prestigious journals and help win large research grants for them, their lab, their university or research institute. Related to this is the pressure to publish at all costs. Quantity rather than quality encourages slipshod and dishonest work. Similar pressures arise from the intense competition for tenured posts and for promotion. Technological advances have also made it easier to fabricate and to forge, for example, to create illustrations for which there is no data or to change photographic evidence. The Internet has made plagiarism easier, to “cut and paste” without proper attribution. What is remarkable is not that cases of fraud and misconduct in research have occurred, but that, given the enormous volume of scientific and scholarly work, there are relatively so few of them that have proven fraudulent.

Whatever the reasons for fraud and whatever the number of cases, it is important that the academic research community consider this problem in a cool and rational manner, ensuring that allegations are dealt with through fair and impartial procedures. The issue of fraud and misconduct should not be left to the government by default. We hope that the definition of academic fraud and misconduct presented here, along with the provisions for investigating allegations of fraud and misconduct, will contribute to more appropriate responses in dealing with these matters.
Investigating Scientific Misconduct

SCIENTIFIC MISCONDUCT AND LIABILITY FOR THE ACTS OF OTHERS

Roy G. Spece * and Carol Bernstein **

Abstract: We argue that two ambiguities in [U.S.] Public Health Service ("PHS") misconduct regulations make them so vague that they are unconstitutional and unfair: (1) they provide no guidance concerning when one can be held responsible for others’ actions; and (2) they simultaneously are intended to allow misconduct findings only when there are “significant departure[s] from established practices of the relevant research community” but even if one complied with customary standards of practice in her research community, thus providing confusion rather than guidance. The effect of these ambiguities is not only to leave researchers without notice as to proscribed or prescribed conduct but also to give officials discretion to apply the regulations arbitrarily and discriminatorily. The regulations’ effect is illustrated by applying them, hypothetically, to facts relating to the central charge in the misconduct case pressed by the University of Arizona in 1997 through 2003 against then Arizona Regents’ Professor Marguerite Kay.

Keywords: U.S. Public Health Service; Misconduct regulations; Marguerite Kay case

This article analyzes two of the ambiguities in the scientific misconduct regulations that govern [U.S.] Public Health Service (“PHS”)-funded research.¹ These ambiguities make the regulations so vague that they deny due process of law and are fundamentally unfair: (1) they provide no guidance concerning when one can be held responsible for others’ actions; and (2) they simultaneously

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¹ Additional and sometimes related ambiguities are discussed in our companion piece in this theme issue: Med Law (2007) 26:493-510.
are intended to allow misconduct findings *only when* there are “significant departure[s] from established practices of the relevant research community” but *even if* one complied with customary standards of practice in her research community, thus providing confusion rather than guidance concerning when customary standards can be overridden. The effect of these ambiguities is not only to leave researchers without notice as to proscribed or prescribed conduct but also to give officials discretion to apply the regulations arbitrarily and discriminatorily. The regulations’ effect will be illustrated by applying them, hypothetically, to facts relating to the central charge in the misconduct case pressed by the University of Arizona in 1997 through 2003 against then Arizona Regents’ Professor Marguerite Kay.  

The current PHS regulations, significantly amended in 2005, replace “scientific misconduct” with “research misconduct” and define the offense as follows:

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. (a) Fabrication is making up data or results and recording or reporting them. (b) 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. (c) Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. (d) Research misconduct does not include honest error or differences of opinion.”

The regulations also stipulate the following “requirements for findings of research misconduct:” (a) There be a significant departure from accepted practices of the relevant research community; and (b) The misconduct be committed intentionally, knowingly, or recklessly; and (c) The allegation be proven by a

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3. 42 C.F.R. § 93.103 (as amended 2005).
It must be pointed out before discussing ambiguities concerning the meaning of research misconduct that the requisite findings are made in the first instance by panels of one’s peers—i.e., professors and scientists who usually have little or no legal training. Moreover, there is no substantial body of reported opinions to which these laypersons can turn for guidance. This situation invites confusion, error, and inconsistency in application of the regulations. Although one theoretically can pursue appeals all the way to a de novo hearing before an administrative law judge, the reality is that this is often beyond the financial and emotional resources of a researcher who is found guilty within her own institution. For example, in the Marguerite Kay case, local proceedings consumed several years at an expense of well over a million dollars to the University itself. At the end of the process, Kay was left bankrupt, emotionally exhausted, and apparently unable to pursue relief within the federal bureaucracy.

It is our “gut” opinion that the failure of the regulations to provide for financing of counsel for accused researchers, the inability of most researchers to afford counsel and ancillary resources necessary to fight an institution on relatively even terms, and the possibilities for research misconduct proceedings to become instruments of institutional politics should deter countries with research cultures similar to those in the United States from creating a scientific misconduct apparatus. If they nevertheless do establish such an apparatus, they should provide for financing of counsel for accused parties, explicitly include making of false charges within the definition of scientific misconduct, and avoid ambiguities such as those discussed here.

Given the nature of research, it is obvious that misconduct allegations can address situations in which multiple personnel perform various functions within complex experimental protocols. It is therefore axiomatic that misconduct

5. 42 C.F.R. § 93.310 to 93.313 (as amended 2005).
6. 42 C.F.R. §§ 93.500–523 (as amended 2005). (The administrative law judge’s decision is forwarded to the Assistant Secretary for Health, who makes the final administrative ruling.)
regulations should specifically address when researchers are liable for the actions of others. Liability for the actions of others can be with or without fault. Vicarious liability is when A, regardless of any culpable behavior on her part, is held responsible for the actions of B solely because they have a certain relationship, such as principal/agent or employer/employee. (To simplify the discussion all such situations will be referred to herein as principal/agent relationships.) Vicarious liability is similar to strict liability, which is personal liability imposed on persons or entities regardless whether they have engaged in any culpable behavior. Vicarious liability is usually imposed on a principal who has not engaged in any culpable behavior because of the fault of her agent. This is not strict liability because there is fault, the agent’s. There can be vicarious and strict liability simultaneously, however, if the law imposes liability on the agent regardless of fault. Vicarious liability is nevertheless similar to strict liability because it imposes liability on the principal regardless of any personal fault. Vicarious liability must also be distinguished from liability for misconduct or harm done by another that is imposed on a person because she has contributed to the misconduct or harm. For example, a principal can be held liable for negligence of, or harm done, by an agent that was made possible because the principal negligently chose or failed to supervise the agent.

The PHS regulations, just as their predecessors applicable since 1989, do not state whether they intend to create vicarious liability, nor do they specify the degree of personal culpability, if any, there must be before one can be held liable for the actions of colleagues or assistants. In the absence of explicit direction, one must seek guidance in the law generally. Tort and criminal law are the most salient areas in which principles of vicarious and joint liability are relevant. One should not seek guidance as to research misconduct regulations in the tort law, because the primary tasks and purposes in the two areas are significantly different. The primary task in the tort law is to decide which of two parties should bear loss when it occurs, while its primary purpose is to award compensation to injured victims. Scientific misconduct proceedings, on the other hand, are designed to protect the public by punishing misconduct. Scientific misconduct proceedings are therefore analogous to criminal rather than tort law adjudication.

The following explanation by a criminal law authority concerning the differences in application of vicarious liability to criminal and tort law are therefore apt as to scientific misconduct and tort proceedings:

‘In tort law, the doctrine is employed for the purpose of settling the incidence of loss upon the party who can best bear such loss. But the criminal law is supported by totally different concepts. We impose penal treatment upon those who injure or menace social interest, partly in order to reform, partly to prevent the continuation of the anti-social activity and partly to deter others. If a defendant has personally lived up to the social standards of the criminal law and has not menaced or injured anyone, why impose penal treatment?’… [It is one thing to hold that the faultless [principal] ought to pay for the damage which his [agent] (often impecunious) inflicts upon third persons in the course of furthering his [principal’s] business; it is much more drastic to visit criminal punishment and moral condemnation upon the [principal] who is innocent of any personal fault.10

It is equally drastic and a departure from the basic premise of scientific misconduct proceedings to impose vicarious liability on a researcher. Recall that scientific misconduct is defined to require that, at a minimum, there be reckless behavior. This is beyond the baseline of fault - i.e., negligence - ordinarily required in the tort law.

There are rare instances of vicarious liability in the criminal law. However, vicarious liability can only be applied in the criminal context when a statute manifests a legislative intent to impose it. Insofar as relevant here, there are two types of statutes: those that specifically impose liability on the principal for the bad conduct of his agent and those that do not specifically impose vicarious liability but explicitly delineate the degree of wrongful conduct required for the agent to be liable.11 As to the latter, “it is the rule that the [principal] must personally know or be willful or have the requisite intention to be liable for the criminal conduct of his [agent]; even though the latter is acting to further his


11. Id. at 373-374.
[principal’s] business, the [principal] is not criminally liable unless he knew of or authorized that action.”12

The PHS regulations do not specifically impose vicarious liability, but they do, once again, expressly provide that misconduct can only be found if there is reckless behavior. Therefore, if one were to follow the general body of doctrine developed in the criminal law, a researcher could not be liable for the actions of a colleague or assistant unless she were shown to have been personally reckless, say, in choosing or failing to monitor the colleague or assistant.

Although this is how the PHS regulations should be interpreted, one cannot be confident that they will be so construed. Explaining why this is so requires some “legislative” history. The PHS regulations were amended in 2005 because of a Uniform Federal Policy (“UFP”) promulgated by the Office of Science Technology Policy (“OSTP”) in 2000.13 The UFP required all federal agencies to promulgate misconduct regulations consistent with the UFP within one year.14 When commenting on the UFP’s adoption, the OSTP drew an analogy to federal debarment proceedings.15 The federal debarment regulations explicitly address when individuals will be held liable for the actions of other persons, stating: “We may impute the fraudulent, criminal, or other improper conduct of any organization to an individual, or from one individual to another individual, if the individual to whom the improper conduct is imputed either participated in, had knowledge of, or reason to know of the improper conduct.”16 Moreover, at least some debarment actions require willful or more egregious misconduct,17 and the reference in the just quoted passage to fraudulent behavior connotes intentional misrepresentation. Intentional and willful both connote actual knowledge,18 while “reason to know” connotes something less culpable than intentional or willful conduct.19

12. Id. at 374-375 [brackets substituting “principal” for “employer” and “agent” for “employee”].
14. Id.
15. Id. at 76262.
17. Id. at 66,552, § __.800.
Thus, the debarment regulations at least in certain instances seem to allow one culpability standard for direct or personal liability and a less stringent standard for imputed liability. There is good reason to believe that misconduct panels might similarly apply an imputed liability standard less protective to the accused than the general “reckless” standard the PHS regulations specify for direct liability. In fact, they might apply an imputed liability standard even less protective than the debarment regulations’ “reason to know” standard—perhaps even a negligence or strict liability standard. Who has not heard a colleague state: “A researcher is responsible for everything that occurs in her lab, her grant, or her project”? Such statements signify that some researchers are willing to apply a negligence standard, or even vicarious liability, to misconduct situations. As explained below, it appears that Marguerite Kay was subject to vicarious liability and dismissed from her Regents’ Professorship at the University of Arizona.

By not speaking to vicarious liability, the PHS regulations both fail to give researchers sufficient notice of what conduct is prescribed or proscribed and invite arbitrary and unequal application. These are the factors that characteristically compose violations of due process. To avoid this constitutional difficulty and patent unfairness, the regulations should be construed to allow imputed liability only when the researcher is personally guilty of reckless behavior.

The ambiguity concerning imputed liability is exacerbated by the PHS regulations’ explicit requirement that “[t]here be a significant departure from accepted practices of the relevant research community.” This requirement should be analyzed in light of its “legislative history.” The OSTP observed as follows when announcing the UFP:

Issue: Several comments stressed the need for greater precision in the phrase “significant departure from accepted practices of the scientific community.” Response: This phrase is intended to make it clear that behavior alleged to involve research misconduct should be assessed in the context of community practices, meaning practices that are generally understood by the community but that may not be in a written form. For clarification purposes and in order to be more comprehensive, the term


“scientific community” has been modified to read “relevant research community.” The policy is not intended to ratify those “accepted practices” but rather to indicate that these may vary among different communities.22

Similarly, the PHS observed as follows when announcing proposed amendments to its regulations in 1999:

Burden of Proof: We propose to revise slightly the burden for establishing research misconduct in three ways: First, in keeping with the OSTP policy, the proposed regulation would require that the FFP be a “significant departure” from accepted practices as opposed to ORI’s current standard of “serious deviation.” As discussed in the OSTP policy statement, the phrase “significant departure” intends to make clear that behavior alleged to invoke research misconduct should be assessed in the context of practices generally accepted by the relevant research community.23

The PHS regulations proposed in 1999 and those finally adopted in 2000 are identical on this topic. This legislative history therefore shows that the PHS has gone from a “serious deviation” to a “significant departure” standard without any explanation of the possible difference in meaning between these two phrases. “Serious deviation” seems to connote a greater dereliction than does “significant departure.” In any event, researchers are left to wonder about the meaning of “significant departure” and bureaucrats are given wide latitude to give the vague term a broad range of meaning from case-to-case.

The PHS comment above seems wholly illogical. It is not the phrase “significant departure” that speaks to specific research communities, but, rather, the phrase “generally accepted by the relevant research community.” Moreover, the OSTP’s comment quoted above seems to provide that a researcher can be found guilty even if she did not significantly deviate from the practices in her research community by stating “the policy is not intended to ratify those ‘accepted practices’ but rather to indicate that these may vary among different communities.” There is no mention of what criteria should determine when an “accepted practice” is not to be ratified and must be replaced by a better one. Furthermore, the regulations and comments read together are contradictory.

The regulations state unequivocally that there must be a significant deviation from accepted practices, but, at the same time, the comments state that accepted practices are not ratified, meaning that a researcher can be found guilty even if she followed accepted practices in her research community. A researcher would seem to be guilty of, at most, an honest error or difference of opinion if she followed the “accepted practices” in her relevant research community but the decision makers felt those practices were inappropriate. This is because, as indicated above, research misconduct is defined so as not to include honest errors or differences of opinion.24

Furthermore, the reference to “significant departure” rather than “serious departure” invites decision makers to find merely negligent conduct to constitute misconduct. Professional negligence is typically defined in terms of deviation from accepted standards of care, and accepted standards of care are not ignored unless they are shown to be unreasonable. Accepted standards of care in the tort law seem to be directly analogous to “accepted practices” in the PHS regulations. Following this analogy, the next step up from ordinary negligence is gross negligence, which requires a “gross” or particularly egregious deviation from accepted standards of care. “Significant departure” can easily be interpreted to be less than “gross,” and that leaves negligence as the default baseline standard for liability. Given that the PHS regulations generally require willful misconduct, however, “accepted practices” in one’s research community should not be ignored unless those practices are shown to be reckless.

Applying the PHS regulations to the central charge against then Arizona Regents’ Professor Marguerite Kay shows how they can lead to unjust, erroneous, and unconstitutional results.25

Marguerite Kay spent her childhood in orphanages and foster homes, worked her way through high school and college, and had a meteoric career accentuated by becoming the first woman at the University of Arizona to be awarded the State’s highest academic honor, a Regents’ Professorship. On December 7,

24. See text at note 3 supra.

25. This article does not purport to give a complete descriptive or normative history of the Kay case. It only addresses the case against Kay as presented to the University of Arizona Faculty Senate on December 7, 1998. Copies of a video of that presentation are on file with both authors although the description here is the work of Professor Bernstein. The legal discussions herein are the work of Professor Spece.
1998, then University of Arizona President Peter Likins gave a thirty-eight
minute presentation to the Faculty Senate to present the evidence he relied
upon to determine, as the final decision maker, that Kay was guilty of scientific
misconduct and should be fired. He said he focused all his energy on a single
instance of misconduct in order to make a judgment whether he should adopt
the recommendations of the faculty adjudicatory panel that Kay be disciplined.
This conduct related to data presented in a table included in an article published
by Kay.26 Kay supplied the data she had access to relating to the table—
primarily in the form of another printed table provided to her by a lab technician
named Jeff Poulin—to the faculty panel during its proceedings. Likins displayed
the table provided by Poulin to Kay to the Faculty Senate. This table showed
that there were ten paired points in the original data set from which Kay’s
published table was derived; however, the faculty adjudicatory panel deduced
that probability values showing that the results obtained for test subjects differed
significantly from those of the controls in the table in her article were based on
a truncated set of seven paired data points. Likins emphasized that Kay’s
production of the underlying data showed that she was guilty.

Specifically, the faculty panel studied the data supplied by Kay and then
performed a twenty minute calculation to determine the significance of the
dropping of data. This significance was not on the face of the data table
supplied by Poulin to Kay, the table displayed by Likins to the Faculty Senate.
Likins explained that the significance was apparent from the faculty panel’s
calculations that were added in handwriting, at the behest of the adjudicators,
to the face of Poulin’s printed data table. He repeatedly pointed out that
“technicians” such as those who Kay used to collect and analyze data, such as
the disputed data, typically do not even have bachelor’s degrees, and that this
made clear that all responsibility for dropping any data points belonged to Kay,
saying “[w]e are not talking about coauthors here, just lab technicians, most of
whom do not even have bachelor’s degrees.”

26. Marguerite Kay & Joseph Goodman, Brain and Erythrocyte Anion Transporter Protein,
Band 3, as a Marker for Alzheimer’s Disease: Structural Changes Detected by Electron
Yet Likins went on to observe that the truncated data set was not very central to the point being made in the table in Kay’s article, and rhetorically asked why Kay would manipulate the data given that this might not have even been needed to make her point. Specifically, he explained that her point was supported, albeit less robustly, by the full data set. Any scientist can tell from a cursory reading of the article, moreover, that the conclusions suggested in its Table 1 were peripheral to the article’s main point that Alzheimer’s disease has an immunological component. Finally, Likins stated that he took comfort in a meeting with then College of Medicine Dean Dr. James Dalen and Kay’s then Department Head, Dr. Jack Marchalonis, in which they agreed that she was guilty of misconduct: “The recognition of her responsibility of this scientific misconduct also occurred in the minds of Dean Dalen and Professor Marchalonis.”

Likins’ presentation was misleading at best. First, Dr. Marchalonis stated that he explicitly told Likins that Kay was not responsible for the dropped data points and that she should be exonerated. Marchalonis later honored Kay’s request, made pursuant to University rules, that she be judged by a panel of her peers in the relevant medical fields. The panel consisted primarily of College of Medicine faculty with appropriate expertise, but it also included outside experts in the relevant medical fields. That panel found her innocent on all charges.
Second, contrary to Likins’ implication, the technician who supplied the data to Kay, Jeff Poulin, in fact had a bachelor’s degree and had even co-authored four papers with Kay.\(^{29}\)

Third, although Likins drew the inference that Kay’s production of the underlying data to the faculty panel showed that she was guilty, the common sense inference to be drawn is 180 degrees to the contrary. If she was a corrupt scientist as alleged and she even suspected that the additional data Poulin supplied to her might show inappropriate manipulation, she would have simply stated that she did not have access to that data. Kay testified that she prepared her article and Table 1 in that article (not to be confused with the separate table supplied by Poulin and displayed by Likins, with handwritten calculations added, to the Faculty Senate) based on a summary of data communicated to her by Poulin on the telephone.\(^{30}\) He later faxed her the printed table displayed by Likins to the Faculty Senate (of course without the faculty panel’s handwritten calculations) after the article had been accepted for publication.\(^{31}\)

Given that the panel did the calculations revealing the dropping of data and added them to the table supplied by Poulin, they were not available to Kay. She had no reason to believe that the faxed data did not fully support the summary of data supplied to her by Poulin on the telephone and used by her to create the table in her article, and therefore she did not realize that there had been any dropped data until the faculty panel did the calculations necessary to demonstrate


\(^{31}\) Id. at 13:2-11.
that this was the case. Poulin, who refused to testify under oath before the faculty panel, stated that Kay never requested that he drop specific data to manipulate findings. Rather, he thought this was expected of him as a matter of custom and practice: “She didn’t specifically say ‘drop this number and that number.’ I think it was assumed that I could see which one was too extreme and decide that on my own.”

One other Kay employee, an aide without a bachelor’s degree, testified that Kay directed her to falsify data. However, Likins presented only one instance of data manipulation—that relating to Poulin’s unsupervised data manipulation. Kay did not see a need to micro-supervise him because she trusted him as a competent and trustworthy colleague, as evidenced by her co-authorship with him on four papers. All other witnesses, including those called by the prosecutors, testified that they were never asked to participate in, nor were even aware of any, data fabrication in the Kay lab. How could this be if fabrication were a custom and practice in the Kay lab?

It is likely that Likins would never have reached a decision to fire Kay based on the evidence he presented to the Faculty Senate if the applicable regulations had been sufficient to comport with the requirements of the Due Process Clause of the Fourteenth Amendment to the United States Constitution and of basic fairness. It should be noted that Kay claimed to be a whistleblower. This could possibly explain her firing based on Likins’ flawed analysis because there

32. V CAFT Hearing, supra note 30, at 210: 12-17 (Kay Testimony).
33. III CAFT Hearing, supra note 30, at 111:15-19 (Poulin Testimony).
34. Letter from CAFT Hearing Panel to President Likins 3 (May 4, 1998) (on file with authors).
35. VI CAFT Hearing, supra note 30, at 69:17—70:5 (Doug Johnston Testimony); II CAFT Hearing, supra note 30, at 222:23—223:21 (Crystal Rockey Testimony); IV CAFT Hearing, supra note 30, at 51:7-20 (Dr. Charley Adams Testimony); IV CAFT Hearing, supra note 30, at 85:21—86:14; 91:23—92:3; 94:1—95:7 (Dr. Debra Gamble Testimony); Dr. Timothy Wyant Declaration (not accepted by the CAFT panel).
are many examples of erroneous adverse sanctions being applied to whistleblowers.\textsuperscript{37}

In any event, neither the then extant nor the current PHS regulations would necessarily be construed by faculty decision makers to prevent Kay from being vicariously liable for Poulin’s misconduct. As explained above, neither the current nor the previous PHS regulations even address the issue of imputed or vicarious liability.\textsuperscript{38} In these circumstances, the decision makers might hold researchers vicariously liable for the derelictions of their colleagues and assistants. In fact, that is apparently what Likins did by “reasoning” that Kay was responsible for Poulin’s data manipulation. He apparently did not even study the matter closely enough to realize that Poulin was not one of the lowly assistants he referred to as not even having bachelor’s degrees, but was, rather, a degreed researcher with whom Kay had co-authored four papers.\textsuperscript{39} The clear implication Likins made was that one is vicariously liable for any mistakes made by assistants; there does not have to be any level of personal culpability.

Conclusion

If the [U.S.] PHS regulations properly addressed when a researcher is liable for the actions of others, they would only allow such liability when a researcher is personally guilty of reckless misconduct that allows the third party to engage in fabrication, falsification, or plagiarism. If they correctly spoke to when a researcher can be found liable despite following “accepted practices” in her research community, they would only allow disregard of “accepted practices” when those practices are shown to be reckless. To avoid constitutional infirmity and basic unfairness, the regulations should be interpreted to incorporate these limitations. Applying the regulations to facts relevant to the central charge against Marguerite Kay without the guidance suggested in this article shows how they can become instruments of destruction.


\textsuperscript{38} See text at note 9 supra.

\textsuperscript{39} See text at note 29 supra.
Acknowledgement

Roy G Spece and Carol Bernstein have been critics of the University of Arizona Administrations’ handling of the Marguerite Kay case. Roy Spece has written of the case in articles and Carol Bernstein was a faculty member in Kay’s department during the time of the proceedings.
Investigating Scientific Misconduct

WHAT IS SCIENTIFIC MISCONDUCT, WHO HAS TO (DIS)PROVE IT, AND TO WHAT LEVEL OF CERTAINTY?
Roy G. Spece * and Carol Bernstein **

Abstract: This article traces the regulation of [U.S.] Public Health Service (“PHS”)-funded research from changes begun with the proposal (1999) and then adoption (2000) of a basic, Uniform Federal (“research misconduct”) Policy. It argues that the PHS misconduct regulations deny due process of law and are fundamentally unfair because they fail to specify the level of culpability for guilt, force accused researchers to prove that they are innocent, and, although admittedly quasi-criminal, adopt a standard of proof that tolerates nearly a 50 percent probability of false convictions. The regulations’ infirmities will be demonstrated by applying them to facts relating to the central charge in the misconduct case pressed by the University of Arizona in 1997 through 2003 against then Arizona Regents’ Professor Marguerite Kay, which facts are set forth in our companion piece in this theme issue.

