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Scientific Judgment and the Limits of Conflict-of-Interest Policies

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Abstract

This article argues that the three major elements of typical university conflict-of-interest (COI) policies (i.e., disclosure, management and elimination of conflicts via divestiture or recusal) are likely to be insufficient for screening out many worrisome influences of financial COIs. Current psychological research challenges the effectiveness of disclosure, management plans are unlikely to address the wide range of ways that financial COIs can influence scientific judgment, and it is often impractical to eliminate conflicts. Identifying the limits of these policies highlights the importance of considering alternative strategies, such as encouraging more independently funded research, in order to maintain the integrity of science.

Introduction

In a striking investigation of previous studies that analyzed new biomedical drugs, researchers found that only 5% of the studies funded by companies that developed the drugs gave unfavorable evaluations of the new products under investigation (Friedberg et al., 1999). In contrast, 38% of the studies funded by independent sources gave unfavorable evaluations when analyzing the same drugs. Findings of this sort, indicating that research results tend to be influenced by funding sources, have become common. For example, a review of 11 different studies that have compared industry-funded biomedical research with independent research revealed that the industry-sponsored research was more likely to favor industry in every one of the 11 studies. Pooling the results yielded the conclusion that industry-funded research was almost four times more likely to yield results favorable to industry (Bekelman et al., 2003; see also Als-Nielsen et al., 2003; Barnes and Bero, 1998; Davidson, 1986; Stelfox et al., 1998).

These studies should be interpreted with care because the correlations that they reveal between funding sources and research results may reflect a range of different causal factors. For example, some industry-funded studies might be particularly likely to yield favorable conclusions for the sponsors not because of bias in the interpretation of results, but rather because private sponsors purposely chose projects that were likely to produce supportive findings. Nevertheless, despite the difficulty of disentangling all the reasons for correlations between research results and funding sources, these findings do raise concerns that financial interests could be compromising the judgment of scientists. These worries are

aggravated by the fact that many universities are currently seeking to bolster their research portfolios and boost local economies by developing more extensive partnerships with private industry (Krimsky, 2003). For example, two-thirds of academic institutions now hold equity interests in start-up companies that sponsor research at those institutions (Bekelman et al., 2003). As a result, universities and government agencies have been working in recent years to develop conflict-of-interest policies that can safeguard the integrity of scientific research without unduly limiting industrial partnerships (Task Force on Research Accountability, 2001; Task Force on Financial Conflicts of Interest in Clinical Research, 2001).

This article argues, however, that the three major elements of typical COI policies (i.e., disclosure, management and elimination of conflicts via divestiture or recusal) are likely to be insufficient for screening out many worrisome influences of financial COIs. After a brief overview of the major issues, the next section provides preliminary reasons to think that neither disclosure nor the attempt to eliminate conflicts is likely to meet the twin goals of being both effective and workable in practice. The biggest problem with eliminating the conflicts is that there are likely to be many significant cases in which such a policy is not accepted because of enthusiasm for the benefits that appear to flow from university-industry connections. A major difficulty with disclosure is that psychological research challenges its effectiveness at preventing worrisome influences and enabling those who receive tainted information to discount questionable conclusions. The third section then considers the myriad judgments that scientists make in the course of performing research.[1] It suggests that management approaches are unlikely to be sufficient for blocking the variety of avenues through which COIs can engender worrisome influences on these judgments.

Following this rather pessimistic appraisal of COI policies, the fourth section considers four major options that remain for policy makers and administrators who seek to respond to COIs. It is not clear that any combination of these options is entirely satisfactory, but the hope is that a thoughtful appraisal of the difficulties facing traditional COI policies will facilitate more thoughtful and effective use of alternative options. It is important to clarify that this article should not be interpreted as an attack on all partnerships between university researchers and industry. After all, the fourth section argues that there may be a variety of cases in which the effects of COIs are either insignificant or worth tolerating for the sake of the benefits that they may provide. It is also possible that there are just a few scientific fields (e.g., pharmaceutical and public health research) that are particularly overwhelmed by worrisome influences. This article does not attempt to resolve the range of situations in which the effects of financial COIs can and cannot be tolerated. Rather, its crucial claim is that, in those cases where the effects of COIs are in fact worrisome, the major components of current policies are unlikely to be sufficient for eliminating the resulting problems; additional strategies should be seriously considered.

Policy Options for Addressing Conflicts of Interest

One common definition of a conflict of interest is “a set of conditions in which professional judgment concerning a primary interest (such as patients’ welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)” (Thompson, 1993; see also Davis, 1982 and Resnik, 2006). There are several strengths of this definition. First, it refers to a set of conditions rather than a particular behavior, and thus it emphasizes the fact that there can be justifiable worries about the potential results of conflicted situations, even if they do not always result in problematic actions. Similarly, it refers to conditions that tend to influence the judgment of scientists, again because a COI could be a legitimate source of concern, even if it does not produce problematic effects in every single instance. Finally, it refers to undue influences caused by particular situations. It is, admittedly, difficult to decide what constitutes an undue influence, but conflicting

interests are so widespread that there must plausibly be some threshold below which they are not taken to be a matter of serious concern. It is also important to note that, although the definition acknowledges that there can be different types of secondary influences, this article focuses on secondary interests of a financial sort. There has always been a complex mixture of interests that affect scientific practice in both appropriate and inappropriate ways. A major subject of contemporary debate, however, is whether there are appropriate mechanisms in place to prevent interests of a financial sort, in particular, from having inappropriate influences on scientific judgment.

