

**PROFESSION**

## Doctors cast skeptical eye on pharma-backed studies

Survey results demonstrate that drugmakers face an uphill climb in swaying physicians.

By **KEVIN B. O'REILLY**, amednews staff. Posted Oct. 8, 2012.

Physicians are deeply suspicious of industry-funded randomized clinical trials, even when they are of high methodological rigor, according to recently published findings.

The study, which appeared in the Sept. 20 issue of *The New England Journal of Medicine*, comes amid efforts by leading pharmaceutical companies to close what they see as a “credibility gap” faced by industry-sponsored research. The study’s authors and other experts argue that high-profile controversies such as misleading and selectively reported trial data related to Merck’s Vioxx (rofecoxib) and GlaxoSmithKline’s Avandia (rosiglitazone) have made physicians more doubtful of pharma-sponsored studies.

Researchers surveyed 269 board-certified internists about their reactions to hypothetical abstracts for a recently approved drug, asking them to assume that the studies were published in a high-impact medical journal. The rigor of the study abstracts varied, as did the funding source disclosed.

Physicians gave more credence to higher-quality studies that involved more patients, had longer follow-up times and were double-blinded. But across the board, they were more dubious about the study abstracts that included a disclosure of industry funding.

Doctors were nearly 30% less likely to have confidence in the results of an industry-funded trial than the same abstract presented with no funding disclosure. They were half as confident in pharma-sponsored results compared with those funded by the Dept. of Health and Human Services’ National Institutes of Health. Doctors exhibited a similar degree of skepticism when asked whether they would be willing to prescribe the drug studied, being 52% as likely to prescribe a medication based on a pharma-sponsored trial compared with a study funded by the NIH.

“What’s gone on in medical research in the last five or 10 years has led to a credibility problem,” said Aaron S. Kesselheim, MD, MPH, the study’s lead author. “Disclosure is an important step and a good step, but it seems like it’s not the perfect solution to concerns about the influence of financial relationships on science. We need to think about other safeguards that would allow physicians to be confident in high-quality results.”

Given doctors’ high degree of confidence in federally funded studies, more NIH-sponsored trials could assuage physicians’ doubts and drive evidence-based changes in clinical practice, said Dr. Kesselheim, assistant professor of medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women’s Hospital in Boston.

“The solution to all of this is much more transparency,” said Jerome P. Kassirer, MD, former editor-in-chief of *NEJM*. “The fact is that the pharmaceutical industry has lost the trust of physicians and this study shows it well.”

That doctors judge industry-funded studies more harshly than government-sponsored research should not come as a surprise, said Thomas P. Stossel, MD, director of the Translational Medicine Division, which is also at Brigham and Women’s Hospital.

Critics of pharmaceutical companies “are responsible for the MDs’ prejudices because of their relentless publication of articles demonizing industry,” said Dr. Stossel, co-founder of the Assn. of Clinical Researchers and Educators, a nonprofit that supports physician-industry collaboration.

In an April research letter published in *Nature Biotechnology*, Dr. Stossel and his colleagues analyzed more than 100 articles about physician-industry relationships published in top-tier medical journals from the early 1980s to 2008. They found that 68% of the articles assumed financial ties harm patient outcomes or the public trust, and that most of them did not present related evidence.

### Industry sees tarnished reputation

Whatever is driving pharma’s image problem, drugmakers appear to be taking the matter seriously. GSK, Merck and six other leading pharmaceutical companies have teamed up with medical journal editors as part of a project called the Medical Publishing Insights and Practices Initiative. In May, a panel of 23 company representatives and journal editors outlined 10 recommendations in *Mayo Clinic Proceedings* to “close the credibility gap.” These include making public all clinical results in a timely fashion, describing adverse event data in a clinically meaningful way and giving authors access to complete study data.

The *NEJM* findings demonstrate the importance of the peer-review process in ensuring that the trial results reported are valid, said Howard Bauchner, MD, editor-in-chief of *The Journal of the American Medical Association*. *JAMA* requires that an independent academic statistician review industry-sponsored trial data analysis before publication. Dr. Bauchner lauded

academic investigators who insist on analyzing the data themselves when conducting industry-funded research. He cautioned that the influence of an individual medical journal article on clinical practice is limited.

"I doubt most clinicians pick up a paper and start prescribing the drug tomorrow," Dr. Bauchner said. "I think any randomized clinical trial is just a piece of the puzzle, and I think people should be skeptical about all the data that they read regardless of the funding source."

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**ADDITIONAL INFORMATION:****10 ways to close pharma's credibility gap**

Physicians have good reason to be more skeptical of industry-funded studies due to high-profile examples of misleading disclosure of research data, experts say. To fix the problem, a panel of medical journal editors and pharmaceutical company representatives in May offered recommendations:

- Ensure that clinical studies and publications address clinically important questions.
- Make public all results, including negative ones, in a timely fashion while avoiding redundancy.
- Improve understanding and disclosure of authors' potential conflicts of interest.
- Educate authors on how to develop quality manuscripts and meet journal expectations.
- Improve disclosure of authorship contributions and writing assistance and continue education on best publication practices to end ghostwriting and guest authorship.
- Report adverse event data more transparently and in a more clinically meaningful manner.
- Provide access to more complete protocol information.
- Transparently report statistical methods used in analysis.
- Ensure that authors can access complete study data, that they know how to do so and that they can attest to this.
- Support the sharing of prior reviews from other journals.

Source: "Ten recommendations for closing the credibility gap in reporting industry-sponsored clinical research: a joint journal and pharmaceutical industry perspective," *Mayo Clinic Proceedings*, May ([www.ncbi.nlm.nih.gov/pubmed/22560521/](http://www.ncbi.nlm.nih.gov/pubmed/22560521/))

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"A randomized study of how physicians interpret research funding disclosures," *The New England Journal of Medicine*, Sept. 20 ([www.ncbi.nlm.nih.gov/pubmed/22992075/](http://www.ncbi.nlm.nih.gov/pubmed/22992075/))

"Bias in high-tier medical journals concerning physician-academic relationships with industry," *Nature Biotechnology*, April 10 ([www.ncbi.nlm.nih.gov/pubmed/22491278/](http://www.ncbi.nlm.nih.gov/pubmed/22491278/))

"Clinical Trial Data as a Public Good," *The Journal of the American Medical Association*, Sept. 5 ([jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2012.9661](http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2012.9661))

"Ten recommendations for closing the credibility gap in reporting industry-sponsored clinical research: a joint journal and pharmaceutical industry perspective," *Mayo Clinic Proceedings*, May ([www.ncbi.nlm.nih.gov/pubmed/22560521/](http://www.ncbi.nlm.nih.gov/pubmed/22560521/))

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