Keywords: Research misconduct; Recklessness; U.S. Public Health Service; Standard of proof; Office of Science Technology Policy.

This article traces the regulation of [U.S.] Public Health Service (“PHS”)-funded research from changes begun with the proposal (1999) and then adoption

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1. Federal Policy on Research Misconduct, 65 Fed. Reg. 76260 (Off. of Sci. & Tech. Pol’y Dec. 6, 2000); initially published for public comment at 64 Fed.Reg. 55722-25, (Oct. 14, 1999). This Policy uses the term “research misconduct” and that term and “scientific misconduct” will be treated as equivalent in this article. We will also frequently use “misconduct” to refer to scientific or research misconduct.
(2000) of a basic, Uniform Federal ("research misconduct") Policy ("UFP").

It argues that the PHS misconduct regulations deny due process of law and are fundamentally unfair because they fail to specify the level of culpability for guilt, force accused researchers to prove that they are innocent, and, although admittedly quasi-criminal, adopt a standard of proof that tolerates nearly a 50 percent probability of false convictions. The regulations’ infirmities will be demonstrated by applying them to facts relating to the central charge in the misconduct case pressed by the University of Arizona in 1997 through 2003 against then Arizona Regents’ Professor Marguerite Kay, which facts are set forth in our companion piece in this theme issue.

The UFP, promulgated by the Office of Science Technology Policy ("OSTP") in 2000, “consists of a definition of research misconduct and basic guidelines for the response of Federal agencies and research institutions to allegations of research misconduct.” The Policy stated that it was to be implemented by federal agencies’ more detailed provisions within one year.

The UFP defines research misconduct as follows:

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

2. Although this paper focuses on the PHS regulations and does not attempt to survey and compare various agencies’ regulations, the same infirmities are likely to inform other agencies’ regulations because each agency is required to conform its regulations to the UFP also discussed in the text. That Policy defines misconduct and the standard of proof applicable to it.

3. For brief descriptions of this case and references to other materials relating to the case see Roy G. Spece & John J. Marchalonis, What Should the Standard of Proof Be in Scientific Misconduct Proceedings Relating to Public Health Service-Funded Research? 49(4) CELLULAR & MOLECULAR BIOLOGY 565, 567-70 (2003) [hereinafter Spece & Marchalonis, Standard of Proof] (see note 3infra for a better indication of the standard of proof in each state based on the Federation of State Medical Board’s yearly direct board surveys) ; Roy G.. Spece & John J. Marchalonis, Fourth Amendment Restrictions on Scientific Misconduct Proceedings at Public Universities, 11 HEALTH MATRIX 571, 581-585, 622-26 (2001) [hereinafter Spece & Marchalonis, Fourth Amendment Restrictions]. The authors of this and the cited articles were all outspoken critics of the University of Arizona Administrations’ handling of the Kay case.

4. See note 1 supra.

5. Id.
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.6

The UFP also states that “[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.”7

When the OSTP was considering the UFP, the then current PHS working definition of scientific misconduct required a finding of intentional fabrication, falsification, plagiarism, or other serious deviation from accepted practices within the scientific community and explicitly excluded “honest error or honest differences in interpretations of judgments of data.”8

PHS did not formally propose regulations until April 16, 2004.9 At that time, it explained that it was adopting the UFP’s use of the term “research misconduct” as well as the Policy’s definition of that term and its expansion of “the level of intent” “beyond an intentional and knowing standard to include recklessness.”10 It also observed:

[T]he proposed regulation is consistent with the OSTP position on who has the burden of proving honest error or a difference of opinion. Proposed sections 93.106(a) and 93.516(c) provide that the respondent bears the burden of proving any affirmative defenses raised, including honest error and differences of opinion and any mitigating factors that the respondent wants the institution or HHS (Department of Health and Human Services) to consider in imposing administrative actions. Section 93.106(a) provides that once the institution or HHS makes a prima facie

6. Id. at 76262.
7 Id. at 76260.
10. Id. at 20779, 20780.
showing of research misconduct the burden of going forward to prove that the conduct was the result of an honest error or difference of opinion shifts to the respondent.\footnote{Id. at 20780.}

The proposed regulations also incorporated the UFP’s “preponderance of the evidence” standard of proof,\footnote{Id. at 20790, proposed 42 C.F.R. § 93.106.} defined “preponderance of the evidence” as “proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not,”\footnote{Id. at 20791, proposed 42 C.F.R. § 93.220 .} and defined “prima facie showing” as “evidence that on its face is sufficient to establish research misconduct in the absence of respondent’s presentation of substantial contradictory evidence.”\footnote{Id. at proposed 42 C.F.R. § 93.221.}

The PHS adopted final regulations on May 17, 2005.\footnote{70 Fed. Reg. 28370 (2005) (to be codified at 42 C.F.R. pts. 50 & 93).} PHS did not change the proposed regulations’ definition of “research misconduct,” expansion of the mens rea or level of required culpability beyond “knowing” to “reckless,” or adoption of the preponderance of the evidence test. It included a section addressing the burdens of proof:

(1) The institution or HHS has the burden of proof for making a finding of research misconduct. (2) The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether HHS or the institution has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible credible evidence of honest error or difference of opinion presented by the respondent.\footnote{Id. at 28386.}

**The Indeterminate Meaning of “Reckless”**

As explained above, the regulations expand liability beyond intentional and
knowing conduct to include “reckless” behavior. In 1993, Dresser wrote that even intent itself was an insufficiently precise term to define the level of culpability required for a finding of misconduct, stating: “There is a disturbing lack of clarity regarding the specific conduct that ought to be the focus of professional, institutional, and government attention.” She recommended that scientific misconduct regulations draw on decades of refinement of the criminal law reflected in the Model Penal Code (“MPC”) for guidance in defining the necessary level of misbehavior.

The “disturbing” situation Dresser addressed is now much worse. Intent at least seems to convey to nonlawyers the idea that the accused must have known that she was doing something wrong. Now, however, there can be liability for reckless behavior, and the PHS regulations simply refer to “reckless” behavior without including the definitions of that term from the MPC or any other source. Not even the most sophisticated attorneys can define “reckless” or “recklessness” if the term is not accompanied by more specific definitions. For example, “reckless” has different meanings within the MPC, on the one hand, and the Restatement (Second) of Torts, on the other hand. The primary difference is that although both require that the defendant’s behavior portend a substantial level of danger, the MPC requires actual knowledge of the danger, while the Restatement (Second) of Torts does not require such actual knowledge.

There is even authority that it can constitute a denial of due process to make

18. R. Dresser, Defining Scientific Misconduct: The Relevance of Mental State, 269 JAMA. 895, 896 (February 17, 1993).

19. Id. at 896. Dresser also suggested that mere negligence be included within the ken of “misconduct,” albeit with lesser sanctions. We believe this to be ill-advised because “misconduct” carries with it a stigma too pungent to apply to merely negligent professionals, including scientists. In fact, it is our impression that virtually all professionals are negligent on rare occasions. It is an exaggeration to characterize infrequent lapses as “unprofessional.” It is beyond the scope of this article to fully explore either that point or our further belief that “recklessness” too does not merit the characterization of unprofessional conduct unless it is further defined to require conscious disregard of serious danger to important interests. We invite others to consider these issues.

certain allegedly reckless behavior criminal even when there is some specification of the meaning of “reckless.” Although in the criminal context specification is sometimes considered to occur by implicit incorporation of the meaning ascribed to the term over decades of criminal adjudication, there is no such defense of the bare use of reckless in the misconduct context. There the decision maker does not know whether to turn to criminal, tort, or another body of law for the required specification.

To avoid the possible constitutional infirmity and clear unfairness, the PHS regulations use of a recklessness standard should be interpreted to require that the accused have knowledge that her behavior creates a serious risk of interfering with the pursuit of scientific advances or of physically harming individuals.

**Requiring the Accused to Prove that She Is Innocent**

Here it is necessary to trace the history of the concepts of honest errors and differences of opinion as they relate to the definition of misconduct. The first PHS regulations defining misconduct in August of 1989 stated “[i]t does not include honest error or honest differences in interpretations or judgments of data.” The UFP included almost the same language as the original PHS regulations insofar as honest errors or differences of opinion are

21. *City of Columbus v. Black*, Nos. 76AP-262 and 76AP-263, 1976 WL 190088 (Ohio Ct. App. Aug. 3, 1976) (Code section prohibiting solicitation to engage in sexual activity when the offender knows such solicitation is offensive to the other person or is reckless in that regard apparently found violative of both the First Amendment and the Due Process Clause of the Fourteenth Amendment). See also *State v. Boyer*, 512 S.E.2d 605 (Ga. 1999) (Sears, J. joined by Fletcher, J., dissenting) (reckless conduct statute that was specified to penalize conscious disregard of substantial and unjustifiable risk or harm to others unconstitutionally vague as applied to day care center employee who addressed a twelve-month-old child who would not sleep at nap time as follows: “Boyer lifted the child and ’plopped her on her belly’ and dragged the child’s sleeping mat a short distance; and that when the child ‘kind of popped up again … Boyer pushed her down by the back’”; the Justices felt the statute failed to give the defendant fair notice and encouraged arbitrary and selective enforcement).


concerned, stating: “Research misconduct does not include honest error or differences of opinion.” In fact, the UFP broadened the scope of the phrase by deleting the limiting words “in interpretations or judgments of data.” However, the OSTP included the following incomprehensible explanation in response to requests that the phrase be clarified:

Issue: Despite general support for the rationale for the phrase “does not include honest error or honest differences of opinion,” several comments requested various clarifications. Response: This phrase is intended to clarify that simple errors or mere differences of judgment or opinion do not constitute research misconduct. The phrase does not create a separate element of proof. Institutions and agencies are not required to disprove possible “honest error or differences of opinion.” The phrase has been retained, with the deletion of the second “honest” of the phrase as redundant.

On the one hand, the quoted language states that honest errors or mere differences of opinion are not research misconduct. It logically follows that there cannot be a finding of misconduct if there is an honest error or honest difference of judgment or opinion. However, the quoted language goes on to establish a contradiction by stating that the “phrase does not create a separate element of proof.” This is equivalent to misrepresenting that conduct can contain “X” and “non-X” as elements at the same time.

This illogic was apparently seized upon by bureaucrats at the PHS as an opportunity to make it easier to obtain convictions. To be sure, when it finally issued proposed regulations years after the deadline set in the UFP, the PHS retained the same phraseology excluding honest errors or differences of opinion or judgment from the definition of scientific misconduct. At the same time, however, it included sections designed to make honest errors or differences of opinion or judgment an affirmative defense as to which the accused has the burdens of presenting evidence and of persuasion.

At the same time, PHS defined “prima facie showing” as “evidence that on

24. See text at supra note 6.
its face is sufficient to establish research misconduct in the absence of respondent’s presentation of substantial contradictory evidence.” 27 Therefore, the prosecutors could establish a prima facie case without presenting any evidence whatsoever concerning honest errors or differences of opinion or judgment. Moreover, they would not have any burden of presenting such evidence until such time as the accused adduced “substantial contradictory evidence.” I doubt lawyers would be able to determine what constitutes “substantial” contradictory evidence because that term has been given many different legal interpretations. 28 Non-lawyers would have no point of reference whatsoever in applying this rule. Finally, even if the accused presents substantial evidence and thereby requires the prosecutors to present some contradictory evidence, the burden of persuasion is explicitly placed on the accused.

This itself poses constitutional questions because it is a rudimentary precept of Anglo-American jurisprudence that one is innocent until proven guilty. 29 This entails that the prosecutor has the burdens of presenting evidence and of persuasion concerning the elements of the crime charged. The plaintiff usually has the burdens of establishing her claims in the civil law as well, although there are exceptions. Defenders of the PHS regulations might argue that the regulations’ placement of burdens of proof regarding honest errors or honest differences of opinion or judgment on the accused is permissible because scientific misconduct proceedings are civil in nature.

However, the PHS subsequently admitted that the misconduct context is at least quasi-criminal in character when it tried to finesse the due process and fairness problems created by its proposed regulations regarding honest errors or honest differences of opinion or judgment. Specifically, when issuing final regulations, it “reasoned”:

There were a number of objections to that section on the grounds that shifting the burden of proving honest error or difference of opinion to the respondent effectively shifts the burden of the institution and HHS to prove each element of research misconduct or, at the least, creates

27. Id. at proposed § 93.221.
28. 32(a) C.J.S. Evidence § 1304 (2000).
confusion..

[W]e recognize that there is an overlap between the responsibility of respondents to prove this affirmative defense and the burden of institutions and HHS to prove that research misconduct was committed intentionally, knowingly, or recklessly. Accordingly, consistent with the opinion of the United States Supreme Court in *Martin v. Ohio*, we have amended Sec. 93.106 to require consideration of admissible, credible evidence respondent submits to prove honest error or difference of opinion in determining whether the institution and HHS have carried their burden of proving by a preponderance of the evidence that the alleged research misconduct was committed intentionally, knowingly, or recklessly.30

The quoted language does nothing to remove the contradiction between defining “misconduct” to explicitly exclude errors or differences of opinion of judgment and, simultaneously, making such errors or differences an affirmative defense as to which the accused has the burdens of presenting evidence and of persuasion. In fact, by citing to a United States Supreme Court case—*Martin v. Ohio*31—discussing the requirements of the Due Process Clause of the Fourteenth Amendment in the criminal context, the PHS admits that the scientific or research misconduct context is at least quasi-criminal in nature and should be governed by principles identical or at least similar to those within the criminal law.

The holding of *Martin* also indicates that the PHS regulations are unconstitutional. *Martin* reaffirms the constitutional mandate that the government must bear the burden of proof regarding each element of an offense but holds that this requirement is not violated by giving the accused the burden of proving an affirmative defense that consists of elements distinct from the offense charged.32 There, the offense was aggravated murder and the defense was self defense. The Court recognized that some evidence might be relevant to both elements of the offense and elements of the defense, but that the offense and defense were nevertheless distinct.33 The defendant was not required to

32. *Id.* at 231-232.
33. *Id.* at 230-234.
prove that she was innocent because the jury had been instructed that it should consider any evidence relevant both to the offense charged and to the claim of self defense when considering whether the elements of aggravated murder were present.\textsuperscript{34}

In \textit{Martin} there was no overlap in the elements of aggravated murder, on the one hand, and self-defense, on the other hand. This was true even though much evidence could be relevant to both the elements of aggravated murder and the separate elements of self-defense. In the PHS regulations, to the contrary, the offense of research misconduct is specifically defined so as to exclude honest error or differences of opinion.\textsuperscript{35}

It is obvious that the \textit{Martin} Court would have found the Ohio Code unconstitutional if it defined aggravated murder to explicitly exclude homicide committed in self-defense but then required the defendant to meet the burden of proof concerning self-defense. Yet this is the equivalent of what the PHS has done. Moreover, scientific misconduct and research misconduct have been defined to explicitly exclude honest errors or differences of opinion or judgment from the first promulgation of PHS regulations in 1989 to the present.\textsuperscript{36}

To be sure, the comments to the UFP and to the most recent PHS proposed and final regulations sheepishly attempt to pretend that honest error or differences of opinion or judgment have always been an affirmative defense. The explicit wording of the regulations has been consistently to the contrary.

At the very least, requiring a researcher to prove herself innocent if she invokes an honest error or difference of opinion is both likely to significantly confuse non-legally trained decision makers and certain to offend our traditional moral commitment against erroneous convictions. If this commitment is to be abandoned, the bureaucrats at PHS should be forced to openly state their intentions and to remove the language excluding honest errors or differences of opinion from the definition of misconduct. This would at least give the research community an opportunity to express outrage and seek appropriate

\textsuperscript{34} \textit{Id.} at 233.

\textsuperscript{35} \textit{See supra} text at notes 6 & 15-16.

\textsuperscript{36} \textit{Id.} and text at note 23 \textit{supra}.
amendments to the regulations.

The Standard of Proof Tolerates a Nearly Fifty Percent Probability of False Convictions

Commentators have recognized the impropriety of a preponderance of the evidence standard of proof in misconduct cases, but they have failed to appreciate that this deficiency is one of constitutional proportions. Dresser summarized the controversy that existed concerning the standard of proof in misconduct proceedings in 1993:

In the criminal setting, culpable behavior must be proven “beyond a reasonable doubt.” Should this high standard of proof apply in the misconduct setting as well? There is a broad range of opinion on this point. Some scientists reportedly believe that misconduct must be proven “not only beyond a reasonable doubt, but as in their own work in the laboratory, beyond the possibility of an alternative explanation.” According to the National Academy of Sciences panel, institutions and federal agencies now may adopt different evidentiary standards, ranging from the lowest (preponderance of the evidence) to the highest (beyond a reasonable doubt). The disparity is distressing. The interests of the accused scientist and of the public would be better served if a common proof standard were adopted.

Standards of proof serve to allocate the risk of an erroneous finding between the parties to a legal proceeding. The high standard applied in the criminal setting represents a judgment that the magnitude of the defendant’s potential losses justifies minimizing the chance of an erroneous conviction. Although the scientist found guilty of misconduct also has much to lose—career, reputation, livelihood—these losses are less substantial than the physical freedom and other deprivation imposed on the individual convicted of a serious crime. Courts and legislators have chosen an intermediate proof standard, “clear and convincing evidence,” to govern civil commitment, deportation, denaturalization, and other proceedings in which individuals face more than just monetary loss, but less than the heavy consequences of criminal conviction. It would be appropriate to apply this standard to scientific misconduct adjudications as well.37

37. Dresser, supra note 18, at 897.
Although, contrary to Dresser’s blanket statement, the consequences of scientific misconduct conviction can be more serious than those attendant to conviction of a crime, we agree that at least a clear and convincing evidence standard of proof is appropriate. The same conclusion was reached by Mello and Brennan in 2003:

Arguably … the potential penalties faced by researchers accused of scientific misconduct are sufficiently serious to warrant a higher standard of proof, such as “clear and convincing evidence.” … In the case of *Mathews v. Eldridge*, the Supreme Court developed a balancing test for evaluating the constitutional necessity for additional due-process protections in a range of circumstances…. Although misconduct investigations do not pose constitutional issues, this test provides a useful framework for thinking about reasonable safeguards for such investigations. It asks the adjudicator to weigh three factors: the importance of the individual interest that is at stake, the risk of the person’s being erroneously deprived of his or her interest under the status quo and the probable value of the procedural safeguard proposed to reduce that risk, and the government’s interest. First, misconduct investigations clearly jeopardize important individual interests: the accused researcher’s livelihood and reputation. A finding of misconduct carries with it potentially severe sanctions, including job termination and debarment, and even a mere investigation into an allegation of misconduct has serious implications…. Second, the risk of an erroneous finding of misconduct is fairly high, given the complexity of the scientific issues involved…. Third, the government—representing society as a whole—has an important interest in avoiding scientific fraud. False scientific reports can affect public health and the progress of science, but some falsifications are trivial and others are important but are revealed to be false before harm is done. In our view, the government interest is not compelling enough to forgo procedural safeguards that might make it somewhat more difficult


Mello and Brennan cite a single case, *Popovic v. United States*, for their incomplete and misleading statement that “misconduct investigations do not raise constitutional issues.” First, *Popovic* held that “with regard to the due process claim against Hadley, whatever actions she may have taken and whenever she may have taken them, to the extent that she was acting as a federal official, she enjoyed qualified immunity.” Supporting this conclusion, the court reasoned that Popovic had no constitutional right that triggered due process protections, that, in any event, any such right was not clearly established, and, finally, that he was afforded due process. Therefore, the court’s discussion of whether there was a property or liberty interest that triggered a right to due process protections of some nature was arguably dictum. If due process was afforded, there was no reason to discuss qualified immunity. If the liberty or property right was not well established, moreover, it was not necessary to discuss whether there was in fact a liberty or property right.

Nevertheless, concerning the claims to liberty and property, the court reasoned:

The investigation that Popovic complains of involved AIDS researcher Dr. Robert Gallo and, among others, Popovic, his associate. The inquiry and investigation grew out of allegations that Gallo and his associates may have misappropriated the French AIDS virus isolated by the Institute Pasteur and thereafter may have misled government officials about the nature and timing of their research. Popovic claims he was deprived of a property right in not being considered for government employment and a liberty interest by reason of damage to his reputation which made him unemployable. Both contentions are flawed. To the extent that he is arguing that he had a property or liberty right not to be investigated or not to have the investigation continue, or to have the investigation conducted in a particular way or at a particular pace, Popovic’s claim has no foundation in law. An individual has no constitutional right not to be investigated for suspected violations by agencies authorized to conduct such authorizations. Indeed, to the extent that a government agency is performing an investigative as opposed to adjudicative function, it is not affecting legal rights and an individual is not entitled to the protections

41. 997 F. Supp. at 672 (D.Md. 1998); cited id. at note 11.
42. 997 F. Supp. at 677.
usually associated with the judicial process. Finally, the Due Process Clause does not require anonymity of those investigated. OSI/ORI conducted an investigation in this case but adjudicated none of Popovic’s rights. What it did do was to recommend a finding of scientific misconduct at the conclusion of its investigation. This finding, however, was “merely preparatory to some further proceeding” and “determined the rights and liabilities of no one.”

Whatever the validity of the court’s reasoning when applied to the procedures that existed when Popovic was investigated, Mello and Brennan concede that what is ultimately at stake in scientific misconduct proceedings is “the accused researcher’s livelihood and reputation,” and they further observe that “misconduct carries with it potentially severe sanctions, including job termination and debarment….” As demonstrated by the Marguerite Kay case (discussed later in this paper), moreover, these sanctions can attach immediately upon the conclusion of institutional proceedings, at which time the accused can be physically, emotionally, and financially unable to pursue the theoretical right to appeal to federal authorities. In such situations, it is indisputable that the researcher has suffered deprivations of liberty and property sufficient to constitutionally require application of the Mathews v. Eldridge balancing test, the test Mello and Brennan apply as a matter of policy to conclude that the clear and convincing evidence standard of proof should be employed.

The OSTP commented as follows concerning the standard of proof when announcing the UFP:

Shouldn’t the burden of proof be more stringent, e.g., require “clear and convincing evidence” to support a finding of research misconduct? While much is at stake for a researcher accused of research misconduct, even more is at stake for the public when a researcher commits research misconduct. Since “preponderance of the evidence” is the uniform standard of proof for establishing culpability in most civil fraud cases

43. 997 F. Supp. at 678-79.
44. Mello & Brennan, supra note 40, at 1284.
45. Spece & Marchalonis, Standard of Proof, supra note 3, at 570.
46. Id. at 570-74.
47. 65 FR 76260, 76262 (Dec. 6, 2000).
and many federal administrative proceedings, including debarment, there
is no basis for raising the bar for proof in misconduct cases which have
such a potentially broad public impact.\textsuperscript{47}

There is no support for the OSTP’s statement that “‘preponderance of the
evidence’ is the uniform standard for establishing culpability in most civil fraud
cases.” It is quite common for various jurisdictions to require that civil fraud
be established by “clear and convincing evidence.”\textsuperscript{48} The OSTP’s comments
do not represent objective reasoning, but bureaucratic embrace of an easy
path to convictions regardless of their fairness.

Furthermore, one of us has established elsewhere that although the public can
suffer from failure to convict a researcher, it can also suffer from false
convictions. The risks both ways arguably cancel each other.\textsuperscript{49} As one of us
has also explained elsewhere, moreover, the Supreme Court precedents in this
area heavily favor a presumption of innocence in the professional disciplinary
contexts, including the scientific misconduct arena.\textsuperscript{50} Therefore, if one balances
the individual and government’s interests, as required by Mathews \textsuperscript{v. Eldridge},
the balance obviously tips in favor of the individual. Still again, Mathews \textsuperscript{v. Eldridge}
requires that, in addition to this balance, there must be an examination
of the chances of erroneous determination with the existing procedure and the
likelihood of improved decision making with greater protections.\textsuperscript{51} We agree
with Mello and Brennan that the risks of erroneous deprivations are relatively
high given the nature and complexity of scientific misconduct proceedings and
that decision making would be improved under the clear and convincing standard
of proof. Mathews \textsuperscript{v. Eldridge} and its progeny\textsuperscript{52} make this policy determination
a constitutional mandate.\textsuperscript{53}

\textsuperscript{48} Charles Toutant, Clear and Convincing Evidence Is Standard of Proof for Legal Fraud; But

\textsuperscript{49} Spece & Marchalonis, Standard of Proof, \textit{supra} note 3, at 573-74.

