



EFFECTIVE AND PRACTICAL DISCLOSURE POLICIES: NRDC PAPER ON WORKSHOP TO IDENTIFY KEY ELEMENTS OF DISCLOSURE POLICIES FOR HEALTH SCIENCE JOURNALS

Jennifer Sass, Ph.D.

Natural Resources Defense Council

ACKNOWLEDGEMENTS

I am grateful to our Advisory Committee: Susan Booker, Arthur Caplan, Britt Erickson, Merrill Goozner, Herman Gibb, Sheldon Krimsky, and Hugh Tilson.

I am thankful to the following people that joined our Advisory Committee members for the workshop, and provided reviews and comments on this report: Thomas Babor, David Egilman, David Jorgensen, David Michaels, Mark Seeley, Paul Thacker, Jeremy Theobald, and Charles Trowbridge (affiliations listed elsewhere in this report).

Thank you to Merrill Goozner, who served as co-host and participant.

Thank you to Linda Greer for guidance and peer review. Thanks to Monique Waples, Dylan Atchley, and Rebecca Reindel for their superb assistance in all aspects of organizing and meeting logistics.

Support and funding for this project was generously provided by the Beldon Fund and the Bauman Foundation.

INTRODUCTION

In the summer of 2008, the Natural Resources Defense Council (NRDC) hosted a day-long workshop to discuss disclosure policies for health science journals. The workshop participants sought to identify the key elements they believed would contribute to practical and effective policies, without designing or recommending a one-size-fits-all comprehensive disclosure policy. Workshop participants included journal editors and other journal staff, academic scientists, scientific consultants, ethics experts, and publishing house representatives. This report includes the workshop's findings and recommendations. Although efforts were made to accurately represent the consensus views of the workshop participants, all final editorial decisions were made by the author.

BACKGROUND

Among the editors and staff of environmental and occupational health sciences journals, there is a recognized need for disclosure policies that are simple, clear, and effective. The goal of such policies is to provide sufficient information about any existing competing interests so that readers may exercise judgment about the objectiveness of the information. Science plays a critical role in arbitrating the safety and efficacy of pharmaceutical, consumer, and industrial products. Just as critical is the role of scientific journals, which can give published science the imprimatur of independence and therefore credibility.

Publication in a peer-reviewed journal is a forceful argument that the information is trustworthy. Effective disclosure policies play an essential role in protecting journals from becoming unwitting agents of propaganda, distortion, corporate marketing, and other types of misinformation, thereby constituting an important cornerstone of the journals' credibility and reputation.

In his essay published in the May 2005 issue of *PLoS Medicine*, Richard Smith warned that “Medical journals are an extension of the marketing arm of pharmaceutical companies.”¹ Smith, an editor for the *British Medical Journal* for 25 years, argued that the drug industry had become reliant on industry-funded studies that are published in major journals to give the research a “stamp of approval,” distribute the conclusions globally, and even attract media coverage. “The quality of the journal will bless the quality of the drug,” Smith wrote. Although disclosure of author interests will not end undue drug industry influence like that reported by Smith, we believe it will be a crucial step in the right direction to make possible conflicts more transparent to readers and the public.

The real nub of the problem of heavy-handed sponsorship of scientific studies lies in studies that are biased or even inaccurate in favor of their funders. In his essay, Smith reported that “overall, studies funded by a company were four times more likely to have results favorable to the company than studies funded from other sources.”² Independent analyses reported similar findings.³ In fact, the practice of publishing biased or even inaccurate data that defend funders’ interests has become so widespread in the medical field that it is no longer contestable. Marcia Angell, former editor of the *New England Journal of Medicine*, published a book in 2005 in which she criticized the drug industry for its use of public funds and its relationship with regulatory agencies to first create a market for its products and then fast-track commercialization.⁴ In 2004, *Lancet* editor Richard Horton specifically named scientific journals in this process, saying, “journals have devolved into information-laundering operations for the pharmaceutical industry.”⁵ The potential for scientific reporting to be biased toward a sponsor has also been documented for research on many hazardous agents, including the plasticizer bisphenol A (BPA), secondhand tobacco smoke, chromium, asbestos, lead, and others.^{6,7,8,9,10,11} In *Doubt Is Their Product: How Industry’s Assault on Science Threatens Your Health*, former Assistant Secretary of Energy David Michaels documented how industries influence regulatory agencies so as to weaken or delay the regulation of their products.¹²