Some of the major sources of financial COIs for contemporary academic and government researchers include consulting fees with private companies, grants or contracts to fund university research projects, honorariums, gifts, equity holdings, management positions with start-up companies, and revenue streams from intellectual property. There are also growing concerns that universities themselves may face institutional COIs as a result of intellectual property holdings and investments in companies that fund research at their institutions (Resnik, 2006; Task Force on Research Accountability, 2001). Commentators have worried about numerous ways that these COIs might harm scientific research. Most obviously, they threaten the objectivity of scientific publications and the peer review process. Effects of this sort range from outright falsification or fabrication to more subtle influences on experimental design, interpretation of research results, and evaluation of studies (Brown, 2002). Other influences could include: more research directed toward projects that are likely to reap financial benefits for sponsors; decreased sharing of data and research materials among scientists; less concern for human and animal research subjects; and less “public interest” science directed toward public health and environmental issues (Brown, 2002; Krimsky, 2003; Resnik, 2006).

University policies for addressing financial COIs currently focus on three major options: disclosure, management and removal of the conflict (through divestiture or recusal) (Task Force on Research Accountability, 2001; Shamoo and Resnik, 2002). The first option is to require researchers to disclose their conflicts to one or more of the following groups: university COI committees, institutional review boards (IRBs), government funding agencies, attendees at oral presentations, and the readers of publications (Task Force on Research Accountability, 2001, pp. 4–5). The second option is to develop management plans for addressing COIs that merit further action than just disclosure. A potential source of confusion is that the term “management” is sometimes applied to an entire COI policy (which could include requirements for disclosure or removal of the conflict under some conditions), but it is sometimes also applied to a more narrow range of responses to COIs. Throughout this article, “management” will be used in the narrower sense that refers to various strategies for monitoring research to ensure that it is not subject to problematic influences. For example, in a case where a biomedical researcher has a financial interest in the drug that she is studying, one might require that she not be directly involved in recruiting participants for a clinical trial (in order to prevent the possibility that she would exert inordinate pressure in favor of participation). One might also require that an external panel, such as a data safety monitoring board (DSMB), review the research protocol and the final statistical analysis to ensure that there are no obvious flaws. Finally, in cases of particularly serious financial COIs, a third option is to require that researchers eliminate the conflict, either by recusing themselves from particular research projects or by divesting themselves of the financial ties that create the conflict.

Unfortunately, there appear to be good reasons for thinking that the first and third options (i.e., disclosure and divestiture/recusal) will be problematic in many cases. Regarding divestiture and recusal, the primary worry is that it will often be too difficult to implement. There is currently great enthusiasm for university-industry partnerships, and a variety of federal policies have been created over the past 30 years to encourage these relationships

(Johnson, 2004). Furthermore, the motivation behind these arrangements does not just reflect self-interest on the part of universities. Besides the obvious goals of bringing in research funds and making money through the creation of intellectual property, the hope is that these collaborations can provide valuable research expertise for industry and produce start-up companies that will boost local and national economies. As a result, however, the variety of cases in which universities and researchers are willing to eliminate financial COIs entirely is likely to be fairly limited. For example, when the National Institutes of Health instituted a strict policy in 2005 that prohibited almost all forms of financial COIs, it was extremely controversial, and it resulted in the resignation of several influential researchers (Derenzo, 2005). Few universities are likely to risk such losses. This is reflected by the fact that the influential AAU report on COIs places the majority of its focus on developing disclosure guidelines and suggests a general prohibition on COIs only in cases involving human subjects research (Task Force on Research Accountability, 2001, p. 4). Although this lack of enthusiasm for eliminating conflicts might seem to be merely a descriptive point rather than a normative one, any reasonable evaluation of COI policies needs to take account of the manner in which they tend to be applied in practice. If universities are likely to be overly cautious in calling for divestiture or recusal in response to conflicts, then this element of COI policies is insufficient unless it can be supplemented with further approaches.

Ethicist David Resnik (2006) suggests a much more aggressive policy for eliminating COIs. He claims that one should consider three factors when deciding whether or not to prohibit a financial COI: the significance of the conflict (e.g., the amount of money at stake), the ability to manage it, and the consequences of prohibiting it. On the basis of these considerations, he proposes a variety of situations in which financial COIs should generally be eliminated, including: peer review (both for grants and journal articles), research regulation or oversight (e.g., membership on IRBs or IACUCs), management or ownership of a private company while performing research for the company, and receipt of payment to enroll patients in clinical trials. In contrast, he argues that it is generally acceptable for university scientists to perform research for companies under other arrangements (e.g., as employees or paid consultants) and to perform research on products while holding intellectual property rights on them. Resnik's proposal seems more likely to block worrisome influences than that of the Association of American Universities (AAU), but it still faces two problems. On one hand, it may be too ambitious. As already noted, most universities seem far too enthusiastic about developing start-up companies to consider preventing researchers from holding management or ownership relationships to companies for which they do research. On the other hand, Resnik's proposal still allows COIs that appear to be worrisome. In particular, the biomedical studies presented in the introduction to this article suggest that financial COIs may affect research significantly even when the conflicts involve only the provision of funding for studies. Thus, it currently appears rather unlikely that prohibition by itself can prevent most worrisome effects of financial COIs. Resnik is aware of this problem, and he appeals to disclosure as an important additional strategy for addressing financial conflicts.

