



# **A Common Standard for** **Conflict of Interest Disclosure**

**Merrill Goozner, Arthur Caplan, Jonathan Moreno,  
Barnett S. Kramer, Thomas F. Babor, Wendy Cowles Husser**

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The reporting of conflicts of interest in science and medicine in the scientific literature<sup>1</sup> has come under increasing scrutiny in recent years. Failures to disclose conflicts of interest have become front page news, and a major embarrassment to publishers, editors, and professional societies.<sup>2</sup>

These failures to disclose relevant relationships have stemmed in part from a lack of uniform definitions for conflicts of interest and confusion about what needs to be reported. Academic investigators operate under varying institutional rules, and many are unable to accurately describe their institutions' policies.<sup>3</sup> Science and biomedical journals have a range of disclosure policies with differences in definitions of conflicts of interest, reporting requirements, and promises to publish.<sup>4</sup>

In the face of heightened scrutiny, several publishers have moved in the past several years to implement stricter conflict-of-interest disclosure and publication rules.<sup>5 6</sup>  
<sup>7</sup> Organizations are paying greater attention to conflict-of-interest disclosure in the

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<sup>1</sup> Conflicts of interest most often refers to financial relationships, but can also involve personal, professional, ideological, political or religious views, which are sometimes referred to as competing interests. For the purpose of this paper, conflicts of interests refer to both financial and non-financial relationships.

<sup>2</sup> David Armstrong, "Amid Suits Over Mold, Experts Wear Two Hats," *Wall Street Journal*, Jan. 9, 2007; Christopher Rowland, "Medical Group Puts Stop to Talks on Drug Firm Ties," *Boston Globe*, Dec. 27, 2006; David Armstrong, "Financial Ties to Industry Cloud Major Depression Study," *Wall Street Journal*, July 11, 2006; Reed Abelson, "Charities Tied to Doctors Get Drug Industry Gifts," *New York Times*, June 27, 2006; Tinker Ready, "Divided Loyalties?" *Washington Post*, Feb. 7, 2006; Erika Check, "Journals Scolded for Slack Disclosure Rules," *Nature*, Jan. 18, 2006.

<sup>3</sup> Boyd EA, Cho MK, Bero LA, "Financial Conflict-of-Interest Policies in Clinical Research: Issues for Clinical Investigators," *Acad. Med.* 2003;78:769-774.

<sup>4</sup> Krinsky S, Rothenberg L.S. "Conflict of interest policies in science and medical journals: editorial practices and author disclosures. *Sci Eng Ethics.* 2001;7:205-218.

<sup>5</sup> Flanagan A, Fontanarosa PB, DeAngelis CD, "Update on JAMA's Conflict of Interest Policy," *JAMA*, 2006;296:220-21.

<sup>6</sup> Graf C, Wager E, Bowman A, Fiack S, Scott-Lichter D, Robinson A; "Best Practice guidelines on Publication Ethics: a Publisher's Perspective," *Int J Clin Pract*, 2007;61(Suppl. 152):1-26.

<sup>7</sup> "Ethical Guidelines to Publication of Chemical Research," American Chemical Society, January 2006.

context of redefining the rules of engagement between academic investigators and private industry.<sup>8</sup> The need for common standards in defining conflicts of interest has never been greater.

Since the first conflict-of-interest disclosures appeared in the *New England Journal of Medicine* in the early 1980s,<sup>9</sup> the rationale for including this information in published scientific articles has not changed. Scientific discourse depends on objectivity. The conduct of science can be influenced by biases introduced by conflicts of interest, whether they are financial, professional, intellectual, or fueled by academic competition. The potential for bias is real, whether or not researchers believe those conflicts of interest influence their conduct.

