# *Raising the Standard of Pharmaceutical Publication Practice*

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**Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies. Curr Med Res Opin 2003;19:149-54.**

Journal editors have been quick to highlight unacceptable publication practices in drug companies, but until recently no guidelines were aimed specifically at raising the standard of industry-sponsored publications.

A meeting in 1998, organized by Leni Grossman (then at Merck) under the auspices of CBE (as it was then), was the starting point for guidelines published in the middle of 2003. The meeting brought together medical-journal editors, independent clinician investigators, and drug-company employees. Listening to the discussion, those of us in the pharmaceutical industry concluded that there was a need for guidelines to supplement those of the International Committee of Medical Journal Editors (ICMJE) and CONSORT—specifically, to assist people preparing publications within industry.

After discussion with several companies and informal consultations with editors and clinicians, members of the GPP Working Group (comprising three CSE members—Liz Wager, Betts Field, and Leni Grossman) have now published "Good Publication Practice [GPP] for Pharmaceutical Companies". Its aim is to encourage responsible reporting of clinical trials and to reduce problems of publication bias and inappropriate sponsor involvement.

Publication bias may occur when unfavorable findings are not published or when there is deliberate multiple publication of favorable results. Such bias distorts the literature and skews the outcomes of meta-analyses. The GPP guidelines aim to prevent publication bias by encouraging companies to publish results of all clinical trials and by recommending the use of trial identifiers (such as protocol or trial register numbers).

Companies have rightly been criticized for nonpublication, but they have sometimes also been censured for using professional medical writers. We accept that companies have sometimes sought too much control and should never veto publications. However, many of us in the industry believe that we have a legitimate role in getting trials published responsibly. Professional writers can raise the quality of reporting and can accelerate publication. The GPP guidelines therefore provide recommendations for medical writers to ensure that their involvement is appropriate and acknowledged.

Some of the problems that occur with industry-sponsored publications are caused by ignorance of the rules and conventions. Although experienced writers are familiar with the ICMJE and CONSORT statements, we often come across colleagues and investigators who are not. The GPP guidelines therefore emphasize relevant recommendations about redundant publication, authorship, and related issues that might present problems.

The GPP guidelines were presented in 2003 at the CSE meeting in Pittsburgh and the European Association of Science Editors meeting in Bath. We have been encouraged by support from many editors and hope that some might consider including a link to our Web site (*www.gpp-guidelines.org*) in their journals' instructions for contributors. Pharmaceutical companies have been slower to take up the guidelines, but we are encouraged that six have publicly endorsed them so far, and we know of several others that have used GPP as a basis for their internal policies. Several contract research organizations and specialist communication companies have also agreed to recommend GPP to their customers.

The guidelines are available from the publishers of *Current Medical Research & Opinion* via their Web site either as a PDF or as a paper reprint. They are also available at *www.gpp-guidelines.org*. We recognize that the best guidelines result from an iterative process, and we hope eventually to hold another three-way meeting to review GPP. In the meantime, we believe that GPP represents a step toward raising the standard of industry-sponsored publication practices and encouraging the responsible reporting of clinical trials.