Unreliable Threats: Conflicts of Interest Disclosure and the Safeguarding of Biomedical Knowledge

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ABSTRACT. Medical epistemology lately has seen a strengthening of the view that the construction of evidence should be sensitive to the social context in which it is produced. A poignant illustration of this is the undue influence of the pharmaceutical industry on research results and reporting. I challenge a particular application of this view by examining a common practice in the medical and scientific community: mandatory author disclosure of conflicts of interest (COIs) in published articles. In illustrating problems with COI disclosure policies in biomedical publishing, including unappreciated shortcomings of the scant empirical data supporting mandatory disclosure, I hope to demonstrate that the value given to journal COI disclosure policies as a way to protect the reliability of medical evidence might well be misplaced. Rather than extract away the “messy” details of the real world, the analysis is ultimately more responsive to how medical knowledge is produced and disseminated.

1. INTRODUCTION

Biomedical journals have been requiring authors to disclose conflicts of interest (COIs\(^1\)) since the 1980’s (Relman 1984). Partly this has been due to the systematic distortion of the evidence base and other abuses committed by the pharmaceutical industry (Angell 2005; Every-Palmer and Howick 2014). Recently, the rhetoric surrounding COI reporting has increased to a boiling point, marked by heavy debate and diametrically opposed positions over what COIs are, what effects they are likely to engender, and how they should be managed—if at all (Acquavella and Ramlow 1997; Cappola and FitzGerald 2015; Elliot 2014; Fineberg 2017; Fontanarosa and Bauchner 2017; Johnson and Horn 2010; Lee...
2008; Loewenstein, Sah, and Cain 2012; Mayes, Lipworth, and Kerridge 2015; McKinney and Pierce 2017; Mintzes and Grundy 2018; Psaty 2009; Resnik and Elliot 2013; Rosenbaum 2015a, 2015b, 2015c; Rothman 1993; Steinbrook, Kassierer, and Angell 2015; Stossel 2008; Stossel, Barton, and Stell 2015; Tarone 2018; Wiersma et al. 2018a, b). More and more journals require disclosure, and recommendations have been made that religious (Smith and Blazeby 2018), dietary (Ioannidis and Trepanowski 2018), and other non-financial disclosures be added to the list of financial disclosures (Wiersma et al. 2018a, b). Calls to strengthen COI disclosure policies even stretch to the point of recommendations to establish a public global registry of authors’ disclosures (Bero and Grundy 2009) or a public “dashboard” indicating how much fame and fortune a researcher can expect to gain from publication (Cappola and FitzGerald 2015).

Recent philosophical work (e.g. Holman 2019; Holman and Bruner 2017) on social/medical epistemology emphasizes the importance of not abstracting away worldly complications when evaluating medical evidence. The fundamental standpoint of the present article embraces this move and readily acknowledges that industry and other types of relationships are a pervasive feature of biomedical research and publishing. These intricate relationships may be relevant to many aspects of how evidence is produced and interpreted, especially given the many reports of corruption, academic misconduct, and undue influence by the pharmaceutical industry on research and marketing (Lee 2008). However, contrary to common belief, the practice of author disclosure of COIs in biomedical journals is deeply problematic. Given the ubiquity of disclosure policies and calls for stricter requirements, it is timely to more fully interrogate the legitimacy of the practice lest mandatory disclosure of COIs continue to be automatically accepted as an ethically mandated feature of biomedical publishing, or risk serving a specious role in otherwise salutary philosophical arguments on the epistemic reliability of medical knowledge.

My chief claim is that the value given to journal COI disclosure policies as a way to protect the reliability of medical evidence is likely misplaced. Once the depths of the issues are plumbed a cacophony of reasons emerges both for and against disclosure. The purpose of this article is not to repeat all these arguments or to present a balanced overview of the issues or arguments on all sides. This is a contentious subject, marked by a paucity of hard empirical data that directly address the issues at hand. This lack of data, particularly as to whether COIs actually represent an important-enough risk for bias to justify their mandatory disclosure, is one reason
to question the continued endorsement of COI disclosure policies. The absence of evidence should not be taken as evidence of absence, however. The similar paucity of data supporting abandonment of COI disclosure requirements underscores the need for more studies. Of the empirical data that do exist, I argue in §4 that alternative explanations undermine the claims such data are typically taken to support. My purpose, however, is not to sketch details of proposed studies, but instead to critically analyze the logic of COI disclosure. Accordingly, I present arguments on the shortcomings of COI disclosure policies, reinterpret conclusions from some studies on the effects of author COIs, and survey and suggest alternative methods to current journal disclosure policies.