Disclosure is a particularly popular approach that has become the cornerstone of most COI policies adopted by universities and academic journals. For example, five of the 10 operating guidelines in the AAU report involve responsibilities to disclose financial COIs (Task Force on Research Accountability, 2001, pp. 4–6). The National Institutes of Health (NIH) and National Science Foundation (NSF) now require universities that receive their funding to develop COI policies that require various forms of disclosure. A growing number of professional societies and associations are also starting to recommend disclosure of COIs (Resnik, 2006). Despite the increasing prevalence of disclosure, however, it is not clear that it is actually a sufficient strategy. Some commentators worry that disclosure policies are inconsistent across universities, that too few journals require disclosure, and that

investigators do not comply with the policies (GAO, 2003; Krimsky, 2003). For example, Sheldon Krimsky and L. S. Rothenberg found in 1997 that, of the 61,134 articles published that year in journals that had COI disclosure policies, only .5% of the articles included the disclosure that an author had a financial COI (Krimsky and Rothenberg, 2001). But this low disclosure rate flies in the face of common sense as well as an earlier study in 1992 by Krimsky and his colleagues, in which they found that 34% of the articles published in 14 prominent scientific journals had a lead author with a financial COI (although none of these COIs were disclosed in the articles) (Krimsky et al., 1996). They concluded that the low disclosure rate of COIs was not caused by the failure of journal editors to publish the information supplied to them, because 74% of editors surveyed reported that they "always" or "almost always" published disclosures when they received them. It seems quite plausible, then, that many scientists are not complying with disclosure policies.

A much more significant and yet less frequently discussed reason for thinking that disclosure policies are insufficient to address financial COIs is that they may do little or no good even when there is adequate standardization of policies and compliance with them! The assumption behind the recent emphasis on disclosing financial COIs is that this approach mitigates many of the worrisome effects of COIs while causing minimal disruption to the activities of researchers. Ideally, the disclosure requirement allows those who receive information to be on the lookout for worrisome influences, and it provides motivation for scientific researchers to provide untainted information. Unfortunately, a fascinating body of psychological research challenges these hopes for the effectiveness of disclosure policies.

Daylian Cain and his coworkers (2005) have highlighted a variety of psychological considerations that support skepticism about the notion that those who receive disclosures about COIs can then successfully discount biased information that they receive. A crucial problem is that successful "judgmental correction" requires having a sense of the direction and the magnitude of a biasing influence. Unfortunately, it is very difficult to estimate the extent to which a particular conflict may have influenced an information source. In fact, the disclosure that an information source has a conflict of interest may even have the paradoxical impact of increasing trust in the source, thereby decreasing one's likelihood to expect biasing influences (Cain et al., 2005, p. 117). In general, people underestimate situational influences on the behavior of others, and they overestimate the influence supplied by an individual's character, values, and dispositions (Ross and Nisbett, 1991). The result is a poor ability to predict the extent to which conflicts of interest affect the judgment of those who provide information. Moreover, those who receive tainted information must overcome anchoring biases, which cause both lay people and experts to remain influenced by initial information, even when they subsequently try to correct their judgments. It is noteworthy that anchors are influential even when one knows that information is being manipulated by someone with conflicts of interest (Galinsky and Mussweiler, 2001). A further problem related to the anchoring bias is that people have difficulty unlearning false information. They continue to be influenced by information even after it has been shown to be false, and a "sleeper effect" can cause people to start believing information again after it has been discredited (Pratkanis et al., 1988).

Despite this disconcerting psychological research, one might still hope that COI disclosures can do some good, even though they may not be as effective as they initially appear. The problem with this assumption is that COI disclosures may also cause the sources of information to be more biased than they would otherwise be. First, advisors may engage in "strategic exaggeration," purposely skewing their advice to a greater extent than they otherwise would in order to counteract the extent to which their information is discounted. Second, as a result of "moral licensing," advisors may feel more comfortable providing biased information once they have the moral "cover" of having admitted their COI. And, even if those providing information consciously try to be as objective as possible, research

indicates that people consistently overemphasize both their objectivity and the extent to which they deserve any benefits that they receive from conflicted situations (Chugh et al., 2005). Whether as a result of these or other factors, Cain and his coworkers have in fact found in various experiments that information sources provide more biased information when they have disclosed a COI (2005, p. 116). Thus, they conclude that disclosures may actually do more harm than good, given that people have such a hard time accurately discounting information that they know to be tainted by COIs. Admittedly, one might still question whether these results hold outside the laboratory, both because real-life situations involve higher stakes and because there is more potential for people to learn how to discount biases. Nevertheless, Cain et al. (2005) contend that neither of these factors seems likely to be very helpful in light of current psychological research.

Although much more work remains to be done in order to understand the conditions under which COI disclosures are likely to be helpful or not, the current evidence indicates that it would be unwise to count on disclosure as the fundamental strategy for responding to COIs. If university administrators want to employ more promising approaches, they need to consider the other main elements of COI policies. We have already seen that the elimination of conflicts via divestiture or recusal is likely to be accepted only in cases of particularly severe conflicts. And the psychological literature indicates that divestiture is still not likely to be a completely effective solution, because the biasing influences of COIs remain, even after the conflicts themselves have been eliminated (Miller, 2005). Of the three major options proposed in current COI policies, the only remaining strategy is to develop plans for managing the conflicts. The next section considers the challenges that management plans are likely to face in addressing the variety of judgments that researchers make in the course of performing research.

Management Plans and Judgments in Science

Compared to disclosure, management plans for addressing financial COIs have received relatively little attention in current COI policies. For example, the Association of American Universities report on COIs provides two sorts of advice: a set of operating guidelines and a set of promising practices. The operating guidelines are supplied as normative suggestions for all universities to adopt, whereas the promising practices provide helpful ideas that university administrators may wish to consider. The operating guidelines say almost nothing about management practices in the narrow sense discussed in this article. The only exception is in guideline #2, which suggests that one might respond to some COIs by altering the original experimental protocol.