There are two clear advantages for disclosure of competing interests. First, knowing the competing interest in advance may raise the level of scrutiny given to the article by reviewers and readers, leading to a more careful examination of the manuscript. Second, if such interests are not disclosed, but then discovered later, it may seem that either the author or the journal was intentionally hiding this information from readers.

Environmental and health sciences journals exhibit a range of author disclosure policies, with variations in definitions of conflicts of interest and reporting requirements.¹³ In this report we recommend key elements of an effective and enforceable disclosure policy to guide journals in shaping and refining useful disclosure policies.

KEY ELEMENTS OF EFFECTIVE CONFLICT OF INTEREST DISCLOSURE POLICIES

Disclosure Policies

In phrasing the disclosure policy, the term “conflict” or “conflict of interest” may be off-putting to authors, who might perceive it as an admission of bias and therefore be discouraged from disclosing. Hence we recommend using the term “competing interests” instead of “conflict of interests.” In addition to specifying types of interests that should be disclosed, we also advise that policies request broad disclosure of all interests that could be perceived by the readership as creating bias.

As a general rule of thumb, disclosures must include any financial interests that could constitute a potential source of bias or perceived bias in the eyes of the general public, the media, the scientific community, peer reviewers, or editors. We therefore recommend the following language for requesting disclosures:

All financial interests must be disclosed. This includes but is not limited to employment, clients, honoraria, travel expenses, grants, and litigation support. The approximate monetary value of any financial interests must be declared and should distinguish between funding for research and monies paid to the author. Disclosures should include anticipated future competing interests and past competing interests going back a minimum of three years. Any other competing interests or potentially competing interests, financial or otherwise, should be disclosed if these interests, when known to the public, could compromise the standing or integrity of the journal, peer reviewers, or author. The journal editors will decide how best to manage these situations.

The public statement (as well as the detailed listing of competing interests) should be written in language such that the average person would be able to identify a potential competing interest. A mere listing of funding sources for a study or the author's salary or honoraria is not adequate if the average person is not able to establish the link to a potential source of bias.

Journal staff should clearly identify how far back they wish their journal policy to extend, considering what is appropriate for the journal. JAMA asks for disclosures to go back five years and into the foreseeable future.¹⁴ The journals *Science* and *The Lancet* policies go back three years.^{15,16} *Nature* does not specify a time, but does state that disclosures are required only if authors may gain or lose financially through the publication under question.¹⁷ In any case, under no circumstances should policies be limited only to current conflicts.

Who Discloses How Much and to Whom?

Many individuals, when asked to disclose competing interests, may have difficulty in determining whether or not something is a competing interest. If there is any doubt on the part of the author, he or she should err on the side of disclosure. The journal should then determine what portion to publicly disclose; it will undoubtedly be necessary for journals to exercise some discretion in what is printed. However, the rule to the author should be, "if in doubt, report." Along with the full disclosure statement to the journal, each author should submit a statement to be printed with the article and thereby made public. Journal staff will have to evaluate, based on the full disclosure, whether the public statement is appropriately comprehensive. The public statement should be no more than a few sentences and should include relevant patents, employment, collaborations, consulting, etc., where these could be seen as possible competing interests. If no competing interests are disclosed, then this should be stated in the public statement.

Journals must decide individually whether disclosures should be made available to peer reviewers. The obvious reason not to provide author disclosures to peer reviewers is that journals want the peer reviewers to provide a blind review of the article, without regard to potential competing interests. However, some participants in our workshop noted that experts within a professional field can often deduce the identities of authors on the basis of the research, the perspective, or even the tendency of scientists to preferentially cite their own work in the reference section. An argument for providing the disclosure form to the peer reviewer is that it may stimulate the reviewer to increase the level of scrutiny and skepticism, thus leading to a more rigorous review.