2. PEELING BACK THE LAYERS OF A MISGUIDED POLICY

Widespread agreement exists that author disclosure of COIs in biomedical journals is necessary and serves a strong scientific and public interest (Angell 2018; Bero and Grundy 2016; Cappola and FitzGerald 2015; ICMJE 2019a; IOM 2009, 2018). Approximately 90–99% of influential biomedical journals require authors to disclose financial COIs, with 57–70% of such journals requiring non-financial COI disclosures (Bosch et al. 2013; Dal-Ré et al. 2019; Shawwa et al. 2016). COI disclosure is recommended by various professional organizations, including the International Committee of Medical Journal Editors (ICMJE) (2019a), Committee on Publication Ethics (COPE) (2016), and the World Association of Medical Editors (WAME) (2009); the ICJME COI disclosure form in electronic format was launched in 2009 (Drazen et al. 2010), and many journals follow ICMJE recommendations (ICMJE 2019b). Disclosure of COIs has been trumpeted as serving a number of important goals, including discouraging problematic relationships; enhancing transparency; preserving the public trust and that of scientific communication; protecting the integrity of professional judgment and the credibility of published articles; facilitating interpretation of the scientific and medical literature; helping to identify, preclude the appearance of, prevent, and mitigate the risk of bias; and avoiding harms from biased review articles or reporting of study results (de Melo-Martín and Intemann 2009; Dunn et al. 2016; Fineberg 2017; Fontanarosa and Bauchner 2017; Gasparyan et al. 2013; Grundy et al. 2018; ICMJE 2019a; IOM 2009, pp. 5, 28; Loewenstein, Sah, and Cain 2012; Silverman et al. 2010). These are certainly laudable goals, with disclosure of COIs seemingly a crucial, though possibly insufficient (Cappola and FitzGerald 2015) means of
dealing with this problem. Philosophers and others have been right to emphasize the “threats to reliable medical knowledge” (Holman 2019, p. 4386) from undue pharmaceutical industry influence (Rodwin 2012; Stegenga 2018).

Yet disclosure policies have compellingly been argued to fail to achieve their goals of facilitating the identification of bias and preventing actual or apparent bias (de Melo-Martín and Intemann 2009; Doucet and Sismondo 2008). For example, de Melo-Martín and Intemann (2009) cite evidence showing that disclosure policies do not dissuade researchers from having financial relationships with industry, and they argue that such policies also do not enable readers to scrutinize the decisions informing the research and article. Moreover, the value of disclosure might be small if a suspicious study is not repeated to confirm the results.

While the failure of current disclosure policies could be seen as cause for abandonment, it could also be seen as cause for strengthening or better enforcing disclosure policies. Disclosure supporters (Loewenstein, Sah, and Cain 2012, p. 670) predict: “More comprehensive and uniform disclosure should make it more likely that physicians will be discouraged from entering into problematic conflicts because of the threat of having to clearly disclose them to patients and others.” There are reasons to think COI disclosure policies do not achieve their goals, however. The increasing prevalence of author COI disclosure—by making disclosure seem more “normal” (de Melo-Martín and Intemann 2009)—could take out the sting felt by an individual author upon disclosure and attenuate any perception of bias in the eyes of a reader. Simply disclosing, regardless of the content of what is disclosed, could falsely signal to readers that the COIs do not represent any bias. Disclosure could also have unintended consequences by engendering more bias, such as when authors strategically write something to preemptively counter a reader’s potential reaction. Moral licensing (“the often unconscious feeling that biased advice is justifiable because the advisee has been warned”) might also take place (Loewenstein, Sah, and Cain 2012, p. 669). There is also the problem of unconscious bias (Ibid.). However, if sources and effects of unconscious forms of bias are likely to be even more remote, ill-defined, and productive of multiple results (some contradictory) than conscious forms of bias then it’s unclear how disclosure could serve its avowed purposes, especially given the difficulties of identifying to which authors and interests unconscious bias applies.

In biomedical publishing, and other fields, including law and business, there is no standardized definition of COIs (Davis 1993). That many
definitions of COIs exist, and thus that different authors might disclose different relationships or conflicts, is not problematic in and of itself, and may merely point to the need for better definitions and harmonization⁴. However, the prevailing definitions in biomedical publishing leave too wide a berth between what are or might be considered a COI and whether what is disclosed actually carries a salient risk of bias. There is no universal standard by which COIs can be identified—different authors may have different opinions as to what constitutes a COI—and it is an empirical matter whether certain COIs lead to fraudulent data, scientific misconduct, or biased reporting. If certain relationships are to a priori count as COIs in the sense of definitely causing bias, then a better approach to managing such COIs might seem to be to ban them, rather than just requiring their disclosure. Policies (such as federal regulations, those of research institutions, and journal guidelines) that specify certain financial thresholds only make clear when a financial interest should be reported, not whether the interest actually constitutes a COI.

