

◆ Developing Publication Guidelines for the Pharmaceutical Industry

Follow-up on the “Common Aims/Different Languages” Retreat

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The November 1998 CBE retreat “Common Aims/Different Languages” achieved great success in initiating discussion among people in the pharmaceutical industry, academe, and biomedical journals (CBE Views 22:41-2, 1999). Concerns and misunderstandings were identified, and the benefits of developing guidelines setting out industrywide standards for publications became clear. Although existing guidelines such as those of the International Committee of Medical Journal Editors (ICMJE) and the Consolidated Standards of Reporting Trials (CONSORT) group are helpful, participants agreed that people working in industry would benefit from elaboration or guidance on topics that are not covered and that those outside the industry would appreciate greater transparency. A group of us from the pharmaceutical industry who attended the retreat have therefore started to draft guidelines on peer-reviewed publications arising from industry-sponsored research.

The first stage has been to discuss a draft. The draft was refined by burning some midnight oil during the CBE annual meeting in Montreal while the rest of you were enjoying the banquet. We have also been discussing the guidelines in our companies and identifying routes for obtaining approval. Our next step will be to seek endorsement from as many pharmaceutical companies as possible; this process will probably take several months,

as anyone who has had dealings with huge multinational organizations will understand. We plan to set a deadline for endorsement of the guidelines and then publish the document with a list of the companies that “signed up”. We shall be looking to journal editors for support in publicizing this activity and publishing the resulting document.

The current draft guidelines cover relations between companies and external investigators, issues of duplicate or redundant publication, suggestions for the use of study identifiers (such as protocol numbers), authorship policies, and the role of professional medical writers. Wherever possible, they incorporate ICMJE and CONSORT guidelines and are designed to be used alongside them.

For many companies, the concept of a publication policy is new, although they already work within regulations that affect publication activities (for example, US Food and Drug Administration and Association of the British Pharmaceutical Industry codes), and many have standard operating procedures for some aspects of the publication process. We often speak of “the pharmaceutical industry” as though it were a uniform monolith, but our discussions have revealed the diversity of ways in which companies organize publication functions. This makes the discussions a fascinating learning exercise for the participants. Differences in organizational structure will probably affect mechanisms for approving and implementing the guidelines, but we believe that there is sufficient common ground to agree on standards and policies that are applicable to most major companies.

Our aim in creating the guidelines is to ensure that publications arising from pharmaceutical-industry-sponsored research are produced responsibly and ethically. We also hope that the process of developing the guidelines will improve relations between companies, editors, academics, and investigators. One of the purposes of the November retreat was for each constituency to define “the view from here”, and we hope that the first set of guidelines will further this process and increase understanding of the arcane ways of the pharmaceutical industry. Once the initial guidelines have been widely accepted, we hope that they can be developed further to encourage increasingly high standards for industry-sponsored publications. However, we want first to discuss them with as many companies as possible and to get endorsement from many of the major players. We know that some companies will not yet feel able to endorse the guidelines, but we hope to educate companies as to their usefulness.

As noted, our next step is to seek endorsement from major pharmaceutical companies; for example, those involved in the November retreat included Glaxo Wellcome, Merck, Astra Zeneca, and Eli Lilly. We hope eventually to include smaller firms and service companies such as contract research organizations and communication agencies that handle publications. We also hope to work with such groups as the European Association of Science Editors, the American and European Medical Writers Associations, and, of course, CBE, whose retreat started the whole thing off. ■