Collaboration Between Science and Industry: Pro's and Con's of the Conflicts-of-Interest Movement

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TABLE OF CONTENTS

Introduction	4
The Conflicts-of-Interest Movement	4
Evaluations of the Influence of Industry on Science	5
Patient Safety	6
Advisory Panels	7
The Spectrum of Conflicts of Interest	8
Preventing Abuses	9
Peer Review	9
Disclosure	11
Publication Bias and the Registration of Clinical Trials	12
Where's the Harm?	13
Perspective	15

Introduction

For about a century, industry has played an important role in creating new technology and funding scientific research. Recently, though, the collaboration between science and industry has been threatened by the development of a movement that proposes to end or drastically limit such cooperation on the grounds that it involves unacceptable conflicts of interest.

The idea that science should be "pure" and untainted by any potential conflicts of interest may seem appealing in theory, but its application in the real world has hidden pitfalls. In this report, which is based on a detailed American Council on Science and Health white paper by Ronald Bailey, science correspondent for *Reason* magazine, the conflicts-of-interest movement is exmained, with an emphasis on the following topics:

- The scientific evidence on whether industry ties are actually leading to biased decisions, threats to patient safety, and distorted research results;
- The bias that may be created by focusing exclusively on industry-related financial conflicts of interest, while ignoring other types of potentially conflicting interests;
- The mechanisms currently in place to protect the integrity of scientific research; and, most importantly
- The very real harm that can result from limiting industry/university collaborations and preventing industry-connected scientists from serving on government advisory boards.

The Conflicts-of-Interest Movement

An influential movement to prevent conflicts of interest has been sweeping through the U.S. research and regulatory communities, especially those pertaining to biomedical research. Its arguments are based on the assumption that ties between scientists and industry are inherently corrupt. Conflicts-of-interest activists claim that collaborations between researchers and industry are harming the public and undermining public trust in science.

The conflicts-of-interest activists have proposed that several measures should be taken to decrease collaboration between university-based or government-based science and industry, such as:

• Creating increasingly elaborate and restrictive conflict-of-interest rules that would eliminate or drastically limit opportunities for scientists based at univer-

- sities to collaborate with industry researchers or receive grants from industry to support their studies.
- Having all clinical trials of potential new medicines in human volunteers be funded by the federal government, rather than by pharmaceutical companies.
- Requiring that scientists who have received industry support for their research be excluded from serving on scientific advisory committees that counsel government regulatory agencies such the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA).
- Excluding scientists with industry ties from serving on committees of the National Academies (the National Academy of Sciences, Institute of Medicine, National Academy of Engineering, and National Research Council). The Academies are independent non-profit groups chartered by Congress to provide free scientific and technical advice to the government. They carry out their work by recruiting special committees of experts to prepare reports on each subject that they investigate.

Are such restrictions actually needed? Would they do more good than harm or vice versa? To address these questions, we will first look at the evidence on whether the involvement of industry in scientific research has led to biased research results, increased risks to patients, and distorted decision-making.

Evaluations of the Influence of Industry on Science

Many analyses have attempted to determine whether industry funding leads to research results that are biased in the direction favorable to the sponsoring company. Thirty-seven such analyses, involving a total of more than 1,000 biomedical research studies, were considered together in a review conducted by Yale University researchers in 2003. The review found that industry-sponsored studies were significantly more likely than non–industry-funded studies to reach conclusions favorable to industry. At first glance, this finding may seem to indicate that industry funding did indeed lead to biased scientific research. But a closer look at the analysis leads to different conclusions.

The industry-funded research was not poor-quality research. In fact, this and other analyses have concluded that on the whole, industry-funded studies are as good or better in terms of scientific quality than studies with other sources of funding. Then why the difference in results?

One likely reason is that, given limited resources, industry only funds studies of the most promising therapies. Although it might be intrinsically interesting to study other potential therapies, given the enormous cost of research and the need to make a profit, industry focuses its attention only on therapies most likely to succeed.

