J Acad Ethics (2008) 6:229–243
DOI 10.1007/s10805-008-9069-5

Taking Conflicts of Interest Seriously without Overdoing It: Promises and Perils of Academic-Industry Partnerships

Jason Borenstein · Yvette E. Pearson

Published online: 14 January 2009

Abstract Academic-industry collaborations and the conflicts of interest (COI) arising out of them are not new. However, as industry funding for research in the life and health sciences has increased and scandals involving financial COI are brought to the public's attention, demands for disclosure have grown. In a March 2008 American Council on Science and Health report by Ronald Bailey, he argues that the focus on COI—especially financial COI—is obsessive and likely to be more detrimental to scientific progress and public health than COI themselves. In response, we argue that downplaying the potential negative impact of COI arising out of academic-industry relationships is no less harmful than overreacting to it.

Keywords Conflicts of interest · Disclosure · Research integrity · Academic-industry collaboration

Academic-industry partnerships have led to countless advances, but concern persists that such relationships may give rise to conflicts of interest (COI) and COI-related problems that have the potential to compromise the integrity of scientific research. In a March 2008 American Council on Science and Health (ACSH) report, Bailey offers an analysis of recent developments in the COI debate and argues that attempts to address COI have been excessive and a hindrance to scientific progress. He draws attention to the notion that we ought to focus not only on *financial* COI (FCOI) but also nonfinancial COI (e.g., those arising from political agendas, religious beliefs, or other ideological commitments). But his analysis falls short in part because of his unwillingness to acknowledge the implications of his analysis for academic-industry partnerships. That is, he clearly perceives the potential for non-industry interests to generate COI-related problems, but fails in many cases to see that industry influence can be equally influential in this regard.

J. Borenstein
School of Public Policy, Georgia Tech, 685 Cherry Street, Atlanta, GA 30332-0345, USA

Y. E. Pearson (✉)
Department of Philosophy, BAL 9011, Old Dominion University, Norfolk, VA 23529, USA
e-mail: ypearson@odu.edu

Providing Background

Much of the debate about COI is related to the exponential growth in private funding for biomedical research and the increased frequency with which academic institutions and private industry are collaborating. While some hail these developments as unmitigated progress, others, perhaps soured by high-profile cases of misconduct, criticize partnerships with industry as the bane of genuine scholarship. Bailey's report focuses on individuals in the latter group whom he believes are trying overzealously to eradicate COI.

Although Bailey (2008) hints that concerns about FCOI related to academic-industry partnerships "rarely came up until the 1990s" (p. 14), trepidation about these collaborations is not new. For instance, Fred (2008) asserts that COI-related misconduct has been "a recurring problem for the American scientific community since the early 1960s" (p. 10). Along similar lines, Chin-Dusting et al. (2005) remind us of "a long tradition of distrust about the motivations for collaborating on the part of academia and industry" and go on to claim that "industrial pharmacologists were barred from membership of the American Society for Pharmacology in experimental therapeutics until the early 1940s" (p. 895). The expansion of academic-industry partnerships has led to increased concern about the influence of such relationships, but the problems are not entirely new.

Scholars have spent much time delineating the perils associated with COI, but there is no clear consensus on a definition of the concept. In the ACSH report, Bailey (2008) presents three main definitions of COI. The most basic definition is a conflict between one's self-interest and his professional duties (p. 15), but Bailey (2008) notes that the concept can be defined more broadly to include cases such that the person "might be influenced, consciously or unconsciously," or those in which execution of fiduciary obligations "tends to be unduly influenced" by competing interests (p. 16). Financial interests usually top the list of self-interested considerations that affect a person's judgment in a way that is at least potentially at odds with the interests of those to whom they are professionally obligated. However, Bailey (2008) observes that FCOI are not the only relevant or potentially harmful type of COI. Jansen and Sulmasy (2003) also share the insight that political, religious, and other affiliations or commitments can at times be more influential than a financial stake in the research. Even though ideological commitments may also bias one's choice of problems to research or one's interpretation of experimental data, the potential influence of FCOI should not be ignored.

COI raise the probability that one's professional judgment might be unduly affected, but a person can act ethically, legally, and professionally in the face of COI. Despite the pervasiveness of COI and the strong propensity to view them as prima facie evidence of unethical behavior (Bailey 2008, p. 13), Bailey (2008) concludes correctly that COI are not identical with misconduct (p. 17). Moreover, COI are not always avoidable, especially in very specialized and technical fields. For example, few individuals have the relevant expertise to review competently an esoteric article on nanotechnology, but the publication of the article might impact them financially. A laudable goal is to reduce temptation and minimize the chances that existing COI will lead to unethical behavior.

Inquiry about the existence and potential impact of COI is necessary in part due to the lack of transparency regarding the terms of some academic-industry partnerships. Typically, outsiders do not know the specific details of a research contract, including whether the industry partner has the right to access research data or to provide advice prior to publication. The recent controversy about whether Virginia Commonwealth University secretly receives funding from tobacco companies is one manifestation of this concern (Finder 2008). An added complexity is that seemingly independent foundations are

sometimes set up by industry without revealing their funding source (Harris 2008). Hence, extensive industry backing of certain types of research can be concealed from public view.

That said, industry investment has contributed significantly to advances in science, and it would probably be impossible to match the current rate of progress without substantial continued investment. Citing a 1990 study by Maxwell and Eckhardt, Chin-Dusting et al claim that industry contribution was 53%, while the non-industry contribution was 47%, making the industry and non-industry contributions *nearly* equal at one point in time (Chin-Dusting et al. 2005, p. 892 (Fig. 1), 894). They conclude that most "high-impact, innovative drugs come about because of significant, synergistic efforts from both sectors" (2005, p. 894). In short, it would be unwise to ban academic-industrial partnerships, but it is necessary to work toward ensuring that they are structured appropriately.

One should avoid making broad generalizations about academic-industry partnerships, as they fail to capture the nuances and complexities of these collaborations, which are neither always beneficial nor always harmful. Among other things, there is variation in both the genesis and management of academic-industry partnerships. For example, Henry et al. (2005) point out that the researcher rather than an industry representative may initiate the relationship, which may be managed by a contract research organization (CRO) instead of the company sponsoring the research. Additionally, the phenomenon of "spin-out" companies emerged in the early 1980s as a "completely different species of academic-industrial alliance" (Chin-Dusting et al. 2005, p. 893). Further, while some contracts stipulate that the industry partner has the right to review data before publication, others do not. Hence, making categorical assumptions about academic-industry partnerships will prove unhelpful in determining whether COI-related problems exist or are likely to emerge in a particular context. Instead a closer look at the details of specific academic-industry relationships is necessary to facilitate making such determinations. However, this requires a certain level of transparency from the parties to the relationship. We will discuss the potential merits and pitfalls of transparency in due course.

Characterization of the Opposition

An overarching thread throughout Bailey's report is that COI activists are trying to halt academic-industry partnerships. Some of the alleged "activists" he names include Senator Chuck Grassley,[1] Sidney Wolfe, Sheldon Krimsky (Bailey 2008, p. 28), and Marcia Angell (Bailey 2008, p. 43), the Center for Science in the Public Interest, and the Union of Concerned Scientists (Bailey 2008, p. 8–9). Yet many accusations against these so-called activists, such as Bailey's (2008) allegation that "most conflicts of interest activists clearly have prior strong ideological commitments against markets and corporations" (p. 5), are not attributed to anyone in particular. Bailey (2008) appears ambivalent about one of his main targets, Public Citizen, a group he repeatedly criticizes but also cites favorably when it supports his preferred viewpoint (p. 29–30, 45).

