Medical Infomercials

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Recently I've become aware of the increasing use of academic reports to promote sales in the form of infomercials published as research. This isn't a new development, but seems to have become more common. Their frequency is nearing that red line at which "something must be done." Drug companies must do research and must publish their results. Obviously, a drug needs to be proven both safe and effective before it can be approved by the Food and Drug Administration (FDA), and its effects need to be understood by those of us who may prescribe it. In the best of all worlds, we'd also like to see a new intervention compared to old ones, but that's a rare event, since the risk of a new, more expensive drug being found to not be better than an old generic would be a killer event. One can't put Humpty Dumpty back together again.

Most of us, when we consider drug studies, think about the clinical trials that led to FDA approval, or the basic research studies that preceded the clinical trials. However, new drugs are often the subject of "real-life" reports. "Real-life studies" are to be distinguished from research protocol studies. Although there has been much made of "evidence-based medicine," there really aren't appropriate evidence bases for most medical decisions. Data for most studies have stringent inclusion and exclusion criteria which "real-life" patients often don't meet. A "real" patient is 83 and the studies showing drug efficacy excluded patients over 80. The "real-life" patient takes an anti-platelet drug, which was prohibited in a study of anticoagulants. And on and on.

These biased studies are usually sponsored in some way by the drug companies. In some they hire a professional writer, and have a group of known "key opinion leaders," or, "KOLs," as they are known in the trade, paid to meet at a conference, who then later read the manuscript, contribute a critique, and are then considered co-authors.

There are good reasons for these types of studies. I have published retrospective studies of medications used in Parkinson's disease in my own patients. How effective was the drug? How well tolerated was it? I may do this because I have found the drug to be more or less effective, worse or better tolerated than commonly thought, or more flexible in its use than approved by the FDA, which must adhere strictly to the experimental protocol. If a drug was tested only on people under age 65, it can be recommended only for those people, but an individual doctor, or clinic, can report on its findings in people of all ages. Some drug companies will fund such a venture, but most of these studies are not subsidized. I do these studies because I think the contribution may help guide treatment decisions, and, like most academics, I like to see my name in print. I do not do this for money. But some of these studies *are* funded by drug companies, and therein lies the potential for bias. Please note the word, potential. Not all such studies are biased.

I recently reviewed a handful of papers showing that a particular drug, still with patent protection, has a better safety profile than its competitor drug. The methodology was quite reasonable, but, like most methodologies, subject to question. One can usually quibble as to how to categorize responses as mild, moderate or severe, or what is "clinically meaningful," or what constitutes a positive response, or what scale to use to use when 10 different ones to measure the same thing are available. These are unavoidable issues for which there will be differences of opinion. However, a good paper will specifically point out the potential drawbacks of a study, such as the limited study population, the number of subjects being less than would be ideal, the age variation, the concomitant disease prevalence, and so on. However, the papers I thought biased only mentioned the possible flaws in reports

that showed the drug in a less positive light. The supportive studies were not criticized.

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On the other hand, I recently was asked to review another industry-sponsored study that concluded that the study drug was not superior to the comparator generics. I was very happy to see an industry-sponsored study not endorse its drug, although disappointed that the drug wasn't better. The positive aspect was that patients could save money by buying the generic. I don't know how often this occurs. I do not think that companies practice a "catch-and-kill" ethos that pulp newspapers do, but companies try to shy away from explorations that will not likely show their product in a light that will help them sell a product. They favor the much less expensive review of large databases or the personal experience of a physician who endorses their product. I have no idea if they do exploratory forays into the data to get a good idea of the answer before they ask the question. My own motto has been, "never do a drug study that you don't know the result."

Choosing peer reviewers who can recognize bias and maintain an absolute policy of rejecting biased reporting is the best approach to curbing this problem. As far as I'm aware, no article I've recommended rejection due to bias has been accepted by the journal I've reviewed for. The authors will have received an anonymous critique from this peer reviewer recommending that after they revise their paper to submit elsewhere, they have an unbiased reader review their paper as they are apparently unable to recognize their own bias. I am hopeful that each of the authors will have learned a lesson, as an accusation of bias is as scorching a criticism as most researchers ever will get. I am optimistic that such rejections will chasten them forever. ❖

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