While there is no consensus about a definition of COIs, the most widely used definitions approximate that of the Institute of Medicine’s (IOM; 2009, p. 6), which is “circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest.” The immediate problem with this definition is that “risk” indicates potential, not actual, problems, and is ill-defined as to its level. This is problematic as the basis for COI disclosure requirements because the risks—especially in specific cases—are too uncertain, variable among authors, and for some authors potentially at such an insignificant level that were this known no reasonable policy would be able to justify mandatory disclosure for all authors. Of course, in any given case the level of this risk is unknown, which provides just the cloak of uncertainty needed to justify sweeping disclosure policies. Yet this leaves it unclear if the COIs disclosed by authors in biomedical journal articles are disclosed because of what authors think could be a reasonable perception in readers that they pose an appreciable problem at high risk, an appreciable problem at low risk, a negligible problem at high risk, or a negligible problem at low risk of bias. There are of course multiple shades in between. With these myriad possibilities readers are faced with the confusing task of assessing which is which. Without further information this task is bound for futility, possibly leading readers to adopt a default judgment (which could differ significantly among readers) depending on certain types of COIs. The public nature of disclosure raises the question whether COI
disclosure can be adequately interpreted and understood by readers of diverse preconceptions and epistemic abilities. Some readers opposed to vaccinations, for example, could unfairly assume that authors who work on or receive money from companies that make vaccines are somehow biased. Subjective, general judgments not based on logic or even any explicable rationale (much less proof) is not a fair way for an article’s findings to be impugned. That disclosures are generally directed to the research community does not obviate the need for good policies to avoid misinterpretation by people outside of that community.

In summary, while the presence of COIs could raise the specter of impropriety, in the absence of further data it is premature to assume that any given author’s COIs represent a high enough risk of bias such that their disclosure protects against the subversion of credible scientific evidence. I discuss in the next three sections extant data on this topic and reasons for this claim.

3. A PRIORI AND EMPIRICAL APPROACHES TO DETERMINING EFFECTS OF CONFLICTS OF INTEREST

Which factors are considered relevant for COIs can be informed by a priori and empirical approaches. Most of the COIs that have been proposed as candidates for disclosure—including financial relationships—have been identified on the basis of a priori rationalization; in essence, speculations based on intuitions about human behavior/motivations that a relationship or characteristic could lead a person to bias. It may indeed seem reasonable to suppose, as attested to by psychological research on self-interest and value-transfer (Katz, Caplan, and Merz 2003; Moore and Loewenstein 2004), that an author who stands to gain financially from a drug discussed in an article might be biased in the direction of that drug. However, universally assuming such psychological tendencies as a general fact about authors elides any differences among individual authors regarding whether these psychological tendencies are operative in a given context and whether counteracting factors are not also present. There is no guarantee—and in many cases not even any direct indication—that a token researcher would exhibit such bias. The risk of false positives is potentially high, or at least highly uncertain.

The empirical approach, by contrast, would seem to eliminate the need for such armchair speculation. However, there are limitations in relying on the empirical approach to guide biomedical journals’ COI disclosure policies. To start, firm, actionable, individual-level data, and not simply
associational population-level data, are difficult to obtain because they would require an audit of an author’s chain of input into a suspect article. This should not always be seen as the bar that needs to be met, though, because so-called meta-evidence can play an important role in adjusting the credibility of first-order evidence (Fuller 2018). Indeed, taking financial relationships into account, such as via the results of meta-research (like the Lundh et al. [2017] meta-analysis I discuss in §4), has been argued as being an important way to supplement more direct ways of evaluating the credibility of scientific research (Elliott 2014; Fuller 2018; Resnik and Elliott 2013); Every-Palmer and Howick (2014) have even suggested that the funding source should be added as an independent item to the Cochrane Risk of Bias tool. Yet such approaches encounter the same problem as the psychological-disposition data mentioned with respect to the a priori approach—a high or highly uncertain rate of false positives. Nonetheless, Djulbegovic and colleagues (2007) recommend further empirical research to solve the problem of COIs. While this indeed could be useful for some purposes, whatever data are generated should be interpreted properly. This, unfortunately, does not always happen, as I discuss next.

