Conflict of Interest and Scientific Journals

Can you believe what you read?

Scientists financial interests can bias the papers and review articles that they write, studies suggests. But what can editors do to police the issues? Frank van Kolfschooten examines journal's policies on conflicts of interest.
Responsibility of Scientific & Medical Journals

Many scientific and medical journals have begun to address the conflicts of interest (COI) of authors, editors, and reviewers that have become endemic to science publishing.

“Journals have devolved into information laundering operations for the pharmaceutical industry.” *

“We found that conflicts of interest were rarely, if ever, published in clinical guideline reports funded by the government, universities or professional physician organizations.” *

Setting COI Policies

Increasingly, scientific and medical journals have come to recognize and acknowledge that contributing authors hold conflicts of interests with respect to the subject matter of the published study.

Medical journals have been the first to respond with requirements for transparency. Some journals have gone beyond disclosure and do not accept certain author contributions such as scientific reviews and editorials when the contributor holds a significant conflict of interest.

Among the leading organizations in setting COI policies is the International Committee of Medical Journal Editors (ICMJE), which makes recommendation to its dozen member journals and serves as a model for others.
Journals as Gatekeepers of COI Transparency

- How have journals responded to perceived or acknowledged conflicts of interest?
- What types of policies exist among journals?
- What is known about author compliance with such policies?
- Why is disclosure of financial interests important?
- Is disclosure sufficient to address ethical responsibility?
When did journals introduce COI policies?

In 1984 the *New England Journal of Medicine* requested that “all authors disclose to [the editor] any associations they had with businesses that could be affected by their work—including direct employment and consultancy, stock ownership, and patenting licensing arrangements.” *

The *Journal of the American Medical Association* introduced a conflict of interest policy soon after *NEJM*. By the 1990s other medical and science journals followed.

How many journals have COI Policies?

In a 2001 study, out of a potential pool of nearly 30,000 science and medical journals, the authors chose the top 1000 journals ranked in *Journal Citation Reports* in two categories: “times cited” and “impact factor.”

- This search resulted in 1396 distinct high impact science and biomedical journals.
- Using 1997 as a base year, we found 16% of the journals had COI policies. *

Survey of COI Policies in Medical Journals 1994-95

1,202 English-language journals in medical science and economics with circulation > 1,000 were chosen from Ulrich’s guide.

- Almost half (46%) of U.S. medical journals had written COI policies for authors.
- Most medical, biology and economic journals did not have written COI policies in 1995.

Rates of Disclosure of Journals with COI Policies

• 2001 study asked: What is the disclosure rate for journals with COI policies?

• Beginning with two sets of 1,000 journals from Journal Citation Reports, 181 peer reviewed journals with COI policies were found.

• Using 1997 as the test year, 61,134 articles were examined; only 327 (.5%) articles had anything to disclose.

• 66% of the journals comprising 58% of the articles published had no positive disclosures of authors’ personal financial interests for 1997.

E-Mailed on 12/22/03

Dennis J. Cotter
President
Medical Technology & Practice Patterns Institute, Inc.
4733 Bethesda Ave., Ste. 510
Bethesda, MD 20814

Mr. Cotter:
I have now heard back from a third reviewer of your EPO editorial, who also recommended that it be published.

As all three of the reviewers who recommended that your editorial be published were nephrologists (some rather prominent), I think that you are underestimating the underlying sentiments within the nephrology community.

Unfortunately, I have been overruled by our marketing department with regard to publishing the editorial.

As you accurately surmised, the publication of your editorial would, in fact, not be accepted in some quarters... and apparently went beyond what our marketing department is willing to accommodate.

Please know that I gave it my best shot, as I firmly believe that contrary points of view should always be provided a forum, especially in a medical environment, and especially after those points of view survive the peer review process.

I truly am sorry.