\textsuperscript{50} Spece & Marchalonis, \textit{supra} note 38, at 118-19.

\textsuperscript{51} \textit{Id.} at 118.

\textsuperscript{52} \textit{Addington v. Texas}, 441 U.S. 418 (1979) (clear and convincing standard required in civil
in parental termination proceedings);

\textsuperscript{53} Spece & Marchalonis, \textit{supra} note 38 at 111-35; Spece & Marchalonis, Standard of Proof,
\textit{supra} note 3, at 567-70.
Applying The Regulations To The Central Charge Against Marguerite Kay

As noted above, the relevant facts concerning the Kay case are set forth in our companion piece in this theme issue.54

A. Kay Would Have Been Even More Vulnerable Under the Current “Recklessness” Standard than Under the then Extant Intent Requirement

As explained above, prior to the UFP, it was assumed that misconduct required a finding of intent.55 It is obvious that Kay would have been even more vulnerable under the current recklessness standard. Likins could have adopted the tort definition of “reckless” that does not require knowledge of the danger posed by one’s alleged derelictions.56 One could conceivably argue, under such a loose standard, that it was reckless not to police Poulin’s data paring.

B. Kay’s Use of the Data Summary Supplied by Poulin or Her Failure to Police Poulin’s Data Paring Seems to Have Been Either an Honest Error or an Honest Difference of Opinion Concerning the Extent to Which She Was Required to Police Poulin’s Conduct, but the Current Regulations Would Improperly Place the Burdens of Presenting Evidence and of Persuasion Concerning These Issues on Her.

Kay did not dispute that Table 1 in her article was mistaken because of Poulin’s data paring. This seems to be a classic case of honest error. Under the current PHS regulations, however, Kay would be unfairly and unconstitutionally presumed guilty until she produced sufficient evidence to convince the decision makers that there was an honest mistake. 57

Alternatively, one could argue that Kay was reckless because of a failure to police Poulin’s data paring. This would at the very least, however, raise an honest difference of opinion concerning the extent to which a researcher such

54. See text at supra note 3.
55. See text at supra note 8.
56. See text at supra note 20.
57. See text at supra notes 23-36.
as Kay should police a technician, co-author such as Poulin. The question is complicated because this issue, as any of the issues discussed herein, could be paired with the ambiguity concerning the PHS regulations’ statement that there must be “a significant departure from the practices of the relevant research community.” One bent on convicting Kay could dilute that requirement to virtually nothing, or elevate it to a major hurdle to prosecution when a favored colleague were involved. In any event, one of us is a scientist with decades of experience in academic research and was in Kay’s department during the relevant time period, and, as such, was part of the relevant research community. It is that author’s opinion that, given the circumstances, there was no reason for Kay not to rely on the data summary Poulin supplied to her and not to inspect the additional data supplied by Poulin after Kay’s paper was accepted. Even more so, there was no reason for her to demand and review Poulin’s lab notebooks which contained the data underlying all the information provided to Kay. Kay’s conduct discussed in this theme issue certainly did not significantly deviate from any established practice; rather, unless she knew of or induced Poulin’s data pairing, she complied with all applicable standards. Kay had a large lab with many projects and several assistants and students. She relied on qualified people like Poulin to collect and analyze data. As a Ph.D. and a practicing physician with an M.D., she had significant responsibilities concerning teaching, research, public service, and clinical care. The disputed data was neither necessary to the point made in Kay’s Table 1, nor was Table 1 central to the point of her article.  

As indicated above, however, one can usually find members of any research community who are willing to place a duty on a head researcher to check and be responsible for everything that appears in an article she publishes. This is an unrealistic view, but it might raise an honest difference of opinion concerning when a researcher must police her colleagues. Thus, as explained above, the current PHS regulations would unfairly and unconstitutionally put the burdens of presentation of evidence and of persuasion concerning this dispute on Kay, the accused.  

C. The Constitutionally Required Clear and Convincing Evidence Standard of Proof Is Designed to Prevent Injustices Such as

58. See our companion piece in this theme issue, text at notes .

59. See text supra at notes 23-36.
Those Evident in the Kay Case.

It is difficult to understand how one could conclude from Likins’ presentation either that Kay was guilty of misconduct based on a preponderance of the evidence or that she deserved to be fired. The point of the preponderance test, however, is that great chances of erroneous decision making are tolerable. It is inconceivable that any reasonable person could conclude, based on Likins’ presentation to the Faculty Senate, that there was clear and convincing proof that she was guilty of misconduct. That is the point of the clear and convincing standard of proof. It does not sacrifice justice to utility. Ironically, in the Kay case it appears that both justice and utility were sacrificed. What danger did her Table 1 pose? What has been lost by the end to her research into Alzheimer’s disease and aging? What is lost when a researcher and her research are easily destroyed?

Conclusion

We have argued that the [U.S.] PHS misconduct regulations deny due process of law and are fundamentally unfair because they fail to specify the level of culpability for guilt, force accused researchers to prove that they are innocent, and, although admittedly quasi-criminal, adopt a standard of proof that tolerates nearly a 50 percent probability of false convictions. The predecessor regulations, although not quite as Draconian, allowed applications such as those indicated in the Kay case. Researchers and their research are now even more at risk.

Acknowledgement

Roy G Spece and Carol Bernstein have been critics of the University of Arizona Administrations’ handling of the Marguerite Kay case. Roy Spece has written of the case in articles and Carol Bernstein was a faculty member in Kay’s department during the time of the proceedings.
“SPIN” IN SCIENTIFIC WRITING: SCIENTIFIC MISCHIEF AND LEGAL JEOPARDY

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Abstract: In science, the data are supposed to speak for themselves. However, investigators have great latitude in how they report their results in the medical literature, even in an era of research protocols, pre-specified endpoints, reporting guidelines, and rigorous peer review. Authors’ personal agendas, such as financial, personal, and intellectual conflicts of interest, can and sometimes do color how research results are described. Articles in peer-reviewed medical journals are the evidence base not only for the care of patients but also for legal decisions and the scientific record may be tailored for legal reasons as well. Journal editors preside over where and how the results of scientific research are published. We therefore suggest some actions that editors can take to foster a more trustworthy evidence base both for the care of patients and for legal decisions.

Keywords: Evidence base; conflict of interest; Daubert; litigation; editors

INTRODUCTION

In science, the data should speak for themselves. The scientist has a question, gathers objective data, performs the appropriate analyses, and reports the results fully and without alteration. In this ideal, there is no room for personal agendas.

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However, both practicing scientists\(^1\) and philosophers of science\(^2,3\) have asserted that this is an artificial view of the scientific process. They have pointed out that scientific inquiry is not necessarily carried out in a linear, preplanned way, and that published reports may be an idealized or even self-serving picture of what was done and found. As Nobel Laureate Peter Medawar wrote, “Deductivism in mathematical literature and inductivism in scientific papers are simply the postures we choose to be seen in when the curtain goes up and the public sees us. The theoretical illusion is shattered if we ask what goes on behind the scenes.”\(^1\)

The line between mechanical reporting of scientific results and telling a story with data has never been distinct. Consider the work of Louis Pasteur, generally lionized for his commitment to the “scientific method” and the dispassionate triumph of facts over opinions. When Pasteur’s laboratory notebooks and personal correspondence became available to the general public in 1971, a somewhat different picture emerged. A scholar of these papers, Gerald Geison, wrote in The Private Science of Louis Pasteur, “Here we deal with … discrepancies between Pasteur’s public and private science in cases where the word ‘deception’ no longer seems inappropriate, and even ‘fraud’ does not seem entirely out of line in the case of one or two major episodes.”\(^4\) Yet Pasteur’s scientific assertions have been proven correct, over and over again.

A modern view of the scientific enterprise suggests that observation is not purely objective, but rather conditioned by the observer’s past experiences and current theories; and that science is a “social practice” involving many contributors, each bringing his/her experiences and theories to bear on observations.\(^2\) If so, then scientific results published in medical journals are not simply the recitation of facts, following from an original protocol and objective data, but rather the reflection of a complex set of social forces that might distort the message.


\(^2\) Chalmers AF. What is this thing called science? 2nd Ed. London; University of Queensland Press, 1982.


In the following, we point out how investigators have broad latitude in reporting study results, even in the era of research protocols, pre-specified end points, and reporting guidelines. We describe how choices among data analyses and presentations, each of which may be legitimate in the right context, can, when taken together or out of proper context, create an inaccurate impression of a study’s results. Personal agendas color these choices and so can erode the evidence base, as recorded in the medical literature, both for patient care and legal process. Because medical journal editors decide where, when, and how medical research is published, and so have substantial influence over the final form of publications, we will end by suggesting ways in which editors can minimize “spin” in the medical literature.

We will not comment on scientific choices that are simply wrong on the face of it - for example, failure to assure allocation concealment in randomized trials, inconsistent follow-up in cohort studies, or patently different cases and controls in a case-control study. Neither will we hazard opinions about whether misleading choices result from ignorance of the scientific issues (Alvan Feinstein called it “statistical malpractice”); unconscious bias, or willful intent to deceive. We will, however, show how misleading results do often serve the authors’ interests.

External Constraints on Scientific Reporting

Limits on the content of scientific articles are imposed on authors for practical reasons. To assure completeness and order, many journals have adopted templates for reporting, such as CONSORT for randomized trials and STARD for studies of diagnostic test accuracy. Print journals limit the length of articles, which compels authors to leave out information they would have preferred to include. (This limitation is in principle overcome by electronic publication and by offering to make available additional information to interested readers).

Authors must also limit the length and number of agendas per articles to


accommodate readers’ attention span. Only the most interested readers could be expected to wade through the many twists and turns of a research project and all the results it has produced. And of course, to be published scientific writing must be attractive to peer reviewers and editors. Indeed, many seasoned investigators teach junior colleagues that they should “tell a story” with the data, one that is sufficiently clear, coherent, and compelling to engage reviewers and readers. The issue, it seems, is not whether to tell a story, but whether it is a true story.

Opportunities for “Spin” in Scientific Reporting

In writing an article, investigators have many opportunities to shape the impression their results produce in readers - by the statistical analyses they choose, the words they use to describe them, and the selection of results they choose to include in the article. This is so even though each analysis, word, and included piece of information might be legitimate in its own right.

Choosing Friendly Analyses. The statistical significance of a result depends in part on which statistical test is used. Statistical packages commonly report several different test statistics, with corresponding P values, for each analysis. It is up to the investigators to choose, often after the fact, which test to report. The best guide for this choice is the extent to which the various tests’ assumptions are met. But an alternative is to choose the test that best supports the desired result.

Analyses of major studies include multivariable modeling, in recognition that most diseases have multiple, interacting causes and that it is not feasible to take all of them into account with simpler methods such as matching or stratification. But these multivariable methods are “quirky,” even in expert hands. Different models, and even the same models of random subsets of a data, come to different conclusions as to which variables are important, and their relative importance. To the extent that modeling is an art form, without strict guidelines and carried out by trials and errors, it is possible to chose a version that suits the purposes of the investigator.

Continuous data are often dichotomized (for example, into high and low, abnormal or normal, or success or failure). If the choice of cut-off point is not

made before the data are examined, the line may be drawn where it is most favorable to the investigator’s purposes. This “moving the target to hit the bullet,” can introduce the investigator’s preferences into the interpretation of data.

Right Analyses But Leading Words. Authors can signal how they want the results to be perceived by the words they use to describe them. For example, it is common practice to say a result with a P value somewhat above 0.5 is “marginally significant” or “did not achieve statistical significance” (as if it should have, in a just word, but for annoying statistical reasons it did not).

Very low P-values are not uncommonly represented as evidence of a strong effect. Statisticians have been railing against this practice – asserting that statistical significance does not imply clinical importance – for decades. Nevertheless, appeal to the clinical importance of statistical significance is still alive and well.

On the other hand, P values >0.05 may be described as ruling out an effect when in fact they have simply failed to establish it. In reality, showing equivalency or non-inferiority is a very demanding task, requiring both unusually rigorous study design and conduct as well as larger sample sizes than superiority trials. With weak methods or low statistical power, the study is biased toward failing to find a difference, even if a difference is present in nature.

Selective Reporting. Authors must pick and choose among the data analyses available to them, which commonly amount to many linear feet or printouts (or megabyte of memory). In the process, their selections can result in a self-serving story, one that leads readers in the direction authors want them to go. This is so even for studies, such as FDA-approved, registered, randomized trial of drugs, which begin with elaborate protocols and pre-specified analyses.

The extent of selective reporting of outcomes was estimated in a Danish study comparing protocols for randomized trials to published reports. In 62% of trials at least one primary outcome had been changed, introduced, or omitted.


The authors surveyed the investigators, and found that “eighty-six percent of survey responders (42/49) denied the existence of unreported outcomes despite clear evidence to the contrary.”

Selective reporting often occurs in the context of multiple comparisons. Many variables can and should be compared: multiple strata defined by baseline characteristics, different levels of intervention, intermediate and clinical outcomes, various times to response, and their combinations. Taken together, the potential contrasts might number in the hundreds. Some comparisons are likely to be statistically significant at the conventional level by chance alone. Some of these are more attractive than others, for reasons that might have to do with the investigators’ intellectual passion, personal relationships, or financial interests. If these attractive findings are reported with their separate P values, and other comparisons are left out of the report (perhaps without mention that they were even made) readers are given a misleading impression of the scientific force of these particular comparisons. If a rationale for the isolated findings is added post hoc, the findings seem even more “real.”

An example is a study of the performance of digital versus film mammography for breast-cancer screening. Overall diagnostic accuracy was similar for the two methods. However, the authors reported that digital mammography performance was better for three subgroups of women, younger women, women with dense breasts, and those that were pre- or peri-menopausal. But if there was no overall difference, it must also be true that performance was worse in the complementary subgroups – older women, those with less dense breasts, and those after menopause. The authors were not explicit about results in these other subgroups, either in the manuscript itself or in response to letters complaining that this information had been withheld.

Authors may also gloss over limitations in their study. A controversial report of the effectiveness of CT screening on survival of patients with stage I lung cancer included a vigorous promotion of the CT screening but no discussion of limitations. The authors did not address well-recognized threats to validity in


a screening study of survival, especially lead time and length time biases.\textsuperscript{14} Annals of Internal Medicine now requires that study limitations be addressed in a separate section of the structured abstract.

If limitations are acknowledged, they may be buried in an obscure place the text, while a different view is promoted in the abstract, the highest-profile part of the article. For example, in a study comparing the sensitivity of immunologic and guaiac-based fecal occult blood tests, the authors stated in the abstract that “FIT returned a true-positive result significantly more often in cancer (n=24, 87.5\% versus 54.2\%)…”\textsuperscript{15} The remarkably high sensitivity was covered by the media as if it were an estimate of true sensitivity. In the Discussion section of the paper, the authors noted that their results were relative, not true, sensitivity and were “likely to overestimate the true sensitivity.”

**Misleading Articles and the Law**

Researchers do not normally turn to the court system for guidance on how to conduct their studies or how they should select and frame results when they publish. For most scientists, the law is terra incognita, as is science for most judges and lawyers. The symmetry of this ignorance is not perfect, however. Where scientists generally give the law little thought (other than to obey it in their day-to-day lives), courts must regularly assess the reliability and validity of scientific work when expert witnesses propose to testify about it. Federal (and many state) judges are required to exclude testimony they find unscientific, and if they make such a ruling it may effectively end a case before trial.

Although not without longstanding precedent,\textsuperscript{16} the widespread judicial screening of science is a fairly new phenomenon, largely the result of a 1993 U.S. Supreme Court case called *Daubert v. Merrell Dow Pharmaceuticals, Inc.*\textsuperscript{17} The decision by Justice Blackmun clarified the Federal Rules of Evidence and told federal district judges they “must determine at the outset . . . whether the


\textsuperscript{16} *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923.

\textsuperscript{17} *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)
expert is proposing to testify [about genuine] scientific knowledge . . . This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.”

How are judges to go about this rather daunting task? The Court set no absolute standards, but did provide five “general observations”: (1) testability and testing; (2) peer review and publication; (3) error rate; (4) the existence of standards; and (5) general acceptance in the scientific community. Thus has peer review, the second of the five, achieved a legal significance neither sought nor expected by the editors responsible for publishing scientific journals? For while the Supreme Court made clear its list was not binding or exhaustive, when it speaks the lower courts listen. As Chief Justice Rehnquist noted in a partial dissent, “‘[g]eneral observations’ by this Court customarily carry great weight with lower federal courts.”

Whether courts have done a good job when judging science is open to much unresolved debate. A 2001 study published by the Rand Institute for Civil Justice found that judges have taken the Supreme Court’s mandate seriously. Judges are examining expert testimony more closely and excluding it more often. However, the authors noted, “…even though there is convincing evidence that practices and standards have changed, our findings do not allow us to determine whether the changes have resulted in better outcomes.”

Daubert’s impact on peer review and publication is similarly difficult to quantify, but anecdotal evidence indicates at least three interesting developments. Some experts, perhaps at the behest of the lawyers who retained them, have sought to legitimate work done for litigation by having it published in a peer reviewed journal. In other cases, the publication of work not originally done for litigation may have been held back or slanted to avoid or reduce its legal consequences. Finally, on a more positive note, there are cases in which information became known and eventually published only because of the litigation process.

Examples of litigation-driven publication are described in a review by Anderson et al. In one series of cases about birth defects allegedly caused by exposure


to a fungicide, the plaintiffs’ law firm “funded a series of research projects . . . [the results of which were] submitted . . . for publication in the journal Neurotoxicology, but the journal did not require any conflicts disclosure, and the authors [did not reveal] that the studies were funded by a law firm and conducted on behalf of a testifying expert.”

In another case, which pre-dates Daubert but reflects a similar legal analysis, a defense expert published an article based on data collected in the course of litigation. He sought to show that asbestos levels inside certain school buildings were no higher than the ambient levels outside. An Ohio appellate court upheld the trial judge’s decision to admit testimony about this article, even though the litigation “taint” was not disclosed in the published version. Moreover, the journal in question, Regulatory Toxicology and Pharmacology, has since been severely criticized for bias in favor of corporations. A 2002 article in The Chronicles of Higher Education reported on a letter from forty-five scientists that urged the publishers “to reform the journal or stop publishing it.” One scientist complained that “[e]ssentially it reads like an industry trade publication, but it’s masked as a peer-reviewed journal.”

The problem of selective and slanted publication extends well beyond testifying experts. Consider the example of an article about rofecoxib (Vioxx) that appeared in the New England Journal of Medicine in 2005, about six months after the drug was taken off the market and in the midst of the manufacturer’s defense of litigation about injuries it is alleged to have caused. The article reported on cardiovascular adverse events in a trial designed to compare rofecoxib with placebo for the prevention of recurrent colon polyps in patients with a history of colorectal adenomas. The trial was terminated early.

the cardiovascular risks became apparent. The authors stated in the abstract to the article, “The increased relative risk became apparent after 18 months of treatment; during the first 18 months, the event rates were similar in the two groups.” It later became apparent that this post hoc analysis was flawed and the journal published a correction to delete the “18 month” language.25

Obviously we do not know what was in Merck’s mind when the erroneous analysis was published. And given our topic – how bias can shape publication choices – we must disclose that both of us have been involved in this litigation (BB as a lawyer representing the plaintiffs and RF as an expert for the plaintiffs on the scientific peer review and publication process). That said, we do note that from the company’s perspective the incorrect eighteen month argument was helpful to Merck in defending the lawsuits that have resulted from the withdrawal of rofecoxib. Whatever the motives of either paid experts or scientists paid by industry to do research, law-related conflicts of interest cast doubt on the objectivity of the authors and the integrity of the review and publication process.

In some cases, however, the law can affect publication in a more positive way. A good example relates to the now withdrawn anti-cholesterol drug cerivastatin (Baycol). (Again full disclosure requires that we make clear one of us (BB) represented plaintiffs in the litigation about this drug.) Bayer, the manufacturer of cerivastatin, had conducted a number of analyses of adverse event rates which it had neither published nor fully disclosed to the Food and Drug Administration. Plaintiffs’ experts learned of this information because of their work in the litigation, and later – with full disclosure of their role – published about it in the Journal of the American Medical Association. In particular, the unpublished analyses showed that “[t]he incidence of Rhabdomyolysis in . . . [cerivastatin] monotherapy treatment was 2 to 6 cases per 100,000 patient years while the other statins, based on data from the [FDA’s Adverse Event Reporting System], were in the range of 0.2 to 0.6 cases per 100,000 patient years.”26


Thus the impact of the law on peer review and publication has been both negative and positive. Looking to the future, more stringent disclosure requirements will help solve the problem of obvious conflicts of interest but will not much affect selective or slanted publication. Physicians and their patients should not have to depend on the litigation discovery process to learn about studies that reveal potential adverse effects of the medications they prescribe and take.

Possible Remedies During Peer Review and Publication

Editors can prevent the publication of misleading articles in several ways.

1. Publish authors’ financial conflicts of interest. Authors with conflicts of interest are more likely to report positive findings.27 Financial conflicts of interest are usually managed by publishing a disclosure of those conflicts with the article. Or are they? In a survey of 91 peer-reviewed biomedical journals 77% reported collecting conflict of interest information on all authors but only 57% published these disclosures.28 There is an undercurrent of resistance to mandatory disclosure, which has been called “the new McCarthyism in science”29 But the problem is so intrusive that some leading journals are becoming more aggressive in their handling of it. JAMA recently decided to require disclosure of all financial conflicts of interest within the past 5 years and for the foreseeable future and to publish all disclosures.30

Investigators’ judgment can also be affected by their beliefs and the public positions they have taken (lawyers call these “positional conflicts”) and see evidence against these beliefs as undermining their own credibility and reputation. Editors may be alert to these non-financial conflicts of interest but have given them considerably less attention in formal journal policies.

2. Ask authors whether they were restricted in what they could submit for publication. Investigators often enter into restrictive agreements with industry sponsors and academic medical centers vary in their standards concerning these practices. There are well-publicized examples of investigators who had been bound by restrictive contracts with industry sponsors and paid a heavy price. The AAMC has taken a stand against investigators entering into restrictive contracts with industry. In any case, industry can exert control over publication by arranging for its own employees to participate on the research team. For example, in the New England Journal of Medicine paper that asserted the cardiovascular risk related to Vioxx occurred only after 18 months of use, five authors were Merck employees and the rest had received consulting fees from Merck. Because all authors must agree before a manuscript is submitted to a journal, authors paid by industry have an opportunity to affect the form and timing of the paper.

3. Choose reviewers for all of the manuscript’s agendas. Research results sometimes span traditional specialties. For example, in an early study comparing Vioxx to Naproxin, the primary outcomes were control of arthritis symptoms and occurrence of upper gastrointestinal events. For these outcomes, rheumatology and gastorenterology reviewers are appropriate. But another important result, not anticipated in the protocol, was an increased rate of myocardial infarctions in patients taking Vioxx. For that outcome, review by a cardiologist was in order.

4. **Hold studies with industry participation to a higher standard.** Financial conflicts can dwarf all others sources of bias; company income as well as authors’ jobs, friendships, and loyalties are on the line. There are differences of opinion about whether and how to be more vigilant with industry-sponsored studies. At one extreme, *JAMA*’s policy is that “industry-sponsored studies in which the data analysis has been conducted only by statisticians employed by the company sponsoring the research will not be accepted for publication in *JAMA*.“ At the other extreme, Rothman has called stricter review for these manuscripts “unfair – and absurd.” At the very least, when reviewing these manuscripts editors and reviewers should especially alert to bias favoring the sponsor’s product.

5. **Do not put the journal in the position where the balance of power in negotiating revisions shifts to the authors.** If the authors know that a journal is anxious to publish their manuscript – for example, because of its newsworthiness or because it is planned for a special issue with an imminent deadline – then they are in a better position to prevail while negotiating revisions. Also, if peer review and revision is rushed, it more likely to miss subtle problems.

6. **Require authors to describe the limitations of their study.** The published version of a manuscript should discuss not only whatever limitations the authors choose to volunteer but also those that reviewers and editors have identified. We support the practice pioneered at *Annals of Internal Medicine* of making limitations part of the structured abstract.