Nature does not allow author conflicts to be disclosed to reviewers during the peer-review process. In contrast, competing interest disclosures submitted to *Pediatrics* are shared in full with reviewers. One journal, *Accountability in Research*, provides an option for authors to delete their own names from the references and thus hide the authors' identities from peer reviewers. The same journal also provides peer reviewers with the option of sharing their name with the authors. This flexibility provides both authors and peer reviewers with an opportunity to exercise some personal choice in the level of blinding during the review process.

How Much Is Too Much?

The disclosure policy should address both financial and nonmonetary relevant competing interests. If competing interests are being declared, then the approximate monetary value should also be stated to the journal. Although there is no obvious threshold value at which a financial interest becomes a conflict, nonetheless, if a competing interest is monetary, then the approximate amount should be declared to the journal, though generally not to the readership unless the journal editor determines otherwise.

Religious, political, or intellectual perspectives may also influence a researcher's conclusions. If an author's perspectives on an issue are a matter of public record, then this may not necessarily need to be declared. However, if the author earns an income as an expert in litigation related to the subject of the manuscript, or if the author routinely consults for a trade group whose members have an interest in the subject of the manuscript, this should be disclosed with a simple statement such as "clients of the author have a financial interest in compound X," or "the author routinely consults for clients that have a financial interest in compound X," or "the author earns income from litigation related to compound X."

Freedom from Sponsor's Influence

A strong competing interest policy requires that all authors declare that the manuscript is free from the sponsor's influence. Many journals already incorporate some kind of statement regarding the role of the funding source. For example, *The Lancet* asks that all sources of funding be declared and that authors "must describe the role of the study sponsor(s), if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication."¹⁸ If there was no such involvement, then a statement to that effect must be provided. *The Lancet* further requires a signed statement from the author confirming that the name and funding source of any medical writer or editor involved in the preparation of the manuscript is declared in the acknowledgments and/or contributors sections.

In an effort to avoid conflicts from sponsorship, *JAMA* requires at least one author who is independent of the funding source to verify that he or she "had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis" by including that exact phrase in the acknowledgments section. If the study was industry sponsored, an independent statistical analysis must be performed and the independence verified.¹⁹

To Whom Should the Policy Apply?

Disclosure policies should apply to all authors and should also be extended to peer reviewers and journal editors; editors include everyone involved in the peer-review and decision-making process about articles, thereby excluding copyeditors, managing editors, proofreaders, etc. This is the position of the International Committee of Medical Journal Editors (ICMJE), supported by the editors of *JAMA*, *New England Journal of Medicine*, *The Lancet*, and other prominent biomedical journals.²⁰ For editors and authors of review articles and editorials, a greater level of scrutiny and public disclosure is warranted because special circumstances may influence the selection of science that will be reviewed or published.

Journals may want to consider a policy that bars editors and authors of review articles from having any conflicts. The ICMJE policy states that disclosure is, "particularly important in connection with editorials and review articles, because bias can be more difficult to detect in those publications than in reports of original research."²¹

PLoS Medicine, a peer-reviewed online journal of the Public Library of Sciences (PLOS), has its editors update a statement on competing interests, which is posted online and is publicly accessible.²²

For authors, either each submitting author could be required to fill out a disclosure form, or one single form could be required from a senior author who takes responsibility for the others. Policies of the *New England Journal of Medicine* and *The Lancet* specify that review articles may be rejected if there is any competing interest on the part of any of the authors. In 1996, editors at the *New England Journal of Medicine* eliminated the right of authors with competing interests to write reviews after discovering that several prominent reviewers had not disclosed relevant conflicts.²³ However, in 2002, new editors for the journal rescinded the policy, feeling that it may disqualify highly qualified people from offering their opinions in the pages of the journal.²⁴ *Science*, *JAMA*, and *Environmental Health Perspectives* maintain the same standards for authors of review articles as they do for authors of original research.

