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Drugmakers pledge transparency to tackle credibility problem in journals

Stung by the Vioxx fiasco and other missteps, pharmaceutical companies are partnering with editors to improve the reporting of industry-funded clinical trials.

By KEVIN B. O'REILLY, amednews staff. *Posted May 21, 2012.*

Eight leading pharmaceutical companies have approved 10 recommendations aimed at improving transparency to address what they call a "credibility gap" that faces industry-funded clinical research.

"Some observers, including some journal editors and academic reviewers, maintain a persistent negative view of industry-sponsored studies," said an article in May's *Mayo Clinic Proceedings*, co-written by 11 drug industry representatives and medical journal editors.

Among other steps, the consensus article recommends that drugmakers and others should:

- Make public all clinical results — even negative findings — in a timely fashion.
- Disclose authors' potential conflicts of interest.
- Disclose who is making what writing contributions to article manuscripts.
- Describe adverse event data in a clinically meaningful way and report them in a standardized fashion.
- Provide complete information on trial protocols and statistical methods used in analyzing trial data.
- Give authors access to complete study data.

The recommendations grew out of a 2010 meeting of 23 medical journal editors and industry representatives as part of the Medical Publishing Insights and Practices Initiative, founded in 2008 by drugmakers and the International Society for Medical Publication Professionals.

There is good reason for suspicion of industry-funded research, say experts who point to examples such as Merck's selective reporting of cardiovascular data related to Vioxx (rofecoxib), which the company withdrew from the market in 2004 due to the increased heart attack risk linked to the anti-inflammatory drug.

Merck is one of the eight companies participating in the initiative, along with Amgen, AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Pfizer and Takeda. Editors at 65 biomedical journals worldwide also have taken part in the initiative.

Editors from *The Lancet*, the *Journal of Clinical Oncology* and *Annals of Internal Medicine* co-wrote the *Mayo Clinic Proceedings* article.

Ghostwriting is another problem that has plagued industry-sponsored studies, with uncredited company-funded medical writers framing the findings for marketing purposes. About 20% of articles published in high-impact medical journals between 1996 and 2008 included ghostwriters (people who do substantial work but are not credited) or honorary authors (writers who do little or nothing but are listed as authors to add prestige to the finished manuscript), according to an Oct. 25, 2011, study in *BMJ*.

Will transparency promise be kept?

"Private industry has been hurt by some bad apples," said Maja Zecevic, PhD, who co-wrote the *Mayo Clinic Proceedings* article and is North American senior editor at *The Lancet*. "We want to avoid bad things happening by being transparent from the start, instead of going back at the end when the publication is out and the drug is out."

Zecevic said she believes drugmakers involved in the initiative will follow through on the recommendations and have a strong financial incentive to improve how their clinical research is perceived. Longtime industry critics questioned the companies' commitment.

"The [recommendations] all seem fine," said Jerome P. Kassirer, MD, former editor-in-chief of *The New England Journal of Medicine* and author of the 2004 book *On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health*. "The question is whether the pharmaceutical companies will practice what they preach. They don't always do this, as is evident from the multiple multimillion-dollar suits we hear about, year after year."

The pledge toward greater transparency should be applauded, said Howard Bauchner, MD, editor-in-chief of *The Journal of the American Medical Association*. Dr. Bauchner was invited to a 2011 initiative meeting but declined to attend, as he was still settling into his position at *JAMA*. He said he is open to working with industry to improve the quality of trial-results reporting.

The *Mayo Clinic Proceedings* article criticizes as unfair a *JAMA* editorial policy adopted in 2005 that requires independent analysis of industry-sponsored trial data by an academic statistician before publishing results. Dr. Bauchner said he will address that and several other journal policies in an editorial to be published in the next few months. He said *JAMA* gives all submissions

a fair shake, no matter who supported the study.

"Our standards for reviewing papers are identical, regardless of who the funder is," Dr. Bauchner said. "We work very hard with authors, regardless of the funder, to ensure that reporting of clinical trials is accurate and valid."

ADDITIONAL INFORMATION:

10 ways to improve industry-funded clinical studies

A panel composed of pharmaceutical company representatives and medical journal editors in May published recommendations to close the "credibility gap" faced by industry-sponsored clinical research:

- Ensure that clinical studies and publications address clinically important questions.
- Make public all results, including negative or unfavorable 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 (**ncbi.nlm.nih.gov/pubmed/22560521/**).

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"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/**)

Medical Publishing Insights and Practices Initiative (**www.mpip-initiative.org/**)

"Honorary and ghost authorship in high impact biomedical journals: a cross sectional survey," *BMJ*, Oct. 25, 2011 (**www.ncbi.nlm.nih.gov/pubmed/22028479/**)

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