7. **Require registration of clinical trials.** If details of the research protocol, such as primary and secondary outcomes, are on public record from the beginning of the study, changes from protocol to publication become transparent. Major journals are now requiring prior registration as a condition of publication.

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but registration information is not yet complete. Although interested readers can use information in trial registrations to discover if the design and main analyses have changed between protocol and manuscript, authors should be encouraged to describe such changes in the manuscript itself.

Peer review and publication do improve the completeness and accuracy of scientific articles but humans being what they are, the kinds of problems we have described are likely to continue. Even so, the research and publishing community can do better. Our goal in this paper is to highlight opportunities for bias in data analyses and written presentation, along with potential solutions, in the hopes that this will lead fewer misleading reports. The published records needs to be a trustworthy evidence-base both for the care of patients and as evidence in courts of law.

Acknowledgement:

Both authors have been involved in litigation concerning the drug rofecoxib (Vioxx), manufactured by Merck, BB as a lawyer representing the plaintiffs and RF as an expert for the plaintiffs on the scientific peer review and publication process.


Table 1. Opportunities for Authors to Introduce Spin into Scientific Reports

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<td>Choose a favorable statistical test</td>
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<td>Choose a favorable statistical model</td>
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<td>Frame quantitative results with leading words</td>
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<td>Selective reporting of outcomes</td>
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<td>Multiple comparisons and reporting the most interesting findings</td>
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<td>Avoid or bury disclosure of study limitations</td>
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Table 2. Opportunities for Editor to Control Spin in Scientific Reporting

1. Publish authors’ financial conflicts of interest.
2. Ask whether authors were restricted in what they submitted for publication.
3. Choose reviewers for all the manuscript’s agendas.
4. Hold studies with industry participation (not necessarily funding) to a higher standard.
5. Do not put the journal in the position where the balance of power in negotiating revisions shifts to the authors.
6. In negotiating revisions, make clear authors’ and editors’ respective responsibility for content.
7. Require that authors describe the limitations of their study.
Addressing Scientific Misconduct

SCIENTIFIC MISCONDUCT AND BREACH OF PUBLICATION ETHICS: ONE EDITOR’S EXPERIENCE

Robert B. Daroff*

Abstract: I summarize my experience with scientific misconduct and breach of publication ethics during my 10 year term as Editor-in-Chief and my first 3 years as Scientific Integrity Advisor for *Neurology*, the official publication of the American Academy of Neurology.

I describe in some detail the highly publicized, lengthy saga involving the accusation from a former colleague that James Abbs falsified data in an article published in *Neurology*. Nine years later, after numerous investigations and law suits, Abbs was found to have engaged in scientific misconduct which prompted the retraction of the article.

Most of the problems I encountered were less complex and involved claims of plagiarism (regarded as “scientific misconduct”) and self plagiarism (regarded as a “breach of publication ethics”).

I conclude by providing helpful sources for editors in dealing with these infractions.

Keywords: Scientific misconduct; publication ethics; plagiarism; self plagiarism; fabrication; falsification; retraction; Office of Research Integrity.

I began a ten year term as Editor-in-Chief of *Neurology*, the official publication of the American Academy of Neurology, in 1987 and became Scientific Integrity Advisor for the journal in 2004. I will summarize my experience in both roles, relating to scientific publication misconduct and ethical breaches.

Scientific misconduct basically consists of fabrication, falsification, and plagiarism

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(F.F.& P), with an intent to deceive\textsuperscript{1,2} although, as detailed in the Council of Science Editor’s White Paper in Promoting Integrity and Scientific Journal Publications (http://www.councilscienceeditors.org/editorial_policies/white_paper.cfm), some agencies utilize expanded lists. Breach of publication ethics includes a variety of misbehaviors, the most common being redundant/duplicative publications, omitting a deserving author, and self plagiarism without attribution.\textsuperscript{3}

In April 1987, four months after commencing my editorship, a letter from Steven M. Barlow, PhD, started one of the most complex and publicized odysseys of publication misconduct in recent years. Barlow claimed that a paper published in \textit{Neurology} by James H. Abbs, PhD\textsuperscript{4} contained falsification of data in a key figure. Abbs was previously Barlow’s thesis advisor at the University of Wisconsin. After receiving Barlow’s letter, I notified Abbs, the University of Wisconsin, the Gundersen Medical Foundation (where Abbs’ two co-authors worked), and the National Institute of Neurological, Communicative Diseases and Stroke, the funding agency for the research study. Then came multiple internal and external investigations, and lawsuits as recounted by Friedly.\textsuperscript{5}

In June 1987, an internal investigation at the University of Wisconsin, concluded that the accusations against Abbs were unsubstantiated and the Gundersen Medical Foundation concurred. The NIH Office of Extramural Research also found no evidence of misconduct in March 1988, which a second NIH investigation reaffirmed five months later. Thereafter, NIH physicist, Charles McCutchen\textsuperscript{6} and University of Wisconsin faculty member, Gary Weismer,\textsuperscript{7}

\begin{thebibliography}{9}
\bibitem{5} Friedly, J. Scientific misconduct: After 9 years, a tangled case lurches toward a close. \textit{Science} 1996; 272:947-948.
\end{thebibliography}
sent critical letters to *Neurology*, followed by Abbs’ replies.\(^8\,9\)

The Office of Research Integrity (ORI), the authorized investigative agency of the United States Public Health Service (PHS), started its own investigation in 1990, but a lawsuit by Abbs, claiming lack of due process, curtailed the investigation until 1992. Four years later, and nine years after I received Barlow’s letter, the ORI notified me on May 27, 1996, that they found Abbs had “engaged in scientific misconduct by deliberately falsifying and fabricating certain figures and research results” in the article published in *Neurology*. A complex agreement between Abbs and the ORI, permitted him to convince me that a retraction was not justified and he suggested a compromise ‘partial retraction’. I would only have done so if the ORI agreed, and I sent Abbs an example of our journal’s format for retraction, that complied with the International Committee of Medical Journal Editors recommendations.\(^10\) Abbs then suggested that our retraction language was “harsh and malevolent” and urged me to tone it down. The ORI wrote me that Abbs’ proposed language misrepresented their findings and recommended that I use our standard retraction wording.

The retraction\(^11\) included a “Note from the Editor-in-Chief” stating, “The retraction of this paper is based upon the Department of Health & Human Services’ Office of Research Integrity (ORI) Investigation Report finding that James H. Abbs PhD, engaged in scientific misconduct by deliberately falsifying and fabricating certain figures and research results that were published in the above paper. The ORI believes it is necessary to retract the paper to correct the scientific literature.”

Sox and Rennie\(^12\) discussed other high profile cases of research misconduct. In June 1989, during the Abbs’ saga, the Alcohol, Drug Abuse, and Mental Health Administration of the PHS, sent me a report by the National Institute of

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Mental Health citing scientific misconduct and erroneous publications of Stephen M. Stahl, MD, PhD, and co-workers, that appeared in several journal articles and a 1983 abstract published in Neurology.\textsuperscript{13} I immediately retracted the abstract\textsuperscript{14} “because of methodological and procedural flaws in the study,” but later discovered that some editors refused to retract the Stahl papers.

Colleagues associated with the PHS told me that the ORI regarded me as a “poster child” for responsible editorship. Apparently, my Abbs and Stahl retractions, and the publication of letters critical of Abbs\textsuperscript{6,7} displayed a unique bravado, contrary to what seemed to be pervasive timidity among journal editors. Indeed, after we published McCutchen’s letter\textsuperscript{6} he wrote me, “I thank you for publishing the exchange. After so many important people have behaved so timidly, it was wonderful to see someone with the power to do something who dared to do it. Maybe I have read too much Nevil Shute and Dashiell Hammett, but I think courage is good stuff, and I’m proud to be your fellow scientist.” I was confused by such laudatory praise because, at the time, I was unaware of Abbs’ exoneration by two NIH committees.

In 1990, the Office of Scientific Integrity (the predecessor to the ORI) hosted a meeting for a small group of journal editors. One of the editors explained why he wouldn’t retract a paper by Stahl that was judged fraudulent, and another editor, to my surprise, stated that only an author, and not an editor, can retract a paper. I am hopeful that most Editors now understand their roles in maintaining the integrity of science. We must bring questionable behavior to the attention of investigative bodies, the authors’ institutions, and funding agencies. Thereafter, we must publish findings by these groups that sometimes warrant a retraction or at least “an expression of concern.”\textsuperscript{3} The editors’ role does not include investigations; as articulated by Stephen P. Lock, Editor Emeritus of the \textit{British Medical Journal}, at the 1990 Office of Scientific Integrity meeting, “We are the JCI [referring to the \textit{Journal of Clinical Investigation}, as symbolic of all medical journals] and not the FBI.”

As my ten year term as Editor was coming to a close in November 1996, a reviewer noted that a manuscript contained a spectroscopic figure alleged to


be from two different mice, had to be from a single mouse and not from a
diseased and control mouse, as stated by the authors. I had these figures
reviewed by spectroscopists who agreed that it was impossible for the figures
to be from different mice. We rejected the paper and notified the authors’
institutions; two in the United Kingdom and one in the United States, whose
investigative panels agreed that the figures were from the same mouse.
However, the panels concluded that the authors did not intend to deceive, but
simply made a sloppy mistake. We accepted that explanation.

In addition to the issues discussed above, we received several other accusations
of misconduct and ethical breaches but none were substantiated or warranted
retraction or punitive action.

After becoming the Scientific Integrity Advisor in 2004, we published our current
procedure for handling accusations of misconduct. Except for plagiarism, we
do not notify the authors or their Chairs, but only Deans, Presidents, funding
agencies, and the ORI. Notifying authors might lead to the alteration or
destruction of records. Chairs may be personally attached to their faculty and
could notify them prematurely before the institution secures all records to prevent
destruction or tampering.

I reported my experience in the first three years (2004-2006) as the Scientific
Integrity Advisor15,16 To avoid plagiarizing myself, I will only touch upon a few
highlights. Readers can obtain more detail from the published accounts. Some
examples follow:

1. The Chair of an Institutional Review Board (IRB) wrote us that a paper
we published required prior IRB approval. The author stated that his IRB didn’t
think it needed such approval. Although his IRB may have been mistaken, I
didn’t think that the author should be penalized. I personally feel that some
IRB regulations are too strict. For example, if a medical school evaluates a
curricular change and presents it at an educational meeting, prior IRB approval
is required because the research “is subject to federal human research standards
and governance.”17 Nevertheless, we must obey the rules.

64:588-589.
2. Plagiarism may be difficult to discern, or even define. A plagiarism claim prompted me to consult with the World Association of Medical Editors (WAME) for advice as to when quotation marks are required, as distinct from a simple citation. The response was, “anything but the shortest and commonest of phrases needs to be in quotes, indicating that it is a literal, word-for-word quote from someone else. Simply citing a statement is not the same thing; it implies you were stating where the idea or fact came from, not that you are repeating someone else’s words verbatim. I would say a complete sentence, and particularly more than one, that is verbatim, absolutely ought to be in quotes, indicating that they are NOT the present author’s words, but someone else’s.”

Whether one regards the above position as excessive, is irrelevant. Failure to heed such a guideline might prompt a charge of plagiarism.

3. Self plagiarism is not regarded as misconduct but rather a breach of publication ethics that constitutes a copyright violation. At times, however, self plagiarism may warrant a retraction.

As stated previously, many of the problems we encountered stem from author naivety, sloppiness, and the ambiguities involved in plagiarism and self plagiarism. One doesn’t have to be a flagrant sociopath to encounter charges of misconduct or breach of ethics. Ignorance of the rules can cause considerable embarrassment and ruin an otherwise promising professional career.

As a resource for editors, I strongly suggest Roig’s website (http://facpub.stjohns.edu/~roigm/plagiarism), revised in August 2006, for an excellent discussion of the plagiarism issues.

Other recommended websites include:

- The International Committee of Medical Journal Editors Uniform Requirements (icmje.org),
- The Committee on Publication Ethics (COPE) (www.publicationethics.org.uk),
- The World Association of Medical Editors (WAME; pronounced “wam-ee”) (www.wame.org),
- The section on research misconduct of the Council of Science Editor’s White


Finally, Graf et al.\(^9\) provides helpful flow charts to guide editors through the process of dealing with research misconduct and ethical violations.

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Addressing Scientific Misconduct

WHAT DO JOURNAL EDITORS DO WHEN THEY SUSPECT RESEARCH MISCONDUCT?

Elizabeth Wager

Abstract: Several published guidelines urge journal editors to ensure that cases of suspected scientific misconduct are properly investigated. Using cases submitted to the Committee on Publication Ethics (COPE) I tried to discover what editors actually do when faced with such cases. Of the 79 cases referred to COPE between 1998 and 2003 relating to author misconduct, 33 related to redundant publication, 16 to unethical research, 13 to fabrication, 10 to clinical misconduct and 7 to plagiarism. Outcomes were reported in 49 cases. Authors were exonerated in 16 cases and reprimanded in another 17. An impasse (no or an unsatisfactory response) was reached in 16. Editors contacted the authors’ institutions in 24 cases. Nearly half the cases (36) lasted over a year. This small survey highlights the difficulties faced by editors in pursuing cases of suspected misconduct and the need for better training and guidance for editors and more cooperation from institutions.

Keywords: Committee on publication ethics; research misconduct; fraud, falsification and fabrication; plagiarism; role of journal editors

INTRODUCTION

Concerns about possible scientific misconduct sometimes emerge during journal peer-review and editing. The Committee on Publication Ethics (COPE) code of conduct for journal editors states that ‘If editors suspect misconduct … then they have a duty to take action’. It also explains that this duty extends both to published and submitted papers. COPE recommends that editors should first seek a response from those accused but, if they are not satisfied with the

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1. www.publicationethics.org.uk/guidelines/code (accessed 17/2/05)
response ‘they should ask the employers of the authors … or some other appropriate body (perhaps a regulatory body) to investigate.’ This seems a reasonable expectation, and not unduly burdensome, but the next clause outlines the extent of editors’ responsibilities. According to COPE ‘Editors should make all reasonable efforts to ensure that a proper investigation is conducted’ and if this does not happen ‘editors should make all reasonable attempts to persist in obtaining a resolution to the problem’. As the COPE code notes ‘This is an onerous but important duty’.

The World Association of Medical Editors (WAME) advises that: ‘Journals do not have the resources or authority to conduct a formal judicial inquiry or arrive at a formal conclusion regarding misconduct. That process is the role of the individual’s employer, university, granting agency, or regulatory body. However, journals do have a responsibility to help protect the integrity of the public scientific record by sharing reasonable concerns with authorities who can conduct such an investigation.’

While these guidelines are clear, I could find only anecdotal descriptions of what actually happened when editors endeavored to follow them (and such published anecdotes probably represent the most extreme cases). I therefore sought to discover what happens when editors attempt to pursue cases of suspected scientific misconduct by authors from the cases reported by COPE.

**Methods**

I based my study on COPE’s annual reports from 1998-2003 (these are all the cases available that report outcomes). The reports detail 79 cases involving suspected misconduct by authors. After reading all the cases, I grouped them into categories according to the type of misconduct and noted whether the author(s) had been exonerated or reprimanded, and whether the case had been satisfactorily resolved or not. If the editor failed to get a response from the author’s institution, or got an unsatisfactory response (for example stating that the institution did not consider there were grounds for an investigation) I

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2. http://www.wame.org/resources/publication-ethics-policies-for-medical-journals#misconduct
5. www.publicationethics.org.uk (accessed 8/3/07)
considered the case to have reached an impasse. I also noted whether the editor had contacted the author’s institution or professional governing body and whether the case had taken at least 12 months to resolve. These last two categories were not exclusive.

Findings
The main outcomes are shown in Table 1. The most common type of suspected misconduct was redundant publication (i.e. submitting or publishing findings that had already been substantially published in another journal). This was followed by suspected unethical research, data fabrication, clinical misconduct and plagiarism.

Redundancy
Of the 33 cases, 15 did not report a sufficiently detailed outcome for classification, leaving 18 that could be categorised. In three cases, the editors exonerated the authors or decided the duplicate submission had been caused by a genuine error. In four cases, the editor considered that, although there was substantial overlap between articles, there was no intention to deceive, so these constituted poor publication practice rather than misconduct. However, in one case in which identical papers had been submitted to two journals by a single author accompanied by statements that they had not been published elsewhere, both journals retracted the redundant article and banned the author from publishing in their journals for the next two years. Six notices of redundant publication were published (thus publicly reprimanding the authors). In one case of a redundant article detected before publication, the authors withdrew the submission and the journal did not take the matter further. Three cases could not be resolved and were classified as reaching an impasse.

Unethical research
These cases involved authors who had not obtained appropriate approval for their research (e.g. from an institutional review board or research ethics committee) or where journal editors had ethical concerns about the research despite formal approval having been granted or the authors having been informed that approval was not required. Of the 16 cases referred to COPE, four did not report outcomes.

Of the remaining 12 cases, five were resolved after the authors provided
satisfactory explanations for their actions. In another case, the institution responded promptly to the journal’s enquiry, agreeing that supervision of undergraduate projects had been inadequate (resulting in projects being carried out without the necessary ethical review) but had now been improved. In one case it turned out that one of the authors had already been investigated and struck off the medical register for fraud but the journal was able to work with the co-authors (who had alerted the editor to a problem over forged ethics committee approval) and decided to publish data from those centres where the trial was conducted properly (and with the appropriate approval). In one case, the relevant guidelines (relating to animal experimentation) had changed during the course of the study, so the journal agreed to publish the findings with an editorial explaining that such methods were no longer considered acceptable. However, in four cases, the journals reached an impasse and the issues could not be resolved. In one of these cases, the author’s institution failed to respond to at least two letters from the journal. Another case was referred to the national professional body that licenses doctors but was not taken up because the author had retired.

**Fraud and fabrication**

COPE discussed 13 cases of suspected fraud (i.e. falsification or fabrication of results) in the period studied. Outcomes were unavailable in four cases. Of the nine other cases, two of the authors were exonerated: one case in which fraud was suspected following major changes in a revised manuscript, turned out to be a genuine error caused by the author sending the wrong file to the journal; in the other case, the authors provided a satisfactory explanation for their findings. Editors contacted the authors’ institution in five cases. From these contacts, the outcome of one was not reported, one editor got no reply, and one received an unsatisfactory response (stating that the university could not take responsibility because the author no longer worked there). One hospital instigated an inquiry but only after initially stating that this would be impossible unless the journal would fund the work. However, the persistent editor managed to persuade the institution to look into the case, and it turned out that the author had already been suspended for other misdemeanours. In another case involving published material, investigation by the journal revealed that the doctor had already been struck off the national medical register for similar offences, so the journal issued a retraction. In one case involving submitted data, the journal rejected the paper without taking any sanctions against the authors. In another case, the editor felt that, despite misgivings about a submission from overseas
describing results that were 'too perfect', he did not have sufficient evidence to approach the authors’ institution so he rejected the paper after the authors denied any wrongdoing. Another long-lasting case could not be pursued because the journal lost the correspondence. One case related to a fraudulent letter written (and published) under a false name which came to light when the purported author contacted the journal stating that he had neither written nor submitted this letter. The journal published a retraction and the editor notified the dean of the medical school (since the culprit was believed to be a fellow student) but he declined to investigate the case.

Clinical misconduct

Cases of suspected clinical (as opposed to research) malpractice mostly involved the use of unorthodox treatments and concerns about inadequate patient consent for treatment. The editor contacted the authors’ employer or regulatory body in six out of 10 cases (and in all cases for which the outcome was fully reported). The author had already been disciplined in two cases and had retired in another. One of the regulatory bodies chose not to act, and two organizations (including a European national medical association) did not reply to the editor despite repeated letters. One case relating to the treatment of a single individual (reported as a case study) was discussed with the patient, who decided to take it no further. This unusual course of action was possible because the case had been written-up by clinicians at a tertiary referral centre but the alleged malpractice occurred at another centre. The journal peer-reviewer, on reading the case, suggested that the patient should sue. The editor relayed the reviewer’s concern to the authors (who had not been involved with the earlier treatment) and they were able to contact the patient.

Plagiarism

Cases of plagiarism were relatively uncommon (only seven cases) but tended to be resolved more quickly than other types of misconduct (all but one within a year). In two cases, the editor reached an impasse and could not get a reply from the author. Of the two cases where the editor contacted the author’s institution, one produced a satisfactory inquiry (and the submission was withdrawn) while the other provoked prolonged correspondence from the author who clearly felt aggrieved by the editor’s action. (The latter case was first referred to COPE in 2000 but re-referred to the committee because of further
difficulties and was not closed until 2003.) One case was resolved with a reprimand for the relatively junior and non-native English speaking author.

**Time taken to resolve cases**

Almost half the cases (46%) took at least one year to resolve, and some lasted for several years. Cases of clinical misconduct and data fabrication were the most likely to take more than one year while cases of plagiarism tended to be resolved more rapidly. One case (of suspected data fabrication) lasted over ten years, partly because the author produced raw data which proved very difficult to analyse, and this occupied a statistician for over 2 years. Then, various national authorities were slow to reply or passed responsibility onto other bodies. The journal was keen to alert readers to its concerns but the author threatened legal action, which involved further discussions with the journal’s insurers and legal advisers.

**Discussion**

What conclusions can be drawn from these cases? The first is that, even though editors are not expected to carry out investigations themselves, just getting a response from authors, institutions and regulatory bodies can be time-consuming and requires tenacity. In many cases, an impasse is reached because the author and/or his/her employer or professional governing body fails to respond to the journal despite repeated communications.

However, several cases suggested that journal editors, despite referring a case to COPE, did not pursue it completely or as thoroughly as might be hoped. For example, one case of possibly fraudulent data was simply rejected, and another case was not pursued because the journal lost the correspondence. These outcomes fall short of the behaviour expected by editors in the COPE Code of Conduct.

Editors contacted the authors’ employer, institution or governing body in only 30% of cases. Editors appeared most likely to contact such authorities in cases of suspected clinical (rather than research) misconduct, unethical research or fraud, and least likely in cases of plagiarism or redundant publication. This perhaps suggests that editors reserve this sanction for more serious types of misconduct. The COPE flowcharts which offer guidance on how to handle

various types of research and publication misconduct indicate that the accused author must always be given a chance to respond but, in several of the cases reported to COPE, authors responded only after the journal threatened to contact their institution or employer. The Council of Science Editors’ White Paper on Promoting Integrity in Scientific Journal Publications\(^7\) recommends that ‘notifying an author’s institution should not be a reflex reaction for editors. Editors should consider the impact such notification may have on the career of the accused scientist.’ However, the CSE White Paper also notes that ‘In the United States, by regulation, institutions have the primary responsibility to conduct investigations of misconduct allegations.’ CSE also notes that ‘Relatively few editors opt to notify the relevant federal agency because the jurisdiction of the agencies is often unclear … and because the agencies will only refer the matter to the employing institution for investigation. Also, notification of a federal agency makes the journal the accuser and creates a role for the journal in a misconduct investigation whether the journal wants one or not.’ An important limitation of the US Office for Research Integrity is that it will only consider cases in the US relating to federally funded research and does not investigate alleged misconduct occurring in research funded by other sources such as industry or charities.

Academic institutions may be reluctant to instigate investigations since they wish to avoid bad publicity which might be associated with a finding of misconduct. In this respect, institutions have a conflict of interest in the outcome of any finding. Yet, in most countries, no other organization with the authority, expertise and resources to carry out such investigations exists. Journal editors and others with an interest in research integrity should, perhaps, lobby for academic institutions in their country to be held accountable for investigations and to have proper procedures in place to ensure that any investigations follow due process.

Sanctions taken against authors found guilty of research or publication misconduct included retracting articles, publishing notes of concern, informing the authors’ employer and banning the author from publishing in the journal for two years. When an editor has serious concerns but insufficient evidence to be sure that an author has committed misconduct, and when the author’s institution is uncooperative so a proper investigation does not occur, it can be particularly hard to determine the best course of action. Simply rejecting a submission

\(^7\) [http://www.councilscienceeditors.org/editorial_policies/whitepaper/3.3_reporting.cfm#3.3.2](http://www.councilscienceeditors.org/editorial_policies/whitepaper/3.3_reporting.cfm#3.3.2)
leaves the author free to submit elsewhere, and even raising concerns about the conduct of a study could provide unscrupulous authors with suggestions for altering their reports to make them more acceptable to another journal. It is an unfortunate paradox that honest authors may be shamed or frightened by a reprimand or expression of concern while dishonest scientists may be undeterred. A reviewer involved in a long-running case involving large numbers of papers commented ‘Every time the errors on his manuscript were pointed out, they were cleaned up for the next submission. So, in effect, the reviews were giving him a tutorial.’