Too frequently, Bailey resorts to ad hominem attacks on his opponents, as in his criticism of the *International Journal of Occupational Environmental Health*'s special issue

[1] In fact, Senator Grassley recently criticized the NIH for how it has managed COI and is seeking to strengthen make the disclosure requirements of federally-funded researchers stricter (NIH Fails, 2008).

on "Corporate Corruption of Science". Without either explaining or refuting the claims made in the articles, Bailey (2008) simply presents authors' and editors' affiliations with the implication that they should not be trusted (p. 9), which seems inconsistent with his assertion that the "existence of COI does not imply wrongdoing" (p.17). Furthermore, his demonization of practices aimed at identifying and minimizing the negative impact of COI as "anti-industry ideology" is unhelpful in the effort to promote constructive dialogue about a problem he purports to take seriously (Bailey 2008, p. 8). Not only does Bailey's characterization of "COI activists" as "anti-industry" suggest a failure to acknowledge that COI and COI-related problems may not promote the interests of industry or those with whom they develop partnerships, but his ideological commitments also make him vulnerable to similar attacks from the opposition. The goal, however, should be to focus on the merits of the arguments instead of perpetuating the cycle of personal attacks that routinely dominates public debates.

Bailey (2008) argues that the COI activists are powerful and do not really want the "problems they promote" to be solved (p. 30). He believes that COI activists are selling fear just as tobacco companies sell doubt (Bailey 2008, p. 30). However, while tobacco companies stood to profit immeasurably by "selling doubt" as part of their strategy, selling fear is unlikely to help COI activists. Granted one could publish articles on the issue, but questioning the integrity of one's colleagues is more likely to breed hostility and animosity than accolades, promotions, or job offers. Further, if these activists did not really want the problems related to COI to be solved, a more effective strategy would be to refrain from talking about COI. More publicity could probably be generated by allowing cases of COI to continue than by preventing COI-related violations from occurring in the first place. Bailey's view strains credulity, as it implies that these activists are not only working irrationally against their own interests, but also that they and industry leaders are really not at odds—both benefit from the status quo wherein certain types of COI help boost industry profits and keep the activists entertained. Even if COI-related problems were largely eliminated, there would still be some cases of COI and plenty of work for so-called COI activists. However, attempting to reduce instances of COI-related problems would probably translate to fewer negative consequences for those who tend not to benefit from the promotion of the interests of parties to problematic partnerships.

Alleged Side Effects of COI Activism

Bailey warns that overzealously targeting COI could lead to numerous problems.[2] For example, he claims that journal editors have been "intimidated" into adopting overly restrictive COI policies (Bailey 2008, p. 6) and that this could prevent valuable data from getting into the research literature. However, given that some journals have altered their COI policies in response to cases of COI-related misconduct, a more plausible explanation is that the journal editors adopted such policies to prevent similar misconduct from

[2] A lingering fear is that overly restrictive COI regulations may push researchers abroad (Bailey, p. 7). Critics assert that it could be similar what has occurred due to funding restrictions on embryonic stem cell research. Yet we should not violate ethical norms even if there is a risk that researchers will leave. For instance, researchers such as Panos Zavos favor human reproductive cloning. But if it ethical analysis shows that that it is inappropriate, then the researchers may be forced to leave U.S. laboratories. Analogously, if researchers refuse, for example, to disclose their COI or divest themselves of their financial interests, they may have to travel elsewhere. Research integrity should not be compromised.

tarnishing the journals' reputations. Changes to COI policies are likely made by journal editors to better ensure that the research they decide to publish will be consistent with the journal's mission. Arguably some responses were excessive, but even Bailey (2008) acknowledges that "draconian" polices tend to be scaled back and refined over time (p. 22). The NEJM, for example, has revised its COI policy, which at one time may have been too rigid (Gottlieb 2002). Thus indicating that the drawbacks of overly restrictive polices can be remedied.

Academic Freedom

Bailey claims that COI campaigns may obstruct researchers' academic freedom. He embraces Stossel's assertion that "university and governmental rules that prevent wide-ranging interactions between academic researchers and industry limit creative and economic opportunities and are a far greater violation of academic freedom than any documented interference by industry" (Bailey 2008, p. 15; Stossel 2005). However, as he seeks to address the perils of "COI activism", Bailey understates how industry partnerships can interfere with academic freedom. For example, when Gurkirpal Singh tried to investigate the potential side-effects of Vioxx, threats were purportedly lodged against him. While testifying in front of the Senate Finance Committee, Singh stated that "I persisted in my enquiries—and I was warned that if I continued in this fashion, there would be serious consequences for me. I was told that Dr. Louis Sherwood, a Merck senior vice-president, and a former Chief of Medicine at a medical school, had extensive contacts within the academia and could make life 'very difficult' for me at Stanford and outside. But as a research scientist, I felt that it was unethical for me not to discuss my concerns in public" (Singh 2004). There remains much uncertainty about how frequently similar troubling scenarios arise. Yet the absence of information regarding the frequency with which industry interests inappropriately exert pressure on researchers does not support Bailey's position that the impact of attention to COI is more far-reaching than that of industry.

Bailey (2008) states that "it is easy for COI activists to stampede timid university administrators and non-scientist academicians into adopting highly restrictive conflict of interest regulations" (p. 15). But he fails to acknowledge that if academic administrators are so "timid" in the face of COI activists, then there is little reason to doubt that they could just as easily be trampled by industry's financial enticements or by the fear of losing industry support. In fact, this likely contributes to the current research climate where universities accept very restrictive research contracts. Along similar lines, Bailey refers to the recommendations in a 2006 Institute of Medicine (IOM) report entitled *The Future of Drug Safety* and maintains that even "the IOM committee succumbed to the COI campaign" (Bailey 2008, p. 30). Again, he ignores the possibility of multi-billion dollar companies exerting a similar kind of influence. If anything, there is more transparency with a publicly funded group than with industry in terms of their internal workings. Thus if we accept Bailey's conclusions about the influence of COI activists, it follows that we must also acknowledge the equal or greater likely impact of industry.

Slowing Down Innovation

According to Bailey (2008), "there is some evidence that the push to tighten COI rules may well already be slowing down the process of getting vital new drugs and other treatments to

patients" (p. 6). Contrary to Bailey's view (p. 28), however, the mere fact that the FDA has approved fewer new medications in recent years is not clearly connected to the COI issue at all. In fact, the article that Bailey cites on this point mentions other possible reasons for this decrease, including companies focusing on finding new uses for already developed medications, fewer applications for FDA approval of new drugs, and improved drug-safety screening (Kaiser Family Foundation 2008). Bailey (2008) admits that the approval rate is also affected by reviewers waiting to "submit drugs to advisory panels for evaluation until they are reasonably sure that they are safe and effective" (p. 29). Hence, it appears that even Bailey is not fully convinced that "COI activism" or anything related to COI is to blame for the decrease in FDA approvals of new drugs. In the remainder of this section, we discuss other plausible explanations for the slowing of innovation.

Purportedly, a byproduct of the COI movement may be the exclusion of leading experts in the field from FDA review panels. Bailey (2008) highlights findings from Public Citizen indicating that voting results on drugs evaluated by the FDA would not have changed if panel members with COI were removed (p. 29). Yet if this is true, then why is it so detrimental to the process to remove these panel members? He decries that valuable expertise could be lost (p. 31), but if the results are ultimately the same, then the expertise of "conflicted" panel members may not be as crucial as he thinks.

A plausible explanation for the decrease in the number of new medications approved by the FDA is the development of so-called "me-too" drugs. Bailey (2008) admits that 65% of the drugs approved from 1989 until 2000 "contained active ingredients that were already available in previously approved drugs" (p. 27). But he provides a charitable interpretation of the practice and believes it is largely defensible (Bailey 2008, p. 43). Bailey correctly states that "me-too" drugs can sometimes be beneficial; similar drugs can have different outcomes for different people. Yet it is crucial to note that 76% of those drugs offered "no significant clinical improvement over currently marketed products" (NIHCM 2002, p. 8, figure 5).