4. ALTERNATIVE CONCLUSIONS FROM STUDIES SHOWING EFFECTS OF CONFLICTS OF INTEREST ON STUDY RESULTS OR READERS’ PERCEPTIONS

There is a dearth of empirical research on the effects of authors’ COIs on various aspects of a study or article. Of the solely correlational research that does exist, it is generally of two types: those assessing the impact of COIs on readers’ perceptions, or on various features of the article or study itself. For example, Kjaergard and Als-Nielsen (2002) reported a positive correlation between authors’ financial COIs and favorable conclusions on randomized studies of medical treatments. Friedman and Richter (2004) found similar results in their study of articles in the New England Journal of Medicine and the Journal of the American Medical Association. Similarly, Ahn and colleagues (2017) found that articles in which authors had financial ties with industry, even after controlling for industry funding of the study, were independently associated with positive study results. Combined with the positive correlation found between industry funding of studies and study outcomes favorable to the sponsor’s treatment (Lundh et al. 2017), these data seem to offer at least prima facie support that financial COIs are concerning.

Lundh et al. (2017) do recognize that such a correlation could reflect factors unrelated to bias, such as industry sponsoring treatments with
higher chances of success than non–industry-sponsored treatments. Yet an even more pressing concern for author COI disclosure policies—even if it’s assumed that industry bias is present—is that the studies included in the Lundh et al. and similar meta-analyses are widely heterogenous, involving multiple therapeutic areas. Not all studies included in the Lundh et al. meta-analysis found a positive relationship between industry sponsorship and favorable outcomes. While the positive relationship between study outcomes and financial relationships could justify authors disclosing their financial COIs directly related to the industry-sponsored study in question, this does not support disclosure requirements on unrelated studies or non–industry-funded studies. If the worry about sponsorship bias is so acute then this suggests a compromise position that dispenses with general disclosure to instead only require disclosure of those COIs related to the sponsored study in question (see §6). With respect to the fact that industry-funded studies often contain authors with financial COIs, a non–bias-related explanation for the favorable study outcomes is pharmaceutical companies who simply want to promulgate the results from their successful studies with in-demand thought leaders who may have many financial relationships because of their expertise (Cain et al. 2005a; Rosenbaum 2015c) and prolific authorship on successful studies. Given the length and complexity of bias-related causal pathways, even if the presence of a COI were associated with a biased publication, there is no way for a reader to know whether the COI was responsible for that effect, or was related to common factors that did the causal work.

That being said, there are multiple ways in which financial COIs could influence a study’s results and reporting (Smith 2005); Bero and Grundy (2016, p. 4) list “the framing of the question, how the study is actually conducted, and whether it is fully and accurately reported.” Mechanisms by which the evidence base can be systematically distorted include “design bias, multiple trials with predictable outcomes, fraud, rhetorical effects and publication bias” (Doucet and Sismondo 2008). The presence of “spin” (distorted or misleading reporting) in industry-funded study reports may be particularly concerning, especially for results that are not statistically significant (Boutron et al. 2010).

While a close reading can uncover some biases, further investigation, as well as access to data that are not always available, are typically needed to uncover the more difficult-to-spot biases or forms of misconduct. Indeed, one motivation for COI disclosure and the use of meta-research such as the Lundh et al. meta-analysis is that in individual cases bias could be hidden
or difficult to detect (Fuller 2018). As adumbrated in §3, however, meta-
research on author COIs is based on average effects that obscure important
differences among subpopulations and that engender a potentially high
risk of false positives. It is only after bias is discovered that a definitive
link to an author’s COIs can be established. Otherwise, the connection is
merely being assumed, and perhaps unjustifiably so, especially considering
the multiple authors often present on biomedical publications, any one of
whom could actually be responsible for a biased article.

Other types of studies have investigated the effects of authors’ COIs on
an article’s perceived credibility. For example, Silverman and colleagues
(2010) reported finding that physicians did not alter their perceptions of a
study on the basis of the study authors’ COIs. By contrast, a study published
in BMJ showed that the type of COI influences readers’ perception of an
article’s credibility (Schroter et al. 2004). In this randomized survey, the
same article, save for the presence of a disclosure statement indicating
author financial COIs, was sent to two groups of readers. Rather than the
differences in perceptions of the article indicating a negative effect of the
financial COIs on the credibility of the article’s findings, the study could
just as convincingly show that the presence of financial COIs illogically
influenced readers’ perceptions of the credibility of medical articles. This
is because for both groups the article’s content was exactly the same. De
Melo-Martín and Intemann (2009) interpret the results to mean that
the disclosure policy itself undermined readers’ confidence in research
integrity—the content of the disclosures did not appear to play a role in
this interpretation but simply the fact that COIs were declared. If this is
true—as it may well be—then this supports the notion that disclosure
policies do not avert the appearance of bias. Such an explanation and
result is not mutually exclusive with the idea that readers may grossly
misjudge the effects of COIs.