Where allegations relate to published (as opposed to submitted) work, editors may consider issuing an ‘expression of concern’. This is recognised as a lesser sanction than a full retraction and may be used when there is insufficient evidence for a full retraction or while an investigation is underway. The COPE cases are too small a sample to provide meaningful information about this, but it is interesting to note that PubMed (from 1966 to mid-2007) contains only 22 expressions of concern compared with 821 article retractions, suggesting that this sanction is rarely used. One reason why editors may be reluctant to publish accounts of concerns relating to specific individuals, especially if they have only patchy evidence, is that these can provoke threats of legal action. Another option is to publish an educational article on a type of research or publication misconduct (such as plagiarism or redundant publication) without identifying actual cases. A series of cases of questionable research prompted one journal to prepare guidelines for editors and a discussion document about the difficult borderlines between acceptable innovation, or routine audit, and research.

This small study has several limitations. It was based solely on the published COPE reports, and the outcomes for some cases were either missing or incompletely reported. Since the COPE cases are always published without attribution, it was impossible to contact the journal editors to obtain more information. Unfortunately only cases up to 2003 are currently available. While COPE is now an international organization, with around 300 members, the majority are European journals, with a predominance of UK publishers and editors. In the United States, at least for federally funded research, the system for investigating research misconduct via the Office for Research Integrity is

more highly developed than in many other countries (such as the UK), so it may be easier for editors to initiate investigations so impasses may be less common. However, many of these cases highlighted the difficulties faced by editors trying to raise concerns about possible misconduct by overseas authors. Even discovering which authority the editor should contact can be troublesome, and in several cases, the editor received no response from the overseas institution or regulator.

As the COPE code notes, investigating suspected author misconduct is, indeed, an onerous responsibility and editors may be frustrated at their inability to resolve cases. It is disquieting to note that 15 of the 79 COPE cases (i.e. 19%) were not satisfactorily resolved and this is probably an underestimate given the number of cases with no outcome reported. Fiona Godlee (former Chair of COPE) has observed that ‘Rather than embark on a potentially troublesome and protracted investigation, an editor may be tempted simply to reject the paper on other grounds’ but she then states, unequivocally, that ‘COPE takes the view that this is not acceptable’.

More work is needed to establish how often journal editors have to deal with concerns about research or publication misconduct, and to study systematically how they act. Members of COPE may be more likely than other editors to pursue such cases, but even among COPE members there is considerable room for improvement. This series of cases clearly demonstrates that pursuing suspected misconduct can be time-consuming, even though editors are not expected to conduct inquiries themselves. It seems likely that academic editors with little or no administrative support may be more tempted to let cases drop if they cannot easily be resolved while full-time editors working from well-staffed offices may be better placed to pursue cases (although the current study did not investigate this). Forums such as COPE and WAME, and resources such as the COPE flowcharts, the WAME policy statements, and the CSE white paper offer guidance to editors so that they should know what is expected of them. However, few editors undergo formal training, so many may be unaware that such resources exist. Organizations such as COPE, WAME and CSE need to promote understanding among journal editors about their responsibilities and also provide practical guidance and training about what editors should do if they suspect misconduct. Journal publishers can also play an important role in training and supporting editors and it is encouraging to note

that one major publisher has recently produced guidelines for its editors, with links to the COPE flowcharts, and is actively promoting these.\textsuperscript{11} Researchers and editors in countries that lack national bodies to investigate misconduct should try to get them established. Senior academics should also work within their institutions to ensure they take their responsibilities to investigate misconduct allegations seriously. As Richard Smith commented, in relation to two protracted cases ‘the scientific community has an obligation to the public to do better’.\textsuperscript{4}

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\textbf{Table 1}

Outcome of cases involving author misconduct from COPE reports 1998-2003

<table>
<thead>
<tr>
<th>Type</th>
<th>Total cases</th>
<th>Author(s) exonerated</th>
<th>Author(s) reprimanded</th>
<th>Impasse Contacted institution*</th>
<th>Outcome not reported / unclear</th>
<th>Lasted \textgreater 1 yr*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redundancy</td>
<td>33</td>
<td>7</td>
<td>8</td>
<td>3</td>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>Unethical research</td>
<td>16</td>
<td>5</td>
<td>2</td>
<td>4</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Fraud/ fabrication</td>
<td>13</td>
<td>2</td>
<td>4</td>
<td>3</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Clinical misconduct</td>
<td>10</td>
<td>0</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Plagiarism</td>
<td>7</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>\textbf{Total}</td>
<td>\textbf{79}</td>
<td>\textbf{16 (20%)}</td>
<td>\textbf{17 (22%)}</td>
<td>\textbf{16 (20%)}</td>
<td>\textbf{24 (30%)}</td>
<td>\textbf{30 (38%)}</td>
</tr>
</tbody>
</table>

* These outcome categories are not exclusive

Dealing with Scientific Misconduct in the Future

ROLE OF EDITORS AND JOURNALS IN DETECTING AND PREVENTING SCIENTIFIC MISCONDUCT: STRENGTHS, WEAKNESSES, OPPORTUNITIES, AND THREATS

Ana Marusic,* Vedran Katavic,* Matko Marusic*

Abstract: Scientific journals have a central place in protecting research integrity because published articles are the most visible documentation of research. We used SWOT analysis to audit (S)trengths and (W)eaknesses as internal and (O)pportunities and (T)hreats as external factors affecting journals’ responsibility in addressing research integrity issues. Strengths include editorial independence, authority and expertise, power to formulate editorial policies, and responsibility for the integrity of published records. Weaknesses stem from having no mandate for legal action, reluctance to get involved, and lack of training. Opportunities for editors are new technologies for detecting misconduct, policies by editorial organization or national institutions, and greater transparency of published research. Editors face threats from the lack of legal regulation and culture of research integrity in academic communities, lack of support from stakeholders in scientific publishing, and different pressures. Journal editors cannot be the policing force of the scientific community but they should actively ensure the integrity of the scientific record.

Keywords: Editors; journals; research integrity; scientific misconduct; SWOT analysis

Trust but verify.
Damon Runyon,
American journalist
(1884-1946)

Ideally, the whole enterprise of scientific research is based on trust: the public trusts science and scientists because of their contribution to humanity, scientists

* Croatian Medical Journal, Zagreb University School of Medicine, Croatia
trust each other because collaboration is an essential requirement for research, and granting bodies trust scientists and fund their research ideas even if there is no guarantee that research will be successful. Journal editors trust their authors that they have submitted original and valid work. And finally, to close the circle of trust - the readers trust scientific journals that they have done their best to select the most important research in the field.

Despite the fact that the whole scientific community is responsible for the integrity of scientific discovery, it is scientific journals that are usually the place where the breach of trust - scientific misconduct - is discovered. This is because scientific publication is perhaps the best documentation of the actions of scientists involved in particular research and best visible to the scientific and general public. This is also the reason why the focus of the public, and often the blame, is on the journals and their editors and reviewers. Judging from newspaper titles, such as “For Science’s Gatekeepers, a Credibility Gap,” public perception is often that editorial and peer review processes fail to protect the integrity of science. Because editors are the first to face the “disease” of scientific fraud, they are blamed for failure to protect from the disease. This is analogous to the differing roles of prevention and treatment in medicine and public health. A scientific journal is the place where the disease is diagnosed. However, the causes of this disease are not in the journals themselves, but in the whole scientific community. Just as one does not blame the x-ray machine for displaying a bone fracture, journals and editors should not be the sole recipients of the blame when fraudulent or irresponsible research is published.

In terms of health, preventing diseases is always better than treating them, and this has been true from the beginning of medicine. To quote Galen, the founder of modern medicine: “Since, both in importance and in time, health precedes

the disease, so we ought to consider first how health may be preserved, and then how one may best cure disease.” Health of the scientific endeavor - the responsible conduct of research - should be preserved by active and preventative work of all stakeholders - researchers themselves, their institutions, policy makers, granting bodies, scientific journals, and the public.

As journal editors have a central position in communicating research, they also have the most important role in ensuring the integrity of its published record. If we liken the editors to public health workers, they then have an important role in preventing, detecting, and dealing with scientific misconduct and questionable research practices. To analyze their current position and explore future possibilities, we will apply SWOT analysis - a technique often used to analyze a specific situation and develop suitable strategies and tactics, assess core competencies and capabilities, and provide evidence for change. SWOT stands for Strengths and Weaknesses (representing internal resources and capabilities), and Opportunities and Threats (representing factors external to the organization or group).

**Strengths**

In recent disclosures of fraudulent research, the public questioned the credibility of journal editors and reviewers, stating that journal editors “shift the blame to the authors and excuse themselves and their peer reviewers” or that “the current manner of peer reviewing research articles provides no assurance that the proffered work is not the result of fraud.”

However, we will argue here that journal editors, among all stakeholders in research integrity, have due expertise in research integrity issues and have made a major contribution in formulating and implementing editorial policies that go beyond publication ethics. Other strengths of editors in promoting and preventing research misconduct are their independence as editors and, at the same time, authority in the scientific community, and formal responsibility for the integrity of the published record.


Editorial independence

Editorial independence is the prerequisite for editorial involvement in research integrity issues. This independence is very important for medical editors, who often face pressures from their owners, publishers, as well as commercial enterprises\(^8\). Editorial freedom is not important only for ensuring the validity of the published work but also for the transparency of all procedures guarding against different conflicts of interest. Editorial independence is something that did not come easily to editors of medical journals, both in large\(^9,10\) and small journals\(^11\).

Editorial freedom and independence gives editors the means for ensuring responsible publishing in their journals. According to the World Association of Medical Editors (WAME) policy statement\(^8\), editors “should resist any actions that might compromise these principles in their journals, even if it places their own position at risk.”

Authority in the scientific community

Most medical editors are also respected professionals in their academic or research community. This gives them strength to promote responsible conduct of research and publishing and to serve as educators of their scientific community\(^12\). In some countries, editors have been major factors in the development of research integrity policies at the country level. An example is our journal, Croatian Medical Journal, published in a small scientific community burdened by many adverse factors, including the legacy of corruption and

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egalitarianism in the post-communist transition period. Recognizing the importance of research integrity for a small and vulnerable community of scientists, and learning about the work of the agencies promoting research integrity, we set it as our goal to promote these issues at all levels of our work: working with authors, working with medical students and medical researchers, and informing the policy makers about the need for public engagement in promoting and ensuring responsible conduct of research.

Expertise in research integrity issues

Among stakeholders in research integrity, editors are rather unique in their efforts for continual evaluation of their own work and practices. In an effort to base their action on evidence, editors have been pioneers in collecting evidence about all aspects of scientific publishing, including research integrity. The best example are the Peer Review Congresses, which have grown from a small gathering of editors in 1989 to a respectable field of research, as judged by the increase in the number of reports submitted to the Conferences and the number of published research articles (Figure 1).

Power to formulate and implement editorial policies

Perhaps the greatest power of journal editors is their responsibility and privilege to formulate and implement editorial policies to ensure the validity, objectivity, fairness and transparency of the publishing process in science. For the last 50 years (the age of the oldest professional editorial organization, Council of Science

Editors; ref 20), editorial organizations have been instrumental in defining and implementing policies and best practices in scientific publishing. Medical editors are particularly active in addressing the issues of research integrity and scientific misconduct because fraudulent reporting in medicine may have direct effect on human lives. Table 1 lists major professional editorial organizations and their policies outlining ethical issues and editorial responsibilities.

The need for clear ethical guidelines and adherence to them has been recently emphasized in the finding of an external committee that investigated how Science handled the two articles on stem cell research by W. S. Hwang and his colleagues, shown to be a clear case of fraud that could have been caught with more editorial vigilance21. Among other suggestions, the Committee made the recommendation that high-profile journals, including Science and Nature, should come together and establish common standards for ensuring data integrity. This “elitist recommendation”22 should be worrying for editors because they obviously failed to communicate to their authors and readers (including members of the external committee) that the policies for good practice in scientific journals already exist. This case also illustrates how strength (policies) can at the same time be a weakness, when editors obviously did not succeed in informing the community about their work.

**Responsibility for the integrity of published records**

Editors are not, could not, and should not be the policing force of science and scientific community23-25, but they can contribute to research integrity and ensure

the trust of the public by enforcing their major responsibility - the integrity of
the published record in science. The recent CSE White Paper on Promoting
Integrity in Scientific Journal Publications defined in detail different types
of correcting the literature and defined the responsibilities of editors in this process.

The editor should publish the correction as soon as reasonably possible, but
timely correction may be hindered by the tardiness of the official investigation
of scientific misconduct, as it usually takes a long time for the conclusion of the
investigation. According to the Ethics Flowcharts of the Council for
Publication Ethics (COPE), the editor can publish literature correction if the
response from the authors is not satisfactory, as well as if there is no response
from the institution or relevant authority in a reasonable time period.

Retractions are easily identified in the major bibliographic database in medicine,
Medline/PubMed because they are assigned a special publication type tag
(“Retracted Publication [PT]”). Also, the list or all citations identified and tagged
as a retracted publication can be accessed using the Special Queries tool of
the time of writing this article, there were 827 retractions in the PubMed (Table
2). Retractions were common in some but not all large and prestigious medical
and life-science journals (Table 1). The reasons why some journals have few
retractions and others much more, especially in relation to the number of
published articles, are not clear and certainly warrant further investigation.

In the absence of action from authors or responsible institutions or bodies,
editors can use another form of literature correction before the final decision
on retraction of correction - “expressions of concern” about the conduct or

26. Budd JM, Sievert M, Schultz TR, Scoville C. Effects of article retraction on citation and
27. Sox H, Rennie D. Research misconduct, retraction, and cleansing the medical literature:
integrity of the work\textsuperscript{28, 30}. Table 3 shows how often the editors of major medical and life-sciences journals (the same in Table 2) have used this form of editorial action as their contribution to the query into the integrity of the published record. As with retractions, the journals differ in their practices of expressing concern about published research. Editors are not afraid to make a correction of their statement if they think it is in order, illustrated by the example of a “retracted expression of concern” (Table 3).

**Weaknesses**

The weaknesses of editors in addressing scientific misconduct are closely related to their strengths because they often do not use the strengths to their advantage, for a number of reasons.

**No mandate for legal actions**

Journal editors do not have the mandate or resources to conduct a formal judicial inquiry or to make formal judgments about allegations of scientific misconduct\textsuperscript{31}. What they can do, in order to protect the integrity of the public scientific record, is to share their concerns with the authorities - authors’ employer(s), university, granting agency, or regulatory body\textsuperscript{31}. Many editors are reluctant to investigate cases arising in their journals because they are sometimes threatened by legal actions\textsuperscript{27}. Few journals have a system to monitor research integrity issues and regularly report on their activities\textsuperscript{14, 32}. More often, editors may share their concerns with authorities but these may not respond at all or respond in an inappropriate or untimely fashion\textsuperscript{33, 34}, making it difficult for the journal editors to protect the integrity of the public scientific record. The


worst scenario for editors is when there is no official authority for reporting their concerns.35

Reluctance to get involved in delicate issues

Editors may not want to get involved in allegations of scientific misconduct not only because of legal problems but because such cases are delicate and sensitive. This is often the case for editors who work in small scholarly journals. Already burdened by professional obligations and working voluntarily as a journal editor in an academic community that refuses to get involved in research integrity issues, an editor’s typical mechanism of defense is denial. This is particularly true for journals in small scientific communities, where editors are also active researchers and personally know or have collaborated with most of the researchers in the community. We have encountered such behavior in several of the cases from our journal, the *Croatian Medical Journal*. In cases where we needed the response from an editor, the most common reaction was no response at all. As there are no professional bodies for regulating and monitoring editorial work, there are also no adverse consequences for editors who simply refuse to deal with research integrity issues. The only organization that obliges its members to a code of conduct and any possible consequences in processing allegations against editors is the Committee on Publication Ethics (COPE), but its policies and procedures oblige only COPE member journals.29

Few means of action

Editors have two ways of reacting to the findings of research misconduct: they can correct the literature and they can alert the institutions or organizations of authors found to be involved in the allegation of misconduct. Although these actions constitute the strengths of editors, they often do not use it for the benefit of their journals and scientific community. A recent investigation into retraction policies and practices in 122 high-impact biomedical journals showed that only 4 journals had statements about their retraction policies on their websites, and that 78% of them had no policy on issuing retractions. Even if the retractions are published and clearly tagged in the Medline/PubMed, they continue to be

cited, often in either implicitly or explicitly positive mention of the retracted research\textsuperscript{26,27}.

\textit{Possible damage to journal’s reputation}

Laxity in the corrections of published literature and reluctance to get involved in cases of misconduct is often related to the perception that such actions would bring damage to the journal’s reputation. Although there is no formal research into this matter, behavior of journals in several well-publicized cases clearly show that journals often do not get involved not only by ignoring their responsibilities but often byactively evading involvement or action. For example, in the case of 47 articles with manipulated or invented data from two German researchers, published in 19 journals, a follow-up of the journals’ reactions to official findings of misconduct showed that only 2 of these journals retracted the articles, a half of the journals never responded to the query, and those that replied stated that they had no knowledge about misconduct findings and that the retraction was the responsibility of the authors\textsuperscript{37}. One of the reasons for the laxity in correcting the published literature is a common misconception among editors that authors must write and approve a retraction. However, literature corrections can be made by different authorities, such as authors, editors, publishers, department chairpersons, institution heads, laboratory directors, or legal counsel\textsuperscript{28}, and there are examples of different types of literature correction in Medline/PubMed\textsuperscript{28}.

\textit{Lack of education and staff to implement adequate procedures}

Although the procedures, policies, and codes are available to editors, and their journals officially subscribe to them, there is a great precipice between the formal acceptance of and actual adherence to rules and procedures. Many journals subscribe to international editorial policies only formally, without real implementation. This is true not only for small, scholarly journals from small communities but also for large and financially well-off journals. Journal’s vigilance in research integrity issues is a demanding activity, both in personnel and funds\textsuperscript{38}, and journals often cannot afford them. For example, only the largest

\textsuperscript{37} Cooper-Mahkorn D. Many journals have not retracted “fraudulent” research. \textit{BMJ}. 1998;316:1850.

\textsuperscript{38} Rossner M, Yamada KM. What’s in a picture? The temptation of image manipulation. \textit{J Cell Biol.} 2004;166:11-15.
medical journals have dedicated staff for verification of registration data for each trial submitted to the journals, according to the ICMJE policy on trial registration 39.

Even when journals have trained staff and techniques, they may still perform poorly in detecting evident fraud. Mike Rossner, managing editor of the Journal of Cell Biology and a pioneer in addressing image manipulations in scientific journals, recently recounted his experience, albeit indirect, with the Hwang stem cell fraud case from the Science22. His staff at the Journal of Cell Biology, a journal that systematically screens all images in accepted articles38, trained Science editors in image screening, but the Science insists that these methods would not have discovered the manipulations in Hwang’s article.

Opportunities

Regardless of the “smallness” of his or her journal, organizational, financial, or staff problems, a conscientious journal editor today has many opportunities to prevent, detect, and investigate research misconduct, as well as to promote responsible conduct of research.

Editors are well positioned to detect scientific misconduct

Regardless of possibly adverse conditions for their journals, editors are often the first or the only public body that discovers or is alerted about indications for fraudulent research. Only by ensuring the validity of the published record in a transparent and responsible manner, editors can keep the trust of the scientific community and the public.

Availability of new technologies for detecting misconduct

Even an understaffed and financially less privileged journal editor has at his or her hand a number of electronic tools for checking the integrity of the published articles. For example, Office of Research Integrity (ORI) of the US Department of Health and Human Services, offers free electronic tools for examining electronic images in articles (http://ori.dhhs.gov/tools/data_imaging.shtml). They

are easy to use and do not require extensive training. ORI also offers very useful tips for addressing suspicious numerical data [http://ori.hhs.gov/misconduct/Tips_StatisticalForensics.shtml and http://ori.hhs.gov/misconduct/Tips_StatisticalForensics2.shtml].

In small journals and small scientific communities, plagiarism is a common form of misconduct\(^{33,40}\), often related to the pressure to publish in circumstances of inadequate funds. Thus, small journals should be especially vigilant in protecting against duplicate publications or outright plagiarism\(^{14}\). In the past, a journal could rely only on a knowledgeable and well-read reviewer to notice overlap of articles. Today, there are free programs on the web that can search for similar texts. For example, the Eblast web-program [http://invention.swmed.edu/etblast/etblast.shtml] searches the PubMed not by keywords (the PubMed search strategy), but for whole paragraphs, and returns PubMed abstracts that are similar to a large extent\(^{41}\). Apart from this free web-service, there are a number of commercial software solutions for detecting plagiarized articles.

**Editorial policies developed by editorial organizations**

Editorial policies (Table 2) were described as the internal strength of the editorial profession to ensure the integrity of scientific communication. Even for an editor working in isolation, outside of formal editorial organizations, these policies provide both guidance and protection in their community. We can personally testify to the importance of international editorial policies for editors in a small academic community burdened by the lack of knowledge about handling misconduct, or by personal conflicts and academic hypocrisy. Our journal has successfully resolved two cases of redundant publications\(^{42,43}\) by prompt action.


and adherence to international rules for handling misconduct allegations in journals.

Policies developed by national ethics/integrity bodies

In countries where they exist, policies for promoting responsible conduct of research and procedures for handling misconduct allegations are a great opportunity for editors who take an active part in protecting and promoting the integrity of research published in their journals. The oldest governmental bodies charged with handling misconduct cases are Research Integrity Committees in the Nordic countries - Denmark, Norway, Sweden and Finland. They were followed by the development of the Office for Research Integrity in the USA, addressing biomedical research, and a similar office at the National Science Foundation for other fields of science. Such bodies, of varying structures, mandates, and responsibilities exist in many countries, including Germany, Switzerland, India, Japan, China, UK, and Croatia, and in other countries, such as Canada, journal editors and other stakeholders in research enterprise make urgent calls for such a body.

Research integrity bodies have different mandates and legal frameworks for their actions in different countries, but they provide an important opportunity for journal editors in pursuing their concerns about work submitted to their journals. Editors cannot conduct legal inquiries into possible scientific misconduct and have to rely on other authorities, which often take a long time to conclude misconduct investigations or never respond to editor's communications or concerns. In such cases, editors could turn to a national research integrity body, which should ensure that there is adequate procedure for handling allegations of scientific misconduct at all levels of research and academic


45. Abbott A. Germany tightens grip on misconduct... Nature. 1997;390:430.


infrastructure. For editors, especially in small scientific communities, this line of action may provide at least some protection from the adverse reactions from their local academic or research communities, as they often experience the fate of research integrity whistleblowers°.

**Greater transparency of publications on the web**

In the past, searching the literature involved cumbersome and time-consuming tasks of going through huge print issues of bibliographical databases. Today, free access to the largest medical bibliographical database, Medline/PubMed, and availability of full text articles on the web is an opportunity for editors to use it in promoting the integrity of their journals. Journals may use special software solutions to search for content similarities, but even the use of the PubMed feature “Related Links”, which appears with each retrieved citation, can help in identification of potential overlapping, duplicate, or plagiarized publications. Although “Related Links” feature was not developed to aid editors in detecting fraud but to help researchers find articles on a similar topic, it is a great aid for a vigilant editor to spot possible misconduct.

**Greater transparency of literature corrections on the web**

In the “paper only” age of scientific journals, retractions and corrections were difficult to retrieve. Today, electronic databases specifically tag such items, and PubMed developed a special feature and publication categorization to retrieve all retractions and corrections (Tables 2 and 3). There are also programs, like eXtyles from Inera in the US, which checks each reference in an article against PubMed and specifically tags citations that were retracted. Such tools are useful not only for editors but also for authors to ensure the integrity of the work they cite. Some editors call for mandatory requirements to authors to attest that they have checked manuscript’s references against the PubMed master list27.

**Threats**

There are many threats facing journal editors actively engaged in promoting research integrity and detecting scientific misconduct.

*Lack of legal regulation and culture of research integrity in the scientific community*

Regardless of the size, influence, and financial means of a journal, absence of
a legal framework for their activity and poor culture of responsible conduct of research in the community are serious threats to the integrity of the journal and editor. In the absence of norms which can be enforced, authors will continue to cite retracted articles or refuse to retract or correct reports of their own work, whereas institutions or other journals will not answer queries from editors. Editors will be drawn into the vicious circle of irresponsible science, work in frustration or burn out as ill-treated whistleblowers.