Another reason for the higher rate of favorable results is that industry-funded studies of new drugs are more likely than other studies to compare the new drug to an inactive placebo rather than to drugs already on the market. Studies that involve comparisons to placebo are more likely to have favorable results. The reasons why industry studies tend to use placebos is simple: these are the types of studies that FDA requires for the approval of new drugs, and their higher likelihood of favorable results increases the chances of bringing a new product onto the market. Drug companies are not likely to spend the extra money involved in comparing new drugs to existing drugs because FDA does not require them to do so and because such studies are less likely to further their goal of marketing their products.

Similar results were found in a 2006 analysis of the results of more than 300 trials of new cardiovascular therapies. The analysis found that trials sponsored by profit-making companies were more likely than those funded by not-for-profit organizations (government agencies or foundations) to have results favoring a new therapy. But, as was the case with the Yale analysis, this was not indicative of bias. Instead, it appeared that the not-for-profit organizations were sponsoring the earlier stages of drug development, where the risk of failure is high. When preliminary studies funded by not-for-profit organizations had negative results (i.e., results indicating that the potential new therapy was not effective), no further research was likely to be done. But when the preliminary studies had positive results, profit-making companies would jump in to sponsor the later stages of research, where positive results were more likely, in the hope of developing a successful product. This is the way the system is supposed to work. Not-for-profit organizations are the only ones who are likely to fund early-stage research that has only a small likelihood of success; it does not make financial sense for forprofit companies to sponsor such studies. But once the results of preliminary research suggest that a successful product might be developed, profit-making organizations can and should take over the funding of research because they have the financial motivation to do so. This spares the limited funds of the not-forprofit organizations for the kinds of research that only they can sponsor.

Patient Safety

Another major concern is that industry funding might threaten the safety of volunteers involved in clinical trials of new therapies and of patients who receive

new therapies after they come on the market. However, CenterWatch, a Boston-based publishing firm that is tracking about 59,000 clinical trials in the United States involving more than 20 million participants, has found that the record of safety for participants in industry-sponsored drug trials is actually better than that for participants in trials at academic institutions funded by the government. As for newly approved drugs, the numbers do not support concerns that recent increases in the involvement of industry scientists in the drug approval process have led to an increased proportion of dangerous drugs on the market. The percentage of drugs withdrawn from the market for safety reasons during the years 2000–2004 was only about half of that in the 1980s and 1990s, and the data show that FDA is now withdrawing unsafe drugs from the market much more quickly than it used to.

Advisory Panels

Examining possible bias introduced to government advisory panels by the presence of scientists with industry ties, a study conducted by Public Citizen, an organization that campaigns against industry involvement in science, found no evidence that the industry ties of members of FDA committees who advise the agency on whether to approve particular drugs had changed the panels' decisions. Public Citizen's analysis showed no relationship between the rate of industry links among panel members and voting outcome. Although for each advisor with a tie to industry, there was a 10 percent greater likelihood that the meeting would favor approving a particular drug, excluding all panel members with industry affiliations would not have changed the outcome of the vote on any drug. Moreover, even though a standard conflict-of-interest interpretation would imply that advisory committee members who had ties to a particular drug company would vote to reject drugs made by competing companies, the panel members actually tended to vote *against* the financial interests of the companies with which they had ties by voting to approve competitors' drugs.

Similarly, when another organization that disapproves of science/industry links, the Center for Science in the Public Interest (CSPI), examined the involvement of scientists with industry ties in National Academies committees, it found no evidence of inappropriate behavior by such scientists. Michael Jacobson, head of CSPI, admitted, "Whether complete avoidance of conflicts of interest on committees would have improved the committees' recommendation is impossible to know." Jacobson also acknowledged that National Academies "reports invariably earn high marks from the scientific community, and this study, which did not evaluate the quality of any particular [National Academies] report, makes no

effort to question that consensus view." In other words, all CSPI did was to confirm the well-known fact that a significant proportion of scientists serving on National Academies committees have ties to companies that have an interest in the topic under investigation. This is to be expected because it is through their collaborations with industry that these scientists have developed the expertise on the topic that would make them valuable committee members. CSPI's recommendation that future National Academies committees be "balanced," where "balance" was defined as "never having more than three [industry-affiliated] scientists on any committee and always balancing pro-industry scientists with at least an equal number of public health oriented scientists" is not based on the organization's own findings, which uncovered no problems with the current system; it is based merely on CPSI's opinion that the system should be changed.