Sincerely,

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Study says authors are averse to declaring conflicts of interest

Jonathan Knight, San Francisco

Authors are ignoring journal policies that require them to state any conflict of interest over their papers, a new study suggests. But editors of leading journals disagree about whether this poses a real problem and, if it does, what to do about it.

The study, from Tufts University in Massachusetts, examined 61,134 articles that appeared in 1997 in 181 leading journals that had disclosure policies. The journals examined included Science, The Journal of the American Medical Association and Proceedings of the National Academy of Sciences. But Nature and Cell, for example, did not have disclosure policies, and so were excluded.

The researchers counted every occurrence of a positive disclosure, including honoraria, patents pending, stock holdings or other forms of personal or financial interest. The research appears in Science and Engineering Ethics (7, 205–218; 2001). Only a third of the journals surveyed contained papers carrying any disclosure. Of those, fewer than 1% of papers contained a disclosure.

A possible explanation is that few researchers had anything to disclose. But the study’s lead author, Sheldon Krimsky of Tufts’ Department of Urban and Environmental Policy, says this is unlikely. “What is the chance that in two-thirds of the journals there was no one with a patent, equity interest or honorarium?” he asks.

But some journal editors say that such information is of little value to readers. Keviri Davies, editor-in-chief of Cell Press, says editors usually consider that good science stands on its own merits. “It’s the quality of the research that counts,” he says.

Science’s editor-in-chief Donald Kennedy agrees. But the journal’s authors must provide information on potential conflicts of interest. These disclosures are reviewed by editors, but not given to external reviewers. “The peer reviewers’ job is to evaluate the science and not to be our ethicists,” he says. But Krimsky argues that complete
Study Says Clinical Guides Often Hide Ties of Doctors

BY SHERYL GAY STOLBERG
WASHINGTON, Feb. 5 — A survey of medical experts who write guidelines for treating conditions like heart disease, depression and diabetes has found that nearly 9 out of 10 have financial ties to the pharmaceutical industry, and the ties are almost never disclosed.

It has long been known that contact with the pharmaceutical industry can influence individual doctors' prescribing patterns and that financial support from drug manufacturers can affect the course of academic research.

But the survey, a relatively small study conducted by a team from the University of Toronto, is the first to document the extent to which the industry may influence so-called clinical practice guidelines. These voluntary guidelines, which are typically published in medical journals and endorsed by medical societies, are followed by countless doctors.

"These clinical protocols should not be seen by the public as unbiased," said Sheldon Krimsky, a health policy expert at Tufts University who has written extensively on financial conflicts of interest. "The fact that there is a veil of secrecy over most of these guidelines is bad for the community which is trying to ensure trust in the public.''

The survey, which this week's issue of the Journal of the American Medical Association reported, sought the opinions of 102 medical experts who participated in writing 44 sets of practice guidelines covering treatments for asthma, coronary artery disease, depression, diabetes, high cholesterol, pneumonia and other ailments.

Of the 102 who responded, roughly 9 out of 10 had some type of financial relationship with a drug manufacturer, including research funding and speaking, travel or consulting fees. About 8 out of 10 had financial ties to companies whose drugs were either considered or recommended in the guidelines they wrote.

Eleven of the 44 practice guidelines were underwritten by pharmaceutical companies and carried declarations stating so. But of the 44 guidelines, just one reported a potential conflict of interest.

"That's a problem," said Dr. David Blumenthal, a health policy expert at Harvard Medical School who has written about financial conflicts in the medical profession. "This is just emblematic of the extensive, often undisclosed relationships that exist between medical experts and pharmaceutical companies.

Financial conflicts of interest are the subject of intense debate in medicine. Pharmaceutical companies often underwrite the cost of medical conferences and hire prominent academic doctors to serve as speakers or to lead symposiums at which the companies' drugs are discussed.

Proposals to eliminate such payments have been adopted by some medical societies, but critics have complained that such financial relationships jeopardize the integrity of scientific research. This week, more than two dozen prominent scientists and doctors sent a letter to more than 200 scientific journals urging them to strengthen their requirements for disclosing conflicts of interest.