Policies by *Environmental Science & Technology*, *Environmental Health Perspectives*, and *Nature* explicitly require disclosure by editors and peer reviewers. A similar policy would also be relevant for a journal such as *Toxicological Sciences*, the journal of the Society of Toxicology, because Bristol-Myers Squibb is a financial sponsor of the journal, the editor, and the editorial staff.²⁵

Enforcement

All workshop participants agreed that enforcing a policy is critical to making it effective. The participants also agreed that disclosure policies boil down to a mechanism in which disclosure will enable peer reviewers and other professionals in the same field to alert journal staff if authors fail to disclose appropriately.

If an author is found to have failed to disclose competing interests appropriately and further refuses to disclose in response to a request by the journal staff, punitive methods could include retraction of the article or banning the author from publishing in that journal for a specified length of time. *Environmental Health Perspectives* strengthened its policy in 2004 to allow a three-year ban for authors found to have willfully failed to disclose competing interests.

The journal editor could reject the paper at any stage for failure to disclose, and in cases where that failure appears to be deliberate or suspicious, the editor should consider referring the possible infraction to the senior author's institutional superior for further investigation.

Because the critical issue underlying disclosure is the reliability of the information being reported in a manuscript, workshop participants also suggested that journals could conduct audits in which authors of a randomly selected article are asked by the journal for a more detailed data report, potentially including submission of raw data.

CONCLUSION

Many of the most respected scientific and medical journals have instituted effective, practical disclosure policies. Although these policies may differ from journal to journal, they share certain elements that can be adapted to the specific needs of any journal. Given the importance of the scientific literature in guiding consumer and industrial health policy, it should be the goal of all journals to ensure integrity in the articles they publish. Strong disclosure policies are a critical tool for achieving this goal.

WORKSHOP PARTICIPANTS AND ADVISORY COMMITTEE

Note: Affiliations are included for identification purposes only and do not necessarily constitute an institutional endorsement of information contained in this report.

Thomas Babor
Associate Editor-in-Chief, *Addiction*

Susan M. Booker
Editor, *Environmental Health Perspectives*

Arthur Caplan
Emanuel & Robert Hart Professor of Bioethics
University of Pennsylvania

Britt Erickson
Associate Editor, *Chemical & Engineering News*
(Note: Dr. Erickson served as an advisory committee member but was unable to attend the workshop)

David Egilman
Editor, *International Journal of Occupational and Environmental Health*

Herman Gibb
President, Tetra Tech Sciences

Merrill Goozner
Director, Scientific Integrity Program, Center for Science in the Public Interest

Linda Greer
Director, Health Program, Natural Resources Defense Council
(Note: Dr. Greer served as a peer reviewer and advisor, but was unable to attend the workshop)

David Jorgensen
Publications Commissioner, American Meteorological Society

Sheldon Krinsky
Professor, Department of Urban and Environmental Policy & Planning
Tufts University

David Michaels
Head, Department of Environmental and Occupational Health
George Washington University

Rebecca Reindel
George Washington University
Consultant to the Natural Resources Defense Council

Jennifer Sass
Senior Scientist, Natural Resources Defense Council

Mark Seeley
Senior Vice President & General Counsel, Elsevier

Brian Selzer
Journal Production Manager, *American Journal of Public Health*

Paul D. Thacker
Investigator, United States Senate, Committee on Finance

Jeremy Theobald
Treasurer, Committee on Publication Ethics (COPE)
Executive Editor, *Emerging Health Threats Forum*
London, England

Hugh Tilson
Editor-in-Chief, *Environmental Health Perspectives*

Charles Trowbridge
Assistant Director, Editorial Office Operations, Publications Division,
American Chemical Society