On a related note, Frangioni (2008) criticizes the overemphasis on "incremental improvements instead of quantum improvements"(p. 506), in part because these incremental advances are costly and take away precious time and resources that the FDA might otherwise put toward a drug or device that would mark a more significant advance over those currently available to patients. Additionally, the machinations of drug companies, including the use of legal roadblocks, can keep generics off the market for quite some time (Angell 2005, pp. 173–192). Reformulating or repackaging similar drugs can "help" to keep prices high and to eliminate competition. In fact, the Federal Trade Commission (FTC) has concluded that some of the practices used by companies to keep generics off the market may violate anti-trust laws (Bartz 2008). Hence, our trust that the free market will provide the best healthcare appears misplaced since companies employ anti-competitive practices that prevent fair competition.

Highlighting a worrisome tension that warrants continued examination, Lieberwitz (2005) argues that "communal values are undermined by increased secrecy resulting from private economic concerns about preserving proprietary rights in research results" (p. 767). For example, restrictive contracts can make it difficult for researchers to gain access to data from industry-funded research (Meier 2004). In short, the drive to secure patent rights encourages the growth of a culture of secrecy. Moreover, once a patent has been granted, the prohibitive financial costs of obtaining a license can effectively prevent other researchers from working in a subject area. In fact, the cost of purchasing a license to work with embryonic stem cells may be a decisive factor in slowing down progress (Somers 2006). The potential impact that these practices have on the morale and productivity of the academic community should not be ignored.

Frangioni (2008) maintains that "[Intellectual Property] protection costs are high" (p. 504), not only in terms of dollars spent on licensing fees but also because it restricts the dissemination of data and materials among researchers as well. It may also lead to costly patent infringement lawsuits and "encourages [academic medical centers] to focus resources on inventions that could…potentially reap higher royalties instead of those inventions that might benefit only a small number of patients but do so effectively" (p. 504). According to Frangioni (2008), the focus on protection of intellectual property rather than dissemination of information and the focus on potential commercial value instead of scientific value slow or impede translation of new discoveries or inventions from "bench to bedside" (p. 505). Although he admits that some delay in translation from bench to bedside is due to "technical" problems, a lot is due to "IP and licensing issues, profit calculations and regulatory burdens" (p. 505). These latter factors contributed significantly to the fact that it took PET more than 50 years to move from invention to clinical application and 20 years for the translation of CT and MRI (Frangioni 2008).

Taylor (2007) reports an increased unwillingness among academic clinical and nonclinical researchers to share data or materials, noting a correlation between this "sharing failure" and the focus on protecting intellectual property. Lexchin (2005) points out that "faculty members with industry support were almost twice as likely as those without (11.1% vs. 5.8%) to refuse to share research results or biomaterials…" (p. 194). He also notes that this "impedes scientific progress in a number of ways: forcing the unnecessary repetition of research, depleting scarce resources, and causing the discontinuation of projects because of the unavailability of information" (Lexchin 2005, p. 194).

The Integrity of Science

Bailey provides the overarching conclusion, which overlaps with aforementioned issues, that there is "no evidence that integrity of science is being threatened by commercial influences" (Bailey, p. 8). Exhibiting his divergent views on the ability of industry versus non-industry interests to influence research, Bailey expounds on the case of George Ricaurte as a demonstration of the influence of *government* funding on research. George Ricaurte, a researcher who investigated the health effects of ecstasy (Bailey, p. 37–38), conducted a variety of studies, which mainly involved administering the drug to baboons and monkeys. He received significant federal funding after his early findings indicated that ecstasy might cause brain damage. Unfortunately, many shortcomings plagued his work, including that he may have injected the wrong drug into at least some of his animal subjects (LeVay 2008, p. 88–98). Bailey speculates that "Ricaurte was funded because his research dependably found what federal officials wanted it to find" (Bailey, p. 38). Bailey concedes that the government's priorities can influence funding decisions, but he stops short of acknowledging that industry priorities can also strongly influence funding decisions.

If Bailey is correct that researchers try to "please their sponsors" (p. 26) and their sponsor is industry, researchers might try to produce results that support industry interests so that they will continue to receive funding. For example, if a researcher receives funding from a company with a large financial stake in medical devices and the researcher consistently reports that the company's devices are flawed, it would be unsurprising if the company discontinued sponsorship of his research or altered the research program to coincide with the company's business interests. In some cases a company's ability to profit

or remain solvent rests on the outcome of a particular study. Thus, a company might steer a researcher toward a "preferred" outcome. The company might also be tempted to suppress a researcher's results if they could compromise its business-related goals.

The Gelsinger Case

Diverging from the tone of most of his arguments, Bailey concedes that the Jesse Gelsinger case illustrates the perils of COI (Bailey, p. 54). Bailey surmises that this kind of case is a rare exception rather than the rule (p. 54). Yet his confidence is not reassuring (Titus et al. 2008). Even if we accept Bailey's debatable "few bad apples" claim, situations that call into question the integrity of researchers have a lasting and damaging impact on public trust. The reluctance to enroll in clinical trials still lingers, for example, from the USPHS-Tuskegee syphilis study several decades ago.

The Gelsinger case reveals why COI are still potentially dangerous in situations where researchers genuinely want to help the public. Problematically, Jesse was enrolled in a gene therapy study even though he did not fulfill the inclusion criteria. Further, some of the key risks of participation were not disclosed to him and his family, nor was the fact that the lead investigator, Dr. James Wilson, had a significant financial stake in the study. Commenting on the situation, Paul Gelsinger, Jesse's father, states that, "The over-enthusiasm of the clinical investigators led them to paint a misleading picture of safety and efficacy. That enthusiasm blinded them to the ill effects that they were witnessing…Following Jesse's death, Penn continued misinforming us as to what they knew, telling us only what would keep us on their side" (Gelsinger 2006, p. 28).

Granted the researchers did not intend to harm Jesse, but that is precisely the point. The subtle psychological effects that COI can have on researchers are often overlooked. Most COI-related harms probably do not result from a deliberate attempt to commit misconduct. Instead, harm is more likely a byproduct of ignorance and self-deception, which can be exacerbated by COI. A researcher's or clinician's judgment can be influenced (consciously or unconsciously) by self-interested considerations (Tonelli 2007). For instance, the authors of a 2007 AAMC report argue that "physicians who will personally benefit from recommending a particular drug, treatment, procedure, or clinical trial will have no problem figuring out ways to justify that decision as being in their patients' interest" (AAMC, 2007, p. 21). Unconscious bias is probably a more serious problem than deliberate misconduct when evaluating the risks associated with COI (AAMC, p. 25–28). Hence, even if a sponsor does not control the study design, interpretation or presentation of data, or the timing of publication, concerns about the sponsor's influence on researchers do not vanish.

"Commercial Influences" and the Research Literature

Bailey points out that research funded by the tobacco industry was riddled with moral shortcomings and admits that the problem does not end there (Bailey, p. 23). He states that "Unfortunately, some unscrupulous corporations have short-sightedly used this Tobacco Institute model of 'selling doubt' to defend their products" (Bailey, p. 23). His claim that "some unscrupulous corporations" followed patterns set by tobacco companies (Bailey, p. 23) hastily brushes aside the possibility that companies act unethically when supporting research projects. He also fails to provide any reassurance that this "model" is not more pervasive. In fact, Bailey's assertion provides justification for more skepticism about industry practices, but he does not explore this issue adequately. Granted, not all companies

duplicate the tobacco industry's efforts to distort science, but given the power companies can wield over policy and people's lives, once is more than enough.[3]

One need not revisit the tobacco industry saga to show why Bailey's arguments stretch the bounds of believability. Instead, consider the disputes circulating around Beryllium, a metal that has many industrial applications. David Michaels contends that by the 1940's, the research literature had already shown that beryllium caused disease (Michaels 2008, p. 124–125). One reason to be skeptical about the industry's response to the literature is revealed within an internal memo from Brush Wellman, a company that supplies beryllium products. According the memo, "the literature on beryllium published in the last 20 years has been very damaging…What is needed to combat this situation is a complete, accurate and well written textbook on beryllium health and safety…To be fully accepted and credible, however, it will have to be published under the auspices of some not-for-profit organization such as a university or medical group" (Powers and Preuss 1987). Giving the memo's authors the benefit of the doubt, they might honestly believe that beryllium is safe. However, the memo implies that no matter where the evidence may lead, only information that vindicates beryllium will make its way into the proposed textbook. Having a predetermined goal "to combat this situation" before the relevant project has been undertaken, greatly increases the likelihood that errors, including self-deception, will occur.