Among those who signed is Dr. Marcia Angell, the former editor of The New England Journal of Medicine. In an interview today, Dr. Angell said that disclosing financial ties to industry was the least doctors could do and added that in most cases, the ties should be simply severed.

"Most consulting arrangements are simply a way for researchers to make money and the industry to buy their good will," Dr. Angell said. "Researchers serve on advisory boards and speakers boards, and they travel around the world, ostensibly to educational programs. But really, they are just enriching themselves, and the drug companies retain influence over them to a remarkable extent.''

Others, including Dr. Allan S. Detsky, an author of the Toronto study, take a less stringent view, arguing that conflicts should be made public and that doctors should discuss them openly before writing guidelines.

"It's not possible to stamp this out," Dr. Detsky said. "The answer is to sensitize people to accept that it's a problem.''

Only 7 percent of the doctors in the Toronto study said they believed that their relationships with industry influenced their recommendations, although 19 percent said financial ties influenced the recommendations of their colleagues.

A spokesman for the Pharmaceutical Research and Manufacturers Association, an industry trade group, said today that the organization was not opposed to doctors' disclosing their ties with industry.

But the spokesman, Jeff Trehub, said drug companies did not want to see doctors with drug industry ties excluded from writing guidelines.

"Too many exclusions would mean not allowing some well-respected experts to work on these important guidelines," Mr. Trehub said.
Study of COI in Clinical Guidelines

- University of Toronto researchers surveyed 192 medical experts who participated in writing 44 sets of guidelines covering the treatment of asthma, coronary artery disease, depression, high cholesterol, and pneumonia.

- 100 respondents indicated that 9 out of 10 had some type of relationship with a drug manufacturer.

- About 6 out of 10 respondents had financial ties to companies whose drugs were either considered or recommended in the guidelines they wrote.

- Of the 44 guidelines, just 1 reported a potential COI.*

Journals that publish psychotropic drug studies

• The drug industry has been under the media lens in recent years on issues of drug pricing, withholding of data, and suppressing clinical trials.

• Journals that publish drug studies should be attentive to conflicts of interest.

• What percentage of journals that publish articles on psychotropic drugs have COI policies?
A survey of psychiatry journals that publish drug studies

• A search was done on Ulrich’s Periodicals Directory using the terms:
  • psychiatry and drugs;
  • psychopharmacology;
  • drugs and mental illness;
  • psychiatry and medication.

• Journals were selected according to:
  • active,
  • academic/scholarly,
  • English language,
  • refereed.

• 45 journals appeared: 19 had COI policies (42%) *

Non-Compliance in COI Policy:
An investigation of four leading journals

• Center for Science in the Public Interest examined the quality of COI disclosures in New England Journal of Medicine (NEJM), Journal of the American Medical Association (JAMA), Environmental Health Perspectives (EHP) and Toxicology and Applied Pharmacology (TAP).

• First and last authors were examined for 163 original articles published between Dec, 2003 to Feb, 2004 where there was no disclosure statement for either author.

• CSPI found 13 articles (8%) where relevant, COIs were not reported to readers: TAP 6.1%; JAMA 11.3%; EHP 8.6%; NEJM 4.8%.*

Simple Statements:

The journal requests information about the authors’ professional and financial affiliations that may be perceived to have biased the presentation.

- Perceived by whom?
  - By the author?
  - By a hypothetical reader?
  - By the editor?
Complex COI Statements

From *Arthritis and Rheumatism*:

“All authors (basic or clinical research, case reports, reviews, editorials or commentary) accepted for publication will be asked to sign a full disclosure form regarding possible conflicts of interest for that individual, any member of his or her immediate family, or any other individual or entity with whom the author has a significant relationship including: a) ownership or control of stock; b) service as a consultant or adviser to a company developing or distributing a product studied or discussed in the manuscript or a competitive product; c) existence of any patent/license/royalty arrangement for any material studied or discussed in the manuscript; d) any other possible financial benefit such as derived income from a diagnostic test or product described or discussed in the manuscript, or frequent legal work as an expert witness or consultant in the cases related to the content of the manuscript.”
Authors are usually asked to check the appropriate box, where they are given several choices:

