

*Defining Scientific Misconduct*

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

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**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).”<sup>1</sup> 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.”<sup>2</sup> 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.<sup>3</sup> 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

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1. D.F. Thompson. Understanding financial conflicts of interest. *New England Journal of Medicine* 329:573-576 (1993).

2. P.M. Tereskerz and J. Moreno. Ten steps to developing a national agenda to address financial conflicts of interest in industry sponsored clinical research. *Accountability in Research* 12:139-155 (April-June 2005), p. 143.

3. Sheldon Krinsky. Autonomy, disinterest, and entrepreneurial science. *Society* 43(4):22-29 (May/June 2006).

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.”<sup>4</sup> 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.<sup>5</sup>

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4. Richard Smith. What is Research Misconduct? A background paper prepared for the joint consensus conference on misconduct in biomedical research. [http://www.rcpe.ac.uk/publications/articles/supplement7\\_misconduct/C\\_what\\_is\\_research\\_misconduct.pdf](http://www.rcpe.ac.uk/publications/articles/supplement7_misconduct/C_what_is_research_misconduct.pdf)

5. David J. Cullin. Ghostwriting in scientific anesthesia journals. *Anesthesiology* 87:195-196 (August 1997).

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."<sup>6</sup>

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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6. Cullen, 1997, p. 196.

drug companies.”<sup>7</sup> 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.<sup>8</sup> 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.<sup>9</sup>

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.<sup>10</sup> Another study published in *PLOS Medicine* reported a high prevalence of ghost authorship in industry-initiated clinical trials in Denmark.<sup>11</sup>

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.<sup>12</sup> 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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7. Antony Barnet, public affairs editor. Revealed: How drug firms 'hoodwink' medical journals. *The Observer*, December 7, 2003.

8. Sarah Boseley. Scandal of scientists who take money for papers ghostwritten by drug companies. *The Guardian*, February 7, 2002.

9. David J. Cullen. Ghost writers in scientific anesthesiology journals. *Anesthesiology* 7(2):195-196 (August 1997).

10. A. Flanagan, L.A. Carey, P.B. Fontanarose et al. Prevalence of articles with honorary authors and ghost authors in peer-reviewed medical journals. *JAMA* 280(3):222-224 (July 15, 1998).

11. Peter C. Gøtzsche, HrÓbjartsson, AsbjÓrn, Johansen, Helle Krogh *et al*, Ghost authorship in industry-initiated randomized trials. *PLOS Medicine* 4(1):6pp (January 2007).

12. Frank Frizelle. Research dishonesty and conflict of interest. *The New Zealand Medical Journal* 115:1-3 (December 13, 2002), p. 2.

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.”<sup>13</sup> 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”<sup>14</sup> 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 ideologists, 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.”<sup>15</sup>

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13. S. Ngai, J.L. Gold, S.S. Gill *et al*. Haunted manuscripts: ghost authorship in the medical literature. *Accountability in Research* 12:103-114 (April-June, 2005), p. 104.

14. Ngai, 2005, pp. 108-110.

15. Elke Brüser. Interview with John Rengen, former business head for Eli Lilly in Sweden. *Iche habe Menschen bestochen. Die tageszeitung*. January 12, 2007.

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.<sup>16</sup>

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.<sup>17</sup>

Whittington *et al.* examined the published and unpublished clinical trials of a class of drugs used to treat childhood depression.<sup>18</sup> 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.”<sup>19</sup> The revelation that clinical trial data are selectively published has prompted some observers to call for a centralized registration of all clinical trials.<sup>20</sup> As a condition for publication in their member journals, the ICMJE requires relevant authors to register their trials in a public registry.<sup>21</sup>

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

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16. Richard A. Knox. Biomedical results are often withheld. *Boston Globe* April 16, 1997.

17. Gardiner Harris, F.D.A. says Bayer failed to reveal drug risk study. *New York Times* September 30, 2006.

18. C.G. Whittington, T. Kendall, P. Fonagly et al. Selective serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data. *The Lancet* 363(9418):1341-1345 (April 24, 2004).

19. Whittington *et al.* 2004, p. 1341.

20. K. Dickersin and D. Rennie. Registering clinical trials. *JAMA* 290:516-523 (July 23/30, 2003).

21. International Committee of Medical Journal Editors (ICMJE) , website. <http://www.icmje.org>. Accessed June 7, 2007.

authors only reported six months of their data when they had twelve months of data.<sup>22</sup> The full data set reveals a different risk outcome. Another prominent and highly visible study in which results were withheld from *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 rofecoxib (Vioxx) or naproxen (Naprosyn), but data on cardiovascular events were also monitored. Three myocardial infarctions, all in the rofecoxib group, were not included in the data submitted to the *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.”<sup>23</sup>

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.<sup>24</sup> 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.