Moreover, the positive association between conflicts of interest and the outcomes of research has been documented many times in many fields. Virtually all of this research has focused on financial conflicts of interest.<sup>10</sup> The causation of the relationship is the subject of much speculation. Frequently cited factors include protocol construction, sample selection bias, and selective interpretation. Because these potential causes of bias have never been studied systematically, controlling for bias through publication criteria is nearly impossible, although at least one medical journal, the *Journal of the American Medical Association*, took steps in that direction when it required that the author primarily responsible for “the integrity of the data and the accuracy of the data analysis . . . not be employed by any commercial funding source.” The editors also expressed a preference for studies where “data collection and data management are conducted independently of the study sponsor and with additional monitoring and oversight, such as under the auspices of an independent data and safety monitoring committee.”<sup>11</sup>

But that is the exception. The general consensus among editors is that disclosure of financial conflicts of interest – at the outset of the submission process, during the editing process, and, finally, to the readers – is the most practical available tool for managing conflicts that can influence or even appear to influence scientific research.

But is disclosure a sufficient remedy for managing conflicts of interest in all situations? The evolution of existing policies over the years shows there have been sharply diverging views about what is allowed for authors of reviews, for instance, or editorials. In 1990, editors at the *New England Journal of Medicine* adopted a policy limiting the right of authors with conflicts of interest to write reviews and editorials. The policy was reaffirmed in 1996 when readers complained that several prominent reviewers

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<sup>8</sup> Brockway LM, Furcht LT; “Conflicts of interest in biomedical research – the FASEB guidelines,” *FASEB Journal*;20:2435-38.

<sup>9</sup> Relman AS, “Dealing with conflicts of interest,” *NEJM*. 1984; May 3; 310(18):1182-3.

<sup>10</sup> See, for instance, Bekelman JE, et al. “Scope and impact of financial conflicts of interest in biomedical research,” *JAMA*. 2003; Jan 22-29;289(4):454-65. Review; Ridker PM, Torres J, “Reported outcomes in major cardiovascular clinical trials funded by for-profit and not-for-profit organizations: 2000-2005,” *JAMA*. 2006; May 17;295(19):2270-74; Lesser et al, “Relationship between funding source and conclusion among nutrition-related scientific articles,” *PLoS Medicine*. 2007;

<sup>11</sup> Fontanarosa PB, Flanagan A, DeAngelis CD, “Reporting conflicts of interest, financial aspects of research, and role of sponsors in funded studies,” *JAMA*. 2005; 294(1):110-11.

had not disclosed relevant conflicts of interest, and an internal investigation revealed the policy was frequently ignored.<sup>12</sup> In 2002, a different set of editors amended the policy to allow editorials and reviews to be written by authors with conflicts of interest below \$10,000 a year as long as they were fully disclosed. The editors explained that they didn't want to disqualify highly qualified people from offering their opinions in the pages of the journal.<sup>13</sup>

The argument in favor of the older policy rests on a desire to reserve a high standard of independence and objectivity for reviews that claim to represent the state of the science. Prohibiting reviewers from having conflicts of interest protects journals against the perception of bias influencing the analyses that appear in their pages. In that sense, evidence reviews written by individuals or groups have a lot in common with medical groups that author clinical practice guidelines. Both review the available evidence, assign each component a weight based on its quality, and derive a conclusion based on the overall weight of evidence. When the conclusions are controversial and the authors have financial ties to affected parties, allegations that conflicts of interest influenced the analysis are inevitable.<sup>14</sup> While the model policy described in this paper does not include this restriction, journals may choose to adopt this strategy – insisting that writers of reviews and editorials adhere to a strict no-conflict-of-interest policy – as one way of ensuring high ethical standards for their journal.

Those journals that choose to adopt this standard will not close themselves off from including the opinions of their fields' leading thinkers if they have financial ties to industry. In addition to reviews and editorials, many journals allow signed commentaries to appear in their pages. Such commentaries, as long as they are accompanied by appropriate disclosure statements, would still be allowed under such a policy. Nor should it make it difficult for editors to find reviewers or editorialists. The talent pool is broad enough to accommodate such a policy. For instance, leading institutions in the field of evidence-based medicine have adopted strict rules limiting the use of conflicted scientists on its clinical practice guideline-writing committees. The U.S. Preventive Services Task Force at the Agency for Healthcare Research and Quality excludes scientists from specific discussions if they have extensive ties to companies with a stake in the outcome.<sup>15</sup> The Office of Medical Applications of Research within the National Institutes of Health, which impanels scientists to develop “state of the science” statements on controversial or underutilized medical technologies, prohibits scientists with relevant conflicts of interest from serving on its panels.<sup>16</sup>

But note the caveat in that last sentence. When does a potential conflict of interest become relevant? Here, existing policies provide very little guidance. One journal

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<sup>12</sup> Angell M, Kassirer JP, “Editorials and conflicts of interest,” *NEJM*. 1996; 335(14):1055-6.