It is important to recognize that revelations about the inner workings of privately funded research usually occur only during legal proceedings. A case in point is the controversy surrounding Vioxx. It has been reported that ghost authors drafted studies for Merck (Ross, et al. 2008). "Ghost authorship" means that the identity of the individual(s) who drafted some, if not all, of a particular manuscript was not disclosed. What follows is that the authors listed on the publications in question might not have contributed significantly to articles they purportedly wrote. The typical motivation underlying ghost authorship is to conceal the identity and extent of involvement of researchers employed by companies as ghostwriters. In this context, ghost authorship is essentially marketing masquerading as scholarly writing. It is a practice that professional societies and journals roundly criticize and one that must be rooted out and condemned. The burden of proof should be on those who claim that the practice of ghost authorship of scientific publications is justifiable.[4] Outsiders, including medical professionals and the public, are usually unaware of ghost authorship and may therefore misplace their trust in the information contained in such articles. In the clinical setting, for example, such misplaced trust could have serious negative consequences for both patients and physicians. Drawing attention to COI and encouraging some level of transparency might discourage scientific ghostwriting and its problematic sequelae.

When examining the authenticity of the research literature, the case of Remune, a drug designed to help treat HIV, is important to scrutinize as well. Immune Response

[3] It is important to keep in mind that "selling doubt" is not the only strategy used by tobacco companies and other businesses. Appeals to emotion are quite common and effective in shaping perceptions about the product a company is marketing. Even if scientific studies are not compromised by a company's behaviors and are free of COI-related problems, subsequent marketing strategies may cloud the ability of both clinical researchers and laypersons to assess information from the studies. For example, the pharmaceutical company that developed OxyContin pleaded guilty to deceptive marketing (Johnson 2007). Thus one must consider not only whether industry partners are likely to interfere with the research process but also how companies will use data obtained from industry-sponsored studies.

[4] An examination of whether ghostwriting is permissible in non-scientific contexts is beyond the scope of this paper.

Corporation (IRC) invested over $190 million to develop the drug (Niiler 2000). When Joseph Kahn, the lead researcher on a key Remune study, sought to publish findings that cast doubt on the drug's effectiveness, a legal battle ensued between Kahn and IRC. IRC tried to prevent publication and then sued Kahn after the relevant article appeared in print (Haack 2006, p. 60). Issues central to their prolonged dispute included who had the authority to decide when data were ready for publication, which data should be included, and how the data should be analyzed. According to Haack (2006), "IRC's efforts to prevent publication and to put its own spin on the results cannot have failed to make an already scientifically hard task exponentially harder in other ways" (p. 63). Data indicating that the drug did not halt HIV, including from Kahn's work, nearly caused the company to shutdown (Haack 2006, p. 61).

Niiler states that "A similar incident occurred in August 1997, when Knoll Pharmaceuticals…agreed to pay up to $135 million to settle allegations that it tried to suppress research showing its prescription thyroid drug Synthroid is no better than cheaper alternatives" (Niiler 2000, p. 1235). Included among the allegations was that the company prevented the publication of articles for 7 years that would have shown that generic drugs were just as effective as Synthroid (Wise 1997). This kind of interference can clearly contaminate the accuracy of the research literature.

In short, whether data will be presented accurately, completely, and in a timely manner may ultimately hinge on the expected impact of the data on future prospects. A compounding factor is that instances of data manipulation are unlikely to be detected for a variety of reasons. For one, the publication of raw data is rare. Correspondingly, it is difficult to determine whether data has been intentionally excluded and for what reasons. If the authors reveal their motives, readers have to trust that the explanation is honest and sincere. What is more, the replication of experiments is atypical. Frequently, it is impractical or impossible to do so, and originality is usually more highly prized.

On a related note, arguments have been swirling for some time about publication bias in the research literature. More specifically, Bailey (2008) asserts that "positive studies" are more likely to be published and cites an anonymous researcher at the National Institute of Environmental Health as stating that researchers who "find an effect" get support, while those who do not go without support (p. 26). Bailey (2008) concludes too hastily that this "would seem to imply financial conflicts of interest that have nothing to do with business ties" (p. 26). However, even if COI are not related to existing ties, the desire for a *future* relationship with industry should not be ignored as a potential source of COI (Sismondo 2008).

With regard to medical therapies, Bailey (2008) says that industry-funded research is more likely to obtain positive findings and investigate promising therapies than non-industry research (p. 20). Taken in isolation the bias toward publishing positive studies *might* not be problematic, but when one considers that this occurs in conjunction with other questionable practices, it no longer appears innocuous. Sismondo (2008) describes some of these practices such as sponsors or CROs designing studies in ways that are likely to "produce favorable results" (p. 1911). He suspects that some research designs are flawed, "involving: placebos or other poor comparators, inappropriate doses, carefully constructed experimental populations, poor surrogate endpoints, trial durations unlikely to show side-effects, and definitions likely to show activity or unlikely to show side-effects" (Sismondo 2008, p. 1911). Sismondo (2008) points out that many trials are constructed "to test an already-studied drug in a way known to be effective, on a population for which it is known to be effective" (p. 1911). According to Sismondo, this accounts for the fact that hundreds of articles on "blockbuster" drugs are available but only a few on non-blockbusters (p. 1911).

Bailey (2008) accepts the notion that "industry preferentially supports trial designs that favor positive results" (p. 19). Yet he ignores a difference between industry picking and choosing from among different types of study designs and designing the studies in a manner calculated to produce desired results.

Another layer of publication bias is the repeated representation of the *same* positive data. For example, "42 trials [of SSRIs, a category of antidepressants] produced 38 articles, but the 21 positive trials produced 19 stand-alone articles [some appearing more than once], whereas the 21 negative trials produced only 6" (Sismondo 2008, 1912). In addition to the selection bias, over-representation of the same data in multiple publications must also be taken into consideration (Sismondo 2008; Melander et al 2003). Sismondo contrasted findings from a Medline search on articles for blockbuster and non-blockbuster drugs and found 2089 articles on blockbuster drugs and only 5 articles on non-blockbuster drugs "of a similar age but with small patient populations" (2008, p. 1911). Sismondo rightly questions whether the quantity of articles is due to effective marketing or genuine independent interest in these particular types of drugs.

"Commercial influences" seem to affect the peer review system as well. For example, a "prominent diabetes expert", who had received "$75,000 in consulting and speaking fees from GlaxoSmith-Kline," faxed a confidential drug study that he was supposed to review for a journal to the company (Fred 2008, p. 13). His action had the effect of "tipping the company to the imminent publication of safety questions regarding its diabetes drug Avandia" (Fred 2008, p. 13). It is a type of practice that professional journals clearly forbid. Although it is difficult to know what the expert's motives were in this circumstance—even he seemed mystified—it definitely tarnished his reputation and the credibility of the peer review system.

Thus, contrary to Bailey's reassurances, "commercial influences" *have* tarnished the integrity of science and will likely retain the potential to do so. Of course, how frequently this occurs is unknown in part because of the secrecy surrounding industry-sponsored research. But it is essential to emphasize that if lessons are not learned from past distortions of the scientific record and the role of COI in generating dubious behavior, these practices and the corresponding harms can and will be repeated.