Kesselheim and colleagues (2012) studied physicians’ perceptions of
disclosure of industry funding and found that physicians downgraded a
study’s rigor compared with studies that didn’t disclose funding. Kesselheim
and colleagues (2012, p. 1119) stated, “Physicians discriminate among
trials of varying degrees of rigor, but industry sponsorship negatively
influences their perception of methodologic quality and reduces their
willingness to believe and act on trial findings, independently of the trial’s
quality.” Because the funding was made-up, as with the BMJ survey
(Schroter et al. 2004), what this study could also be interpreted to illustrate
is that readers illogically and unnecessarily are negatively influenced by
knowledge of financial relationships.

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Occasionally an author to a publication will add a disclaimer to their COI, such as to the effect that they hope to still remain objective and respectful of opposing positions despite being a long-time advocate of xyz. Or they will explain what might be perceived as a tie to, for example, the tobacco industry when in fact it was money paid to the author’s institution for “impartial consulting” (whatever that may mean). Is the addition of the disclaimer supposed to assuage readers’ worries about potential undue influence? Typically, authors’ disclosures do not contain disclaimers. Yet could they be said to carry an implicit disclaimer that the relationships disclosed did not have an effect on the article? Why aren’t explanations of COIs allowed or typically proffered? After all, there may be clear-cut cases where a certain relationship might appear to give the perception of carrying undue influence, yet when explained would not. An example of this is “paid consulting for a pharmaceutical company” that actually pertains to an unrelated project for which an author is paid very little and which involves the author providing expertise on how to improve safety reporting.

Under current journal practice authors are generally not given the opportunity to justify their disclosed COIs. Presumably, though, this should not be a problem given the policy of many journals to request of authors that they disclose “all relationships/activities/interests listed below that are related to the content of your manuscript” (ICMJE 2021). However, blanket disclosure militates against an author applying a hierarchy of pertinence, despite the inherent subjectivity of pertinence. The result either gives the impression to readers that the author believes all the disclosed COIs are equally pertinent, of varying importance, or that their pertinence is indeterminate. This not only prejudices authors from having their COIs being judged fairly but hampstrings the reader’s ability to assess their possible impact on the article. Yet in all cases a COI’s risk for bias is still unknown because the amount of information in COIs is too sparse to allow a full risk-of-bias determination. COI disclosure could, though, provide a springboard to a conversation with journal editors and peer reviewers to determine whether a high risk of bias is present. To mount a case against an author in which the author has any chance of successfully defending themselves, however, would require an impartial forum and just procedures for gathering, presenting, evaluating, and adjudicating upon evidence. But, as Epstein (2007) asks, “Who guards the guardians?” Even if
a fair “court of COI” could be created, to serve all the purposes for which COI disclosures are required public accountability and transparency would have to be present. It is difficult to see how this could be harmonized across multiple journals and publishers, each with their own editors, reviewers, and readerships who might have varying attitudes as to which COIs carry high risks of bias, and what threshold of evidence is needed to support such claims against authors. Not only does such an approach risk failing or having unintended consequences, it and the practice of mandatory COI disclosure could breed a culture of mistrust and second-guessing. A culture of assuming people are fundamentally honest and will take steps to avoid or correct conscious and unconscious bias may sound quixotic. But given the lack of evidence either way it could result in the same or even less bias in articles than the current culture. Hard empirical data—were it to become available—might reveal just a small number of individuals whose interests rise above the ideals of unbiased science. Allowing the putative existence of these bad actors to determine the status quo may marginalize the concerns of good, honest authors wary of underwriting a pervasive publication practice on the basis of perceived but unsubstantiated threats. I suggest that this should serve as a fundamental starting point for further, in-depth analysis of the sort I have provided here.

