Conflicts of Interest in Biomedical Publishing: A Discussion with Sheldon Krimsky

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Sheldon Krimsky, professor of urban environmental policy and planning at Tufts University, presented the keynote address, "Conflict of Interest Policies in Science and Medical Journals", at the CSE retreat "Conflicts of Interest and Scientific Publication" in October 2004. As follow-up, I interviewed Krimsky on conflicts of interest (COIs) in biomedical journals and other subjects he has been interested in over the years.

Krimsky grew up in Brooklyn, New York, and attended New York City schools. He graduated from Stuyvesant High School in 1959, Brooklyn College in 1963 with a bachelor's degree in physics, and Purdue University in 1965 with a master's degree in physics. He then attended Boston University, where he earned a master's degree and a PhD in philosophy in 1968 and 1970, respectively. He is the author of more than 130 articles and reviews on science and ethics, biotechnology, risk analysis, and endocrine disruptors.

Krimsky is the sole author of four books: *Genetic Alchemy: The Social History of the Recombinant DNA Controversy* (MIT Press, 1982); *Biotechnics and Society: The Rise of Industrial Genetics* (Greenwood Publishing Group, 1991); *Hormonal Chaos: The Scientific and Social Origins of the Environmental Endocrine Hypothesis* (Johns Hopkins University Press, 2000); and *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?* (Rowman & Littlefield Publishers, 2003). In addition, he is coauthor of two books: *Environmental Hazards: Communicating Risks as a Social Process* (Auburn House Publishing Group, 1988) and *Agricultural Biotechnology and the Environment* (University of Illinois Press, 1996). He has been coeditor of two books: *Social Theories of Risk* (Praeger Publishing Company, 1992) and *Rights and Liberties in the Biotech Age* (Rowman & Littlefield Publishers, 2005).

In addition to teaching and writing, Krimsky serves on editorial or advisory boards of eight publications. He is an associate editor of the journal *Accountability in Research*; an advisory-board member for *Science, Technology and Human Values*; an editorial-board member for *Expert Opinion on Pharmacotherapy*; and an editorial-board member for *Genewatch: Bulletin of the Committee for Responsible Genetics*.

The responses below are drawn from interviews with Krimsky, from *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?*, from his articles, and from his keynote address at the October 2004 CSE retreat.

Science Editor: *You spoke on COIs during the October 2004 CSE retreat. What are some of your other interests?*

Krimsky: My interests have changed over the years. There was a period of time, about 6 years, when I was interested in risk, including risk analysis, risk management, and risk communication. I spent a lot of time researching and writing about this topic, and when I felt that I had said what I wanted to say, I went into other areas. I became very interested in chemicals and health and the emergence of a new hypothesis on the etiology of chemical disease. I spent about 5 years researching endocrine disruptors.

For 20 years or more, I have been interested in biotechnology and how it contributes to our lives and in ethical issues in biotechnology. I started writing about biotechnology in 1980 and over the years have come back to it in one way or another. It is a rich area of inquiry that always raises new questions, whether about human genetics, stem cells, or genetically modified crops.

I recently edited a volume of commentaries on rights and liberties in the biotechnology age. The volume addresses 10 major issues in biotechnology that lend themselves to a discussion of fundamental rights—issues like DNA testing and genetically modified human eggs. This is the fourth volume that I have done on biotechnology and society.

My current interests include biomedical science, ethics, science and the law, biotechnology, and human gene therapy. I've done a systematic review of the kinds of infrastructure that are involved in the commerce of human gene therapy—where the money goes, what kinds of companies have invested, and types of clinical trials. An article about this was published in the February 2005 issue of *Human Gene Therapy*.

[Krimsky says that sometimes a subject will pique his attention. He was working on four or five different projects when this article went to press. One of his most recent projects was writing an article on the "weight of evidence" for a special supplement to the *American Journal of Public Health*. The article was inspired by a symposium discussing science in the courts that he attended while working for a group interested in law and science. Krimsky says that one often hears about the "weight of evidence", but no one knows what that really means. The lack of investigation into the matter encouraged Krimsky to do his own investigation.]

Science Editor: *How did you become interested in COIs?*

Krimsky: After I received my doctorate, I taught philosophy of science for a few years before I came to Tufts University, where I helped to develop a policy program. While working on the policy pro-

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gram, I was also supervising a study of a contaminated community in the town of Acton, Massachusetts, a suburb of Boston. The case study involved the W R Grace Company and the town of Acton. Two wells were closed in Acton during December 1978 because of chemical contamination.

The town had reason to believe that the contamination came from production facilities at the Grace chemical plant. In exchange for the right to extend its manufacturing site, Grace provided funds for the community to contract for a study that would investigate the source of pollution. Before we published our findings, the vice president of the company came to the president of Tufts University, then Jean Mayer, and asked him to stop the publication and asked that I be dismissed for being "unfriendly to corporations".[1] The president did nothing of the kind. It occurred to me that this multinational chemical company had not given any money to the university and that the university was not heavily invested in it, and I wondered whether the president would have been so protective if the company had contributed significantly to the university.