<sup>13</sup> Drazen JM, Curfman GD, “Financial associations of authors,” *NEJM*. 2002; 346: 1901-2.

<sup>14</sup> Daniel Coyne, “Influence of Industry on Renal Guideline Development,” *Clin J Am Soc Nephrol* 2:3-7, 2007.

<sup>15</sup> Email communication from Mary Barton, Scientific Director, U.S. Preventive Services Task Force, Nov. 7, 2007.

<sup>16</sup> See NIH Consensus Development Program (<http://consensus.nih.gov/aboutCDP.htm#panel>, accessed October 1, 2007).

recommends that authors unsure if a particular financial arrangement is relevant “should always err on the side of full disclosure.”<sup>17</sup> This presumes that there are some relationships that need not be disclosed, even to editors. A safer standard would require that authors disclose all financial or other relationships on the forms submitted to editors, and draft a statement to accompany the submission that reflects the author’s interpretation of relevance. The editors will then have the information readily at hand to review the self-reported statement and make adjustments if they think greater disclosure is warranted.

This safeguard still doesn’t provide guidance to editors or authors for determining relevance, however. If an author has a financial relationship with a company on a subject entirely apart from the subject of the article, is that relevant? If the financial relationship is with a company that competes with the company whose product is being discussed in the article, is that relevant? If the financial relationship with the competitor company is on a subject entirely apart from the subject of the article, is that relevant? How about patents and pending patents in an area related to the article subject, held either directly or by the researcher’s institution? What if research funding comes from a non-profit group or research institute that is funded by industry? What percent of a research institute’s funds must come from industry before it is considered industry-funded for disclosure purposes? How long does a financial relationship persist?

The safest course for avoiding even the appearance that authors or editors are hiding a potentially relevant conflict of interest would be to err on the side of greatest disclosure, while still recognizing that some relationships are clearly irrelevant. Any financial relationship with a company with a direct stake in the contents of a submission, whether or not that relationship is on that subject, ought to be disclosed under the theory that one might hesitate to bite the hand that feeds one. The same is true for a relationship with a firm that competes with another firm’s product that is the subject of the article, even if that relationship isn’t on that subject. But one could imagine a scenario in today’s corporate world where two firms compete on some products, but not on the product that is the subject of the article. If the author’s financial relationship with the competitor firm is on a different subject, too, then the article need not disclose this relationship, which could be referred to as a conflict-of-interest twice removed.

Defining relevance for patenting disclosure is difficult. Clearly, a patent on a fuel cell technology needn’t be disclosed in an article about receptors on a particular type of cancer cells. But a pending patent identifying the potential medical use of a receptor on one type of cancer cell should be disclosed in an article about a similar receptor that happens to be on a different type of cancer cell. Arguments that this is not relevant will ring hollow if later that patent is licensed to a company developing a drug that influences both receptors. As commercialization has pushed further upstream in the scientific process, the potential utility of patented inventions has become much more difficult to predict. Scientific advances in one area may increase the value of patented technologies in another area that at first blush years earlier may have seemed only marginally related. A broad definition of relevance that errs on the side of greater disclosure for patents and pending patents is warranted.