Corruption of the scientific community and society

The vicious circle of disregard for responsible conduct of research is a major threat for editors working in many academic communities. This is true not only for small or financially less privileged communities, but also for academic communities in the richest countries. Academic communities are known for “capriciousness and incomplete” handling of misconduct cases, where even the deans from renowned universities may fall victims to the whistleblower’s syndrome.

We have the experience of editors from a country undergoing socioeconomic transition from the communist state, where, like in all countries with similar history, corruption and cheating the state have been firmly rooted among the people. We did not expect that our decision to actively promote research integrity of the Croatian medical academic community through the journal would result in such animosity and finally open threats and allegations to discredit our integrity as researchers, especially because we did not ask for official processing of our findings but tried to educate the authors so that they wouldn’t make the same mistakes again. When a major case of research misconduct of a Croatian researcher was made public in international literature, we were accused of being the ghost authors of the article in the international journal. We were asked to “stop further attacks from the BMJ” and threatened that the “whole system will be used” in destroying our academic and research careers.


52. Hem E. With an open window to the world. [In Norwegian] Tidsskr Nor Laegeforen. August 2007; in press.
Only the strength and transparency of journal policies, the availability of international expertise, and a legal framework for handling scientific misconduct at the highest state level\textsuperscript{10} protected us to some extent.

\textit{No training available}

In many communities, there is little or no systematic training available not only for editors but for researchers in general. Many editors work in isolation of their unsupporting scientific and academic communities and are not aware of the opportunities for them to actively engage in promoting research integrity. Particularly dangerous is common lack of education and training in responsible conduct of research for future researchers, for whom often the only opportunity to learn about research integrity is to watch their mentors and superiors\textsuperscript{53}.

\textit{Lack of support from stakeholders in scientific publishing}

Editors are threatened not only by the lack of positive atmosphere for research integrity in their academic or research communities, but also by the lack of support and training from other stakeholders in journal publishing - professional associations and publishers. While some major publishers are actively engaged in promoting responsible editorial practices for their member journals\textsuperscript{29}, most other journals, published by small learned and scholarly associations and institutions, are left without any support\textsuperscript{11,50}.

\textit{Pressures on editors and journal}

The publishing business is the threat for editors by the very nature of the process, especially when financial conflicts of interest are involved. Journal editors have been fired over disagreements, either political or financial, and conflicts between the journal owners and editors\textsuperscript{9,10}. In medicine, financial interests of the pharmaceutical industry are perhaps the biggest threat to the integrity of the editorial position in promoting responsible conduct of research.

\textit{Conclusions and recommendations}

Using SWOT analysis, we analyzed the role of scientific journals and their editors in promoting research integrity, and assessed their core competencies

and capabilities. When journal editors are regarded as a profession, their strengths and opportunities are definitely greater than their own weaknesses and threats from outside. However, the weaknesses of individual editors and threats imposed to them from their environment may outweigh their strengths and opportunities. The weaknesses of editors of small and scholarly journals usually stem from their ignorance of opportunities for continuing education in a rapidly changing publishing world. Editors of large journals often have great strength and are up to date with all opportunities provided by the editorial profession, but these can still be overridden by the threats stemming from commercial pressures of their publishers and stakeholders, such as pharmaceutical companies.

With their central position in the communication of research in the scientific community, editors can and should do more, and individual weaknesses or external threats should not be an obstacle for taking an active part in promoting research integrity and preventing irresponsible research practices and scientific misconduct. Using the analogy with the x-ray machine, editors cannot be blamed for the bone fracture because they produce an x-ray image, but, as good doctors, they can ensure that they use the best technology to detect even the smallest of cracks and act to prevent a serious fracture. We can also make the analogy of scientific misconduct with the economic rationalization for crime if we consider scientific fraud as a "rational act of balancing the expected utility of scientific promotion against the expected cost of punishment". To achieve a fraud-free equilibrium in science, all stakeholders must ensure that the cost of fraud and assisting in fraud is high and that of informing about and processing fraud low. The role of journal editors, both as individuals and as a profession, in this is - to learn, to stay informed, and to teach. They have to preserve the trust in their authors, but also make sure that they do their best in promoting the integrity of the published record of research. Weaknesses and threats cannot be an excuse for doing nothing. Edmund Burke, an Irish orator, philosopher, and politician (1729-1797) said: “No one could make a greater mistake than he who did nothing because he could do only a little.” This is an important message.


for editors, just as another Burke’s famous saying: “All that is necessary for the triumph of evil is that good men do nothing.”

Table 1. Ethical guidelines and codes of conduct for biomedical journals

<table>
<thead>
<tr>
<th>Editorial organization</th>
<th>Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Association of Science Editors (EASE)</td>
<td>Science Editors' Handbook – Ethical issues [<a href="http://www.ease.org.uk/ese.html">http://www.ease.org.uk/ese.html</a>]</td>
</tr>
<tr>
<td>International Committee of Medical Journal Editors (ICMJE)</td>
<td>Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication [<a href="http://www.icmje.org">www.icmje.org</a>]</td>
</tr>
</tbody>
</table>
## Table 2. Retractions in major biomedical journals, recorded in Medline, July 1, 2007

<table>
<thead>
<tr>
<th>Journal</th>
<th>No. retractions</th>
<th>No. indexed articles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General medical journals:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Eng J Med</td>
<td>13</td>
<td>58,831</td>
</tr>
<tr>
<td>Lancet</td>
<td>10</td>
<td>115,306</td>
</tr>
<tr>
<td>BMJ</td>
<td>6</td>
<td>44,504</td>
</tr>
<tr>
<td>Annals of Internal Medicine</td>
<td>3</td>
<td>24,782</td>
</tr>
<tr>
<td>JAMA</td>
<td>1</td>
<td>58,392</td>
</tr>
<tr>
<td><strong>Major life-science journals:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Science</td>
<td>55</td>
<td>56,069</td>
</tr>
<tr>
<td>Proceedings of the National Academy of Sciences USA</td>
<td>40</td>
<td>89,031</td>
</tr>
<tr>
<td>Nature</td>
<td>35</td>
<td>82,374</td>
</tr>
<tr>
<td>Cell</td>
<td>15</td>
<td>13,203</td>
</tr>
</tbody>
</table>
Table 3. Editorial expression of concern about research published in major journals*

<table>
<thead>
<tr>
<th>Journal</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Journal</td>
<td>Citation</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Ann Intern Med</td>
<td>—</td>
</tr>
<tr>
<td>JAMA</td>
<td>—</td>
</tr>
<tr>
<td>Nature</td>
<td>—</td>
</tr>
<tr>
<td>Cell</td>
<td>—</td>
</tr>
</tbody>
</table>

* Data were collected by searching the PubMed with the combination of the term “expression of concern” and list of all published articles in individual journals retrieved from the Journals Database of the PubMed.
Figure 1. The number of abstracts (bars) submitted to five Peer Review Conferences (PRC) and the number of resulting publications (line) in the Medline/PubMed database. Source: Drummond Rennie, MD; Deputy Editor, *JAMA*. 

![Graph showing the number of abstracts and publications over time for five Peer Review Conferences (PRC 1 to PRC 5). The x-axis represents years from 1986 to 2006, and the y-axis represents the number of abstracts. Arrows indicate the years of each PRC: PRC 1 in 1989, PRC 2 in 1993, PRC 3 in 1997, PRC 4 in 2001, and PRC 5 in 2005.]
Environment and Scientific Misconduct

WHISTLEBLOWING AND SCIENTIFIC MISCONDUCT: RENEWING LEGAL AND VIRTUE ETHICS FOUNDATIONS

Thomas Alured Faunce * and Susannah Jefferys **

Abstract: Whistleblowing in relation to scientific research misconduct, despite the benefits of increased transparency and accountability it often has brought to society and the discipline of science itself, remains generally regarded as a pariah activity by many of the most influential relevant organizations. The motivations of whistleblowers and those supporting them continued to be questioned and their actions criticised by colleagues and management, despite statutory protections for reasonable disclosures appropriately made in good faith and for the public interest. One reason for this paradoxical position, explored here, is that whistle blowing concerning scientific misconduct lacks the policy support customarily derived from firm bioethical and jurisprudential foundations. Recommendations are made for altering this situation in the public interest.

Keywords: Whistleblowers; scientific misconduct; research ethics; virtue ethics; bioethics; human rights; conscience; corporate globalisation

INTRODUCTION

A survey of the world’s top scientific researchers is likely to reveal that a large proportion still affirm their chief career motivation to be the search for truth, or a closely related altruistic and humanitarian goal. Yet, there are now many institutional constraints that seem to cut across such foundational professional virtues. An increasing proportion of scientific research, for example, takes place in privately-funded institutions that necessarily have as a primary purpose, and fiduciary obligation according to corporate law, the maximisation of shareholder

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profit. Scientific researchers in public-funded institutions likewise are finding that a significant proportion of their work is required by legislation or funding body guidelines to be carried out under linkage grants or licensing and royalty agreements with private industry. Many researchers themselves have stock portfolios and shares or board of directors positions, closely related to their research work. Such roles come wrapped in commercial-in-confidence protections for data, as well as prohibitions on insider trading, contractual limitations on press or other public disclosure and more subtle constraints related to career pathways being heavily influenced by the capacity to appear valuable to industry.

Nonetheless, governments in many developed nations continue to acknowledge that public interest disclosures by individual researchers are a valuable source of information about inadequacies, misconduct and illegalities taking place in scientific organizations. This chiefly is evidenced by an increasing number of so-called ‘whistleblower’ protection bills and Acts designed to buffer such individuals against unjust reprisals. Such laws, often somewhat in advance of professional opinion and institutional culture, offer legislative protection for reasonable allegations of whistleblowers made in good faith and in the public interest concerning a substantial and imminent threat to the public good.


The type of scientific misconduct that may be the source of a whistleblower’s defining action ranges from the illegal and negligent, to unethical and inappropriate. Upon ‘blowing the whistle’ many scientific researchers face being cast as a pariah, a ‘trouble maker’ who has betrayed their organisation and / or their colleagues. Whistleblowing in many contemporary research institutions also is likely to be characterised as an act of corporate disloyalty with potentially disastrous consequences for share price and investment opportunities.

There is now considerable anecdotal evidence of the power of large organisations to place substantial financial and psychological burdens on whistleblowers. The perceived likelihood of reprisals or retaliation occurring (often in the guise of performance reviews) has been found to be a strong determinant of whether employees and colleagues will report wrongdoing. Likewise important is the widespread belief that those who report corruption or misconduct are likely to suffer for it. People are more likely to report


wrongdoing if they believe it will result in few personal costs. Exposing deception or misconduct in scientific research manifestly is for the public good, yet this often is countered, regardless of what legal protections are technically available, by the fear of receiving deleterious treatment, retribution or even the end of a career and income security for a family.

There is little, in terms of institutional governance guidelines, on how to best implement or fund the legislative protections afforded to whistleblowers. Few academic institutions seem interested in teaching whistleblowing seriously in any formal sense, for example as an accepted (if last resort) component of governance structures.

**Reinforcing the Ethical Legitimacy of the Whistleblower**

The hypothesis investigated here is that the lack of a firm theoretical bioethical and jurisprudential substrate has contributed to a situation where whistleblowing both generally, but particularly in relation to scientific misconduct, suffers in terms of institutional support and legitimacy.

The good sought by any regulatory system may be termed a telos and philosophies providing guidance on its maximisation are known as ‘teleological.’ Many forms of utilitarianism, for example, focus on the telos of overall community welfare. On certain interpretations, Aristotle offers a non-teleological ethics, provided, that is, we regard the ‘ultimate’ good or telos as

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actually defined by individual human virtues themselves. Some contemporary virtue ethicists accept a utilitarian telos based on a single good describable independently of virtue. Examples include the location of such a telos in a unified individual ‘life narrative’ according to MacIntyre, or scientific investigations of moral psychology according to Anscombe.

Others propound a non-teleological theory primarily emphasising the virtues themselves, or universal principles derived from them, without the conceptual need to posit any additional end-point of conduct. These theories are commonly subjected to objections, particularly by what are known as ethical ‘principlists’, concerning their circularity and failure to provide determinate guides to action. This could be perceived by some to be a major problem with using non-teleological virtue ethics, to provide an academic foundation for whistleblowing in a practical regulatory system.

Teleological theories focused on social aims have the regulatory advantage of providing clearly determined guides to action, though often at the expense of devaluing individual human rights. Thus, it may be an important aspect of providing a firm virtue-based foundation for whistleblowing in relation to scientific misconduct that the scientific enterprise is able to lay claim to a unique individually-focused telos.

In relation to medically-related scientific research, this primary telos can be viewed as involving relief of individual patient suffering. ‘Suffering’, in this context refers to that understood by the health professions as capable of threatening coherence in a patient’s life narrative and not being readily amenable to self-remedy. This emphasis on the individual in the primary regulatory telos overcomes problems of possible conflict between a virtue-based system and the consequentialist approach, such as the communal public health good of relieving suffering in as many patients as possible.


The primary *telos* may be depicted negatively (as relief of patient suffering) to more effectively arouse the conscience of medical researchers toward principled action, much as emphasising injustice operates in other contexts.\(^\text{16}\) A crucial premise in this context, and relevant, most particularly, to whistleblowing about scientific misconduct, is that complete instruction in and recall of relevant bioethical, legal and international human rights principles will not themselves motivate action. Motivation, involving the generation of emotion to encourage performance of an act, also requires convictions, or a sense of conscience, derived from previously established virtue. One suggestion (worthy of note by policy makers) is that such conscience arises most readily from direct proximity to individual patient suffering.\(^\text{17}\)

Finding a conceptually acceptable virtue-based *telos* for whistleblowing in relation to misconduct concerning scientific research is conceptually difficult. It is likely to be formulated as supporting the public importance of the search for abstract truth in accordance with universally-applicable principles of bioethics and international human rights. One potential normative source for such concepts is the UNESCO *Universal Declaration on Bioethics and Human Rights* and its associated database.

Article 18 of this declaration provides:

> “1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge.”

Article 14 provides:

> “2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief and economic, or social condition, progress in science and technology should advance:


(a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good.

(b) access to adequate nutrition and water;

(c) improvement of living conditions and the environment;

(d) elimination of the marginalisation and the exclusion of persons on the basis of any grounds

(e) reduction of poverty and illiteracy

For whistleblowing in relation to scientific misconduct to be taught effectively, it must first be accepted that (1) students need to be taught such universally applicable principles that provide a telos against which scientific conduct can be judged right or wrong, as can public disclosure of information about it (2) these principles must be capable of being incorporated into a professional life narrative, so that their threatened contravention evokes conscience and (3) that scientific researchers can be trained in this method.18

Under this approach action must be based on universally applicable principle, but not necessarily on legal obedience.19 When the primary utilitarian telos of this virtue-based system is formulated prescriptively as the foundational principle of scientific research, it takes on the characteristics of a master principle, intelligibly relating complementary and interstitial or interpretive principles and rules.

We may then say that a researcher in medical science, whose acts consistently emphasise this approach has a high probability of being a good role model.20 He or she is likely to improve trainees’ ethical behaviour.21 The conclusion, that positive role models will encourage the consistent calibration in conscience


of legal norms against universally-applicable bioethics and international human rights principles, followed by their consistent application in the face of obstacles, we would argue, represents a valuable academic virtue-based approach to regulation of scientific conduct. The fact that it may lead to whistleblowing within an ‘unethical’ system should be viewed as a strength by managers seeking to avoid the latter characterisation.

This approach to conceptually reinvigorating the academic foundations of whistleblowing about scientific misconduct finds support in many related policy initiatives. For example, Nordic countries have established a system of centralized national bodies to deal with allegations of research misconduct. Yet such mechanisms are likely to only become effective if linked with educational processes and institutional supports that encourage researchers’ consciences to consistently implement the related universally-applicable principles in the face of obstacles. Such process and supports must systematically create a ‘silent curriculum of learning by what one sees.’

In the recent Hwang Stem Cell Scandal, as will be discussed later, there emerged the disturbing fact that over 80% of biotechnology researchers in South Korea were not even aware of their profession’s basic ethical principles (as traditionally enunciated, for example in the Helsinki Declaration). This lack of knowledge about the necessary conceptual underpinnings for properly organised whistleblowing is likely to represent a wider problem in the scientific research community.

Reinvigorating the Law on Whistleblower Protection

The recent United States Supreme Court decision, in Garcetti et al. v. Ceballos 547 U.S. (2006) (hereinafter Garcetti), contains valuable lessons about the
way in which the type of academic virtue-based approach to whistleblowing could, in the hands of a somewhat more enlightened judiciary, be linked with legal reasoning to provide a firm conceptual foundation for institutional support of whistleblowers.

The respondent, Ceballos, was a public official, analogous, for present purposes, to a scientific researcher at a public-funded institute. He alerted his superiors to what he considered to be serious misconduct within his area of professional responsibility. These concerns were not acted upon. In subsequent legal proceedings Ceballos faced retaliation and claimed his First and Fourteenth Amendment rights were violated. The Supreme Court held that:

“When public employees make statements pursuant to their official duties, they are not speaking as citizens for First Amendment purposes, and the Constitution does not insulate their communications from employer discipline.”

The Majority indicated that “[r]estricting speech that owes its existence to a public employee’s professional responsibilities does not infringe any liberties the employee might have enjoyed as a private citizen.” For the Majority justices by not allowing First Amendment protection to public sector employees they are merely reflecting “the exercise of employer control over what the employer itself has commissioned or created.”

This decision does not completely rule out whistleblowing for public employees. Rather whistleblowing is relegated to “internal policies and procedures that are receptive to employee criticism.” That is, of course, if such procedures actually exist within an institution. The majority indicated that it is in the best interests of the employer to have such internal mechanisms as it will curtail any adverse publicity surrounding the source of the whistleblowers claims. Yet the majority neglects to contemplate the issue, raised by Stevens J in his dissenting opinion, where an employer or supervisor does not want the


27. *Garcetti*, at 10, per Kennedy J, Roberts CJ, Scalia, Thomas and Alito JJ.

28. Ibid.

29. *Garcetti*, at 12, per Kennedy J, Roberts CJ, Scalia, Thomas and Alito JJ.

30. Ibid.
whistleblowers claims to be heard at all.\textsuperscript{31}

Whistle blowing, by its very nature, generally is an external manifestation of poor internal procedures through which potentially unethical, dangerous, unprofessional, unsafe or illegal behaviour may be reported and dealt with. A timely recent example of this has concerned the US Food and Drug Administration (FDA), where whistleblowers such as Dr David Graham have indicated that FDA scientists have been discouraged by supervisors from raising questions about drug safety and sometimes have been prevented from sharing their concern with FDA advisory committees.\textsuperscript{32}

The Majority, in the final part of its judgment, emphasises that the exposure of “governmental inefficiency and misconduct is a matter of considerable significance.”\textsuperscript{33} They then indicate that, despite not having any constitutional protection for this exposure of inefficiency and misconduct, there is a “powerful network …[of] whistle-blower protection laws…” available for those who expose wrongdoing.\textsuperscript{34}

The decision of the Majority seems to imply that the legislative whistleblower protections are adequate. Yet in many instances the legislation provides only limited protective force.\textsuperscript{35}

Further, the type of speech by the whistleblower addressing the official wrongdoing may well fall outside the protected definition of whistle blowing.\textsuperscript{36}

There is also the legitimate and timely concern that the “combined variants of

\textsuperscript{31} Garcetti, at 1, per Stevens J.
\textsuperscript{33} Garcetti, at 13, per Kennedy J, Roberts C.J., Scalia, Thomas and Alito JJ.
\textsuperscript{34} Garcetti, at 13-14, per Kennedy J, Roberts C.J., Scalia, Thomas and Alito JJ.
\textsuperscript{36} For example, in the case of Givhan, where the teacher would not have qualified as a whistleblower as she was fired after a private conversation with the school principle: see Garcetti, at 14, per Souter J (dissenting).
statutory whistle-blower definitions and protections add up to a [complex] patchwork, not a showing that worries may be remitted to legislatures for relief." These diverse and disparate protections indicate that a whistleblower will get different protection for the same disclosure, based solely on “the local, state or federal jurisdictions that happen to employ them.”

The majority decision inadequately recognises the intricacies and importance of whistleblowers and the disclosures they make. For Justice Breyer, the speech at issue in *Garcetti* was that of “professional speech” and such speech is subject to the “independent regulation by the canons of the profession.” And that often those canons provide an obligation to speak in certain instances, as such “the government’s own interest in forbidding that speech is diminished.” As Justice Breyer so eloquently quoted:

“[P]rofessionals must always qualify their loyalty and commitment to the vertical hierarchy of an organisation by their horizontal commitment to general professional norms and standards.”

What would have happened if the justice had then gone on to cite those professional norms present in the UNESCO *Universal Declaration on Bioethics and Human Rights*? Surely, as article 18 of that Declaration requires this to be characterised as a situation where a court should take note of its encouragement of states, individuals, groups, communities, institutions and corporations, public and private (article 1) to promote “professionalism, honesty, integrity and transparency in decision-making.”

Interestingly, Justice Souter focused on the potential deleterious effect the majority decision may have on academic freedom in public colleges and universities, where teachers necessarily speak and write “pursuant to official duties.” The Majority explicitly refused to rule on whether the constitutional

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37. *Garcetti*, at 14, per Souter J (dissenting).
38. *Garcetti*, at 15, per Souter J (dissenting).
39. *Garcetti*, at 3, per Breyer J (dissenting).
40. *Ibid*.
41. *Ibid*.
42. *Garcetti*, at 4, per Breyer J (dissenting).
43. *Garcetti*, at 12, per Souter J (dissenting).
ruling in *Garcetti* would have the same effect on speech relating to scholarship or teaching.\(^4^4\) Ultimately, by taking a less rigid approach, the Minority justices (Breyer, Souter, Ginsburg and Stevens JJ) respected the value of whistleblowers and, at the same time, ensured the efficient function of government.

In response to this uncompromising attack on whistleblowers and the constitutional protection afforded to them, the United States Congress has introduced the *Whistleblower Protection Enhancement Act of 2007* H.R. 985.\(^4^5\) This bill, introduced by Reps. Waxman, Platts, Van Hollen, and Davis on 12 February 2007, seeks to reaffirm the protections for all whistleblowers and to reduce the effect of the Supreme Court’s *Garcetti* decision on federal workers less than six months after the decision was handed down.\(^4^6\) Recently, the House Oversight and Government Reform Committee approved, by a unanimous 28-0 vote, to approve this landmark legislation to overhaul the law protecting government whistleblowers.\(^4^7\)

**Whistleblowers and the Korean Stem Cell Scandal**

Whistleblowers continue to drive quality improvement in the conduct of scientific research, just as they do in healthcare. In late 2005, for example, what was later to become known as the ‘Stem Cell Scandal’ erupted on a very public and global scale. On 29 December 2005 an investigative team from the Seoul National University declared that there was no evidence that Hwang Woo-Suk and his team had produced any of the patient-specific stem cells they described in a June 2005 *Science* paper.\(^4^8\) The report sent shock waves through the research community for two reasons. First, the findings had invalidated what would have been a major breakthrough in stem cell research and for the South Korean research community.

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\(^4^4\) *Garcetti*, at 13, per Kennedy J, Roberts C.J., Scalia, Thomas, and Alito JJ.


\(^4^7\) See *Ibid.*

Secondly, it revealed that anonymous young Korean researchers, involved in the Hwang project, through an act of whistleblowing were essential to revealing major fraud and scientific misconduct that institutional governance and peer review had failed to detect. Indeed, *Science*’s editor-in-chief, David Kennedy admitted that “[p]eer review cannot detect [fraud] if it is artificially done,” and emphasised that the falsifications in the Hwang paper – image manipulation and fake DNA data – are not easily detected by reviewers or editors.\(^{49}\)

The facts of the Hwang case provide an interesting glimpse into the hazardous waters of whistleblowing. The fear of reprisal led one member of Hwang’s team to anonymously tip off an investigative TV news program known as *PD Notebook*. According to Chong, one of the program’s producers, Bo Seul Kim, the whistleblower had informed him that “his conscience had been bothering him over problems he knew of with Hwang’s research,” he then urged the program to contact him, concluding his message with the words, “I hope you don’t refuse this offer to get at the truth.”\(^{50}\)

A meeting between the whistleblower and the program’s producers soon followed. It was revealed that he had left Hwang’s team due to “ethical and technical concerns.”\(^{51}\) Speaking on the condition that his identity would be concealed, he revealed that many of the eggs used in Hwang’s research had in fact been donated by junior members of his research team, and often after great pressure had been placed on them by Hwang. The whistleblower then indicated that he felt that Hwang’s patient-specific stem cells were the result of fraudulent research practices. But he admitted that he had no hard evidence to prove this, and relied solely on his research experience with Hwang.