Reputations on the Line

Aside from the shadow cast by high-profile COI cases, academic-industry partnerships can be harmful in a more subtle and pervasive way. COI-related problems can erode public trust and damage the reputations of researchers, institutions, and companies. For instance, many people choose to participate in clinical trials because they believe that doing so will benefit society.[5] However, Lexchin (2005) and Taylor (2007) caution that academic-industry partnerships may prevent researchers from making good on this promise, which would amount to a betrayal of trust and the abuse of altruism. Moreover, Taylor (2007) warns that the failure to be up front about the "commercial intentions" or the expected extent of public benefit could invalidate the informed consent process (p. 400).

In addition, Frangioni (2008) notes that a potential harm from academic-industry partnerships is that U.S. taxpayers could fail to get a return on their investment. He points out that "taxpayers already pay for the education and training of the industry's best people

[5] In fact, the assumption that research will benefit society and not just a small number of individuals has led some scholars to argue that participation in research is morally obligatory.

and industry only needs to pay a small premium to displace these individuals from academia" (p. 505), and once taxpayer money has been used to educate and train clinical researchers, industry begins its courtship. Quoting a pharmaceutical industry representative, Frangioni vividly illustrates this point: "I can 'out-recruit' you [academic medical centers] any day of the week…If you're looking for industry to help you pay for the training of clinical scientists, you might have fewer friends than you think" (Frangioni 2008, p. 505). In the end, industry profits from the public's investment, while patients often pay high prices for new technologies that make it to the bedside and are deprived of innovative treatments that never make it to the clinic because they are deemed unlikely to maximize profits (Frangioni 2008, p. 505).

Bailey remarks correctly that Harris polls indicate that physicians and scientists are held in high regard, although these polls also reveal that confidence in scientists has been declining since 1977 (Firefighters, Doctors and Nurses Top List 2006). Further, according to a New York Times/CBS News poll, 85% of those surveyed believe that payments from pharmaceutical companies can influence physician's decisions (Harris and Roberts 2007). Another indication that COI should be taken seriously is that some, albeit probably few, physicians and researchers categorically refuse industry funding (Kolata 2008). Apparently, they fear having their reputations tarnished. Plausibly, the negative impact on an individual's (or a company's) reputation could be mitigated or avoided if COI were disclosed, as outsiders could more readily scrutinize the relevant details.

Regarding companies' reputations, a 2006 Harris poll reveals that only 7% of those surveyed believe that drug companies are "generally honest and trustworthy" (Oil, Pharmaceutical, Health Insurance, Managed Care, Utilities and Tobacco Top the List 2006). This gauge indicates that the public has "lost faith" in these companies, although they remain less skeptical of the motives and practices of individual scientists and physicians. Drug companies need to have a reputation beyond reproach, considering the far-reaching and indelible impact that their decisions can have on human life, and this is unlikely to be achieved if their behavior does not justify such a reputation. For example, the South African government's distrust of Western companies has impeded attempts to treat South Africans suffering from HIV (Shah 2006, pp. 102–108). It is an open question how the public's perception will be altered by future partnerships between physicians and scientists, whom they hold in high regard, and companies that they deem untrustworthy.

The Merits and Drawbacks of Disclosure

Uncertainty remains about the frequency with which COI—whether related to industry ties or other relationships or ideological commitments—lead to scientific misconduct or other ethically dubious practices. How pervasive they are and the precise conditions under which they lead to problems remain difficult to determine, but increased transparency appears to be a promising route to achieving further clarity about whether and when COI are relevant. Although we believe that Bailey is too dismissive of COI-related problems, we agree that better management of COI is important. Despite his proposal to broaden disclosure beyond FCOI, Bailey remains fairly ambivalent about it. Quoting Rothman, Bailey (2008) expresses concern that such transparency will lead audiences to neglect the merits of the research itself (p. 13). He suggests that disclosure requirements are an admission of the failure of the peer-review system (Bailey 2008, p. 46), but a system's imperfections do not entail that the system has collapsed or that its flaws are insurmountable. *Contra* Bailey, disclosure is better understood as a proposed corrective measure, aimed at benefiting or

protecting the public or removing roadblocks to the advancement of scientific knowledge, rather than an act of surrender. When disclosure provides the audience with the opportunity to assess critically the information presented, it is arguably a good thing. The expansion of disclosure beyond financial matters to relevant interests, affiliations, or commitments has merit. Because disclosure presupposes self-reflection and, we hope, the recognition of possible sources of bias, it can be beneficial. Yet the goals of disclosure, and the methods used for accomplishing it,[6] are not the only thing to consider; one must also consider how the disclosed information is likely to affect the intended audience.

Leaving decisions about disclosure entirely to researchers is probably going to be inadequate, but making a clear rule regarding transparency about non-financial COI is challenging. For this reason, Jansen and Sulmasy (2003), who also recognize that non-financial COI "may be as important as [FCOI]" (p. 43), hold that disclosure decisions should be made on a case by case basis by journal editors and other regulatory bodies. Noting the "halo effect," wherein "some pieces of information…have a vividness or salience that prevents or obstructs people from adequately taking into account other pieces of information, even when the other information is more relevant to the judgments they need to make," Jansen and Sulmasy (2003) warn that in some contexts disclosure "may do more harm than good" (Jansen and Sulmasy 2003, p. 43). They maintain that disclosure of certain kinds of information might "irrationally and subconsciously" influence people's judgment (p. 43).

The relative merits of transparency depend on the features of the context in which it occurs. As Jansen and Sulmasy (2003) note, "information can distort judgment as well as improve it" (p. 42). Along these lines, Cain et al (2005) reveal a few potential pitfalls of disclosure. They repeatedly highlight that, among other things, disclosure does not eliminate COI and it might be viewed as an alternative to removing sources of COI or to minimizing their impact. More troubling, however, is their conclusion that disclosure can create problems for those whom advocates of disclosure are trying to protect. For example, they argue that disclosure might lead to "strategic exaggeration," meaning that the bias of those making disclosures might be intensified, intentionally or not, thereby offsetting any benefits of disclosure (Cain et al 2005, p. 7).

Because of the more level playing field in the context of researchers making disclosures alongside articles submitted to scholarly journals, some of the pitfalls discussed by Cain et al (2005) may be less troubling than in the clinical context, where the power and knowledge differential between physicians and patients is often quite significant. Moreover, as Jansen and Sulmasy (2003) argue, there can still be limitations on the audience's ability to assess the reported information competently, thus providing a plausible justification for disclosure even among peers. Scientists are better equipped than the average layperson to evaluate scientific literature, especially in their relevant area of specialization. Nonetheless, Jansen and Sulmasy (2003) remark that the lack of time and resources that would be required to replicate a study, and the lack of access to primary data from which the published data are selected place a significant epistemic constraint even on a peer audience. Because of these limitations, Jansen and Sulmasy (2003) plausibly assert that disclosure enables peers to "assess the trustworthiness of their source" and that it "may alert them to the existence of bias in the studies' design and execution" (p. 41). In short, disclosure is certainly not a

[6] For example, whether "disclosure" should involve researchers providing information to an "oversight authority" or the "subsequent provision of that information by the oversight body to the public and specific interested parties" continues to be a subject of debate (Sharpe 2002, p. 24).

panacea. But given the limitations mentioned by Jansen, Sulmasy, and others, it may be necessary.

Conclusion

Despite Bailey's assurances, COI emerging from academic-industry partnerships are a serious matter. Ironically, his criticism of the COI "movement" reinforces its importance by suggesting that more potential sources of COI demand our attention. Not only should scientists, clinical researchers, and the rest of us be concerned about FCOI, but we should also attend to COI arising from professional or personal affiliations and ideological commitments.