Disclosures are sometimes even ignored by physician readers of articles (Silverman et al. 2010). When disclosures are scrutinized by readers they could unjustifiably enhance (Rosenbaum 2015c) or diminish (Schroter et al. 2004) the discloser’s trustworthiness. Given the dearth of information provided by disclosures and the complexity with which they could exert negative (or positive) effects, even when focused on by readers it is hard to say what their effects might be. As Djulbegovic and colleagues (2007, p. 3568) state about author disclosure: “the reader is asked to make complex judgments about the values of research findings based on source of funding and financial conflicts of interest;” they further point to an observation by Parascandola (2007) that readers may be incapable of such complex judgments. Psaty (2009, p. 1478) also notes, “It is not possible to look at a disclosure about industry funding of research, consulting, or speaking and know how to interpret the disclosure or its potential effect on a published clinical trial.” Psychological research supports this contention, undermining the idea that readers are able to correctly interpret COIs to appropriately discount the credibility of potentially biased research and reporting (Cain, Loewenstein, and Moore 2005b; Loewenstein, Sah, and Cain 2012).
Granted, these and other arguments (such as that “mandatory disclosures of all possible COI, however defined, may create ‘noise’ that obscures genuine and serious COI” [Williams et al. 2017, p. 745, citing PLoS Medicine 2012]) are recognized and even agreed with by some of the proponents of COI disclosure (e.g. Williams et al. 2017). Yet with such *prima facie* compelling evidence that COI disclosure might not be effective, why are supportive positions double-downed and the practice still a ubiquitous fixture of journal policy? A sweeping analysis of debates about COI among both sides of the divide reveal positions related to profoundly different worldviews (Purdy et al. 2017), which could be part of the reason. It may thus be futile to try to convince either side to “change ship”.

However, the stakes are too high to avoid trying because each side has cried harm from COIs being disclosed or not. Dunn and colleagues (2016) for example, offer numerous instructive examples where actual bias and fraud had detrimental impacts on science, health care, and the public trust. However, it is uncertain whether mandatory COI disclosure would have helped in these or other situations (such as case studies published by COPE [2022]) because mandatory disclosure guidelines were in some cases already in place but the authors in some instances did not abide by them. Moreover, even if they had it is not certain that the disclosures would have been interpreted in a way to avoid the negative impacts. Possible inability to ascertain the risk any given disclosure represents pertains not just to readers but to the earlier line of defense vested in the journals’ editors and peer reviewers. If editors and peer reviewers cannot act on COIs prior to an article being published, because they don’t know how, how can readers be expected to do the same?

There always remains the goal of protecting the public trust and the integrity of science and medicine. In interviews and focus group discussions some clinicians or medical students viewed having a COI as constituting corruption, with doctors who didn’t have COIs as having integrity and being honest (Williams et al. 2017). Much in fact turned on the discloser’s perceived motives. Focus on the presumed motives of authors, however, detracts from an unbiased evaluation of the content of a publication, and is the epitome of an *ad hominem* approach to science (Acquavella 1997; Rothman 1993; Stossel 2007; Stossel, Barton, and Stell 2015). Avoiding this focus need not gainsay the profound influence authors’ interests can have on the content of their publications; it is only to recognize that such content can be evaluated independently of those interests. After all, bias
could stem from those or other interests, and readers would have no way of knowing without further evidence. An IOM report tried to assuage concerns over the focus on motives, writing, “If [COI policies] are correctly explained, the policies should not be seen as impugning anyone’s motives. They are, in fact, a way of avoiding intrusive investigations into people’s motives” (IOM 2009, p. 26). However, requiring authors to disclose COIs may not be as innocuous as it seems. For an honest author whose article’s credibility is discounted because of the presence of their COIs, the requirement for disclosure can negatively impact the perception of their scientific integrity. While it is possible that readers might not automatically discount an article’s credibility on the basis of the presence of COIs but instead use that as a starting point for further scrutiny or investigation of the article, empirical data (such as psychiatrists having less confidence in positive than in negative outcomes of fictitious industry-funded studies [Tijdink et al. 2019]) do not support this. What this could illustrate is that the positive-outcome bias that exists (such as that demonstrated by Lundh et al. [2017]) may be known to clinicians and may also illogically influence their perceptions of studies.

In addition to being potentially poor indicators of risk of bias, there are reasons to think that whatever motives are bundled with a COI may not have the negative effects of bias and harm that are sometimes attributed to them. This is because a variety of forces can protect against an author’s COIs from having these effects. These include moral and ethical reasons related to authors’ professional commitments, cognitive reasons related to an author’s ability to reflect on any influences their COIs might have on their work and therefore avoid them, and structural protections related to laws and norms that could punish undue influence from a COI (Williams et al. 2017). The existence of such mechanisms does not entail they are operative, but still should not be underestimated as distinct possibilities.