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22. J. B. Hrachovec and Marc Mora. Reporting of 6-month vs 12-month data in a clinical trial of Celecoxib. *JAMA* 286(19):2398 (November 21, 2001).

23. G.D. Curfman, S. Morressey, and J.M. Drazen. Expression of concern: Bombardier et al. Comparison of upper gastrointestinal toxicity of Rofecoxib and Naproxen in patients with rheumatoid arthritis. *N. Engl. J. Med.* 343(21):1520-1528 (November 23, 2000).

24. Marion E. Broome. Scientific integrity-the cornerstone of knowledge. *Journal of Neuroscience Nursing* 35(1):56-59 (2003)

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.”<sup>25</sup> 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.<sup>26</sup>

### **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

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25. ICMJE website. <http://www.icmje.org>. Accessed June 7, 2007.

26. K.A. Schulman, D.M. Seils, J.W. Timbie *et al.* A national survey of provisions in clinical-trial agreements between medical schools and industry sponsors. *N. Engl. J. Med.* 347(17):1335-1341 (October 24, 2002).

Academy of Science. All of these claims are false...None of them are true."<sup>27</sup>

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.<sup>28</sup>

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

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27. Sheldon Krimsky. *Science in the Private Interest*. Lanham, MD: Rowman & Littlefield, Pub., 2003, p. 118.

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.<sup>29</sup>

Deborah Parrish, writing in the *Professional Ethics Report* asks whether falsification of credentials should be considered “scientific misconduct.”<sup>30</sup> 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.”<sup>31</sup> 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.<sup>32</sup>

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29. Jerry Ravetz. *Scientific Knowledge and its Social Problems*. Oxford University Press, 1971. Oxford, UK.

30. Deborah Parrish. The scientific misconduct definition and falsification of credentials. *Professional Ethics Report* IX:1-5 (Fall 1996).

31. Website of the U.S. Office of Research Integrity. <http://ori.dhhs.gov/final/search/php>. Accessed May 7, 2007.

32. [http://ori.hhs.gov/misconduct/cases/investigatio\\_summ\\_1994.shtml](http://ori.hhs.gov/misconduct/cases/investigatio_summ_1994.shtml) Accessed May 7, 2007.

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.<sup>33</sup> 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.”<sup>34</sup> 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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33. H.C. Sox, D. Rennie. Research misconduct, retraction and cleaning the medical literature: Lessons from the Poehlman case. *Annals of Internal Medicine* 144(8):609-613 (April 18, 2006).

34. R. Smith. What is research misconduct? A background paper prepared for the joint consensus conference on misconduct in biomedical research. *J. Royal College of Physicians Edinborough*. 30:4-8 (2000).

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.”<sup>35</sup>

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 antisience interests bent on deciding issues by ad hominem arguments rather than by testable facts.”<sup>36</sup>

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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35. Christopher J. Borgert. Letter. Conflict of interest: kill the messenger or follow the data? *Environmental Science & Technology* 41(3):665-666 (February 1, 2007), p. 665.

36. Borgert, 2007, p. 665.

studies revealed the existence of the funding effect in biomedical research.<sup>37</sup>

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.<sup>38</sup> 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.<sup>39</sup> In a study of studies in the biomedical sciences, Bekelman *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."<sup>40</sup> In another study illustrating the funding effect Stelfox *et al* found "a strong association between authors' published positions on the safety of calcium-channel antagonists and their financial relationship with pharmaceutical manufacturers."<sup>41</sup> 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.

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37. Krinsky, *Sci. & Priv. Int.*, 2003.

38. D.E. Barnes, L.A. Bero. Why review articles on the health effects of passive smoking reach different conclusions. *JAMA* 279(19):1566-1570 (May 20, 1998).

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. *American Journal of Public Health* 93:664-669 (April 23).

40. J.E. Bekelman, Y. Li, and C.P. Gross. Scope and impact of financial conflicts of interest in biomedical research: A systematic review. *JAMA* 289(4):454-465 (January 22/29, 2003), p. 463.

41. H.T. Stelfox, G. Chua, K. O'Rourke *et al.* Conflict of interest in the debate over calcium-channel antagonists. *NEJM* 338:101-106 (January 8, 1998).

## 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 "disinterest" 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.<sup>42</sup>

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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42. S. Krinsky. A conflict of interest. *New Scientist* 179:21 (August 30, 2003).

time.<sup>43</sup> 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."<sup>44</sup>

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.<sup>45</sup> 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.

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43. David Armstrong. Surgery journal threatens ban for authors' hidden conflicts. *Wall Street Journal* December 28, 2005, p. B1.

44. K. Mangan and J.R. Young. Medical journal toughens its conflict-of-interest policy. July 21, 2006. <http://chronicle.com/weekly/v52/i46/46a01401.htm> Accessed May 13, 2007

45. Krinsky, *Sci. & Priv. Int.*, 2003, p. 134.