To reiterate, disclosure is useful even if researchers are not intentionally distorting information. The perils associated with self-deception and the normalization of ethically dubious behavior should not be overlooked and warrant continued examination. Although psychological pitfalls abound (e.g., "strategic exaggeration" or potentially misleading the target audience), transparency is a laudable goal, in part because it emphasizes self-reflection. Ideally, heightened self-awareness will help to lessen the dissonance between one's self-perception and his/her actual behavior (Mazar and Ariely 2006, p. 8–10).[7]

References

Angell, M. (2005). *The Truth About the Drug Companies*. Random House.

Association of American Medical Colleges (AAMC) (2007). The Scientific Basis of Influence and Reciprocity: A Symposium. Washington, D.C.

Bailey, R. (2008). *Scrutinizing Industry-Funded Science: The Crusade Against Conflicts of Interest.* American Council on Science and Health.

Bartz, D. (2008). U.S. FTC reports 14 deals to delay generics in '07. *Reuters*. May 23, 2008. http://www.reuters.com/article/marketsNews/idUSN2328640520080523 (accessed June 26, 2008).

Cain, D. M., Loewenstein, G., & Moore, D. A. (2005). The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest. *The Journal of Legal Studies*, *34*, 1–25.

Chin-Dusting, J., Mizrahi, J., Jennings, G., & Fitzgerald, D. (2005). Finding Improved Medicines: The Role of Academic-Industrial Collaboration. *Nature Reviews. Drug Discovery*, *4*, 891–897. doi:10.1038/nrd1879.

Finder, A. (2008). At One University, Tobacco Money Is a Secret. *The New York Times*, May 22. Firefighters, Doctors and Nurses Top List as "Most Prestigious Occupations, According to Latest Harris Poll." *The Harris Poll #58.* July 26, 2006. http://www.harrisinteractive.com/harris_poll/index.asp?PID=685 (accessed June 16, 2008).

Frangioni, J. V. (2008). The Impact of Greed on Academic Medicine and Patient Care. *Nature Biotechnology*, *26*(5), 503–507. doi:10.1038/nbt0508-503.

Fred, H. L. (2008). Dishonesty in Medicine Revisited. *Texas Heart Institute Journal*, *35*(1), 6–15.

Gelsinger, P. L. (2006). "Uniformed Consent: The Case of Jesse Gelsinger." In *Law and Ethiccs in Biomedical Research: Regulation, Conflict of Interest and Liability*, by Trudo Lemmens and Duff Waring, 12–32. University of Toronto Press.

Gottlieb, S. (2002). New England Journal loosens its rules on conflict of interest. *British Medical Journal*, *324*(7352), 1474. doi:10.1136/bmj.324.7352.1474/a.

Haack, S. (2006). Scientific Secrecy and Spin: The Sad, Sleazy Saga of the Trials of Remune. *Law and Contemporary Problems*, *69*, 47–67.

Harris, G. (2008). Cigarette Company Paid for Lung Cancer Study. *The New York Times*.

[7] For instance, controlled studies indicate that reminders about moral codes before taking an exam may help to reduce the incidence of cheating (AAMC, p. 16).

Harris, G., & Roberts, J. (2007) “Doctors” Ties to Drug Makers Are Put on Close View." *The New York Times*.

Henry, D. A., Kerridge, I. H., Hill, S. R., McNeill, P. M., Doran, E., & David, A. (2005). Newby, Kim M. Henderson, Jane Maguire, Barrie J. Stokes, Graham J. Macdonald, and Richard O Day. Medical Specialists and Pharmaceutical Industry-sponsored research: A survey of the Australian Experience. *The Medical Journal of Australia*, *182*(11), 557–560.

Jansen, L. A., & Sulmasy, D. P. (2003). Bioethics, Conflicts of Interest, and the Limits of Transparency. *The Hastings Center Report*, *33*(4), 40–43. doi:10.2307/3528379.

Johnson, C. (2007). “OxyContin Makers Admit Deception.” *The Washington Post*.

Kaiser Family Foundation (2008). “FDA Approved only 19 New Medications in 2007, Analyst Reports.” *Kaiser Daily Health Policy Report*. http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=49767 (10 January)

Kolata, G. (2008). “Citing Ethics, Some Doctors Are Rejecting Industry Pay.” *The New York Times*.

Lexchin, J. R. (2005). Implications of Pharmaceutical Industry Funding on Clinical Research. *The Annals of Pharmacotherapy*, *39*, 194–197. doi:10.1345/aph.1E224.

Lieberwitz, R. L. (2005). Education Law: The Corporatization of Academic Research: Whose Interests Are Served? *Akron Law Review*, *38*, 759–770.

Mazar, N., & Ariely, D. (2006). Dishonesty in Everyday Life and Its Policy Implications. *Journal of Public Policy & Marketing*, *25*(1), 1–21. doi:10.1509/jppm.25.1.117.

Meier, B. (2004). “Contracts Keep Drug Research Out of Reach.” *The New York Times*.

Melander, H., Ahlqvist-Rastad, J., Meijer, G., & Beermann, B. (2003). Evidence b(i)ased medicine—selective reporting from studies sponsored by pharmaceutical industry: review of studies in new drug applications. *British Medical Journal*, *326*(7400), 1171–1173. doi:10.1136/bmj.326.7400.1171.

Michaels, D. (2008). *Doubt Is Their Product*. New York: Oxford University Press.

The National Institute for Health Care Management (NIHCM). (2002). “Changing Patterns of Pharmaceutical Innovation.”.http://www.nihcm.org/~nihcmor/pdf/innovations.pdf.

“NIH Fails To Oversee Grantees’ Conflicts of Interest, Grassley Says.” Kaisernetwork.org, July 11, 2008. http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=53250 (accessed July 28, 2008)

Niiler, E. (2000). Company, Academics Argue Over Data. *Nature Biotechnology*, *18*, 1235. doi:10.1038/82325.

“Oil, Pharmaceutical, Health Insurance, Managed Care, Utilities and Tobacco Top the List of Industries That Many People Think Need More Regulation.” (2006). *The Harris Poll #78.* October 24, 2006. http://www.harrisinteractive.com/harris_poll/index.asp?PID=705.

Powers, M. B. & Preuss, O. P. (1987). "Memo to J. E. Gulick, Subject: Proposed program of filling need for new and accurate beryllium health and safety literature." Brush Wellman Document. January 23, 1987. http://www.defendingscience.org/upload/powers_1987.pdf.

Ross, J. S., Kevin, P. H., David, S. E., & Harlan, M. K. (2008). Guest Authorship and Ghostwriting in Publications Related to Rofecoxib. *JAMA*, *299*(15), 1800–1812.

Shah, S. (2006). *The Body Hunters*. New York: The New Press.

Sharpe, V. A. (2002). Science, Bioethics, and the Public Interest: On the Need for Transparency. *Hastings Center Report*, *32*(3), 23–26.

Singh, G. (2004). "Witness Statement for Senate Finance Committee Meeting on FDA, Merck and Vioxx: Putting Patient Safety First?" November 18, 2004. http://www.senate.gov/~finance/hearings/testimony/2004test/111804GStest.pdf.

Sismondo, S. (2008). How Pharmaceutical Industry Funding Affects Trial Outcomes: Causal Structures and Responses. *Social Science and Medicine*, *66*, 1909–1914.

Somers, T. (2006). "Foundation's stem cell patents impede research, scientists say." *The San Diego Union-Tribune*.

Stossel, T. P. (2005). Regulating Academic-Industrial Research Relationships—Solving Problems or Stifling Progress? *The New England Journal of Medicine*, *353*(10), 1060–1065.

Taylor, P. L. (2007). Research Sharing, Ethics and Public Benefit. *Nature Biotechnology*, *25*(4), 398–401.

Titus, S. L., James, A. W., & Lawrence, J. R. (2008). Repairing Research Integrity. *Nature*, *453*, 980–982.

Tonelli, M. R. (2007). Conflict of Interest in Clinical Practice. *Chest*, *132*(2), 664–70.