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<sup>17</sup> Fontanarosa et al.,

In recent years, there has been a proliferation of trade associations, social advocacy groups and non-profit research foundations in the U.S. and other countries. They not only fund and conduct research, but may be involved in recruiting scientists to engage in advocacy and promotional activities.<sup>1</sup> Many of these groups receive grants from private firms; some are entirely funded by industry. Yet the exact purpose of these organizations are not readily apparent to the general public, scientists and editors through their names, nor is their financial support from industry.<sup>18</sup> What level of industrial support qualifies one of these non-profits or advocacy groups as industry-funded? If a grant is for a specific research or promotional project, then recipients of those funds clearly have a conflict of interest for purposes of disclosure. And if a group is entirely funded by industry, then any grant from that group, even if industry support is unrestricted, should be considered a conflict of interest. But what if the group receives only part of its funds in unrestricted grants from industry? We believe 50 percent or more funding from industry is a reasonable standard for qualifying a group as industry-funded, and whose financial support for a researcher or project should be disclosed as such.

Another issue that must be addressed by guidelines is how far back to look in determining conflicts of interest. Clearly, there is a statute of limitations on a financial relationship. Some journals and organizations have adopted a standard that says the relationship should be current. In other words, if the check was written yesterday for work conducted in the past, the conflict of interest no longer exists for disclosure purposes. This has been rejected by the vast majority of journals with disclosure policies, whose look-back periods range from one to five years. Given the long lead time between the onset of scientific work and publication, a three-year look back period is a reasonable minimum standard.

Some journals and organizations with conflict-of-interest disclosure policies also set dollar levels below which conflicts need not be declared. This is probably unwise for disclosures by authors to editors because this could wind up hiding potential conflicts of interest that, while small, are still relevant. In no case should a relevant conflict of interest remain undisclosed to readers.

Finally, there is the question of whether to report non-financial competing interests such as academic rivalries or political and religious beliefs. There is a general consensus that while they do exist and can influence research outcomes, they are hard to identify and difficult to describe for purposes of disclosure. Many researchers are unaware of their own biases or are unconcerned about their potential impact on research outcomes, believing that the scientific method will be self-correcting even though many experiments are too expensive, complicated, or narrowly conceived to be confirmed through the traditional safeguard of replicating results. Yet in recognizing that some effort to disclose non-financial conflicts as a source of potential bias is warranted, there is as yet no objective basis for establishing a standard. The relationship between financial

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<sup>18</sup> Typical examples include the Center for Medicine in the Public Interest, which receives funds from the pharmaceutical industry, and the Foundation for Lung Cancer Detection, Prevention and Treatment, a non-profit affiliated with Weill Cornell Medical College and funded by Liggett & Myers, a tobacco firm.

conflicts of interest and research results is well documented. Similar research about non-financial conflicts of interest doesn't exist. Therefore, a voluntary approach to disclosure of relevant non-financial conflicts of interest has been outlined in the model policy.

Ensuring that the disclosed information is complete and accurate ultimately depends on the good will of the investigators, reviewers and editors who voluntarily submit this information. A common understanding of what constitutes a conflict of interest and when it should be disclosed would facilitate voluntary compliance with journal policies. This model policy represents one attempt to arrive at that common understanding.

## **MODEL CONFLICT OF INTEREST DISCLOSURE GUIDELINE FOR SCIENTIFIC AND MEDICAL JOURNALS**

### **For Authors:**

All manuscripts for articles, original research reports, editorials, comments, reviews, book reviews and letters that are submitted to the journal must be accompanied by a conflict of interest disclosure statement, or a declaration by the authors that they have no conflicts of interest to declare. All articles that are published in the journal will be accompanied by a conflict-of-interest disclosure statement, or a statement that the authors have replied that they have no conflicts of interest to declare. If the journal prints unsigned editorials, they should not be written by anyone with a conflict of interest.

To facilitate this policy, all authors must privately disclose to the editors of the journal at the time of their submission ALL potential conflicts of interest. These include all financial and non-financial interests and relationships (see below for definitions), direct employment with a private sector entity (whether full or part-time), and service on private sector and non-profit boards and advisory panels, whether paid or unpaid. Authors should also disclose to editors any conflict of interest that may have influenced either the conduct or the presentation of research, including but not limited to close relationships with those who might be helped or hurt by the publication, academic interests and rivalries, and any personal, religious or political convictions relevant to the topic at hand.

