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Credible Lit

by Wendy Balter and Marsha Scott

Author name recognition gets trials noticed in the literature, so big names have always been desirable. Not so many years ago, companies would first conduct clinical studies, and then seek top opinion leaders in the field as authors—whether they were investigators or not. In fact, on many occasions, journal articles were already written before the first author was approached.

In 2005, this issue came to light when Georgetown University School of Medicine professor Adriane Fugh-Berman, MD, was approached with a draft of a review article. She turned it down, and wound up as a reviewer for the article, which was submitted under another author's name. She subsequently wrote an opinion piece for the *Journal of General Internal Medicine* on publishing practices in the pharmaceutical industry.

Now, all reputable journals have stringent requirements, similar to those of the International Committee of Medical Journal Editors (ICMJE), to eliminate "guest authors" from medical literature. Authors must have a pivotal role in the design of the trial, and acquisition, analysis, and/or interpretation of data; they must have intellectual control of the manuscript, and sign off on the final version.

Review article development is moving in the same direction, with the most forward-thinking companies developing internal guidelines that leave content development entirely to the author. While the use of professional writers is decried by some, most editors prefer to review a well-written manuscript and approve the use of professional writers under the author's control; consequently, the medical publishing industry is moving toward acknowledgement of all contributors to an article, to eliminate ghost writing.

Another development is the requirement for clinical trial registration and posting of the results. PhRMA, the International Federation of Pharmaceutical Manufacturers and Associations, the European Federation of Pharmaceutical Industries and Associations, and the Japanese Pharmaceutical Manufacturers Association issued a joint statement in 2005 requiring online registration of clinical trials and posting of results within one year of first approval. The journals that follow the ICMJE guidelines (over 600) actually require online trial registration at the time of first patient enrollment in order for the eventual manuscript to qualify for acceptance. These new guidelines need to be factored into a publication plan to ensure that the data is interpreted by the investigators, not individuals dredging online databases.

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The trend toward more rigorously developed medical literature is one that can help re-establish the trust among the pharmaceutical industry, publishers, and the medical community—to ensure that the peer-reviewed literature retains the respect that it has enjoyed in the past.

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