- Have no proprietary interest
- Hold patent right
- Have a financial interest
- Are consultants, evaluators, or reviewers for (name location of company or agency)
- Own stock in (name/location of company)
- Receive direct funding, indirect donation or provision of equipment (name.location of company)
- Know of a financial interest by a spouse, minor child, blood relative, partner or business associate.
Disclosure of Financial Competing Interests in Randomized Controlled Trials

The authors performed a cross-sectional review of published randomized controlled trials in five high impact medical journals to assess their adherence to 1997 disclosure requirements.

Of 268 trials identified, 238 (89%) disclosed the source of study support.

Only 8 of the 100 industry sponsored studies reported the role of the study sponsor in the methods section as recommended by the uniform requirements of ICMJE. *

Clinical Guidelines and COI Disclosure

- A 2001 study examined 6 influential medical journals that published clinical guidelines from 1979-1999:
  - *Annals of Internal Medicine, British Medical Journal, NEJM JAMA, Pediatrics, and Lancet*
- Guidelines are not explicitly excluded from COI reporting by the 6 journals.
- 115 guidelines were found published when journal disclosure policies were in effect.
- Only 7 guidelines disclosed potential COIs.
- A disclosure rate of 6.1% for 115 guidelines that had COI policies in place.*

Why Journal COI Disclosure is Important

“When an investigator has a financial interest in or funding by a company with activities related to his or her research the research is

• Lower in quality
• More likely to favor the sponsor’s products
• Less likely to be published
• More likely to have delayed publication.” *


- Authors examined book reviews published between 1999-2001 (N=1,986) in 5 medical journals (*Annals, BMJ, JAMA, Lancet, NEJM*).
- 4 of the 5 journals published book reviews presenting a COI.
- Only 1 of the 30 book reviews included a disclosure statement.
- None of the journals in 2003 had written policies on book reviews.

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In September 2001 the ICMJE, responding to the growth of privately-sponsored clinical trials, issued new guidelines:

- Strongly oppose contractual agreements that deny investigators the right to examine the data independently.
- Sponsor consent should not be required for publication of results.
- Require authors to disclose details of their own and the sponsor’s role in the study.
- Do not review or publish articles based on studies that are conducted under conditions that allow the sponsor to have sole control of the data or to withhold publication.

International Committee of Medical Journal Editors

Authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data or analysis and interpretation of data; 2) drafting the article in revising it critically for important intellectual context; 3) final approval of published version.

All participants in the peer review and publication process must disclose all relationships that could be viewed as presenting a potential conflict of interest. Disclosure of these relationships is also important in connection with editorial review and articles.
Is Disclosure of COIs Enough?

- Should scientists with COIs be allowed to author reviews and commentaries?
- Should clinical investigators with COIs be allowed to participate in clinical trials?
- Should journal editors always publish COI disclosures?
- Should peer reviewers be given the COI disclosure information?
- Should editors reject some papers because of financial conflicts of interest?
Peer Reviewers and COI

- Should journal editors bring peer reviewers under the COI umbrella?
- Should peer reviewers have to disclose their financial interests related to the subject of their review article?
- *NEJM* claimed it was forced to lower the bar on writing editorials and review articles; they would permit reviews from someone who received up to but no more than $10,000 a year per company in speaking and consulting fees.
Disclosure at the Medical Journals

A troubling case of hidden financial conflicts has forced the publisher of some of the world’s most influential scientific journals to expand its editorial disclosure policies. Last week the Nature Publishing Group, part of Macmillan Publishers, announced that it would henceforth require the authors of review articles to disclose any financial ties to the products they evaluate. It was a welcome if belated step to close a loophole in the journals’ previous disclosure policies, which covered only research reports and not the review articles that evaluate progress in a particular field.