In the list of promising practices, management approaches receive a bit more attention, but it is still minimal. For example, when universities consider how extensive a management plan needs to be in response to particular COIs, the AAU suggests several factors to consider, such as the “phase of clinical trial, whether stock is privately held or publicly traded, size of company, kind of intervention (diagnostic vs. therapeutic), if faculty have any influence in the company, and whether a financial relationship is fixed (e.g. fixed payment) or variable (e.g. equity, stock options)” (Task Force on Research Accountability 2001, p. 8). The report also suggests that monitoring processes for COIs focus on “critical control points,” such as “disclosure, grant application, IRB review, any necessary reporting to agencies (such as NIH, NSF, Food and Drug Administration [FDA]), publication, and technology transfer activities” (p. 8). Finally, the report suggests three specific elements of the research process from which conflicted researchers could be excluded as part of a management plan. These elements are the enrollment of human participants, obtaining informed consent from participants, and analyzing data (p. 8).

Although current descriptions of how to manage financial COIs are quite sketchy, the previous section argued that they may hold the greatest balance of practicality and effectiveness in blocking worrisome influences of financial COIs. Therefore, even though it is not clear that many universities are actively moving beyond disclosure requirements and developing management plans at present, it seems valuable to consider whether these plans could, at least in principle, be effective. Current suggestions for management approaches focus on two main strategies. The first is to keep investigators from engaging in particular aspects of a research project, such as the enrollment of human research participants or the analysis of data. The second approach is to have a committee review various elements of the project to ensure that they are not compromised. The remainder of this section argues that when one considers the wide range of ways in which judgments impinge on the research process, it is unlikely that these management plans can prevent all the worrisome influences that administrators would like to prevent. This analysis also supports the previous section's criticism of the effectiveness of disclosure, because it seems very unlikely that those who receive information can successfully evaluate such an extensive range of ways in which a scientist's judgment could be influenced by a COI. Judgments are not the only elements of science that can be influenced by COIs, of course. For example, falsification and fabrication of results could involve outright manipulation of fairly straightforward or routine procedures. Nevertheless, judgments provide particularly important avenues for COI influences because they require subtle weightings of multiple considerations. These weightings can be relatively easily (and unconsciously!) manipulated, and it is difficult to identify precisely where COIs may have influenced them.

This section's argument against the effectiveness of COI management plans rests on a dilemma. Efforts to manage COIs (e.g., via supervision by internal or external committees) are likely to be either limited in effectiveness or extremely bureaucratic and time-consuming because there are so many ways in which judgments that might be influenced by COIs permeate scientific research. On one hand, the plans could focus on blocking a few particularly serious avenues through which an investigator's financial COIs could influence his or her research. This is by far the more likely approach for universities to take, but we will see that it is likely to miss a variety of ways that COIs can affect research. On the other hand, the plans could provide much more detailed scrutiny of research projects, aiming to provide maximal protection against the influences of COIs. Unfortunately, it seems likely to be a bureaucratic nightmare to provide adequate scrutiny of this sort. One might try to avoid this dilemma by arguing that there are relatively few studies or scientists that are genuinely likely to exhibit worrisome influences (as opposed to insignificant influences) from COIs. If this argument were convincing, universities could provide very careful management of a few studies or scientists, thereby blocking almost all problematic influences of COIs and avoiding bureaucratic gridlock. The discussion in the remainder of this article suggests, however, that there appears to be sufficiently widespread potential for serious influences of COIs (in at least some scientific fields) that it is unrealistic to think that universities could carefully manage all studies or scientists where the influences might be present.

To make this argument, let us consider four major ways that judgments impinge on scientific research and examine the potential for management policies to prevent COIs from having worrisome impacts on these decisions.[2] The first category involves judgments associated with the development of research projects, including the choice of research topics, proposal of hypotheses, and design of studies. Many thinkers have pointed out that financial interests can have worrisome effects on these sorts of judgments. For example, a common concern is that pharmaceutical research money is disproportionately skewed toward insignificant but lucrative problems of the West (e.g., baldness, impotence and obesity) compared to more serious problems that face developing countries (e.g., malaria or AIDS). It is also well known that agricultural programs in universities tend to be dominated by chemical-based research that is conducive to profits for large agribusiness firms but that

may not be as beneficial from the perspective of the environment and public health. With respect to experimental design, Kristin Shrader-Frechette has provided a fascinating discussion of the ways that financial concerns have affected many industry-funded studies of public-health threats. She claims that this research often involves problematic models, small sample sizes, short time frames, lack of uncertainty analysis, and theoretical estimates rather than actually measured parameters (Shrader-Frechette, 2007b; see also EPA, 2000 and vom Saal and Hughes, 2005). All these strategies are designed to minimize false positive results while increasing false negatives. For example, in an analysis of ethical and scientific issues associated with industry studies of pesticides on human subjects, the EPA Science Advisory Board found that the industry studies invariably involved sample sizes that were dramatically too small, allowing for huge rates of false negatives (Oleskey et al., 2004).