That happened in the 1980s, and around the same time, biology was becoming heavily commercialized. I began getting interested in what would happen to the university if it became colonized by nonacademic interests. The first time I had anything in print about COIs was in January 1980 for *Nature* magazine.[2] They put me in a room with Nobel Laureate David Baltimore, and we talked about what could happen if biomedical science became commercialized. *Nature* published an edited version of the discussion.

Science Editor: *What are COIs to you?*

Krimsky: As I wrote in my book *Science in the Private Interest,* "the term 'conflict of interest' is used like a flashing yellow signal to alert society to proceed with caution in the face of some actual or potential wrongdoing, or bias primarily among people who hold positions of public trust. COI policies are also meant to describe actions that should be taken to avoid a moral indiscretion, the appearance of wrongdoing, or a violation of law".[3] In my book, I explained Andrew Starks's anatomy of COI behavior,[4] which he breaks down into three stages. First is the "antecedent act" stage. Antecedent acts are factors that compromise authors from their responsibility to foster public interest, rather than personal and private interests (for example, authors' being offered money for a consultation about a drug they are studying). Second is the "state of mind" stage, which represents the affected feelings, predisposition, and liking of the antecedent acts. In this stage a scientist would be more inclined to favor the special interests of financial backers, rather than those who had not backed them. Third is the "outcome behavior" stage, or the actions taken that arise from an affected state of mind as influenced by the antecedent conditions.[4] The scientist allows the money to affect the final results.[3]

Science Editor: *What are the current statistics on COI policies in biomedical journals?*

Krimsky: In a 1997 study I did with L S Rothenberg, we found that of 1396 biomedical journals only 16% had COI policies.[5] [Policies for the disclosure of COIs began as early as 1984 when the *New England Journal of Medicine* requested that authors disclose to their editors any associations they had that could possibly affect their work.[6]] About 50% of medical journals now have some type of COI disclosure policy.

Science Editor: *What types of policies are common in biomedical journals today?*

Krimsky: As mentioned in my keynote address at the CSE retreat, there are two types of disclosure policies: simple statements and more complex ones. The journals with simple statements may request information about the authors' professional and financial affiliations that may be perceived to have biased their

Selected Articles by Sheldon Krimsky

For a complete list of articles by Sheldon Krimsky, please visit *www.tufts.edu/~skrimsky/bio.htm* and select the publications tab. Links are provided to PDFs of some of the articles.

Krimsky S. Commentary on the retraction of scientific articles. Nat Genet 2002;30:139.

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presentation. Simple statements are sometimes in the form of a checklist, where the authors have to check off whether they hold a patent, have financial interests, or were consultants; these lists do not require a full detailed disclosure. More complex statements ask the authors for more detail. For example, many complex statements ask authors for information about specific financial activities pertaining to their published work, such as ownership of stocks, service as consultants or advisers to a company, existence of any patent or license arrangement for materials studied, and any other financial benefits connected to their publication.

Science Editor: *If only 50% of biomedical journals today have COI policies, why do you believe the others have not followed suit?*

Krimsky: Some journal editors feel that the only consideration should be whether there is good science and not whether the author has any ties to a company. Some journal editors do not want to be policemen. Few journals will participate actively in the punishment of authors who do not disclose important information that could show a COI.

Science Editor: *Are COI disclosures to biomedical journals important?*

Krimsky: The disclosure of COIs to journals is very important. Journals that do not disclose author associations can lose the trust and interest of their readers. There will also be skepticism about the peer-review process and about the article. The appearance of integrity is very important. COI disclosure is relevant to reviewers of articles because it provides them with a skepticism that they need to give a good review. Skepticism is good for science. Reviewers need to come to articles with some skepticism.

Science Editor: *How can we increase the number of journals that have COI disclosure policies?*

Krimsky: One way is to have requirements at the grant-application level. If a judge says that as a requirement for getting a grant you (the author) would have to put your article in a journal that requires disclosure, that would help. I also think that more journals would adopt such policies if this requirement were set. Journals should follow the guidelines of the International Committee of Medical Journal Editors.[7] It has a strong policy and has set the standard for the entire publication community. If people followed that standard, we would be in much better shape.

Science Editor: *Should COI policies be expanded?*

Krimsky: I think that disclosure policies should be broadened and expanded to cover letters, editorials, book reviews, and publication of clinical guidelines in medical journals. Some journals have adopted a wider range of policies for book reviews and clinical guidelines, but it is not universal. It varies journal by journal, and these things change. Stronger COI disclosures should also be implemented for federal advisory committees and government scientists.

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3. Krimsky S. Science in the private interest: has the lure of profits corrupted biomedical research? Lanham, Md: Rowman & Littlefield Publishers, Inc; 2003:125-6.

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