

Industry-Sponsored Research and Biomedical Publication

Moderator:

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Speakers:

Rick Ascroft
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Cary Gross
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New Haven, Connecticut

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Journal of the American Medical Association
San Francisco, California

Reporter:

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When industry conducts or sponsors clinical research whose results affect profits, an inherent conflict of interest exists. A pharmaceutical-company representative, a health-policy academic, and a journal editor offered their markedly different perspectives on the problems posed by such conflicts of interest and on recent pharmaceutical-industry initiatives to address some of them.

Rick Ascroft said he wanted to avoid creating a "hostile environment". The tension was broken by laughter when Drummond Rennie was overheard commenting, "Too late!" and we all relaxed and sat back to listen. Ascroft described the recent development of the Pharmaceutical Research and Manufacturers of America (PhRMA) Principles on Conduct of Clinical Trials

and Communication of Clinical Trial Results. His take-home message was that despite some abuses, most pharmaceutical companies do the right thing, although the mass-media portray a different picture. He reminded us that, as Churchill said, industry is "the strong horse that pulls the cart" and that all parties involved in research have an obligation to keep it on a straight path.

Cary Gross presented the academic medical-center perspective. His question was, "Can conflicts of interest be adequately managed by guidelines?" He acknowledged that the PhRMA principles' inclusion of investigator independence is of key importance. However, he noted with concern that industry is not offering investigators full access to study data. He also noted that the PhRMA principles specifically state that investigators with substantial competing interests (such as company equity or holding a patent) should not participate in clinical trials of their agents, and he asked why such an arrangement should be deemed acceptable for corporations. Groups, he noted, tend to behave with less moral restraint than individuals.

Rennie said that conflict of interest is inextricably mixed with sponsorship of clinical trials because of the financial incentives involved. As an illustration, he described the different results obtained by publicly funded and industry-sponsored studies. Although the study results themselves are not the editor's concern, he explained, the apparent bias raises questions about the validity of the reports and their effect on patient care. Rennie pulled no punches in describing how sponsors have buried undesirable results, bullied authors, blocked publication, lied, and halted trials inappropriately. Because the editors who are members of the International Committee of Medical Journal Editors (ICMJE), the "Vancouver group", believed that sponsors had too much control of the

data, writing, and publication, the ICMJE had revised its rules to strengthen the principal investigator's hand.

According to Rennie, the PhRMA principles were developed in response to well-publicized abuses, and they do address some of those. However, he noted, they fail to adequately cover the crucial issues of control over data and reporting, they are voluntary, they don't require disclosure of financial interests to patients, and they don't clearly call for publication of all findings. Furthermore, he said, they do not support trial registration, which is the only sure preventive of publication bias. He disagreed with the claim that it might compromise trade secrets.

Rennie's main point was that trust just isn't there. For example, only authors can and should take complete responsibility for a study report. However, authors have complained to him that they are denied access to all the raw data from industry-sponsored studies. Without such access, they are unable to critically analyze their own studies' conclusions and therefore are unable to take full responsibility. The PhRMA guidelines propose only that the investigator can "review relevant statistical tables, figures, and reports for the entire study at the sponsor's facilities, or other mutually agreeable location". Apparently, the principal investigator cannot even count on getting a copy of the summarized data to take home.

Despite the hidden and not-so-hidden sparring among the presenters, they all seemed to agree that sponsored clinical trials are a fact of life, that lack of trust among the participants is a serious barrier, and that all must find a way to work together with integrity. Important unresolved misunderstandings remain between journal editors and pharmaceutical companies. 🔥