The Spectrum of Conflicts of Interest

One assumption of the conflicts-of-interest movement that is in itself biased (or naïve) is the concept that only *financial* conflicts of interest matter and that among financial conflicts of interest, the only ones that matter are those involving ties with industry.

The principal funder of scientific research other than industry is the government. Given the many recent studies by conflicts-of-interest activists scrutinizing the effects that industry funding has on the outcomes of scientific research, it is surprising to find that there are almost no studies that look at the effects that government funding may have on science. Why this should be the case is not clear. After all, scientists who work for or receive grants from government agencies are operating in a politicized environment. Like scientists with industry ties, they might conceivably be influenced by their funding. But no one knows whether this is happening because the topic has not been adequately investigated. Anecdotally, there have been reports of a few specific instances where government affiliations may have influenced individual scientists' interpretation of research findings. However, it would be poor science to base any conclusions on a few individual cases, and ACSH will not do so here.

It is also important to realize that money is not the only possible basis for a conflict of interest. Human beings are complex creatures who are influenced by many factors. Some scientists may have political views that relate to the topics of their research or may belong to organizations that have expressed views on related topics (e.g., a scientist investigating an environmental topic who is a member of Greenpeace or the Sierra Club). Some may have family members who have

the disease that the drug under investigation would treat or who have suffered adverse reactions to drugs. Some may have relevant religious convictions (e.g., a Mormon scientist investigating a disease for which the drinking of alcoholic beverages, which the Mormon religion prohibits, may be a risk factor). Even a scientist's age, ethnicity, gender, or sexual orientation could be relevant. Yet there has been little focus on any of these possible sources of bias, and there are no widespread calls for creating rules to eliminate such potential conflicts of interest or to exclude scientists who have such potential conflicts from participating in advisory groups. Instead, the conflicts-of-interest activists seem to divide the country's scientists into two groups, "pro-industry" and "public health oriented" (to use CSPI's regrettable terminology). Life is not this simple.

Preventing Abuses

Obviously, conflicts of interest of any type have the potential to prompt abuses, and some controls are necessary to prevent such abuses or to ensure that they are detected when they occur. Conflicts-of-interest activists would like to see this situation addressed by having Congress enact complex and restrictive conflicts-of-interest laws. Such burdensome laws, however, may be unnecessary because the scientific community has proven itself capable of developing mechanisms that can address concerns about the validity of research results without government intervention. Some of these mechanisms have the additional advantage of being able to prevent or detect threats to the integrity of scientific research that are unrelated to conflicts of interest, as well as those that are. Among these mechanisms are peer review, disclosure, and systems for the registration and assured publication of the results of clinical trials.

Peer Review

One of the most important of these mechanisms is *peer review*, that is, the scrutiny of scientific research findings by other qualified scientists.

Traditionally, peer review has worked in the following way: The principal means by which scientists communicate their findings to their colleagues and the world is through publication of reports of their research in scientific journals. After a paper is submitted for publication in a journal, it undergoes a process of peer review in which the editors of the journal ask several other experts in the same field to scrutinize the paper carefully to determine whether it is of sufficient quality to justify publication. This process is usually carried out anonymously. The peer reviewers can recommend that the paper be accepted, require improvements

or corrections to be made before it is accepted, reject the paper but suggest revisions that might make it acceptable for publication, or reject it outright.