Management plans seem unlikely to eliminate in a systematic fashion ways in which financial COIs can influence the judgment of university scientists. Admittedly, it is plausible that management committees could sometimes examine the design of studies to make sure that they are not obviously biased toward producing results that sponsors desire. It would require a tremendous amount of bureaucratic activity, however, if management committees aimed to inspect in detail the study designs of all university research projects (even just those in particular fields, like public health and biomedical research) sponsored by organizations with vested interests in the results. Nevertheless, this sort of scrutiny would seem to be necessary in order to prevent worrisome influences of financial COIs because current reviews in fields like medicine and public health suggest that a large proportion of studies funded by industry sponsors may be designed in a questionable fashion (see e.g., Barnes and Bero, 1998; Bekelman et al., 2003; EPA, 2000). Moreover, management committees would almost certainly be in no position to encourage scientists to pursue research projects or hypotheses that could be in the public interest but that are difficult to fund. Thus, as Sheldon Krimsky emphasized in his book *Science in the Private Interest* (2003), current COI management plans are not equipped to ensure that university scientists continue to fill all aspects of their role as sources of “public interest science.”

A second category of ways in which judgments impinge on scientific research involves the choice of language. Perhaps the most well-known example of how financial considerations can affect scientific terminology and concepts is the manner in which pharmaceutical companies have tried to influence concepts of disease. For example, many commentators have worried that Eli Lilly inappropriately popularized the questionable concept of premenstrual dysphoric disorder (PMDD) largely so that the company could create a new market for fluoxetine hydrochloride (i.e., Prozac) and extend patent protection on it (Brown, 2002, pp. 303–304). Although other financial influences on scientific concepts have received less attention, Schiappa (2003) has provided fascinating examples of how political interest groups can strategically employ different scientific definitions for environmental phenomena like wetlands. I have also argued that terminology and concepts in toxicology sometimes have significant valences that could potentially influence public policy debates (Elliott, 2006a, 2006c). These linguistic choices are likely to fly under the radar of COI management committees unless they are composed of individuals with significant expertise in the field under investigation and great sensitivity to the role of judgments in scientific research and public policy. But creating management committees of this sort to address all financially conflicted research is again likely to be too onerous for most universities to undertake. And, even if a management committee were concerned about particularly biasing choices of language and insisted that they be left out of publications, scientists with financial COIs could still perpetuate worrisome linguistic choices in other contexts.

A third category of judgments involves the numerous methodological decisions involved in interpreting and evaluating study results. For example, Douglas (2000) has highlighted

several difficult judgments associated with toxicology experiments, including determining whether tissue specimens reveal the presence of (benign or malignant) tumors and deciding how to extrapolate from high-dose effects to low-dose effects. These sorts of judgments become even more central in the formulation of review articles, which require weighing evidence from multiple studies. Because of this consideration, the New England Journal of Medicine adopted a particularly strict COI policy in the 1990s for editorials and reviews. The policy required "that authors of such articles will not have any financial interest in a company (or its competitor) that makes a product discussed in the article" (Drazen and Curfman, 2002, pp. 1901–1902). The NEJM policy provides a particularly nice example of contemporary problems associated with financial COIs; the editors had to weaken their strict policy because they could hardly find any well-credentialed authors who were not conflicted. The revised policy prohibits only significant financial interests, thus allowing, for example, honorariums or consulting fees of less than $10,000 per year (Drazen and Curfman, 2002). Another significant way that judgments play a role in the evaluation of studies is in the choice of more or less aggressive efforts to criticize other studies. Kristin Shrader-Frechette recounts cases in which flawed studies of health threats in local communities received little attention because the university faculty who might have evaluated those studies had financial relationships with polluters. In contrast, industry-funded organizations like the American Petroleum Institute (API) are known for allocating large funds to help scientists challenge research that conflicts with industry interests (Shrader-Frechette, 2007b).

Management committees may be able to prevent egregious influences of financial COIs on these sorts of judgments in some cases, but they are unlikely to prevent these influences across the board. In the case of the original investigator performing a study, a management committee could perhaps ensure that the researcher does not make completely unreasonable methodological judgments in the evaluation of study data. Nevertheless, the management committee cannot easily prevent other investigators from making questionable judgments in their evaluation of the data produced by the original researcher. For example, a recent article by Lennart Hardell et al. (2007) provides several brief case studies of highly influential epidemiologists who had undisclosed financial ties to industry groups during recent decades. The conflicted researchers not only produced original research that downplayed a variety of cancer risks, but they criticized and minimized the claims of other scientists who were reporting risks. Thus, the ability of the scientific community to provide appropriate evaluation of research may be weakened by the prevalence of financial COIs.

A fourth way in which judgments permeate science is through the application of research results to decision making in individual or social contexts. This category of judgments can feed back into the other categories in complicated ways. For example, Carl Cranor and Heather Douglas have emphasized that if decision makers decide to take a "public-health friendly" approach to chemical regulation (according to which false negatives should be prevented as much as possible), this approach could have a variety of implications for the design and interpretation of studies. Scientists could alter their statistical analysis of the data, they could characterize ambiguous data differently, and they could employ different methodological judgments to support conclusions on the basis of empirical results (Cranor, 1993; Douglas, 2000). Judgments associated with the application of research could also affect the manner in which scientists disseminate information to the public (Elliott, 2006b). For example, industry-affiliated climate scientists are notorious for overemphasizing uncertainty associated with global warming and failing to give an adequate representation of the views of the scientific community as a whole (Beder, 2000). An even more basic way that judgments affect the dissemination of results is that studies may be disproportionately more likely to be published if they serve the interests of their sponsors rather than if they conflict with those interests. Some of the early scandals associated with financial COIs

involved attempts by industry groups to block university researchers from disseminating research results that reflected poorly on their products.[3]

Many of the same concerns associated with addressing the first three categories of judgments also apply to this fourth category. On one hand, management committees may be able to address some of these influences. For example, most universities now require that their researchers be allowed to publish the results of their work within a reasonable time period, whether or not it is in the interests of industry sponsors. On the other hand, it does not seem feasible to block all worrisome influences associated with this fourth category of judgments. For one thing, there continue to be reports alleging that industry groups are intimidating university scientists who try to disseminate information that conflicts with their interests.[4] Furthermore, scientists with financial COIs may be much less likely than they otherwise would be to employ "public-health friendly" methodological judgments and statistical analyses of their data that decrease the likelihood of false negatives. They might also be more likely to present research results in a questionable manner if it furthers the interests of industry. Although it is plausible that COI management committees can help to prevent obvious problems with experimental design or the dissemination of information, it would be a bureaucratic nightmare for them to inspect in detail the way all conflicted scientists design their studies and disseminate their research results. Moreover, most scientists would probably regard such inspections as an unacceptable exercise in the micro-management of research.

