◆ Research Sponsored by the Pharmaceutical Industry: What Journals Should Know and What They Think They Know That Isn't True

Speakers:
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This session began over a bottle of wine. Drummond Rennie, deputy editor of the *Journal of the American Medical Association (JAMA)*, gave the moderator of the session, Tom Lang, a bottle of wine to create the perception of a conflict of interest. According to Rennie, the perception of a conflict of interest is at the heart of the matter. Disclosure of all potential conflicts of interest allows readers to make an educated decision about the science being reported.

In September 2001, the International Committee of Medical Journal Editors (ICMJE) brought to public attention a problem in the medical publishing industry when it explained a new policy on revealing conflicts of interest for manuscripts submitted to biomedical publications. In an article published in *JAMA* and several other journals, the ICMJE suggested guidelines requiring all authors to disclose all financial interests that could be perceived as conflicts of interest and sponsors to disclose which party had control over the research. Many journals also require authors to sign a statement saying that they accept full responsibility for the conduct of clinical trials described in the publication, had full access to the data, and controlled the decision to publish the research.

Although the guidelines worry industry sponsors and contract research organizations, Rennie said the guidelines were created in response to a breakdown in trust because industry sponsors had compromised scientific integrity.

In part, the problem arises because of the need to get new discoveries into clinical practice faster. Industry sponsors are key to developing and conducting clinical trials necessary for US Food and Drug Administration (FDA) approval. The result can be conflicts of interest not found when academics are free of commercial sponsorship, which can lead to interference by business interests. Rennie said that "universities have total freedom to publish their findings and have an obligation to do so."

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Laurence Hirsch, vice president for medical communications at Merck Research Laboratories, agreed that business concerns have priority, but not the highest one. Merck's mission is "to provide society with products and services to improve the quality of life and satisfy customer needs, to provide employees with meaningful work and professional growth and development, and to provide investors with a superior rate of return." He went on to say, "We do not view this as causing an unworkable conflict of interest, because our studies put the patient first."

Pharmaceutical companies and other industry sponsors have been accused of delaying and at times burying the results of research, particularly when they are negative. Hirsch stated that Merck is selective in implementing clinical trials. One of the reasons that published results from Merck research could appear to be "biased" is that the company runs well-designed studies with a high likelihood of success. According to Hirsch, Merck is committed to the publication of all medically important results regardless of trial outcome.

Jim Sergi, president of ProEd Communications Inc, an outsourcing agency that helps to write reports of research studies for publication, said that only 10 of 200 manuscripts produced by his group were not accepted for publication, and eight of those had negative results. According to Rennie, when *JAMA* publication rates were reviewed, editors found no bias against negative studies, but in general, although not at *JAMA*, they do tend to take longer to get published.

Rennie said many researchers have complained that industry sponsors do not grant them full access to data. Sergi said that to overcome the ICMJE concerns ProEd provides all authors access to the full dataset. Hirsch said all investigators have their own patients' data, but the full study database is maintained and analyzed by the company. Datasets are not made available except to FDA or other regulatory agencies, but all authors are provided with relevant statistical tables, figures, and reports for a manuscript, and any investigator may inspect the database. Merck sends the study protocol and plan for data analysis to any journal editor if this information is requested.