Wise, J. (1997). Research suppressed for 7 years by drug company. *BMJ*, *314*, 1145.

Bioethics, Conflicts of Interest, & the Limits of Transparency

by Lynn A. Jansen and Daniel P. Sulmasy

The movement in bioethics toward disclosure of financial conflicts of interest is well and good, most of the time. But in some cases, disclosure is not only unnecessary but destructive. When bioethicists advance arguments whose premises and logical moves are open to scrutiny, disclosure—far from clearing the air of bias—introduces bias.

Over the past several years, there has been growing concern about the commercialization of bioethics. As ever more bioethicists become paid consultants to private industry and paid advocates in court proceedings, many have warned of the dangers such activity can pose to the bioethicist's integrity as a teacher and researcher.[1] This, in turn, has led to increasing demands for disclsure requirements.

For the most part, we share the concerns of those who worry about the commercialization of bioethics and we welcome the movement to demand disclosure of possible conflicts of interest. However, as editors of another bioethics journal, *Theoretical Medicine and Bioethics*, we are concerned that current efforts to broaden the scope of disclosure requirements may result in extending them to contexts in which they are not appropriate.[2] Doing so, we believe, would itself pose a threat to the integrity of bioethics. This threat needs to be understood if editors are to develop reasonable guidelines for disclosure—guidelines that will correctly identify when disclosure is appropriate and when it is not.

The threat we have in mind concerns the potential of policies of disclosure to undermine the value of reasoned argument. Bioethics is a reasoned enterprise, one in which scholars and students have a responsibility to think seriously and reflect carefully on the merits of competing arguments. Central to this understanding of bioethics is the presupposition that good arguments can come from any quarter and that no argument should be dismissed or discounted simply because of its source. An uncritical preoccupation with disclosure requirements stands in considerable tension with this key presupposition. It can foster an ad hominem approach to evaluating research, one that shifts attention away from the merits of the work and toward the biography of its author.[3]

For this reason, it is important to explain why and where disclosure is needed. We shall argue that it is a mistake to think that if disclosure is a good thing, then more of it is always better. Although transparency is good in some contexts, it may not be good in every context. We shall argue that disclosure requirements should not be extended to cover normative research in bioethics.

The Appeal to Authority

Disclosure requirements are needed in contexts in which an ethicist is presented as an expert or her research cannot be assessed critically by those to whom it is addressed. In these contexts, the claims of the bioethicist typically are taken as authoritative. Those who hear these claims are not in a good position to assess their cogency and so the only way to estimate the value of what is

Lynn A. Jansen and Daniel P. Sulmasy "Bioethics, Conflicts of Interest, and the Limits of Transparency," *Hastings Center Report* 33, no. 4 (2003): 40-43.

claimed is to consider the reliability of the source. Here disclosure of financial relationships that might compromise the judgment of the bioethicist is useful in assessing the reliability of what he or she claims.

To see this point more clearly, it is helpful to consider three contexts in which disclosure has been widely defended and is a good idea. The first concerns an ethicist's expert testimony in a court proceeding.[4] In court, the ethicist's claims are presented as authoritative. While it is possible that some members of a jury may be able to assess them critically, it is likely that many will not have the analytical skill or the motivation to reflect carefully on the rational value of the claims being presented. Not being bioethicists themselves, they will be inclined to accept the claims on authority. For this reason, there is a need for members of a jury to be informed of any relationships, financial or otherwise, that might substantially compromise the judgment of the bioethicist. This is why it is appropriate for lawyers during cross-examination to question "expert witnesses" about possible conflicts of interest. Information about conflicts of interest can help juries assess the witness's reliability as an expert on the issues under discussion.

A second context in which disclosure is needed is the publication of empirical biomedical studies, including descriptive studies of peoples' views on these issues.[5] Readers of these studies generally are not in a position to replicate them. They do not have the time or resources to "test" the study to see if it was conducted properly. They do not have access to the primary data and therefore must trust that data selection and statistical testing have been performed properly. Moreover, readers of these studies typically will not know whether the results of the study are representative.[6] For example, a biotechnology company might fund social scientists with the understanding that the social scientists will publish only polling data favorable to the company's financial interests. If this were the case, then the published studies might constitute only a fraction of the studies that were undertaken. For these reasons, even expert readers of empirical scientific studies are not generally in a good position to assess critically the primary data upon which the conclusions of the study are based. It is therefore important that they be able to assess the trustworthiness of their source. Disclosure requirements can help them do this by providing information that may alert them to the existence of bias in the studies' design and execution.

Disclosure requirements are needed when the only way to estimate the value of what is claimed is to consider the reliability of the source.

A third context where disclosure is needed is when bioethicists appear on television. This is particularly true when they are introduced as authorities on the subject matter being addressed. Here, too, disclosure is appropriate, especially if the interviewer is seeking provocative sound bites rather than reasoned arguments.[7]

In mentioning these three contexts, we do not mean to suggest that transparency is only appropriate in them. Rather, the point of discussing them is to illustrate the general point that disclosure requirements are appropriate when the claims of a bioethicist or a scientist doing research on biomedical issues cannot be critically evaluated by those to whom they are addressed and so must be taken as authoritative. They also shed light on the limits of transparency. Some in bioethics have called recently for extending disclosure requirements to normative editorials in medical journals and to normative research in bioethics.[8] But in these contexts, the rational value of the claims being advanced can and should be critically assessed by those to whom they are addressed. For example, if a bioethics journal publishes a paper defending the moral permissibility of human embryonic stem cell research, then the arguments presented for the conclusion should be open to view. All the "data," so to speak, are present in the arguments of the paper. Anyone who cares to can appraise them. The conclusions are neither presented as authoritative nor intended to be so taken.

The persuasive force of a paper, of course, is not determined entirely by the quality of the arguments it contains. The reputation of the author, as well as the style and rhetoric of his writing, will influence how the paper is received. But if bioethics is to be a reasoned enterprise, then journal editors should encourage their readers to focus on the arguments of papers and not on these subrational influences. We would go further. It is a responsibility of those who do normative research in bioethics to write clearly and to present their arguments in a manner that allows others to assess them. The same holds true for those who write normative editorials in medical journals. If journals such as the *New England Journal of Medicine* or the *Journal of the American Medical Association* agree to publish an editorial about an issue in bioethics, they should do because the editorial can contribute to reasoned discussion of its topic. They should not present it—nor do they—as an authoritative statement on these issues.

It is always possible that some readers may erroneously consider an editorial to be an authoritative statement; but this would tell us more about the limitations of these readers than it would about the purposes of an editorial. Most readers of medical journals fully understand what an editorial is.

More Information Is Not Always Better

We have suggested that disclosure requirements are out of place when the claims of the bioethicist are open to rational assessment by those to whom they are addressed. In these contexts, the focus should be on the plausibility of the claims and arguments rather than the trustworthiness of their source. But some may object that if disclosure requirements can reveal information that helps us judge the trustworthiness of a source, then it is always better for us to have this information than not. Should not readers of normative bioethics, for example, assess both the rational value of the claims being advanced and the trustworthiness of the source from which they come?

Not necessarily. It is a mistake to think that more information is always better. Information can distort judgment as well as improve it. This fact is readily appreciated in many domains. In court proceedings, for example, certain kinds of information about the background of defendants should be withheld from juries. This information, while accurate, can distort a jury's judgment. The same is true of a scholarly paper published in a bioethics journal. If readers are informed that the author of the paper has received financial support from an organization with an interest in the issue, then they may be led, consciously or not, to discount or pay inadequate attention to the claims and arguments that the author presents. This is how disclosure requirements in the wrong contexts can undermine the value of reasoned argument in bioethics.

