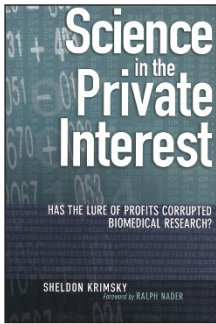


## Conflicts of interest



### Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?

By Sheldon Krimsky

Rowman & Littlefield, 2003

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Reviewed by Bernard Lo

Science is expected to be a dispassionate search for knowledge, and scientists are supposed to be motivated by a quest for truth rather than by money and greed. Sheldon Krimsky's book paints a different picture.

Krimsky describes academic researchers who have extensive consulting arrangements and support from for-profit sponsors, and form their own spin-off companies. He argues that these financial arrangements lead to conflicts of interest among university scientists and are associated with bias in their research. Although this thesis is not new, readers will learn from the detail he presents and from his juxtaposition of a broad range of examples. Bringing together a wealth of evidence from investigative journalism, government reports and peer-reviewed articles, Krimsky shows that these conflicts of interest are not isolated incidents but form a widespread, increasing pattern.

The book argues that the growth of the biomedical-industrial complex and its profit motive have corrupted academic research. Krimsky laments the decline of scientists dedicated to the pursuit of knowledge for the public good. He says the new financial arrangements undermine the fundamental ethical norms of public science, which include open sharing of information and unbiased assessment of findings.

The book describes attempts by sponsors to delay or suppress publication of unfavorable results, to enact research contracts that give them control over data and publications, and to control academic appointments. Krimsky argues that these financial conflicts of interest erode public trust in university scientists, particularly in such controversial areas as environmental policy and dietary standards.

The most vivid examples of conflicts of interest and bias concern the governmental committees that recommended approval of the drug Rezulin for diabetes, and a vaccine for the diarrheal disease caused by rotavirus. These products had to be withdrawn from the market after serious complications and deaths occurred. In the case of Rezulin, the US Food and Drug Administration (FDA) approved the drug on a fast-track basis and did not withdraw the drug after reports of liver failure—even after the UK banned the drug. Krimsky reports that numerous members

of these committees had financial ties—research grants and contracts, consulting arrangements or stock ownership—to industries that would have been directly affected by their recommendations. But these relationships were not identified or disclosed, and the involved panelists were not excluded from deliberations, which is in violation of federal regulations. Krimsky also mentions other examples of bias, including misconduct in clinical trials and contributions by the pharmaceutical industry to professional organizations that set clinical practice guidelines.

The book has many strengths. The writing is clear, lively and accessible to the lay reader. The case studies are richly documented, and even those familiar with the incidents described will benefit from reading the book. However, Krimsky does not maintain narrative flow across a series of disparate cases. More important, the book falls short when analyzing and proposing solutions to the problems it depicts. Krimsky fails to sufficiently describe recent suggestions for keeping science focused on the public good, even though commercial interests are increasingly common.

For example, he argues that gene patenting has deterred research and access to clinical tests for hemochromatosis and hereditary breast cancer. But he does not discuss proposed reforms to address these problems. One solution is to develop patent pools, as has been done in the electronics industry, to address the problems of patent stacking. Other proposals are to grant patents only for products such as diagnostic tests or therapies, or for the processes to produce them, but not for mere DNA sequences.

Krimsky also fails to adequately analyze institutional policies on conflicts of interest. He supports previous suggestions that university researchers conducting clinical trials should not own stock or options, hold management positions or have consulting arrangements with trial sponsors. However, there has been little support for a strict prohibition and, even if widely enacted, it would have no impact on actual or perceived conflicts of interest in the basic sciences.

The book does not consider solutions to the most vexing problem it depicts—financial conflicts among members of federal committees that make recommendations on research priorities, trial designs and drug approvals. Given the web of financial relationships that the book documents, how can such panels include persons with pertinent expertise and yet remain balanced and unbiased? The book's proposal for a national institute of drug testing to oversee clinical trials is a mere sketch, not a fully developed proposal. Such an institute might strengthen the quality of data submitted to the FDA in support of a new drug application. But it is not submission of weak or biased data to the FDA that is the problem.

Krimsky does not indicate how such a new institute would relate to the FDA, which sets standards for clinical trials, requires submission of all data—favorable and unfavorable—on a drug, and reviews primary data from clinical trials. There is also no discussion of how the institute would be funded and where it would be located in the government.

Krimsky calls on university scientists to work for the public good by documenting and proving the detrimental effects of corporate ties. But this is a reactive view of science. A broader, more proactive vision is that science needs to translate laboratory discoveries to marketable new tests, drugs and medical devices in order to benefit patients. If we reject a model that encourages scientists to patent and license discoveries, we need to articulate what the alternatives are and evaluate their effectiveness in translating discoveries from the bench to the bedside.

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