The new policy stems from a conflict of interest case last year involving a review article in Nature Neuroscience that evaluated experimental treatments for depression. As reported by Melody Petersen in The Times last month, the lead author of that article had significant financial stakes in three of the therapies he mentioned favorably. He held the patent on a lithium patch that he described as promising, owned 60,000 shares of stock in a small company whose drug he described as effective, and was a board member and recipient of stock options and consulting fees from another small company whose product he cited. Yet the journal had not asked him to disclose any conflicts of interest, and the scientist had not volunteered the information.

Requiring the authors of original research articles to disclose their financial conflicts has always made sense because industry financing is often associated with pro-industry findings. The case may be even stronger for requiring disclosure from the authors of review articles, which purport to weigh the value of one therapy against another and are, by their very nature, opinionated. Having come so far, the Nature journals may now want to extend their disclosure policy to cover letters as well, given their combative nature and potential influence.

Medical journals have made substantial efforts in recent years to reduce the potential for commercial bias. Full disclosure of financial ties is a powerful disinfectant, but when the conflicts loom too large, the journals should simply shop around for a less conflicted author.
Bowing to company pressure
Journal refuses to publish paper on cancer mortality

The paper in question analyzes mortality records for 32,000 IBM employees over 32 years. The records were submitted to lawyers as part of discovery in litigation. “Lawyers for IBM argue that the data used in the paper fall under a protective court order that prohibits their use for anything other than the Santa Clara lawsuit.” *

Conflict of Interest Policies in Science and Medical Journals: Editorial Practices and Author Disclosures

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Keywords: Conflict of Interests, Financial Disclosure, Scientists, Scientific Literature, Editors, Universities and Colleges, Industry and Education

ABSTRACT: This study examines the extent to which scientific and biomedical journals have adopted conflict of interest (COI) policies for authors, and whether the adoption and content of such policies leads to the publishing of authors’ financial interest disclosure statements by such journals. In particular, it reports the results of a survey of journal editors about their practices regarding COI disclosures. About 16 percent of 1396 highly ranked scientific and biomedical journals had COI policies in effect during 1997. Less than 1 percent of the articles published during that year in the journals with COI policies contained any disclosures of author personal financial interests while nearly 66 percent of the journals had zero disclosures of author personal financial interests. Nearly three fourths of journal editors surveyed usually publish author disclosure statements suggesting that low rates of personal financial disclosures are either a result of low rates of author financial interest in the subject matter of their publications or poor compliance by authors to the journals’ COI policies.

Nature Journal Asks Researchers To Disclose Financial Interests

By Geeta Anand
Staff Reporter of The Wall Street Journal

In response to the ever-increasing private funding of scientific research, the journal Nature plans to announce a new policy today asking researchers to describe any financial interests related to their studies.

Philip Campbell, editor of the international journal based in London, said the goal is to “help the public form judgments” about the research by making authors’ financial interests known. “We’re not saying that links with industry are bad at all,” said Mr. Campbell. “We’re just saying we need to make those links transparent so our readers are free to make their own judgments.”

The decision comes as prominent medical journals, including the New England Journal of Medicine, prepare to announce a new policy next month aimed at forcing drug companies that sponsor clinical trials to allow researchers involved to publish the results even if they aren’t favorable.

Mr. Campbell said Nature changed its policy in response to concern among researchers and others about “the possible undermining of the integrity of scientific research by increasing commercial links.” For many years, leading medical journals have insisted authors declare their financial interests as a prerequisite to publishing. These medical journals, read mainly by physicians prescribing drugs, publish the results of clinical trials. Nature, with its focus on basic science, may be paving the way for scientific journals to change their disclosure requirements. Jeffrey Drazen, editor of the New England Journal of Medicine, said, “It’s good to disclose to people the tensions at play in decision-making.”