In the paper, authors should include a draft statement that discloses all relevant conflicts of interest and affiliations. Relevance for financial conflicts of interest with private firms is defined as a relationship of any value with a firm with a stake in the subject of the manuscript, or its competitors. Relevance for patents is defined as any invention or pending invention connected in any way to the subject. Since relevance is often in the eye of the beholder, you should err on the side of full disclosure in drafting the disclosure statement. Editors will check your draft against the private financial disclosure statement, and initiate discussions toward possible adjustments if necessary.

**What to report:** Any financial relationship from the past three years (dating from the month of submission) of any size should be disclosed. These potential conflicts of interest include:

- Direct employment, either full or part-time;
- Grants and research funding (but not grants to your institution or others within your institution on which you did not work); this includes grants from trade associations and non-profits substantially (50 percent or more) funded by private-sector firms;
- Consultancies;
- Travel grants, speaking fees, writing fees and other honoraria;
- Paid expert testimony for one side in an adversarial proceeding (this does not include testimony as a factual witness in a civil or criminal case);

- Patents granted, pending and applications, whether or not generating royalties;
- Stock ownership, investment in related “sector” funds, or stock options, including those of immediate family members but excluding diversified mutual funds and investment trusts; and
- Membership on private sector scientific or other advisory boards, whether paid or unpaid.

In addition, any current negotiations regarding future employment or current job offers, either full- or part-time, must be disclosed.

In disclosing these financial arrangements to editors, authors can include dollar amounts even though they will not be printed in the journal. Editors may choose to exclude this information from publication, but in no case should an editor or author consider an arrangement irrelevant based on its size alone.

**Non-Financial Conflicts of Interest:** Authors may have strongly-held views about the article being submitted for publication. Authors should consider disclosing and editors may choose to print any affiliations or expressions of these views that may be relevant. These may be personal, political, or intellectual and may include any expression of strongly held views relevant to the subject of the submission. Such disclosures may be original, or they make reference to opinions previously expressed in books or monographs, op-eds or public comments, or to sworn testimony before or lobbying of legislators or legislative bodies. Disclosable non-financial conflicts of interest would also include membership or affiliation with non-governmental organizations that have an interest in the submission.

#### **For Editors, Articles Editors, and Peer Reviewers:**

As a general rule, journals should require that all senior editorial personnel (editors in chief, managing editors, full-time assistant editors) avoid all financial relationships that might constitute a conflict of interest. Editorial managers should also avoid personal, political, or intellectual entanglements, organizational or otherwise, that could be construed as establishing a particular bias that might influence one’s judgments.

The well-established principle in editorial management is that there should be a firewall separating editorial decision making from publishers, advertisers, circulation managers and anyone connected with the business side of the journal’s operations. Editors who maintain financial ties with companies or institutions that have an interest in the content of a journal undermine the editorial independence that is crucial to a journal’s credibility.

Scientific publishing is a highly competitive enterprise. The number of manuscripts rejected far exceeds the number accepted at most journals. Requiring editors to remain conflict-of-interest free assures rejected authors that bias or potential bias did not enter into the editorial decision to reject their manuscript. Similarly, readers have the right to know that the choice of articles, choice of reviewers, and choice of editorial or

commentary writers was made by senior editorial managers whose judgment was not influenced by financial conflicts of interest or ideological bias.

If a journal editor or senior editorial manager has a conflict of interest, it must be disclosed in each edition of the journal near the masthead and be found easily in the online edition. Such notice should also be included on the author guidelines or information page for electronic submissions. The same rules that govern author disclosures should govern editor disclosures.

Some journals publish the names of article editors in the article. Some do not. Peer reviewers have traditionally remained anonymous. Whatever the journal's policy, peer reviewers and articles editors should follow the same rules as authors for disclosing conflicts of interest. In other words, peer reviewers will send disclosure forms to the editors, even though this information does not appear in the publication. This gives editors the tools they need to ensure that peer review panels for individual papers are fairly balanced.

