Of bias, babies, and bathwater

IN LIGHT OF RECENT CONTROVERSY about potential conflict of interest on the part of clinical investigators who author reviews about drugs they have studied, an article in this issue of the *Journal* warrants discussion.[1] Three authors are researchers for Eli Lilly and Company, which manufactures raloxifene, and another received a research grant from the manufacturer. These associations are clearly noted on the first page of the article and were disclosed by the authors when the paper was submitted. Some medical journal editors believe these and other types of associations should disqualify the authors from publishing review articles or editorials on the topic.[2–4] Their goal is to deflect any possibility of overt or hidden bias being manifested in reviews and editorials.

FUNDING OF NEW RESEARCH

Federal money is not generally available for the development of new drugs and devices. Clinical research on new drugs is largely funded by pharmaceutical manufacturers. Data from clinical trials are generally not published until the FDA approval process is completed and the drug is already on the market. Even then, not all the data are published.

The result is that, almost invariably, those with the best qualifications to educate us about a drug when it first becomes available for general use are the same investigators who were involved in the clinical trials or who have discussed the drug in a consultative role for the manufacturer. It is important to acknowledge dual interests, but if we eliminate these experts as review or editorial authors, are we tossing out the baby with the bathwater?

The period when a drug is newly available is the time when clinicians are in greatest need of perspective born of experience, as well as the raw facts from published and unpublished original research. These voices of experience, however, would almost never meet a standard that required total lack of any relationship with the manufacturer. If we want timely and authoritative reviews about new drugs and devices, we need to take a more common-sense approach.

NO AUTHOR IS UNBIASED

The fact is that nobody is totally unbiased in all possible respects, regardless of financial ties.[5] The responsibility of a medical journal, in part, is to make sure that relevant relationships are not concealed, so that readers can draw their own conclusions about validity. We agree with the International Committee of Medical Journal Editors' statement[4] that "...authors are responsible for recognizing and disclosing financial and other conflicts of interest that might bias their work... (and) should acknowledge in the manuscript all financial support for the work and other financial or personal connections to the work."

We strive to have disinterested authors review treatment options, but when an important new treatment comes on the scene, we try to find the most knowledgeable authors to write about it, and to clearly disclose any conflict. Knowledge regarding the clinical pharmacology and results from clinical trials best comes from those who best know the drug. How an individual physician uses that drug in practice is often a decision of preference, or style, and it is in this arena that bias must be most carefully searched for.

Rigorous peer review helps ensure that articles are evenhanded. Our policy is to alert reviewers of any author-disclosed potential for conflict of interest, to obtain more than the usual number of reviews in these instances, and to have full editorial review by senior editorial staff. We describe, on the first page of published articles, any conflicts of interest that, in our judgment, readers should know about.

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