6. ALTERNATIVES TO CONFLICTS OF INTEREST DISCLOSURE POLICIES

Although abolishing mandatory author COI disclosure in biomedical articles may seem like a hardline view endorsed by the pharmaceutical industry, they are generally supportive of author COI disclosure (PhRMA 2020, p. 15). What are some seemingly less radical alternatives? There are numerous people typically involved in the conduct of a clinical trial, only very few of whom are listed as authors yet many of whom (e.g., study investigators and participants) could potentially influence a trial even more fundamentally than an author, such as by influencing the results. However,
COI disclosure is only required of authors, possibly because authors control what gets reported and this is assumed to be more important than other potential sources of bias. While COI disclosures for all involved parties could be required, this is impractical and no more justified than it is for authors. I thus reject this as a feasible and ethical alternative.

Improving the definition of COIs is another potential alternative. An improved COI definition could involve situations whereby pursuit of one interest necessarily negatively impacts the other interest. The notion of risk is entirely expunged from this definition, and applied to authors of biomedical articles entails that in almost all cases, without further proof, no author has a COI that impacts an article’s results or reporting (absent those cases in which the COI is fraudulently concealed). This would make journals’ requirements for disclosure useless.

Another possibility is to identify the conditions under which bias from COIs is more likely. Elliott (2014, p. 935), for example, offers the following criteria:

1. Scientific findings are ambiguous or require a good deal of interpretation or are difficult to establish in an obvious and straightforward manner.
2. Individuals or institutions have strong incentives to influence research findings in ways that damage the credibility of research.
3. Individuals or institutions that have incentives to influence research findings also have adequate opportunities to influence them.

This is a step in the right direction since it avoids painting all relationships with industry with the same brush, and could help triage the cases for which further scrutiny is merited. Yet it is unclear when these criteria should be applied—i.e. before or after an article is published. Application at either point is problematic as a full-scale solution because, if applied after publication, then this is barely different than the status quo since it just adds a helpful layer of suggesting how the disclosed COIs can be interpreted by readers. If applied prior to publication this runs into the problems mentioned in §5 inherent in “a court of COI”.

Some commentators have advocated addressing the problem of COIs upstream; i.e. before they reach the reporting stage, by limiting certain financial arrangements and publishing more details of the study (de Melo-Martín and Intemann 2009). While the latter suggestion has merit, because of journal word limits many details of a study have to be omitted. Rather than obviate the need for readers to scrutinize an article’s content for risk of bias this might instead call for changes in what information journals present about a study. Many journals in fact already require trial
registration; allow for extensive supplementary material, including the posting of raw data; and in some cases require public posting of a trial’s protocol.

These possibilities suggest a preferable alternative to COI disclosure policies. An extensive amount of information now available to readers on many aspects of a study, combined with greater sensitivity to risks of bias (such as based on tools promulgated by evidence-based medicine [EBM], EBM+ [Parkkinen et al. 2018], and philosophical analyses of establishing causality in science [Illari, Russo, and Williamson 2011]), might provide a far better means of interrogating the soundness of a study’s conclusions and safeguarding biomedical knowledge than knowing the relationships of the study report’s authors. This may be especially true when combined with careful, scientifically skeptical reading of publications and sensitivity to the differences between study types and features. For example, the factors able and likely to bias a randomized controlled trial of a drug are different than those that could bias a case report of a psychotherapy intervention. With respect to the latter, Lilienfeld and colleagues (2014), for example, offer a taxonomy of causes of spurious therapeutic effectiveness. Disclosure of these and other causes seems a far better place to shore up valid interpretations of treatment effectiveness than disclosure of personal characteristics of a study’s authors, such as their presumed propensity to be biased because of their financial or non-financial interests. This is particularly true because authors’ COIs, while possibly the ultimate cause of some types of bias, are not the proximate cause—they must work through some mechanism (such as some of the causes Lilienfeld and colleagues highlight) to engender the bias. Other sources of bias include those outlined by the Cochrane Risk of Bias tool for randomized trials (Sterne et al. 2019). Although such tools do not identify all forms of bias or the ones that escape even careful scrutiny of an article, focus on these and other more proximate causes of biased work seems a far more fruitful approach to mitigating risk of bias than focus on COIs. Such factors, which are well studied, direct, and relatively easily evaluated, include issues related to randomization, missing data, how well blinding is maintained, the appropriateness of the sample size and statistical analyses, the nature of the comparator, the relevancy of outcomes used, and the appropriateness of the dosage and method of administration. Psaty (2009) offers a similar antidote to the potential presence of bias in a biomedical article: careful reading and analysis by a reader of the methods, results, and conclusions. More efforts to facilitate and promote the ability of readers to develop
and exercise these skills may engender not only greater ability in readers to detect bias, but an increased propensity in authors and researchers to avoid bias in the first place. Educational and other initiatives to increase the effectiveness of this approach is a preferable alternative to COI disclosure policies. While it could be countered that such efforts could be supplemented by COI disclosure, this only makes sense if there is merit and no downsides to COI disclosure.