This review process ensures that all research published in peer-reviewed journals has undergone systematic scrutiny before publication, and it has the advantage of being based on the content of the research report itself. Thus, it can detect flaws in a study attributable to a wide variety of causes, not just those linked to conflicts of interest. This is important because there is evidence that most ethical lapses in scientific research are unrelated to researchers' ties with industry. Such lapses would be missed by control systems that focus exclusively on conflicts of interest, but they may be detectable through review of the science itself. Moreover, most of the problems that would lead to rejection of a paper for publication are not related to misconduct (which is actually relatively rare) but rather to flaws in the design, conduct, analysis, interpretation, or presentation of the study findings. Control systems that focus on conflicts-of-interest-related issues alone would not detect these types of weakness in a scientific report.

Despite these advantages, however, peer review is not a perfect system. Because it depends on the expertise of only a few individuals, errors, misinterpretations, and even deliberate fraud can be missed. Peer review is also time-consuming, leading to delays in the publication of important scientific findings, and it cannot ensure that a study's results are valid — it only ensures that other experts in a field consider them worthy of publication.

A new, more robust form of peer review is developing, however. Researchers in the physical sciences are already migrating away from peer-reviewed print journals to the world of electronic preprints of scientific papers, and a trend toward this new system are occurring in biomedical research as well. In this new model, peer review is changing from a one-time review of a self-contained research article to a continuous online process. In some forms of the new model, editors will still make decisions on whether or not any particular paper merits publication and may refer it to outside reviewers. But unlike the situation with traditional print journals, publication is not the end of peer review; it is only the beginning. Once an article has been published online, open post-publication peer review involving online annotation, discussion, and rating begins, and it continues indefinitely. This new, permanent, transparent peer review process offers opportunities for greater scrutiny of the quality of scientific research than was possible with the traditional system.

Disclosure

Another mechanism by which the scientific community protects itself against threats to scientific integrity, in this instance those specifically related to conflicts of interest, is *disclosure*. Most scientific journals require the authors of submitted papers to disclose any financial interests relevant to the work being submitted, as well as the source of funding for the research. This information is made available to the peer reviewers and, if the paper is accepted for publication, is published with it.

The exact rules for disclosure differ from journal to journal, and some aspects of disclosure are controversial. For example, some journals require that authors declare any financial interest in products or companies mentioned in their papers but do not require that interests in competing products or companies be mentioned, which seems odd. A few journals require that patent applications in preparation be disclosed, which is problematic because an inventor would risk losing the patent by making public disclosure before filing for it. It has also been argued (and ACSH agrees) that if disclosure is to take place, it should be expanded to include ideological commitments, such as anti-chemical and anti-corporate activism and relevant organizational affiliations, as well as financial interests. There are also some in the scientific community who object to the whole idea of disclosure, preferring that scientific work be judged exclusively on its own merits. However, current trends suggest that disclosure in some form is here to stay. Certainly, disclosure is preferable to one of the alternatives — prohibiting those with potential conflicts of interest from engaging in certain types of professional activity. In 1990, one of the leading medical journals in the United States, the New England Journal of Medicine, declared that no one who wrote a review article or editorial could have any financial interest in a company that made a product the article discussed or in any of its competitors. In 2002, the *Journal* relaxed this rule because it could not find enough qualified authors who had no such interests.

One highly regarded system of dealing with potential conflicts of interest, including non-financial conflicts, through disclosure rather than disqualification is that of the National Academies. In 2004, the Government Accountability Office (GAO) issued a comprehensive report on federal advisory committees that praised the Academies' conflict-of-interest policies. The GAO commended the National Academies for using a standard form to request that potential advisory committee members disclose organizational affiliations, financial interests, research support, government service, and public statements and positions. In

addition, the GAO applauded the Academies for posting candidate information on a website for public comment about any real or perceived conflicts of interest. Advisory committee membership is not finalized until officials of the National Academies have reviewed the disclosure forms and public comments.