It appears, then, that management plans, like the other two standard elements of COI policies, are unlikely to prevent all worrisome influences of financial COIs that administrators and policy makers might be concerned to address. There are so many ways in which judgments affect the practice of scientific research that any practical management scheme is unlikely to keep up with them. To sum up the lessons of this section, it is instructive to compare the traditional worries that management schemes are designed to address with the range of judgments that this article has discussed. So far, proposals for management plans (such as those discussed in the AAU report) seem to emphasize the prevention of harm to human subjects and perhaps also some protection against obviously flawed experimental design and interpretation. To this minimal list of concerns, this section adds worries about the choice of topics that are pursued, the particular questions that are asked, the design of the studies (including subtle choices based on downstream concerns about applying the research to public policy), the definitions and concepts employed, the effectiveness and balance of criticism within the scientific community, and the manner in which scientific information is disseminated to policy makers and the public. One could surely identify other judgments that are susceptible to influences from financial COIs, but the discussion here illustrates how difficult it would be for management committees to keep track of the variety of potential influences or to exclude researchers from all the decisions that could be influenced. This discussion also supports the contention that COI disclosures are unlikely to equip decision makers to discount questionable information. There are so many avenues through which financial COIs can influence the research process that those who receive information are likely to face serious challenges in estimating the sorts and magnitudes of questionable effects that they need to discount. Thus, this article has argued that none of the three main tools in current COI policies (i.e., disclosure, management, and elimination via divestiture or recusal) meets the twin goals of being both practical and effective at blocking worrisome influences on scientific research.

Responses

Despite the weaknesses of the COI policies currently proposed by most universities, there may be other strategies that can go some way toward alleviating questionable influences of financial COIs. The goal here is not to provide a "Pollyanna-ish" conclusion that all the

worries expressed in the previous sections can be easily overcome but rather to suggest that, if policy makers and administrators take the worries expressed earlier in this paper seriously, there may still be some options that they can consider. The four major responses considered in this section are as follows: (1) dismissing the significance of at least some ways in which financial COIs influence research; (2) relying on and perhaps strengthening existing mechanisms that promote criticism and deliberation within the scientific community; (3) developing new strategies in addition to the components of current COI policies in an effort to alleviate questionable influences; and (4) preventing or eliminating COIs in more cases than universities might otherwise consider. As the following analysis indicates, more than one of these strategies can be combined in particular cases. The first option for policy makers and administrators is to argue that some of the ways in which financial COIs can influence science are relatively insignificant or unproblematic. Thus, even if disclosure policies do not enable those receiving information to discount the influences, and even if management committees ignore the influences, administrators could argue that the effects need not be eliminated. This position could be strengthened by arguing that financial ties between university researchers and industry groups have positive effects on local and national economies. Thus, one might insist that any problematic influences are more than overridden by the good that comes from these arrangements.[5] One might also point out that researchers have always been deeply influenced by a horde of personal, social, cultural, psychological, and religious influences (see e.g., Jasanoff et al., 2001; Solomon, 2001). Evaluating the variety of ways in which these sorts of contextual influences contribute to or detract from the quality of scientific research is a very complicated matter (Longino, 1990; Solomon, 2001). Nevertheless, one might hope that diversity within the scientific community goes some way toward ensuring that problematic contextual influences do not go unnoticed (Bauer, 1994).

In some cases, this first option might be fairly appealing. For example, one might hope that influences on the choice of scientific definitions, terms, or descriptions are (in at least some cases) unlikely to be very problematic. Perhaps these linguistic choices are generally not significant enough to change public policy decisions, and other researchers can identify questionable terminology relatively easily. One might also think that it is worth tolerating the existence of less “public interest” science (see Krimsky, 2003) for the sake of the economic benefits to be gained from university-industry partnerships. In fact, many thinkers would claim that economic development is a crucial element of the “public interest” and that some university-industry partnerships are directed at technologies that can serve the environment and public health. Nevertheless, this option seems unlikely to be satisfactory across the board. For example, to the extent that some study designs are subtly manipulated as a result of financial COIs, to the extent that some areas of public health and environmental research receive less attention, and to the extent that the scientific community is deprived (in at least some areas) of enough scientists who can write reviews and editorials without the influence of financial interests, it appears that this option is not entirely adequate. As David Resnik (2006) has pointed out, financial COIs add an additional element of complexity that is distinct from many of the influences that have traditionally been part of science. Thus, policy makers will surely want to consider other options available for addressing financial COIs in at least some areas of scientific research.