Although I generally endorse abolition of mandatory COI disclosure policies, this is distinct from whether a study’s funding should be disclosed. I support this as a continued policy, and even if COI disclosure requirements were abolished, reporting study funding could still continue to be asked of authors just as it is currently typically inquired of by journals independently of asking for authors’ COIs. Since COI disclosure policies are unlikely to be abandoned tout court anytime soon, a compromise, alluded to in §4, may be requiring certain COIs to be disclosed—i.e. only those held by authors of industry-sponsored studies and only when directly relevant to the study in question. This can help avoid situations wherein authors list as many COIs as possible, drowning out the salient COIs or perpetuating a façade of being balanced. Existing checklists, such as that of Rochon et al. (2010), could be adapted for this purpose, especially because they provide a granular breakdown of multiple aspects of a study, who was responsible for each aspect (i.e. funder and/or author), and the specific, detailed nature of an author’s financial interests with respect to that study.

Importantly, I am not suggesting that values do not or should not affect biomedical research and reporting. What is instead needed is better scrutiny of which values should influence a study’s design, the claims made on the basis of that study’s results, and how such claims are communicated in journal articles and other venues. In medicine, such claims typically involve the safety and effectiveness of treatments. In other work (Tresker, forthcoming-a), I in fact argue that non-epistemic values are an essential part of treatment effectiveness claims through the many ways in which decisions related to establishing a treatment’s effectiveness are made under inductive risk (such as regarding trial design and the standard of effectiveness for a treatment). I therefore advocate that when authors make treatment effectiveness claims that they should “disclose” (i.e. discuss and justify) the non-epistemic values involved in why a treatment should be considered effective. Further work can help specify the nature of such “disclosure” and which values under which circumstances are legitimate or not. This disclosure of non-epistemic values is different than disclosure
of COIs, the presence of which might only raise the presumption that non-epistemic values were illegitimately involved in a study’s conduct and/or reporting.

7. CONCLUSION

Throughout this article I have argued that biomedical journal COI disclosure policies are an unfair and likely ineffective means for protecting the reliability of biomedical knowledge. A medical epistemology that recognizes this, rather than abstracting away key features to arrive at an idealized view of research output, might actually be better attuned to the multifaceted realities of authors’ relationships. Consequently, it is able to incorporate such features in an ethically and epistemically responsible way.

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NOTES

1. Definitions of COIs in biomedical publishing abound, and they are not without their problems. For reasons of space I have not included an analysis of prevailing definitions. To avoid confusion, unless otherwise indicated I use COIs to simply mean whatever is disclosed by authors as COIs in biomedical journal articles.
2. I focus on biomedical publishing because of familiarity with the field. My analysis may also be valid for other fields.
3. I use bias to mean any undue influence on a published article’s content.
4. I owe this point to an anonymous reviewer.
5. Whose input into the study may only begin after a study is completed, during which time so-called “external authors” are often invited to join the pharmaceutical company’s “internal authors”.
6. This raises the issue of guest authorship, whereby an “author” is listed on an article despite little substantive contribution. Although this is unethical and far too common an occurrence in biomedical publishing, it is an issue orthogonal to that of whether COIs should be disclosed and speaks instead to
whether the listing of author contributions should be more closely enforced and the contributions themselves verified.

7. This example is based on a real disclosure but I have omitted the reference to preserve the discloser’s anonymity.

8. I owe this point to an anonymous reviewer.

9. Although it is possible that failure to disclose, if discovered, could indicate a lurking issue. I am grateful to an anonymous reviewer for this point.

10. While this suggestion may have merit, since my focus is on COI disclosures, I don’t discuss this here.

11. I recognize that this approach has limitations, such as the increased amount of time and effort required and the fact that not all biases or risks of biases will be detectable.

12. These “disclosures” should not necessarily be made in publications of clinical trials, because of space constraints and because treatment effectiveness, I argue, is best seen as a prediction supported by an argument that typically adduces a plurality of evidence, not just that from a single clinical trial (Tresker, articles forthcoming-a and forthcoming-b). Narrative review articles or specialized reports may be better ways of articulating the reasoning behind treatment effectiveness claims.

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TRESKER • COI DISCLOSURE


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