ENDNOTES

- 1 Smith R, "Medical journals are an extension of the marketing arm of pharmaceutical companies," *PLoS Medicine* 2, no.5 (2005):e138. http://kurse.fh-regensburg.de/kurs_20/kursdateien/inko/2005-05-17PLoS SMITH.pdf
- 2 Ibid
- 3 Lexchin J., Bero L.A., Djulbegovic B., and Clark O., "Pharmaceutical industry sponsorship and research outcome and quality," *BMJ* 326 (2003), pp. 1167–1170.
- 4 Angell M., *The Truth about the Drug Companies: How They Deceive Us and What to Do about It* (New York: Random House Publishing Group, 2005).
- 5 Horton, R., "The dawn of McScience," *New York Review of Books* 51, no. 4 (2004), pp. 7–9. (This cites the original source, not the Smith essay.)
- 6 vom Saal F.S. and Hughes C., "An extensive new literature concerning low-dose effects of bisphenol A shows the need for a new risk assessment," *Environmental Health Perspectives* 113 (2005), pp.926–933.
- 7 Ong E.K. and Glantz S.A., "Constructing 'sound science' and 'good epidemiology': tobacco, lawyers, and public relations firms," *American Journal of Public Health* 91(2001), pp.1749–1757.
- 8 Michaels D., *Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health* (New York: Oxford University Press USA, 2008).
- 9 Markowitz G. and Rosner D., *Deceit and Denial: The Deadly Politics of Industrial Pollution* (Berkeley: University of California Press, 2002).
- 10 Hardell L., Walker M.J., Walhjalt B., Friedman L.S., and Richter E.D., "Secret ties to industry and conflicting interests in cancer research," *American Journal of Industrial Medicine* 50 (2007), pp. 227–233.

- 11 Sass J.B., “Credibility of scientists: conflict of interest and bias,” *Letter in Environmental Health Perspectives* 114 (2006), A147. www.ehponline.org/docs/2006/8749/letter.html
- 12 Michaels D., *Doubt Is Their Product: How Industry’s Assault on Science Threatens Your Health* (New York: Oxford University Press USA, 2008).
- 13 Krimsky S. and Rothenberg L.S., “Conflict of interest policies in science and medical journals: editorial practices and author disclosures,” *Science and Engineering Ethics* 7 (2001), pp. 205–218.
- 14 From *The Journal of the American Medical Association’s* “Instructions for Authors,” under “Conflicts of Interest and Financial Disclosures,” available at <http://jama.ama-assn.org/misc/ifora.dtl#ConflictsofInterestandFinancialDisclosures>
- 15 *Science* magazine’s “Conflict-of-Interest Disclosure,” available at <http://www.sciencemag.org/about/authors/prep/coi.dtl>
- 16 “Information for Authors,” *The Lancet*, available at <http://download.thelancet.com/flatcontentassets/authors/lancet-information-for-authors.pdf>
- 17 *Nature’s* policy on “competing financial interests,” available at http://www.nature.com/authors/editorial_policies/competing.html
- 18 “Information for Authors,” *The Lancet*, available at <http://download.thelancet.com/flatcontentassets/authors/lancet-information-for-authors.pdf>
- 19 From *The Journal of the American Medical Association’s* “Instructions for Authors,” available at <http://jama.ama-assn.org/misc/ifora.dtl#ConflictsofInterestandFinancialDisclosures>
- 20 International Committee of Medical Journal Editors (ICMJE), supported by the editors of *JAMA*, *New England Journal of Medicine*, *The Lancet*, and other prominent biomedical journals.
- 21 Ibid
- 22 From *PLoS Medicine*, “Competing interests of the PLoS Medicine Editors,” available at http://journals.plos.org/plosmedicine/editors_interests.php
- 23 Angell M. and Kassirer J.P., “Editorials and conflicts of interest,” *New England Journal of Medicine* 335 (1996), pp. 1055–1056.
- 24 Drazen J.M. and Curfman G.D., “Financial associations of authors,” *New England Journal of Medicine* 346 (2002), pp. 1901–1902.
- 25 According to the website of *Toxicological Sciences*, their editorial office is located at Bristol-Myers Squibb, Princeton, NJ; see <http://www.toxicology.org/ai/pub/journals.asp>