The program’s producers, spurred on by the allegations made by the whistleblowing former researcher, persuaded two researchers within Hwang’s labs and three independent scientists to assist with their investigation. They soon uncovered evidence that there were inconsistencies with Hwang’s stem cells lines and with his claims on the number of teratomas produced on each line.\(^{52}\)


\(^{51}\) *Ibid*.

\(^{52}\) *Ibid*. 
Using hidden cameras and false claims that prosecution of Hwang had commenced, the journalists then obtained incriminating information from Gerald Schatten, a Hwang collaborator and co-author of the 2005 paper, and Sun Jong Kim, another co-author and former Hwang researcher.53

From this point on the entire Hwang stem cell scandal began to unravel. But not without many obstacles, PD Notebook’s broadcaster, for example, refused to air the exposé after allegations were made of the producers’ unethical conduct and the public backlash (at the time Hwang enjoyed immense public support and respect in South Korea).54 But the whistleblower refused to go unheard, leaving an anonymous posting on a biological research information webpage (BRIC) urging closer investigation of the doctored photographs of Hwang stem cell lines.55

Despite some strategic moves by Hwang to postpone the revelations, eventually his scientific fraud was uncovered. The Hwang case illustrates the vast obstacles, ranging from institutional and personal, that stand before a whistleblower seeking to implement universally applicable principles (such as those, for instance in the Helsinki Declaration or article 18 of the UNESCO Universal Declaration on Bioethics and Human Rights). What remains a disturbing lesson from the Hwang case, however, is the lengths to which the whistleblower had go to in order to be heard, accepted and to uncover the truth.

Even more unsettling was the lack of research, and personal integrity displayed by Hwang, his co-authors and the other members of his research team. But personal failings aside, there were also institutional problems that allowed Hwang to perpetrate scientific misconduct. As many commentators have suggested the large, compartmentalised laboratory structure Hwang worked in could have contributed to his ability to falsify data.56 Cho, McGee and Magnus indicate that such structures, while perhaps encouraging efficiency, could inhibit a free

54. He was often described as a ‘god-like’ figure in South Korea who enjoyed honours that not bestowed upon Nobel Prize winners, see Song, Sang-yong (2006) ‘The Rise and Fall of Embryonic Stem Cell Research in Korea,’ Asia Biotechnology and Development Review, vol. 9, no. 1, pp. 65-67, at p. 67; and Ibid, at p. 23.
55. The Biological Research Information Center (BRIC).
flow of information and dilute responsibility for the integrity of research. 57

The actions of such senior scientific researchers are increasingly affected by institutional factors related to the market potential for their results. 58 The vast amount of investment in research from both government and private enterprise places great pressure on such professionals to produce results, often at a substantial ethical cost. 59 In such a competitive contemporary research environment, with vast amounts of investment dollars on the line, a whistleblower would most likely be under immense pressure from both the institution and fellow researchers not to speak out.

In South Korea, there was an awareness of the need for ethical guidelines for research especially by the Bioethics Advisory Commission, as evidenced by the recent passage of laws about stem cell research and human subjects. 60 Yet it must be noted that the Bioethics and Biosafety Act enacted by the Korean National Assembly did not fully enact the recommendations of the Bioethics Advisory Commission. According to one South Korean commentator the legislation was ‘meticulously’ crafted to protect Hwang, and that if the Commission’s recommendations had been implemented then the Hwang Scandal would never have happened. 61

More concerning, as mentioned earlier, was a report that indicated 8 out of 10 South Korean biotechnology researchers (of more than 900 surveyed) were not aware of the Declaration of Helsinki, an international bioethics research guideline established in 1964. 62 In a research environment that is blind to its

60. Bioethics and Biosafety Act, Act no. 7150, Korean National Assembly, passed 2003, effective date: 1 January 2005.
contribution to the greater public good, its own ethical standards and under financial pressure, the role of the whistleblower is even more crucial in uncovering scientific misconduct and preventing it from continuing. Ultimately the scientific research community needs to educate and pay due respect to not only research ethics, but also to remove the fear and shame involved and legitimise whistle blowing and the whistleblowers by instilling in young researchers’ character the belief in this greater good or telos.

University Policy and Whistleblowers

Guidelines produced by the University of Melbourne (one of Australia’s premier scientific research institutions) provide a valuable case study of how the requirements of whistleblower protection legislation may be effectively incorporated into institutional policy. The purposes of Whistleblowers Protection Act 2001 (Vic.) (the Act) are: (1) to encourage and facilitate disclosures of improper conduct by public officers and public bodies (2) to provide protection for persons who make those disclosures, as well as for persons who may suffer reprisals in relation to those disclosures; and (3) to provide for the matters disclosed to be properly investigated and dealt with.

The Act establishes four criminal offences which incur substantial penalties: to take or threaten to take reprisals against a whistleblower, to breach confidentiality, to obstruct the Ombudsman, to knowingly provide false information.

‘Improper conduct’ is defined under the Act as conduct that is corrupt, or creates: a substantial mismanagement of public resources, a substantial risk to public health, or a substantial risk to the environment, all being serious enough that if proven would constitute a criminal offence or reasonable grounds for dismissal. Public interest disclosures must be made by individuals (that can be anonymously), with reasonable supporting evidence, to the organization where the conduct complained of took place. The Act makes it a criminal offence to reveal the identity of a whistleblower or to take detrimental action in reprisal against a whistleblower.

The University of Melbourne policy states that that institution is fully committed to the aims and objectives of the Act (this stance is not so commonplace as reason would suggest). It neither tolerates improper conduct by University staff and Council members, nor the taking of reprisals against those who come forward to disclose such conduct. It fully implements section 68 of the Act, which requires that public bodies are required to establish detailed procedures
to facilitate the making of disclosures, for protecting whistleblowers and for investigating disclosures.

The University’s policy states that these procedures are to be used only when a student, member of staff or member of the public wishes to make a disclosure about improper conduct or about detrimental action taken against a whistleblower, and seeks the protections afforded by the Act. A senior member of the University staff is by policy designated to take and assess protected disclosures (disclosures may also be made directly to an extra-institutional ombudsman). Another is designated to determine public interest disclosures; appoint a welfare manager and oversee University investigations.

If the disclosure is deemed a public interest disclosure, the Co-ordinator is required to notify the whistleblower and refer the disclosure to the Ombudsman within 14 days for confirmation. The Protected Disclosure Co-ordinator is then required to appoint a Welfare Manager who will provide for the immediate welfare and protection needs of the whistleblower, advise the whistleblower of their legal rights, listen and respond immediately to any concerns about reprisals for making a disclosure and keep notes of all meetings and actions.63 Such policies achieve a tight meshing with the public interest aims of the relevant whistleblower protection legislation. One wonders why it is not more routinely possible to see such procedures developed within the context of clinical governance guidelines for Hospitals, or staff guidelines for health technology safety and quality regulatory agencies.

CONCLUSION

As Thomas Aquinas once explained, “every human law has just so much of the nature of law as is derived from the law of nature. But if in any point it deflects from the law of nature, it is no longer a law but a perversion of law.”64 Whistleblowing, particularly in relation to scientific misconduct should be more widely viewed by academics as, providing a rare example of the confluence of many normative systems, from personal morality, to ethics, law and international human rights.


In an age of increasingly privatised scientific research, it is even more important that support at every academic and institutional level should be accorded to those individuals capable of consistently applying universally applicable principles such as those in the UNESCO *Universal Declaration on Bioethics and Human Rights*. It may be that science itself will assist this process by establishing more information about the physics, as well as the psychology, of conscience. This also will undoubtedly be to the benefit of the relevant professionals, society, future generations and the discipline of science itself.

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Creating Ethical Environments

SENSITIVITY TO RESEARCH MISCONDUCT: A CONCEPTUAL MODEL

Rebecca Ann Lind* and Tammy Swenson Lepper**

Abstract: Ethical sensitivity research suggests techniques for assessing people’s sensitivity to research misconduct (RM). Based on our prior work in assessing ethical sensitivity, we present a conceptual model for assessing RM sensitivity. We propose conceptual and operational definitions of RM sensitivity (RMsen), and consider how the construct could be measured. RMsen is conceptualized as a cognitive ability, a skill which can be learned and assessed. RMsen involves an awareness that the research situation presents the possibility for misconduct to occur, and that one may have to decide what is right or wrong in the situation. Indicators of RMsen can take many forms and represent multiple content domains and dimensions. Four main content domains of RMsen are situational characteristics, RM issues, consequences, and stakeholders. In addition, linkages are potential connections made among elements in the different content domains. Three dimensions applicable to assessing RMsen include time, breadth, and depth. Although our focus is on RMsen, we believe that our model and methods may be extended to assessing sensitivity to the responsible conduct of research.

Keywords: Research misconduct; scientific misconduct; ethical sensitivity; research ethics; responsible conduct of research; RCR.

INTRODUCTION & OBJECTIVES

Research misconduct in the health sciences has significant ramifications. Concern about and attention to research misconduct has been on the rise, and in 2006 Eric Poehlman became the first researcher to receive a prison sentence for research misconduct (RM). Standing in contrast to RM is the responsible...
conduct of research (RCR). Clearly both RM and RCR revolve around ethical behaviors. Because thinking about ethical issues is critical to avoiding RM and enhancing RCR, it is important to assess how well researchers perceive the ethical issues in their research environments. Research in ethical sensitivity suggests techniques for assessing people’s sensitivity to RM. If RM (or RCR) sensitivity can be assessed, RM and RCR training programs can be better evaluated. Training has the potential not only to reduce the harms associated with RM, but also to increase the benefits associated with RCR.

This article presents a conceptual model to guide the assessment of RM sensitivity. The model is based on our prior work assessing ethical sensitivity. After discussing the theoretical foundation, we propose conceptual and operational definitions of RM sensitivity and consider how the construct could be measured. Although we focus here on RM sensitivity, we believe our model and methods may be extended to assessing RCR.

CONCEPTUAL/THEORETICAL FOUNDATION

James Rest presented a model outlining the processes involved in moral behavior. A cognitive developmental psychologist, Rest followed Kohlberg’s...
stage theory of moral development, but did not assume the stages follow an
invariant progressive sequence. Rest’s model of moral behavior is comprised
of four components, the first of which is particularly germane to RM sensitivity.
The four components are (1) interpreting the situation, (2) determining what
course of action would best fulfill a moral ideal, (3) deciding what one actually
intends to do by selecting among competing moral and non-moral values, and (4)
executing and implementing a plan of action. Although the components and the
processes they represent are logically-ordered, the model is not necessarily
linear. Importantly, research can focus on any one or more of these components.
As a general model, this is applicable to diverse situations, and supports parsing
out the complex processes that go into making and acting on a moral decision.

We have successfully adapted Rest’s model to the mass media and to the
organizational communication context. Our work is informed by an information
processing approach, which studies the attention, selection/storage, integration,
and evaluation of information. Our Component 1 research addresses people’s
sensitivity to ethical issues in the television news and organizational
communication contexts. The Component 2 work investigated viewer evaluations
of media content and whether the news story should be run. The Component
research demonstrated that viewers decide what to do, based on their
evaluations of the story, and can suggest behaviors they may enact, whereas in
studying Component 4, we found that viewers differ in their reported actual
behaviors toward TV news and their justifications for such actions.

Adapting the model to the research environment

The research environment is but one of many contexts to which Rest’s model
can be adapted. As with the original, our adaptation (see Figure 1) is logically

9. Woodall WG, Davis DK, Sahin H. From the boob tube to the black box: television news


11. Lind RA, Rarick DL. Public attention toward ethical issues in TV programming: multiple

12. Lind RA. Viewer response to ethical issues in television news. Journalism Monogr 1993;
142:1-45

13. Lind RA. How can TV news be improved? Viewer perceptions of quality and responsibility.
ordered but not linear. That is, an individual may drop out at any point; one
who does not understand the research situation is unlikely to determine the
responsible behaviors of the people involved in it, and even less likely to take
action as a result. Researchers using the model may focus on any one or more
of the model’s four components.

In Component 1, the focus of this paper, an individual in a research environment
may interpret the situation in its context. The individual may (or may not)
understand what’s going on; may consider the relevant scientific principles,
norms, policies or regulations; may be aware of competing values or claims;
may reflect on whether or how the outcome of the situation could affect the
welfare of others. After interpretation, if concern about possible research
misconduct is raised, a transition to Component 2 may occur.

In Component 2, the individual may determine the responsible (moral, ethical)
course of behavior, and whether a researcher is acting appropriately (responsibly,
morally) in that context. The individual may apply certain evaluative criteria;
may consider specific regulations or policies; may reflect on the norms of the
discipline; may consider the presence of competing interests. If a determination
is made regarding the appropriateness of the behavior in the context, the
individual may consider whether any action should be taken in response. If so,
the individual may move on to Component 3.

In Component 3, the individual may decide what action, if any, ought to be
taken. In deciding, the individual may consider the moral or normative values
revealed during Component 2 processes as well as other personal and
organizational values. Alternative courses of action may be considered. Some
individuals will decide to do nothing, whereas others will decide that a certain
activity should be carried out, and may move on to Component 4.

In Component 4, the individual may implement some action based on his or her
evaluation. Such behaviors may be informal (verbalizing an opinion to friends),
or formal (making an allegation of research misconduct).
Figure 1: Understanding and responding to research misconduct: A preliminary four-component model

**Component 1: RM Sensitivity**
- Interprets Research Situation and Context
  - Accurately notices and comprehends pertinent situational characteristics
  - Aware of relevant scientific principles
  - Aware of relevant norms, policies and regulations
  - Perceives competing values or claims
  - Reflects on whether or how others may be affected

**Component 2: Determines Responsible Course of Behavior**
- Applies evaluative criteria
- References specific regulations or policies
- Balances competing values and claims
- Weighs competing interests

**Component 3: Decides Whether to Take Action**
- Considers moral values
- Considers normative values
- Considers other personal and organizational values
- Considers possible actions

**Component 4: Implements Action**
- Acts formally
  - Makes an allegation
  - Calls an anonymous tip-line
- Acts informally
  - Discusses perceptions with involved persons
  - Discusses situation with mentor or supervisor
  - Verbalizes to friends; seeks advice
  - Leaves the situation (resigns, transfers)

No acknowledgement of responsible conduct; no acknowledgement of possible misconduct (Drops out of process)

No decision or solution reached regarding the appropriate behavior called for in the situation (Drops out of process)

Decides not to take action (Drops out of process)

Incomplete attempt; does not follow through on intended actions (Drops out of process)
Having explained Rest’s model, we will describe previous ethical sensitivity research before providing our definition of RM sensitivity. We identify three main strands of ethical sensitivity research. The dominant strand is most closely linked to Rest’s model. Rest, Bebeau and colleagues\textsuperscript{14, 15} developed the Dental Ethical Sensitivity Test (DEST) and found that it reliably assesses ethical sensitivity among dental students and practitioners. Besides our own work applying this concept to the media and organizational communication contexts, ethical sensitivity has been investigated in a number of other contexts. Flower\textsuperscript{16} studied psychologist gender and level of moral sensitivity. Clarkeburn\textsuperscript{17} studied ethical sensitivity in relation to scientific practice. Ersoy and Gündogmus\textsuperscript{18} focused on sensitivity to specific ethical issues: respect for autonomy, non-maleficence, beneficence, and justice. Brabeck \textit{et al.}\textsuperscript{19} created the Racial Ethical Sensitivity Test, examining sensitivity to ethical issues related to race and gender. A subset of this primary research strand considers how education affects ethical sensitivity. Bebeau\textsuperscript{14} and Myyry and Helkama\textsuperscript{20} found that ethical sensitivity could be increased through education. Interestingly, Sadler\textsuperscript{21} suggested that unless course work is focused on the ethical aspects of a specific discipline, it may have little effect on moral sensitivity to issues in that discipline.

The second strand of ethical sensitivity research has roots in Rest’s Component I, but is primarily informed by the Hunt-Vitell model\textsuperscript{22}. This model, which assumes that people make ethical decisions based on deontological or teleological values, is prevalent in the business ethics literature\textsuperscript{23, 24, 25, 26}. The Hunt-Vitell model’s definition of ethical sensitivity is less complex than that presented in Rest’s model, and primarily considers ethical sensitivity as a perception or recognition that the situation presents ethical components.

The third strand of ethical sensitivity research is conceptualized from an alternative perspective. It is found mainly in the nursing and medical fields\textsuperscript{27, 28, 29, 30}. The definition of moral or ethical sensitivity includes understanding not only the vulnerability of participants in the given situation, but also the ethical consequences of one’s actions. The ability consists of six components: interpersonal orientation, structuring moral meaning, expressing benevolence, modifying autonomy, experiencing moral conflict, and confidence in medical knowledge.

A commonality of all three research strands is that ethical sensitivity is highly contextual. It depends on people’s experiences in the particular contexts with

\begin{itemize}
  \item \textsuperscript{24} Bone PF, Corey RJ. Packaging ethics: perceptual differences among packaging professionals, brand managers, and ethically-interested consumers. \textit{J Bus Ethics} 2000; 24:199-213.
  \item \textsuperscript{25} Patterson DM. Causal effects of regulatory, organizational and personal factors on ethical sensitivity. \textit{J Bus Ethics} 2001; 30:123-59.
  \item \textsuperscript{27} Hébert P, Meslin EM, Dunn EV, Byrne N, Reid SR. Evaluating ethical sensitivity in medical students: using vignettes as an instrument. \textit{J Med Ethics} 1990; 16:141-5.
\end{itemize}
which they are confronted. For instance, Swenson-Lepper\(^6\) found that manufacturing plant workers were more sensitive to ethical issues pertaining to manufacturing, whereas teachers were more sensitive to issues related to hiring practices.

**UNDERSTANDING RM SENSITIVITY**

Our definition of RM sensitivity (RMsen) is guided by the definition of ethical sensitivity presented by Bebeau, Rest, and Yamoor\(^15\). It addresses the conscious choice of means and ends by those involved in or observing a situation, the significant impact of one’s actions on others, and the applicability of standards of right and wrong.

Conceptually, we define RMsen as *an ability that involves an awareness that something someone might do or is doing in the research environment can or should be considered in terms of whether it is consistent or inconsistent with a general practice, regulation, or commonly held standard; this can affect others’ welfare directly or indirectly.* RMsen involves an awareness that the research situation presents the possibility for misconduct to occur, and that one may have to make a decision regarding what is right or wrong in the situation. Our definition of RMsen is multi-pronged; it includes one’s own actions or the actions of others; potential or actual behaviors; and violating or upholding ethical research practices.

Our previous work as referenced above has argued that ethical sensitivity can be evidenced by any number of “indicators.” By extension, *indicators of RM sensitivity* are broadly defined, operationally, as verbalizations of discrete relevant concepts or the relationships among these concepts. Indicators of RMsen, in practice, are likely to take many forms. These include, but are not limited to, the ability to: comprehend and understand a situation in terms of the action, the actors involved, and the goals and motivations of participants; recognize as conscious choices the decisions (in terms of means, ends, and actions) made by participants in the situation; perceive the possible positive or negative consequences of decisions; be aware that such choices can or should be evaluated on a right-wrong dimension; recognize the rights and responsibilities of the stakeholders; notice the special circumstances that may affect participants; perceive research misconduct as such, rather than considering the problems and decisions as mundane research issues; and an awareness of differing (perhaps competing) values, goals, interests, meanings, and interpretations of the situation.
More specifically, as reflected in Figure 2, RMsen indicators may be broadly understood as representing multiple content domains and dimensions. We posit that there are at least four main content domains comprising RMsen. Situational characteristics include acknowledgment of relevant elements, actions or contextual features of the research situation being considered. An RM issue is an acknowledgement that a behavior may fall along a right-wrong continuum, or may affect the welfare of others positively or negatively. Consequences are any effects of the RM issue on people, situations, actions, or ideas. Stakeholders are the parties (individuals, groups, institutions) that may feel the consequence of an RM issue. In addition, linkages are the connections made among the situational characteristics, RM issues, consequences, and stakeholders. The linkages represent the relationship among the four content domains.

We also propose three dimensions applicable to assessing RMsen. The time dimension reflects how quickly or spontaneously RMsen indicators are exhibited. An individual with greater RMsen may address the possibility of research misconduct more readily than will an individual with lower RMsen. The breadth dimension, likely the most complex of the RMsen dimensions, reflects the range of different RMsen indicators. Higher levels of RMsen may be associated with an increased number of indicators. The depth dimension refers to the amount of thought or detail in the RMsen indicators. Greater RMsen may be associated with more well-developed presentations of RMsen indicators.
POSSIBLE METHODS FOR ASSESSING RM SENSITIVITY

Researchers may wish to assess RM sen for a variety of theoretical or applied purposes. Two crucial decisions facing anyone interested in assessing RM sen are how to collect subjects’ responses and how to analyze the responses.
Data Collection

Data may be collected using paper-and-pencil measures, interviews, or any variants thereof. For example, researchers may employ interactive computer methods in which subjects type written responses, or may ask subjects to speak their responses into a recording device. Response options may be forced-choice (e.g., ratings or Likert-type scales) or open-ended. Follow-up questions may be part of the protocol. All of these methods have been used in ethical sensitivity and moral sensitivity research, and all of the standard strengths and limitations of those methods apply.

Measuring or evaluating an individual’s sensitivity to these types of issues presents an additional concern. One defining characteristic is whether subjects complete a recognition task or a production task. A recognition task typically involves a closed-survey with Likert-type items. A production task, often done in interview or written form, is more open-ended and asks subjects for their thoughts about the stimulus material. As do Rest and Sirin, we favor production tasks. Recognition tasks may be useful in understanding other processes in Rest’s Four-Component model, but they seem ill-suited to assess the sensitivity component. To understand sensitivity to the underlying issues, we must understand whether and how subjects apply their own knowledge and inner resources.

In particular, we favor the use of a funnel-type structure applied in an interview setting. The interview should begin with broad questions, and the interviewer should not introduce the issue of misconduct until later in the discussion. Applying this method to assessing RMSen, we might first ask subjects to describe the situation, to highlight what stood out to them in the situation, and to evaluate what any participant should do in the situation. Only then might we ask subjects whether actual or potential behaviors could be considered misconduct (or responsible conduct), and if so, why, who might be affected, and how. The funnel-type interview can gauge the extent to which subjects addressed the relevant issues without being prompted to do so, thus allowing consideration of the time dimension.

Data Analysis

Analysis of subjects’ responses can be quantitative or qualitative; analyses can generate scores, or identify relative areas of strength and weakness. Analyses can be diagnostic, especially if integrated into a particular educational experience.

Our prior work referenced herein has assessed ethical sensitivity using a variant of cognitive mapping, a qualitative technique allowing visual representation of relationships between subjects’ verbalized concepts or events. Originating in studies of learning and decision-making\textsuperscript{32, 33}, cognitive maps present concepts and causal beliefs, and can display complex chains of reasoning. Concepts are represented as points, and causal beliefs are arrows connecting the points.

Cognitive maps can only represent verbalized thoughts, and the coding can be somewhat subjective. However, cognitive maps can both provide lists of criteria or rules and reveal some structure of a thinking or decision-making process. They impose neither \textit{a priori} structures on verbalizations, nor researchers’ assumptions of what someone’s concepts or labels for a situation might be\textsuperscript{33}. Cognitive maps can model the schemata subjects apply when interpreting any given situation\textsuperscript{34}. Though cognitive mapping is primarily used in qualitative research, our variant of the mapping process and our conceptualization of RMsen indicators can generate data amenable to quantitative analyses\textsuperscript{6}.

\textbf{ASSESSING RM SENSITIVITY: PROBLEMS AND PROSPECTS}

Several challenges face researchers and instructors who may wish to approach assessing RMsen from the perspective we propose, including the difficulty of creating appropriate (concise, effective, realistic) stimulus material. Using a production task makes the data gathering process time consuming and laborious, and requires the development and application of a coding system which might be usable only for one stimulus.