### **Enforcement**

Conflict of interest disclosure relies on the honor system. Editors do not have the time, resources or inclination to serve as financial auditors or ideological arbiters. Successful disclosure policies depend on the good will and integrity of editors, authors, and peer reviewers. But even the highest quality journals with well-established conflict-of-interest disclosure policies do not have universal compliance.<sup>19</sup> This may be, in part, due to a lack of understanding about the rules for disclosure, which this model policy is meant to address.

Most cases of a failure to disclose relevant conflicts of interest arise because someone brings it to the attention of the editors, either directly or through attention in the press. In such cases, editors should investigate the allegation. If true, editors should determine the cause of the failure to disclose a relevant conflict. The editors may wish to establish a permanent panel that includes external parties to review difficult cases, or consult their editorial board.

In all cases of failure to disclose a relevant conflict of interest, editors will publish an editor's note that becomes part of the permanent record of that article. In those rare cases where editors uncover a willful desire to hide financial conflicts of interest, the editors will consider appropriate penalties, such as refusing to allow that author to publish in the journal for a specified period of time. Some journals have adopted a three-year ban for such instances.<sup>20</sup>

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<sup>19</sup> Goozner M, "Unrevealed: Non-Disclosure of Conflicts of Interest in Four Leading Medical and Scientific Journals," Center for Science in the Public Interest, July 2004 (available at [http://www.cspinet.org/new/pdf/unrevealed\\_final.pdf](http://www.cspinet.org/new/pdf/unrevealed_final.pdf), accessed September 26, 2007).

<sup>20</sup> Goehl TJ, "Embracing Scrutiny," *Environmental Health Perspectives*, October 2004 (available at <http://www.ehponline.org/docs/2004/112-14/EHP112pa788PDF.pdf>, accessed September 26, 2007).

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## **Disclosure**

Merrill Goozner directs the Integrity in Science project for the Center for Science in the Public Interest, which lobbies Congress and regulatory agencies for laws requiring greater disclosure of conflicts of interest in the science literature and on federal advisory committees.

## **Authors:**

Merrill Goozner, M.S.  
Director, Integrity in Science Project  
Center for Science in the Public Interest  
1875 Connecticut Ave. NW, Suite 300  
Washington, DC 20009  
Tel: (202) 777-8374  
Fax: 202-265-4954  
E-mail: [mgoozner@cspinet.org](mailto:mgoozner@cspinet.org)

Arthur Caplan, Ph.D.  
Emanuel and Robert Hart Professor of Bioethics  
University of Pennsylvania  
3401 Market Street, Suite 320  
Philadelphia, PA 19104  
Tel: (215) 898-7136  
E-mail: [caplan@mail.med.upenn.edu](mailto:caplan@mail.med.upenn.edu)

Jonathan Moreno, Ph.D.  
Professor, University of Pennsylvania  
Department of History and Sociology of Science  
303 Logan Hall, 249 S. 36th Street  
Philadelphia, PA 19104-6304  
Telephone: (215) 898-7629  
E-mail: [morenojd@mail.med.upenn.edu](mailto:morenojd@mail.med.upenn.edu)

Barnett S. Kramer, M.D., M.P.H.  
Editor-in-Chief, Journal of the National Cancer Institute  
8120 Woodmont Ave., Suite 500  
Bethesda, MD 20814  
Telephone: (301) 496-1508  
Email: [bk76-@nih.gov](mailto:bk76-@nih.gov)

Thomas F. Babor, M.D., M.P.H.  
Associate Editor-in-Chief, Addiction  
Department of Community Medicine and Health Care  
University of Connecticut Health Center  
263 Farmington Avenue, MC 6325  
Farmington, CT 06030  
Phone: (860) 679-5470  
Email: [babor@nso.uhc.edu](mailto:babor@nso.uhc.edu)

Wendy Cowles Husser, M.A., M.P.A.  
Executive Editor, Journal of the American College of Surgeons  
633 N Saint Clair Street  
Chicago, IL 60611  
Tel: (312) 202-5306  
Email: [whusser@facs.org](mailto:whusser@facs.org)

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