Publication Bias and the Registration of Clinical Trials

One ongoing problem in the current system of publication of scientific research is *publication bias*: studies with dramatic and conclusive results are more likely to be deemed worthy of publication than those with inconclusive findings. Many scientific journals heavily favor the publication of breakthroughs; they have little interest in publishing studies that show nothing new. Thus, if a study indicates that substance X causes a disease or substance Y cures it, and the study is reasonably sound in design and execution, it will be definitely be published. If the study indicates that neither X nor Y has any detectable relationship with the disease, it may not be published, even if its quality is just as good as that of the study with the more dramatic results.

Funders of scientific studies might also play a role in publication bias. It is conceivable that if a study funded by a particular company, government agency, or other organization yields results contrary to the interests of the funder, the researchers might hesitate to publish the findings, either at the request of the funder or out of concern about damaging their future relationship with the funder. At least a few isolated instances of such situations have been reported.

The problem with publication bias, regardless of what prompted it, is that when scientists make efforts to evaluate the overall scientific evidence on a topic, they may obtain a distorted view because in most instances they only have access to research that has been published. They may see five studies linking substance X or Y to a certain disease and none with contrary results and conclude, not unreasonably, that research has consistently shown a link (either beneficial or harmful) between this substance and the disease. But if they could also examine the 20 unpublished studies that showed no link between X or Y and the disease, they would reach very different conclusions.

For clinical trials involving human volunteers, the problem of publication bias is being dealt with through a new system that requires all trials to be registered in a public registry before they begin. Registration is enforced through an agreement in which most of the world's medical journals have stated that they will refuse to publish the eventual results of any unregistered trials. FDA has also set up a reg-

istration system for trials that come under its jurisdiction. When trials are completed, a system has been set up to ensure that all their results will be published, if necessary by resorting to a special publication system set up by the openaccess Public Library of Science in instances where journal editors deem the results to be insufficiently important to warrant publication in their journals. Publication of all trial results enables other researchers, physicians, patients, and regulators to see and evaluate all the information available about the efficacy of any particular intervention or the toxicity of any specific compound. Even trials with negative or inconclusive results provide useful information and may alert other researchers not to waste their time and resources pursuing scientific dead ends.

Ensuring publication of all clinical trial results also demonstrates respect for the volunteers who participated in the trials, who contributed their time, likely experienced some inconvenience and discomfort, and perhaps faced some degree of risk. It can be argued that scientists have an ethical obligation to their study participants to ensure that research findings are made available to the rest of the scientific community so that the maximum value can be obtained from their participation.

Where's the Harm?

The available data, as described above, indicate that conflicts of interest attributable to industry funding are not a major source of scientific bias, that other types of conflicts of interest may be as important as the specific types that conflicts-of-interest activists are concerned about, and that the scientific community is taking effective measures to protect the integrity of scientific research. Nevertheless, one might ask whether it is still a good idea, out of prudence, to take all possible precautions to minimize any possibility of scientific bias resulting from academic/industry collaborations.

ACSH believes that the answer to this question is no. The harm that would result from curtailing academic/industry research collaborations and restricting access of government scientific advisory boards to researchers with industry ties greatly exceeds any benefits that such actions might provide.

Limiting the opportunity of academic scientists to consult for industry can hamper the progress of research. Biomedical firms and other profit-making companies seek advice from university scientists who are on the cutting edge of research. Collaborating with these experts is crucial in helping companies identi-

fy fruitful lines of research and avoid dead ends. Policies that discourage such coooperation can delay or prevent the development of valuable new products, a consequence that is especially harmful in the biomedical field, where new therapies save lives.

The conflicts-of-interest movement is driving some university-based scientists out of the United States. Most academic scientists cannot carry out their research with funds supplied by their universities alone, and the government cannot provide enough grants to support all promising lines of research. Thus, many scientists need to obtain funding from other sources, primarily industry, in order to keep their research going. But conflict-of-interest rules in the United States interfere with this funding search. Therefore, some academic scientists have left the United States for other countries where academic-industry collaboration is encouraged rather than penalized.