A second approach is to depend on and to strengthen existing mechanisms that promote effective deliberation within the scientific community. Philosophers, such as Helen Longino and Miriam Solomon have recently argued that objectivity is most appropriately regarded as a feature of the scientific community rather than as a characteristic of individuals (because individuals are susceptible to such a wide variety of idiosyncratic influences) (Longino, 1990; Solomon, 2001). One might follow up this point by arguing that criticism within the scientific community is the most appropriate strategy for highlighting and challenging unjustified influences of financial COIs. Along these lines, one might note that the

percentage of university research funded by industry sources is still relatively small (10% or less at most universities) compared to the money supplied by federal agencies such as the NSF and the NIH (NSF/SRS, 2007).[6] One might also emphasize that a number of non-governmental organizations (NGOs), some of which employ scientists, have arisen to challenge questionable research conclusions made by industry. All of these considerations might suggest the conclusion that the problematic influences of financial COIs can be overcome even if formal COI policies by themselves are insufficient in many cases.

Unfortunately, there are a variety of reasons for thinking that this strategy will not fix all problems and will require ongoing scrutiny from concerned administrators and policy makers. First, it depends on the assumption that scientists do, in fact, scrutinize each other's work adequately and identify questionable judgments or errors made by their peers. Nevertheless, empirical evidence provides worrying indications that the reproducibility of peer reviews is poor and that the review process may not consistently weed out errors or fraud (see e.g., Rothwell and Martyn, 2000; Wager and Jefferson, 2001). Researchers studying the peer review process also argue that current evidence is inadequate to evaluate its effectiveness or to predict the characteristics of good reviewers (Callahan and Tercier, 2007; Jefferson et al., 2002). Moreover, it is worrisome that universities and the federal government are among the few sources of scientific research that are not already directed by industry. For example, the American Association for the Advancement of Science (AAAS) estimates that, for every $6 that private interests spend on scientific research, the federal government funds only about $1 of nonmilitary research (Koizumi, 2005; Shrader-Frechette, 2007b). Furthermore, some of the most influential universities receive particularly high proportions of their research funding from industry; the proportion of industry funding is 31%, 21% and 20% at Duke, Georgia Tech, and MIT, respectively (Press and Washburn, 2000; Shrader-Frechette, 2007b). Thus, any loss in the small remaining "island" of relatively independent scientific research could be significant.

Thinkers like Longino and Solomon also emphasize that the scientific community must be ordered in an appropriate way in order to ensure that adequate criticism takes place. It appears that some areas of research activity have become so laden with financial COIs, however, that adequate criticism cannot be expected. For example, many commentators have pointed out that the pharmaceutical industry has created an amazing network of institutional relations to further its interests (see e.g., Elliott, 2004; Kassirer, 2005). At least some biomedical articles and reviews are even "ghostwritten" by prominent university researchers who are paid to put their names on studies that are performed and written up by "medical education companies" in the pay of the pharmaceutical industry. Although it is difficult to uncover evidence about such practices, one study found that more than 50% of the articles published on the antidepressant Zoloft between 1998 and 2000 were ghostwritten. Moreover, the ghostwritten articles were published in far more prestigious journals than "normal" articles, were cited significantly more than the others, and gave a more rosy evaluation of Zoloft than the others (Healy and Cattell, 2003; for more on ghost authorship, see Elliott, 2004 and Kassirer, 2005).

Even the regulation of pharmaceuticals is influenced by industry. For example, many members of FDA expert-advisory committees typically have financial COIs (Shrader-Frechette, 2007b). In a particularly infamous case, an FDA committee failed to take the highly controversial pain medications Vioxx and Bextra off the market in February 2005. Reporters for the New York Times subsequently found that 10 of the 32 committee members had consulted in recent years for the drugs' makers. Moreover, "If the 10 advisers had not cast their votes, the committee would have voted 12 to 8 that Bextra should be withdrawn and 14 to 8 that Vioxx should not return to the market. The 10 advisers with company ties voted 9 to 1 to keep Bextra on the market and 9 to 1 for Vioxx's return" (Harris and Berenson, 2005). Thus, rather than passively relying on criticism within the

scientific community to solve all problems associated with financial COIs, administrators and policy makers arguably need to play close attention to whether science is appropriately ordered in particular areas and consider whether steps can be taken to improve the situation.

A third option for addressing COIs is to develop a variety of new strategies, either in place of or in addition to current COI policies, in an effort to alleviate worrisome influences. Recent calls for the systematic development and use of federal drug trial registries provide one example of the sorts of approaches that might fall under this option (see e.g., Angell, 2004; DeAngelis et al., 2004). By requiring those who engage in drug studies to report their trials in the registry, results that do not serve the interests of the trial sponsors cannot be as easily "buried" as they might otherwise be. Justin Biddle has recently proposed a more aggressive strategy, called Adversarial Proceedings for the Evaluation of Pharmaceuticals (APEP), for promoting adequate scrutiny of pharmaceutical research (Biddle, 2006). By developing something like the "Science Court" that Arthur Kantrowitz (1967, 1976) famously proposed in the 1960s, Biddle suggests that one could institutionalize a system in which a group of relatively impartial scientists hears conflicting perspectives on the safety and effectiveness of particular pharmaceuticals and then renders judgments on the debated issues.