Since this point is important, it is worth developing it a bit further. In recent years, social psychologists have amply demonstrated how certain kinds of information can dominate other kinds of information.[9] Some pieces of information, for example, have a vividness or salience that prevents or obstructs people from adequately taking into account other pieces of information, even when the other information is more relevant to the judgments they need to make.[10] In particular, social psychologists have demonstrated the existence of "a halo effect" by which we tend to judge people favorably (or unfavorably) if we are informed of one salient positive (or negative) fact about them.[11] Learning that a researcher is cruel to animals, for example, often leads us to discount the conclusions of his research. In the same manner, disclosures can reveal information that, irrationally and subconsciously, affects the judgment of editors, referees, and readers of journal papers. This is one reason many have thought that masked and blinded review of manuscripts is a good idea.[12] The point of masked review is to ensure that a referee will not have her judgment of the quality of the manuscript distorted by her knowledge of certain facts about the author.

Some might suggest that the same point applies to readers of journal papers. If information about the identity of the author can distort a referee's judgment of the paper, then it can also distort the reader's judgment of the paper. Thus there would be some merit in publishing papers anonymously. For practical reasons, of course, authors need to be given credit for the work they do.[13] But it is important to see that publishing the author's name is for the benefit of the author. It does not give readers information to help them assess the paper.

These remarks bring us back to the idea we stressed earlier. Good arguments can come from any quarter. With respect to normative research in bioethics, editors and referees do their job well when they focus not on facts about the author—gender, race, religious affiliation, professional accomplishments, financial relationships, and so on—but rather on the quality and importance of the arguments. We therefore think it is a serious mistake to suggest, as some have, that editors of bioethics journals should disclose information about the authors of manuscripts to prospective referees and to their readers.[14] This is transparency taken too far.

In other contexts, the claims can and should be critically assessed. If a bioethics journal publishes a paper defending the moral permissibility of human embryonic stem cell research, then the arguments should be open to view.

Disclosure of What?

We have said nothing about the difficult question of what should be disclosed when disclosure is appropriate. Proponents of disclosure requirements have not adequately explored this important topic. Much of the literature on disclosure has given pride of place to financial conflicts of interest.[15] But plainly these are only one kind of conflict of interest. Consider, for instance, the following claims made by a leading proponent of disclosure requirements: "financial or other significant relations (consulting, speaker's fees, corporate advisory committee memberships, expert testimony in legal cases) of the author and the author's immediate family in the last five years with companies, trade associations, unions, or groups (including civic associations and public interest groups) *that may gain or lose financially* from the results or conclusions in the study, review, editorial, or letter."[16] In some respects the disclosure requirements suggested by these remarks are very demanding, but in other respects they are quite lax. They put the emphasis on financial conflicts of interests and do not specify in any de-

tail the many possible non-financial sources of bias, including political, ideological, professional, or religious conflicts of interest.

This is telling. With respect to many researchers, non-financial conflicts of interest may be as important as financial conflicts of interest. But clearly it would be a mistake to require authors to attach a biography to their papers listing all possible sources of bias. How then should we determine, in a principled way, what should be subject to disclosure? Is there any principled reason for discounting non-financial sources of bias and highlighting financial ones?

We suspect that there simply is no cut-and-dried answer as to what should and should not be disclosed. Efforts to formulate precise guidelines on these matters are probably a mistake. Instead, editors will need to exercise judgment in deciding what their readers should be aware of. Likely, this will not satisfy those who are now pressing medical and bioethics journals to adopt strict codified policies on disclosure. But irrespective of how this difficult issue should be resolved, this unclarity over exactly what should be disclosed (if and when disclosure is deemed appropriate) is significant. We should have a better understanding of this matter before we call for more transparency. This gives us another reason to resist the current demands for extending disclosure requirements to all contexts in biomedical ethics.

The Limits of Transparency

Despite the need for disclosure requirements, there are limits to transparency. These limits come into view once bioethics is understood to be a reasoned enterprise. There are some who write on medical and bioethical issues and who do not believe that bioethics is accurately characterized this way. Behind conflicting ethical judgments they see nothing more than conflicting interests. Reasoned argument, for them, is a cover for power. If these views were right, there would be no argument against transparency. Transparency itself would then be the single most useful method of ethical analysis, unmasking all the conflicting interests masquerading as analysis.

But, fortunately, most of those who regard themselves as bioethicists, despite their disagreements with one another, share a commitment to the value of rational discussion. They believe that clear thinking and careful argument can bring us better answers about the difficult normative questions bioethics addresses. In the rush to embrace disclosure requirements, editors should not lose sight of this important shared commitment. While insisting on disclosure requirements where they are appropriate, they should be careful not to extend them to contexts where they may do more harm than good.

Acknowledgments

The authors would like to thank three anonymous reviewers for their helpful comments on an earlier draft of this paper.

Disclosure

Lynn A. Jansen and Daniel P. Sulmasy teach an introductory course in research ethics at Pfizer Pharmaceutical Corporation. All money received for lecturing at Pfizer goes directly into the operating budget for the John J. Conley Department of Ethics.

References

1. F. van Kolfschooten, "Can You Believe What You Read?" *Nature* 416 (2002): 360-63; V. Sharpe and E.D. Pellegrino, "Medical Ethics in the Courtroom: A Reappraisal," *Journal of Philosophy and Medicine* 2, no. 4 (1997): 373-79; V.A. Sharpe, "Science, Bioethics, and the Public Interest: On the Need for Transparency," *Hastings Center Report* 32 (2002): 23-26; S.J. Younger and R. Arnold, "Who Will Watch The Watchers?" *Hastings Center Report* 32 (2002): 21-23; G. Kaebnick, "Difficulties with Disclosure," *Hastings Center Report* 32 (2002): 3; B. Brody et al. "Bioethics Consultation in the Private Sector," *Hastings Center Report* 32 (2002): 14-20.

2. See Sharpe, "Science, Bioethics, and the Public Interest," at 25.

3. K. Rothman, "Conflicts of Interest: The New McCarthyism in Science," *JAMA* 269 (1993): 2782-84.

4. Sharpe and Pellegrino, "Medical Ethics in the Courtroom," 373-79; G. Agich and B.J. Spielman, "Ethics Expert Testimony: Against the Skeptics," *Journal of Philosophy and Medicine* 22 (1997): 381-403.

5. Rothman, "Conflicts of Interest," 2782-84.

6. van Kolfschooten, "Can You Believe What You Read?"

7. See James Rachels, "When Philosophers Shoot from the Hip" *Bioethics* 5, no. 1 (1991): 67-71.

8. See Sharpe, "Science, Bioethics, and the Public Interest."

9. S. Sutherland, *Irrationality* (London: Constable and Company Limited, 1992); L. Ross and R.E. Nisbett, *The Person and the Situation: Perspectives of Social Psychology* (New York: McGraw Hill, 1991).

10. R.E. Nisbett and T.D. Wilson, "The Halo Effect: Evidence for Unconscious Alteration of Judgments," *Journal of Personality and Social Psychology* 35 (1977): 250-56.

11. Nisbett and Wilson, "The Halo Effect"; A.L. Solomonson and C.E. Lance, "Examination of the Relationship between True Halo and Halo Error in Performance Ratings," *Journal of Applied Psychology* 82, no. 5 (1997): 665-74; H. Marsh and P. Bazeley, "Multiple Evaluations of Grant Proposals by Independent Assessors: Confirmatory Factor Analysis Evaluations of Reliability, Validity and Structure," *Multivariate Behavioral Research* 34, no. 1 (1999): 1-30.

12. F. Davidoff, "Masking, Blinding, and Peer Review: The Blind Leading the Blinded," *Annals of Internal Medicine* 128, no. 1 (1998): 66-68.

13. Rothman, "Conflicts of Interest."

14. See van Kolfschooten, "Can You Believe What You Read?"

15. Brody et al. "Bioethics Consultation in the Private Sector"; van Kolfschooten, "Can You Believe What You Read?"

16. Sharpe, "Science, Bioethics, and the Public Interest," at 25 (emphasis added).