However, the potential advantages of our approach may warrant overcoming those challenges. Most importantly, RMsen is conceptualized as a cognitive ability; it can be learned, and it can be measured. Therefore our approach has

\textsuperscript{34} Laukkanen M. Comparative cause mapping of organizational cognitions. \textit{Organization Sci} 1994; 5:322-43
implications for RM training programs. We argue that our general model will apply equally well to the responsible conduct of research (RCR). Each of RCR’s nine conceptual domains provides an educational opportunity, the results of which could have significant impact, could reduce the occurrence of research misconduct, and can be measured. Thus, a second advantage of the proposed approach is inextricably tied to the first: our model and methods can also be applied to sensitivity to the responsible conduct of research, which we could call RCRsen. The combination of funnel-type interview and cognitive mapping could be used to diagnose and address an individual’s specific RMsen or RCRsen strengths and weaknesses.

A third advantage to our approach is that it is grounded not only in theory but also in data. We derive conceptual support from Rest’s Four-Component model, but the precise indicators of RMsen are drawn from subjects’ verbalizations. Our variant of the cognitive mapping technique seems in itself a fruitful analog of the production tasks we favor. Our technique provides for maximum flexibility and minimal intrusion during the creation and analysis of people’s response patterns. Finally, unlike the DEST, our approach does not require coders to be prior experts or professionals in the field. With training, anyone who would be likely to want to learn this system should be able to do so.

In conclusion, we have proposed a conceptual model of sensitivity to research misconduct and suggested a method for assessing RMsen. We believe our model and methods are also applicable to assessing sensitivity to the responsible conduct of research. The obvious next step is to apply our model and methods to an RMsen or RCRsen scenario. Because prior research has shown that ethical sensitivity is both highly contextual and influenced by education, developing a means of assessing RMsen may provide valuable feedback on the efficacy of education about research misconduct and the responsible conduct of research.

We see two viable approaches for measuring RMsen using the techniques presented here. First, RMsen could be examined holistically, where all the conceptual domains related to the responsible conduct of research could be examined simultaneously. This may be desirable, but it is complex and premature.

35. Data acquisition, management, sharing and ownership; conflict of interest and commitment; human subjects; animal welfare; research misconduct; publication practices and responsible authorship; mentor-trainee responsibilities; peer review; collaborative science.
Thus we propose a different approach — to examine sensitivity to issues in just one of the nine RCR conceptual domains, such as conflict of interest and commitment. Though the process could be used for any RCR domain, we will begin by applying our general model and method to assess conflict of interest sensitivity (COIsen). We will conceptually and operationally define COIsen, create relevant scenarios to test COIsen, pre-test them on a small number of subjects, and derive cognitive maps (which could be analyzed qualitatively or quantitatively) from interview transcripts. After the scenarios, interview process, and mapping systems are validated, the process could be used on a larger sample to answer specific research questions or hypotheses. Alternatively, the process could be applied on a small scale, such as assessing the efficacy of RCR educational efforts. Assessing one RCR component at a time can readily be incorporated into classroom-based, online, or other training programs, and represents an important application of the model and method.

Extending the pedagogical application of the model and method, the cognitive maps could be used diagnostically, to assess relative strengths and weaknesses in a variety of learning situations. For example, Bebeau\textsuperscript{14} described how the Dental Ethical Sensitivity Test (DEST) has been used to assess the ethical sensitivity of practicing dentists, including those who have been referred by the state dental board for remedial courses. Using RMsen cognitive maps diagnostically could help in the development of more thorough and effective training methods for those conducting scientific research. The maps could be used in highly individualized applications. For example, cognitive maps could indicate whether a new employee had good understanding of the key RCR issues presented in a particular research situation; if any deficiencies were identified they could be addressed.

While the process for creating and validating the method is costly, if it is an effective diagnostic tool, it could reduce the significant costs related to research misconduct.

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Creating Ethical Environments

THE TEACHING SCHOLARS PROGRAM: A PROPOSED APPROACH FOR PROMOTING RESEARCH INTEGRITY

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Abstract: All research environments are not created equal. They possess their own unique communication style, culture, and professional mores. Coupled with these distinct professional nuances is the fact that research collaborations today span not only a campus, but also the globe. While the opportunities for cross cultural collaborations are invaluable, they may present challenges that result in misunderstandings about how a research idea should be studied and the findings presented. Such misunderstandings are sometimes found at the center of research misconduct cases. And yet in light of highly visible cases of research misconduct, the attitude about ensuring research integrity remains rather opaque. This paper discusses the merits of the Teaching Scholars Program as a mechanism by which to promote research integrity. This paper will examine this education program against the backdrop of the US Office of Research Integrity (ORI), as an established office responsible for ensuring the integrity of federally funded biomedical and behavioral research.

Keywords: Research misconduct; education; responsible conduct of research; Teaching Scholars Program; Office of Research Integrity

INTRODUCTION

Cases of scientific misconduct in biomedical research that occurred in the 1980’s drew the federal government into a role that was not anticipated by researchers. As cases of research misconduct unfolded, it was clear that federal funding for biomedical research could be in jeopardy if public trust was not secured vis-à-vis the establishment of some form of oversight body. Because funding agencies were not equipped to address allegations of research misconduct.

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misconduct, an independent office was established at the behest of the US Congress.

While the public is assured that a federal office is charged with protecting the integrity of federally funded biomedical and behavioral research, there is another side to the dialogue of research misconduct - research integrity.

Research integrity is defined as, “possessing and steadfastly adhering to professional standards as outlined by professional organizations, research institutions and, when relevant, the government and public.” This definition serves as an important anchor in helping to determine what the research community does and does not know about research integrity. Historically, the topic of “research integrity” has not routinely been taught as a course during graduate or medical school training. While not always referred to as “research integrity” the research practices and decorum associated with becoming a scientist was never formally taught but was cultivated on a more individual basis. This approach may have worked when research communities were small, elite and the student / professor relationship was the model by which knowledge was transferred. But, the biomedical research environment in place today is constantly changing and is driven by new technologies, market forces, and research advances that do not remain static.

Highly visible cases of research misconduct continue to beg a number of questions about research integrity. Some of the questions include, but are not limited to: What is the community doing to promote research integrity? What are the best approaches to take to create research environments that are “healthy” and promote research integrity? What topics fall under this rubric? And how should research integrity be developed, taught, and imparted to the next generation of scientists?

Because research cultures and accepted research practices differ significantly across scientific disciplines, it is critical that those responsible for educating the next generation of scientists possess the knowledge needed to promote research integrity. In response to this calling, this paper discusses the merits of the Teaching Scholars Program (TSP) as a mechanism by which to ensure research integrity. This paper will examine this education program against the backdrop of the US Office of Research Integrity (ORI).

Research Misconduct Historical Review

Research misconduct gained public attention in the United States in 1981 when the Investigations and Oversight Committee of the House Science and Technology Committee held the first hearing on the developing problem. While the hearings shed light on a number of research misconduct cases, they also marked a new era for biomedical research that would require those institutions receiving federal funding to establish policies and procedures to address allegations of scientific misconduct. The resulting Final Rule, “Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science”, was published in the Federal Register on August 8, 1989 and was codified at 42 CFR Part 50, Subpart A.

The Office of Scientific Integrity and the Office of Scientific Review were established in 1989 to uphold the Final Rule and were responsible for overseeing the handling of scientific misconduct cases. In 1992 the offices were consolidated into the ORI.

The ORI oversees approximately 4,000 institutions that receive Public Health Service (PHS) funds for biomedical and behavioral research. Institutions that receive these funds are responsible for having policies and procedures in place to address allegations of research misconduct. This federal requirement has existed since 1989 and assures the public that processes are in place that will enable institutions to address allegations of research misconduct. This federal regulation places the responsibility of addressing research misconduct at the institutional level.

Impact of research misconduct

The ORI closed 35 cases of research misconduct in 2006, 28 investigations and 7 inquiries. Fifteen of these cases were confirmed cases of research misconduct, marking the highest number since 1996 and almost doubles the


4. 42 C.F.R. Part 50, Subpart A.
number of misconduct cases from 2005\textsuperscript{5}. These numbers, at first blush, appear to be miniscule when compared to the $28.7 billion dollar budget allocated to the National Institutes of Health (NIH) in 2006\textsuperscript{6}. Despite the obvious gulf between the number of research misconduct findings and the NIH budget, the discrepancy warrants thoughtful consideration to better understand the significance between the effect of research misconduct relative to the dollars spent on funded research.

**Costs associated with research misconduct**

Findings of research misconduct affect a broad range of people. The expenses may entail administrative actions, literature corrections, legal costs and professional reputation damage. While exact dollar figures associated with a research misconduct case are not known, the following list highlights many of the procedures needed when an alleged case of research misconduct occurs:

- Inquiry panel meetings
- Reading relevant documents for allegation
- Writing inquiry report, circulating for comments / revisions
- Sequestration of data
- Investigation panel meetings
- Special data analysis
- Writing inquiry report, circulating for comments / revisions

This list is not exhaustive, but represents hundreds of hours spent addressing issues associated with an allegation. The faculty time spent in committee meetings, reviewing documents, conducting and transcribing interviews, writing and circulating reports for comment, carry an economic burden that is often underestimated.

While many of these responsibilities are delegated to faculty, there are also


\textsuperscript{6}. AAAS R&D Funding Update on R&D in the FY 2006 NIH Budget - http://www(aaas.org)/spp/rd/nih06p.htm accessed 3/1/07.
additional costs an institution absorbs through a host of private services such as:

- Independent audits
- Transcription services
- Expert testimony
- Courier services to adhere to federal timing requirements

These special services entail costs that can run into the thousands of dollars. These costs are separate from those that may surface should a respondent choose to appeal a decision of research misconduct, in which case the legal expenses for a hearing can run into hundreds of thousands of dollars.

**Social / emotional costs**

Another dimension not to be overlooked is the social cost for the public and the scientific community. Research misconduct findings can undermine public trust. It is reasonable to deduce that the public may become skeptical about supporting and participating in research studies if they do not trust the institutions enrolling them.

The trust among researchers is also challenged when allegations of research misconduct arise. The costs associated with an allegation of a research misconduct case include the costs associated with the loss of research time for all persons associated with the questionable research. There is also the time lost in gathering supporting documentation to answer inquiry / investigation questions, gathering lab books, and reproducing experiments, responding to specific inquiry / investigation questions.

**Publication costs**

Published research is a vital link for progress in the research community. The actual journal space used for publishing represents a form of currency for those vying to publish since it is tied to tenure and promotion.

Data that is the product of research misconduct not only misleads other researchers, but can also be viewed as stolen space from other researchers who could have made contributions to the literature sooner. Eric Poehlman, a former professor at the University of Vermont who was found guilty of research misconduct fabricated and falsified research that made its way into 10
publications. These publications required retractions and corrections.

In addition to the wasted publication space absorbed by Dr. Poehlman is the uncertainty of how many others cited his work. Studies have shown that researchers who do not carefully examine the research records of those they cite can continue to reference work deemed unreliable. Fortunately, there are dozens of PHS funded publications that have undergone some type of literature correction – either as a retraction or correction due to a finding of research misconduct. These literature corrections are necessary to protect the integrity of the public record but the corrections themselves also consume valuable publishing space in journals.

**Research Integrity**

The interest in promoting research integrity has evolved largely in response to media attention of research misconduct cases. While the infrastructure established at institutions to address allegations of research misconduct has improved greatly since 1989, the promotion of research integrity varies widely. In 1992 the National Academy of Sciences Report Panel on Scientific Responsibility and the Conduct of Research issued its report that placed the responsibility of ensuring the integrity of the research process directly on faculty and administrators. It would be another 10 years however, before institutions would actively implement programs to ensure research integrity.

In 2000, ORI published the PHS Policy on Instruction in the Responsible Conduct of Research (RCR). The purpose of the policy was to require all institutions

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that had PHS funded faculty, and support staff engaged in research or research training grants, contracts, and cooperative agreements to complete a training requirement in the RCR. The core RCR instructions areas include:

1. Data acquisition, management, sharing and ownership
2. Mentor / trainee responsibilities
3. Publication practices and responsible authorship
4. Peer review
5. Collaborative science
6. Human subjects
7. Research involving animals
8. Research misconduct
9. Conflict of interest and commitment

The RCR policy has not been mandated, due to a lack of consensus and support from the research community. However, it has become the de facto standard for a number of educational initiatives in and outside of the federal government. Beginning in 2002 ORI established an RCR Education Resource Program as a way to facilitate the creation of instructional materials. Since 2002 the program has invested over $1.5 million dollars and funded over 50 projects for the creation of RCR products. These are publicly available and address a wide range of RCR topics.

In addition to ORI funded products, academic institutions and professional associations have also addressed research integrity topics through the development of professional conduct guidelines, courses, workshops, and web-access.

based tutorials to suit the needs of their constituents. The variety of teaching materials currently available speaks to the community awareness and the commitment to promoting research integrity.

**Education**

Many researchers would agree that education is the key to promoting research integrity. However, an educational model should be developed through a research integrity lens. The definition cited earlier in this paper provides a valuable framework for creating an educational model that would work towards ensuring research integrity in academic research environments.

In order to “possess and steadfastly adhere to professional standards as outlined by professional organizations, research institutions and, when relevant, the government and public” one must know what the professional standards are, how they are codified, and implemented. Unfortunately, there is empirical


evidence to suggest that there are young scholars not aware of specific guidelines and principles in science\textsuperscript{25,26}.

A review of the 9 RCR core instructional areas reveals that there are many topics and sub-topics in each core area. Moreover, the literature on RCR varies in content and depth\textsuperscript{27}. Learning each of the RCR areas, and applying the definition of research integrity as the educational frame would require an incredible amount of time to prepare and teach. If one is to cultivate a research environment that ensures research integrity, then a broader, more comprehensive curriculum is needed.

Currently the majority of the RCR education resources, projects, conferences and workshops are single theme\textsuperscript{14,16}. They are often rich in content, but limited to one RCR topic. The 1-2 day conferences and workshops may serve as an introduction to some attendees and continuing education update to others. Conversely, the week long conferences provide a wide variety of topics, yet their purpose is not to develop teaching skills. So while those who attend leave with an understanding and appreciation of the topics, they do not gain extensive teaching skills to share and cultivate this new knowledge with others at their home institution. Another pedagogical approach that has generated interest has been web-based learning. Time limitations appear to have spawned the interest in the development of online tutorials\textsuperscript{28}. This approach may be time efficient, but it does not provide opportunity for discussing complex issues or necessarily impart information effectively to others.

If the goal is to ensure research integrity in the university environment, then developing an educational program that promotes research integrity to the greatest number of people in the most thorough and cost-effective manner seems to be in order. In order to accomplish this goal then two questions need

\begin{thebibliography}{9999}
\bibitem{27} Heitman E, Bulger RE. Assessing the Educational Literature in the Responsible Conduct of Research for Core Content. \textit{Accountability in Research} 2005; 12(3):207-224.
\end{thebibliography}
to be addressed: How can research integrity be taught and how much time is needed to teach the RCR topics so that a researcher gains full competency of the areas and is able to teach it to others?

Recommendation

As previously described, there are various educational resources available to educators for promoting research integrity. However, resource availability does not guarantee that information will be delivered or received in the most effective manner. The success of the Teaching Scholars Program (TSP) as reported by institutions in the US and Canada could serve as an excellent education model by which to promote research integrity. The TSP began in the early 1990’s with the University of North Carolina, Chapel Hill being the first to implement the program. It was designed to promote the principles and ideas of excellence in teaching and learning. To date, a handful of institutions in the US and Canada have implemented this program with great success in institutions with medical and allied health education.

Institutions have reported their success of the TSP through various evaluations which have included surveying those who participated in the program, scoring


31. University of California San Francisco Teaching Scholars Program http://medschool.ucsf.edu/teachingscholars/ accessed 2/15/07

32. University of Colorado President’s Teaching Scholars Program http://www.colorado.edu/ptsp/ accessed 2/15/07

33. University of Missouri New Faculty Teaching Scholars Program http://www.umsystem.edu/ums/departments/aa/nfts/ accessed 2/12/07


35. University of Washington School of Medicine Department of Medical Education and Biomedical Informatics http://www.dme.washington.edu/scholars.html accessed 3/15/07.

the curriculum vitae of those who participated in the program for new educational projects linked to the TSP program, and surveying those who are “beneficiaries” of the program. While the Teaching Scholars Programs to be highlighted in the following section vary slightly in format, their goals are similar: producing educational leaders. Using the TSP model as the framework, the next section will focus on how this approach could incorporate the 9 RCR content areas as a viable way to promote research integrity.

Program Aims and Requirements

The aim of the TSP is to promote professional development by combining one’s area of expertise together with learning about effective curriculum design, educational principles, teaching methods, and program evaluation. Faculty being well versed in their respective disciplines, are not trained formally as educators and therefore the TSP provides an opportunity for faculty to develop a comprehensive understanding of teaching and how to do so effectively. The program not only expands their pedagogical skill set but also provides the opportunity to become better educational leaders.

The TSP once implemented and supported by an institution would seek to market and recruit young faculty at its institution. By cultivating this program at an institution the commitment is being made to promote research integrity through a community of educators who are able to enhance their knowledge of the role of pedagogy and master one or more research integrity issues previously listed. The hallmark of this program is that time is protected for a scholar to engage in this special scholar year while maintaining their faculty positions.

Combining the TSP framework with the topic of research integrity would enable a scholar to focus on a couple of the previously listed research integrity topics associated with RCR. The limitation in topics would enable the scholar to focus exclusively in an area and develop a rich competency base. Most likely, the faculty member is in one of the schools of health related professions, or school of education since one of the benefits of this program lie at the intersection and networking of various disciplines. In some instances, the faculty member may


already be regarded as an expert (for example in authorship practices), and develop that expertise further by studying pedagogical approaches to teaching the information on a more tailored scale to students. Furthermore, experts from within the institution could present a topic such as literature searching. Drawing on identified experts from within the institution could help contribute to a strong institutional network that can easily contribute to the program’s success with little cost.

Those persons interested in participating in the program complete an application process that typically includes providing a goal statement or a project idea, a curriculum vitae, letters of reference, and a letter of support from their respective department chair for release time to attend the program. Generally speaking, the TSP lasts between 10 to 12 months, and the weekly time commitment varies from one-half to one full day per week. This year long time frame enables scholars to have ample time to engage in their projects, attend lectures or seminars designed specifically for the program along with learning all of the principles and best practices in education. The release time is an important hallmark for the TSP because it not only signifies a time commitment for the scholar to engage in new educational endeavor, but it is also a public endorsement for the importance of the program by the department chair.

The schedule and curriculum are developed by the program director(s) once the candidate is identified. Programs require that participants develop specific projects (such as curriculum development, an education portfolio, or a research study of a topic) and in some cases take an active role in the teaching a topic to a group at the respective institution.

**Program Size**

A review of the TSP indicates that 3 to 15 scholars are chosen to participate each year. This size represents a reasonable group to teach and because they meet on a weekly basis, represents a size that could naturally grow to form a new community of educators over the years. The slow but steady growth of program participants would serve as a continual stream of scholars who are part of the institution and have demonstrated competency in a few

research integrity issues and thereby be promoting research integrity through teaching students.

Program Costs

Financial support to implement the TSP varies by institution depending on the funding vehicle. Some are funded by philanthropic support others by the medical school dean and then there are programs partially funded through stipends underwritten by the scholars home department. The program costs vary from cost per scholar $9,000 to the total cost of the program $50,000. Exact figures have been difficult to find because the costs underwritten by the departments releasing their scholars has not been reported. Nevertheless, the most important and overarching theme is that the Deans of the schools support the program and endorse its contribution to developing excellent teaching.

RCR and Teaching Scholars Program

Using the TSP as a model, the steps outlined below provide a brief overview of how a research integrity program could be developed

1. Operate the program through the office of Continuing Medical Education, Office of Medical Education, or other identified office whose mission is to support professional development within the institution. Operating this program through a pre-existing department could help keep administrative costs low and benefit from a pre-existing office with the institution.

2. Identify 1-2 persons who possess committed interest in serving as director(s) for the TSP with research integrity as the core content material.

3. Department chairpersons would be responsible for identifying institutional experts that could serve as educators on RCR topics, as well as experts in theories and principles of education. The merging of both the RCR


content areas together with the theoretical underpinnings of education would provide the framework for a TSP on research integrity.

Table 1 provides a curriculum proposal for a 12-month period, meeting for a half day per month. The topics in Table 1 are interchangeable but represent the merger of RCR topics with educational theories and other assorted teaching tools.

**Benefits**

There are three major benefits to highlight about the TSP as a mechanism for ensuring research integrity. First, the TSP would provide an opportunity for scholars committed to teaching to have a state of the art understanding of research integrity issues and be better equipped to design, teach, and effectively assess the information they impart to their students. This Program would provide a strong knowledge base that is pro-active in promoting research integrity across the institution compared to institutional models that do not formally teach research integrity issues but are more reactive by nature in addressing research integrity issues when allegations of research misconduct surface.

Second, the implementation of a TSP for ensuring research integrity represents a more cost effective investment for an institution in the long run, because the investment is being made in young faculty who would be contributing to the institution over many years. The investment is an overlapping one that would be promoting research integrity on a yearly basis. The knowledge would multiply as faculty share their knowledge with students in the classroom. This approach is also more cost effective than costs associated with a research misconduct case. In addition, this investment could produce a significant cultural change that could result in greater accountability and transparency in the university environment as more faculty and students are aware of the best practices associated with research integrity *vis-à-vis* the responsible conduct of research.

Third, as discussed earlier, the global nature of science together with the numerous scientific disciplines warrant a generous time commitment for learning the topics associated with the research integrity topics how best to teach them. Finally, institutions benefit from having invested in a cadre of scholars who are committed to learning about and teaching the ethos of research integrity and can apply it on a broad basis for the benefit of the entire university community for many years.
CONCLUSION

Where does the responsibility lie for ensuring research integrity? According to Jordan Cohen, M.D., former president of the Association of American Medical Colleges ensuring responsible research is best handled at the institutional level, not with the government. Because those who teach typically have multiple responsibilities, institutions should commit to supporting the TSP because it is not only cost effective, but a pro-active approach to creating a healthy research environment. Little argument can be made against supporting education efforts that are preventive in nature and produce a research environment that is poised to ensure research integrity.

The topics addressed in this paper provide a framework for creating an environment that is knowledge based, accountable, and contributes to promoting research integrity through a multi-dimensional teaching approach. The TSP provides a viable option for preventing research misconduct through an educational model that would promote research integrity. The institutional investment of this program could serve to promote research integrity and engender a healthier research climate.

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Table 1: Teaching Scholars Program for Research Integrity

<table>
<thead>
<tr>
<th>Month in 2008</th>
<th>Activities</th>
</tr>
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| August        | • Program introduction  
• Introduction to higher education principles and teaching  
• Data acquisition, management, sharing and ownership  
• Policies / review/ updates |
| September     | • Mentor/ trainee responsibilities  
• Policies / review/ updates /  
• Educational methods, curriculum development  
• Individual project time |
| October       | • Publication practices and responsible authorship  
• Policies / review/ updates  
• Individual project time  
• Electronic resources and literature searching  
• Peer review  
• Policies / review/ updates  
• Educational methods, curriculum development  
• Individual project time |
| November      | • Collaborative science  
• Policies / review/ updates  
• Individual project time  
• Educational learning technologies |
| December      | • Human subjects  
• Policies / review/ updates  
• Education evaluation and assessment  
• Individual project time |
| January       | • Research Involving animals  
• Policies / review / updates  
• Individual project time  
• Educational learning technologies |
| February      | • Research Misconduct  
• Policies / review/ updates  
• Education evaluation and assessment  
• Individual project time |
| March         | • Conflict of Interest and Commitment  
• Policies / review/ updates  
• Individual project time  
• Education evaluation and assessment |
| April         | • Alumni meeting  
• Education evaluation and assessment  
• Individual project time  
• University Education Colloquium |
| May           | • Educational software resources and execution  
• Final presentations of education portfolio  
• Program Summary and Evaluation |
| June          | • Group critiques of education portfolio  
• Group critiques of education portfolio  
• Group critiques of education portfolio  
• Promoting research integrity to non-scientists |
| July          | • Group critiques of education portfolio  
• Group critiques of education portfolio  
• Group critiques of education portfolio  
• Program Summary and Evaluation |
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