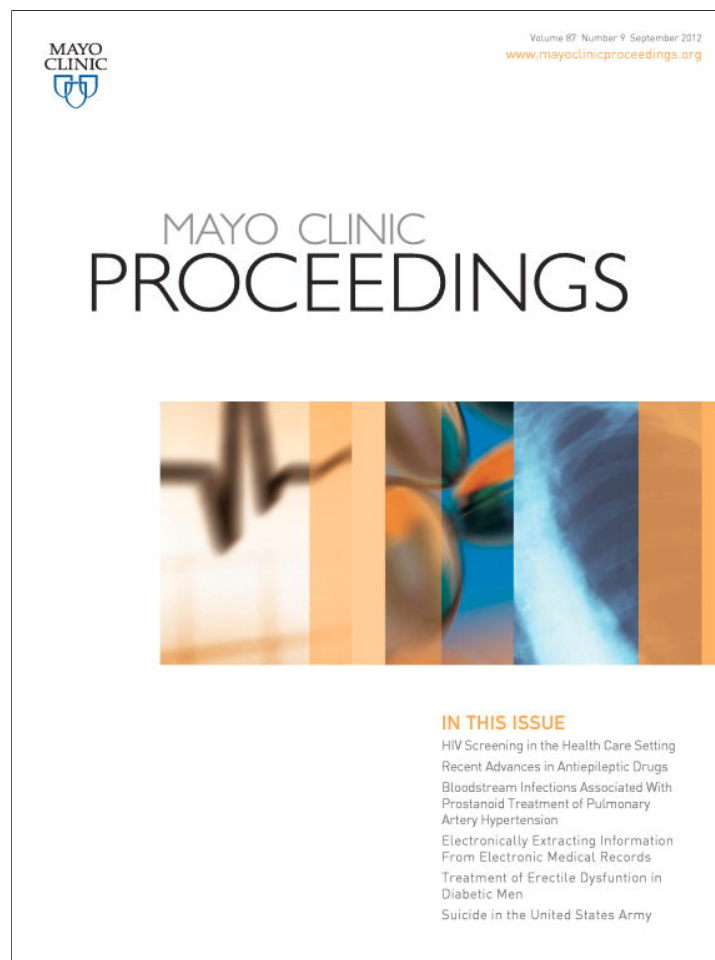


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Credibility of Industry-Sponsored Clinical Research: Hype or Hope?

To the Editor: Will the 10 recommendations developed by the pharmaceutical industry and the publishing representatives close the credibility gap in reporting industry-sponsored clinical research?¹ The guidance lacks targets and commitments. The recommendation on data disclosure does not even require companies to allow authors to have unrestricted access to all data. What's the timeline for the guideline's recommendations? What are the milestones? What are the concrete actions? Who will independently monitor the guidance implementation, which will require money and time?

Too many companies still exhibit poor records of ethics. GlaxoSmithKline recently agreed to pay \$3 billion to settle civil and criminal investigations into its sales practices for numerous drugs, its fourth such case since April 2008, surpassing the previous record of \$2.3 billion by Pfizer in 2009.² In addition, Daniel W. Coyne just disclosed the saga of Amgen's incomplete report on the early major trial of epoetin that misled the medical community about the anemia drug's risks and benefits, which helped make Amgen rich.³ Should physicians be tempted to blindly accept general statements from recidivists?

The guidance promoted by Mansi et al¹ is marked by a major conflict of interest. Publishers highly rely on publication of industry-supported trials, and thus these trials are associated with an increase in journal impact factors. Moreover, drug advertising and sales of reprints provide them with a substantial income.⁴

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Commenting on Ten Recommendations for Closing the Credibility Gap in Reporting Industry-Sponsored Clinical Research

To the Editor: Anna Freud coined the term "identification with the aggressor" to describe how victims sometimes ally themselves with their tormentors.¹ Reminiscent of such self-loathing behavior is a commentary published in the May issue of the *Proceedings* entitled "Ten Recommendations for Closing the Credibility Gap in Reporting Industry-Sponsored Clinical Research." Employees of 5 major pharmaceutical industry publication departments and officials representing medical publishing professional trade organizations to which such employees belong joined medical journal editors in authoring the piece. They billed the exercise a "joint journal and pharmaceutical industry perspective."²

The commentary fails because, instead of assessing the evidence of whether industry-sponsored research is less credible than nonsponsored research, it engages in a public relations exercise to try to repair the tattered image that industry bashers have created. For example, to alter a perceived mismatch, allegedly "shared by many," that industry-sponsored studies fail to meet the needs of the public and clinicians, the authors propose that "clinical studies and publications address clinically important questions." The authors fail to provide a plausible explanation for how wasting resources on trivial questions is widely recognized as advantageous to industry or how a journal's prestige is enhanced by publishing drivel. It urges greater "transparency" concerning protocol design, trial result presentation (including negative outcomes), and reporting

of analysis methods, disclosure of authors' ties to the research, elimination of "ghost-writing," assurance that every listed author can defend the study designs, and improvement of authors' writing and journal policy adherence skills.

However, the credibility gap or, even worse, the *appearance* of a credibility gap that the authors bid to close is based on their uncritical acceptance of industry-bashers' signature framing bias, namely, that industry-sponsored publications are laced with conflicts of interest (actual or potential). Promoters of this bias, cited without rebuttal in the commentary, have failed to provide a quantitative dimension to the problems to be addressed by the commentary's recommendations. Rather than acknowledge the real credibility gap between bona fide problems and the huge denominator of neutral or positive industry contributions to health care, they offer up unrepresentative "trouble stories" provided by politicians, unreliable media sources, and litigators. Some of the problems are speculative and stamped with the all-purpose conflict of interest epithet. Others are at least debatable. Some are fabricated. Concerns about perceptions and appearances should be addressed by a fact-based inquiry to determine their validity, not by a desultory project vainly hoping to alter the perceptions of industry critics who continually perceive corruption.

For example, the commentary's demand for "clinical importance" is a shallow indictment of so-called seeding trials, allegedly motivated by product marketing rather than science. However, all industry-sponsored trials ultimately have marketing in mind, and the trial outcome validity, not the trial motivation, is what matters for patient care. For journal editors, as they have done, to disavow peer-reviewed trials they have published when litigants claim the trials were commercially motivated is intellectually dishonest.³ In addition, the urban legend indictments of selective trial reporting ignore timely publication of economically devastating results, evidence that industry-sponsored trials are predominantly of high quality and that most research misconduct has no industry or professional writer association.⁴⁻⁶

Professional medical writers in and outside the medical products industry have an important role to play in the dis-