Policy analysts have worried, however, that adversarial systems like Kantrowitz's Science Court proposal may be problematic in some contexts. One concern is that, at least as it was originally envisioned, the Science Court would maintain a sharp distinction between factual and value-laden issues, and it would exclude the "lay public" from participating in the deliberation of factual issues (Shrader-Frechette, 1985). Another worry is that adversarial deliberative formats may, under some circumstances, promote political gridlock, distrust, and manipulative communication (see e.g., Busenberg, 1999; Futrell, 2003). In response, numerous authors have proposed consensual formats, such as consensus conferences, community-based research efforts, and science shops, which provide opportunities for members of the public to influence deliberation about science and technology (see e.g., Douglas, 2007; Kleinman, 2000; Sclove and Scammell, 1999). To take one prominent example, the seminal National Research Council (NRC) report *Understanding Risk* (NRC, 1996) suggested that the process of risk characterization is so value-laden that it should incorporate "analytic-deliberative" processes that integrate technical scientific analysis with input from "interested and affected" parties. Deliberative formats of this sort might equip the public to influence judgments in high-profile areas of research that might otherwise be skewed by COIs.

A further approach for alleviating the effects of financial COIs in particularly sensitive areas of research (such as the assessment of pharmaceuticals or toxic chemicals) would be to require independent studies by researchers without significant financial ties to interested parties. Sheldon Krimsky (2003, p. 229) moves at least partway toward this strategy with his suggestion that any company wishing to submit data to the FDA for the approval of a drug could be required to work with a national institute for drug testing (NIDT). The NIDT would negotiate with the company to create protocols that would have to conform with uniform quality-control requirements, and it could contract out the projects to independent university researchers or centers. Similarly, the American Public Health Association (APHA, 2003) supports expanded assessment and testing of pharmaceuticals by independent parties, and Kristin Shrader-Frechette (2007a) calls for more independent testing in the field of nanotoxicology.

An advantage of this third set of strategies is that one can tailor one's choice of approach to particular areas of research. For example, one might think that in many areas of research the scientific community is already sufficiently well ordered to weed out problematic influences of COIs. In a few areas of research, however, there might be so much influence

by vested interests (as well as so much relevance to public welfare) that it would be worth pursuing multiple approaches to bring the influences of COIs under control. For example, it is no accident that a number of new strategies, including drug-trial registries, adversarial proceedings, and new federal institutes, are directed toward COIs in pharmaceutical research. Thus, the effectiveness of this third set of strategies is likely to depend on the extent to which the strategies as applied to particular areas of research are adequate to address the important ways in which COIs influence those areas. For instance, developing a drug-trial registry is a good way to alleviate a specific range of problems associated with the selective publication of study results, but it will not automatically block questionable influences on the design of studies or the interpretation of results. That is why additional measures (such as a requirement of independent testing) may also need to be undertaken.

Finally, a fourth option for administrators and policy makers is to prevent or prohibit COIs in more cases than universities would otherwise consider. The first section of this paper suggested that the approach of divestiture or recusal is likely to be quite unpopular with universities because they are engaged in so many efforts to foster relationships with private industry. Nevertheless, attention to the limitations of disclosure and management might encourage university administrators to consider preventing or removing COIs in more situations. Administrators might also think twice about establishing particularly aggressive institutional links with industry, such as agreements between private companies and entire departments (e.g., the 1998 deal between Novartis and UC Berkeley's Department of Plant and Microbial Biology) (Press and Washburn, 2000). One goal of this article has been to encourage this sort of careful thinking about whether the benefits of particular COIs really outweigh their drawbacks.

Conclusion

This article has attempted to tread a middle ground between unjustified optimism about current COI policies and unproductive despair about the difficulty of blocking worrisome influences of COIs on scientific practice. It argued that all three major components of current COI policies will likely be insufficient to address many worrisome influences of financial COIs. Divestiture and recusal are likely to be unworkable in many cases, and psychological research raises significant questions about the adequacy of disclosure. Moreover, the complex array of judgments associated with scientific research challenges the effectiveness of management plans. Some elements of current COI policies may still turn out to be necessary components of a more adequate response. The present article has focused only on the argument that the elements of current policies are not sufficient for protecting the integrity of research. Thus, whether in conjunction with current policies or in place of them, additional strategies are worth pursuing. In order to give adequate attention to these alternative approaches, however, one first needs to appreciate the weaknesses of COI policies as they stand. The present article has hopefully contributed to that appreciation.

Notes

1. This article uses the term "judgments" to refer to decisions that cannot be reduced easily to a set of rules (Davis, 1982), in part because they require weighing multiple (and sometimes conflicting) considerations. Although most philosophers of science would refer to these decisions as "value judgments" (see, e.g., Kuhn, 1977), I have chosen to omit the word "value" because it might give some readers the false impression that the considerations that enter into these decisions are limited to ethical or political considerations.

2. Others have made similar distinctions among different categories of scientific judgments, but they are not precisely the same categories found here (see e.g., Douglas, 2000; Longino, 1990; Machamer and Wolters, 2004). One should also keep in mind that this four-fold division is primarily valuable for organizational purposes; it need not reflect sharp distinctions in actual practice.
3. A well-known example is the Nancy Olivieri case; see Brown (2002).
4. Consider two recent examples concerning the regulation of pharmaceuticals. GlaxoSmithKline allegedly exerted pressure on Dr. John Buse, a diabetes expert at the University of North Carolina, to keep him from raising questions about the safety of Avandia (Saul, 2007). Similarly, Merck appears to have applied pressure on several researchers, including Dr. Joan-Ramon Laporte of the Catalan Institute of Pharmacology in Spain, to try to silence criticism of Vioxx (Matthews and Martinez, 2004).
5. Although it seems to be generally assumed that ties between university researchers and industry groups are economically beneficial, it would be helpful to collect further empirical information about the effects of these connections. It is possible that the majority of universities and local communities do not benefit significantly.
6. This statistic does not guarantee that there will be a large number of scientists who are free of financial COIs, however. Industry sources could provide a relatively small amount of research funding, but that money might be spread out among a large proportion of the researchers in some fields.

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