Nature will, however, give authors an out not offered by the medical journals. Mr. Campbell said his disclosure form will offer authors the option of not disclosing their financial interests, such as stock in companies that stand to gain from publication or consulting fees from organizations with a stake in publication. Nature will still publish the article in question, noting the author’s refusal to make the disclosure.

The new policy will affect papers submitted after Oct. 1 and apply to Nature and seven monthly research journals specializing in areas such as genetics and neuroscience.
Few Journals Report Authors’ Conflicts of Interest, Study Finds

Very few scientific or biomedical journals report the financial interests of authors that relate to the research they are writing about. A study on disclosure policies has found.

This is so even for journals that have conflict-of-interest policies, the study shows, and for journals with policies calling for such conflicts to be reported.

“Something’s off,” said Sheldon Krimsky, a co-author of a report on the study, which examined the disclosures in more than 61,000 articles of 181 journals in 1997.

Although it is generally acknowledged that such financial interests are becoming more prevalent, disclosures were found in only 0.5 percent of the articles examined in the study.

Among the 181 journals, 119 published no disclosures, and an additional 37 published disclosures in no more than 1 percent of their articles. Only three journals published disclosures in more than 10 percent of their articles.

Of the 1,396 most frequently cited scientific and biomedical journals, the 181 in the study were the only ones that made their policies publicly available in 1997.

Because a majority of the 181 journals said that their policy was to publish financial interests disclosed to them, and because biomedical science is increasingly commercial, Mr. Krimsky and his co-author concluded that “poor compliance is the more likely explanation for the low disclosure rates in most journals.” His co-author is L. S. Rothenberg, a bioethicist at the University of California at Los Angeles. Mr. Krimsky is a professor of urban and environmental policy at Tufts University. Their report appears in the April issue of Science and Engineering Ethics, released last week.

Mr. Krimsky said many of the policies may themselves be the problem, because they “are not explicit enough.”

The study also provides information from a survey of journal editors on how they use the disclosures they receive. Twenty-four of 128 respondents said they had rejected manuscripts primarily because of an author’s potential conflict.

Only 47 of 132 editors said they request financial conflict-of-interest information from researchers they selected to review articles, but 77 out of 104 editors said they had asked editors and reviewers to disqualify themselves if they perceived a conflict of interest.  

—GOLDIE BLUMENSTyk
Medical Journal May Have Flouted Own Ethics 8 Times

Research: Drug reviews by New England Journal did not disclose authors' ties to firms. Editor concedes lapses.

By TERENCE MONMANEY
TIMES MEDICAL WRITER

The renowned New England Journal of Medicine—the world's top-ranked medical journal and a leading voice in biomedical ethics—has apparently violated its own ethics policy numerous times in the last three years, publishing articles by researchers with drug company ties and not disclosing the potential conflicts of interest.

In an analysis of 36 "Drug Therapy" review articles since 1997, The Times has identified eight articles by researchers with undisclosed financial links to drug companies that marketed treatments evaluated in the articles.

The interim editor in chief, Dr. Marcia Angell, said in an interview Wednesday that the journal's practices were at odds with its guidelines on financial conflicts of interest. "We're going to try to do the right thing and bring our practice into conformity with our policy."

"There was a problem with the ['Drug Therapy'] series. There was a misinterpretation of exactly what our policy was." She said the journal had not yet had time to check all the articles identified by The Times.

The Times' finding feeds into a larger social debate over the promotion of company-sponsored research done at academic medical centers, where the goals of seeking knowledge and earning profits may clash. And it highlights the expanding role that drug company funding and
Journal breaks from medical society over conflicts of interest

The *American Journal of Hypertension* and the American Society of Hypertension have severed their 16-year relationship. John H. Laragh, editor of the journal, according to the *Wall Street Journal*, claimed that “the society’s leaders were improperly influenced by financial ties to the pharmaceutical industry and becoming, in essence, marketers for drug companies, which pay them consulting and speaking fees.”