One well-known example involves a researcher formerly at Harvard University, who discovered novel compounds that reversed an Alzheimer-like disease in mice. Harvard's extremely strict conflict-of-interest rules prevent its scientists from having any commercial interest in their work and prohibit them from doing any research that might be associated with the commercial development of the results of their studies. To continue his research, with the hope of eventually developing therapies for Alzheimer's disease in humans, this researcher left Harvard and joined the faculty of an Australian university, which permitted him to continue his work while becoming involved with a new biotechnology company, which has further developed the anti-Alzheimer compounds and has begun to test them in clinical trials.

Excessively restrictive conflict-of-interest rules may also discourage scientists from working for the U.S. government. At the National Institutes of Health (NIH), the U.S. government's top medical research agency, very strict conflict-of-interest rules were adopted in 2005 that, among other things, prohibit NIH scientists from consulting with biotechnology, pharmaceutical, or medical device companies or engaging in teaching, speaking, writing, or editing for compensation with such firms. Thus, NIH researchers can do essentially no outside work to supplement their limited government salaries. An internal NIH survey conducted a year after the rules went into effect indicated that 40 percent of NIH's scientists were looking for other jobs or considering doing so, and nearly 75 percent believed that the conflict-of-interest rules would hamper NIH's ability to attract and retain top research talent.

In the biomedical area, there is evidence that increasingly strict conflict-of-interest rules imposed in recent years may already be slowing the process of getting new therapies to patients. In 2007, FDA approved only 19 new drugs, down from 22 the previous year. This is the smallest number of new drugs approved in any year since 1983.

With regard to government advisory boards, increasingly restrictive conflict-ofinterest rules are making it harder for government agencies to obtain the best possible advice. For example, a 2007 law called the FDA Amendments Act (FDAAA) will make it more difficult for FDA to include scientists with industry ties on the advisory committees that recommend for or against drug approval. One problem here is that industry, like government, seeks to work with the most qualified and experienced researchers. A high proportion of the most knowledgeable experts in pharmaceutical-related scientific fields have collaborated with industry at some point in their careers. Limiting the opportunities to include such scientists on government advisory boards therefore deprives those boards of valuable expertise and may force them to rely on the advice of less-experienced or less-qualified scientists. The new law will also make it harder for FDA to obtain the advice of experts who understand the drug development process as well as the underlying science, and it may create new biases on advisory committees because the restrictions only apply to potential conflicts of interest that are financial in nature, not those based on politics or ideology.

Finally, it is important to note that activists with an anti-industry agenda are using charges of conflicts of interest as a political tool to silence opposition and to delegitimize experts, their work, and the conclusions of panels in which they have participated. Because free expression of opinion is essential to the progress of science, the chilling effect on scientific dialogue that can result from conflicts-of-interest charges may be the most harmful consequence of the conflicts-of-interest movement.

Perspective

The conflicts-of-interest movement presents itself as a campaign for the benefit of patients, public health, and scientific integrity. However, it is important to recognize that most conflicts-of-interest activists have strong anti-industry ideological views. To many of them, the conflicts-of-interest crusade is merely a tool that they are using to attack an enterprise that they oppose on other grounds. In our free society, these activists are entitled to their opinions. However, they are not entitled to impose the harm resulting from their actions on everyone else.

Collaboration between industry and science has generally been highly productive, and the current push to treat all industry-linked scientists as tainted is an impediment to good science. Restricting the opportunities of academic scientists to collaborate with industry limits scientific discovery and the development of new products, and discrediting those who do participate in such collaborations is a politicized move that itself introduces other forms of bias into scientific and regulatory processes.

Conflicts-of-interest activists state that they are striving to safeguard public health, patient welfare, or the environment; however, instead of furthering these goals, their activities are harming them. ACSH believes that entities such as universities, scientific journals, and government legislative and regulatory bodies must realize this and begin to reform and rein in unnecessarily restrictive conflict-of-interest rules. To fail to do this will have the result of reining in scientific progress, including the development of lifesaving medical therapies.

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