



Commentaries

Biased Articles

The *New York Times* recently recounted yet another scandal involving doctors and drug companies. Three prominent psychiatrists, truly “key opinion leaders” in their fields, participated in NIH-funded trials of commercial drugs, ardently advocated reassessments of traditional diagnoses and treatments, even made public documentaries on diagnostic criteria for children with potential psychiatric disorders and gave public talks - without revealing their financial ties to the drug industry. When challenged, the trio made woefully inaccurate responses. We are talking about flagrant disregard in some cases, arguably flagrant in others. This particular column, however, was about articles written by professional writers employed by the drug companies.

Every time I read about a pharmaceutical industry-associated “black eye” for doctors, I assess my own record. The only way to be “squeaky clean” is to avoid contact with industry. I am not so clean. I don’t think it’s possible to be such, even if so inclined, in the area of clinical research in movement disorders, but I’m sure readers will quibble. I started listing my drug company associations at the end of each column last year, quite belatedly I think; but, on the other hand, no one ever asked during the preceding decade or I would have awakened then.

The *New York Times* article concerns medical articles funded by industry, which seem to fall into a few categories. One is the article written by a ghost writer who gives the paper to the purported lead-writer who then edits it, or accepts it, puts his name as the author, possibly gets paid, although each paper published is an advancement in the academic race so that money may not be the only reimbursement. Other authors may or may not be included, although they may do little but read (or not) the manuscript. These are usually write-ups of multi-center studies and are probably accurate although one is never sure if the authors actually saw the data. It is considered “bad form” in academic medical circles to put your name, at least as first author, on a paper you didn’t write. On the Brown main campus it would be a firing offense.

An even more grievous sin was the report of a company writing an opinion piece extolling the company’s drug allegedly written by a famous cardiologist. Most likely she agreed with the opinions. Many of us actually do prefer one drug over another for a variety of reasons, even when there’s no evidence to base this choice on, and feel that one particular drug works better than its competitors. She may have felt that the article would have looked the same whether she wrote it or not. She should, at least, have said that she got paid by the company to write the piece, as well as give talks for them.

So, here I am, in the middle of a controversy involving a manuscript reporting a multi-center trial of a drug in a study I helped to design. I’m a paid consultant to the company, by the way. Many months after the study ended, the results presented at meetings (all abstracts approved by others plus me, and accurate), I received a manuscript written by Dr X and me according to the title page. I asked if Dr. X had written it, and the answer was no. I hadn’t seen it before either. I suggested that the real authors be included as authors and that I’d remain as the last author if I contributed to the manuscript. The paper incidentally was quite good. It was a very honest portrayal of the study results, with the good results presented along with the bad results, the uncertain efficacy of a drug in a study targeted at testing safety.

Then Dr X got hold of the manuscript and decided that these results were spectacular proof of his pet theory on neuropharmacology that he’s been trying to establish for several decades. Unfortunately for all of us, Dr X, world famous in his area, was accurately described by a colleague, as being too difficult to debate with because, “I can’t yell that loud.” And so it was. First of all, the statistics were incorrect, “Everyone knows the two-tailed t-test should have been one-tailed, which would have shown statistical significance in a major outcome that had been insignificant.” Of course one can only use one-tailed tests in a treatment that could not possibly have any negative outcome, whereas our drug had never been

tested in humans. The idea that the experimental drug could possibly have a negative effect floored him. How could we be so dense? So we rewrote his version of the paper, making it more even-handed, and he rewrote it, again, preparing a claim for the Nobel prize. Revised drafts went back and forth, biased, less biased.

“Dr X, the reviewers are going to see this as biased. I see it as biased. The company sees it as biased. It needs to be more even-handed.”

“Let’s submit to the *New England Journal* and see what the reviewers say.”

At this point the manuscript is still evolving. Dr X is a major consultant to this and other drug companies. I am a minor consultant, easily replaced. The company agrees with me, but will have great trouble disengaging from Dr X because they own the data but his life’s purpose lies in the study results. I suggested submitting the paper without my name, since I cannot sign on to its conclusions and biased statistical assessments in its current iteration. I can’t imagine any journal publishing it so I’m not worried about making a public fuss.

What attracted me to the topic, however, was the difference in motivations for biased articles. The drug company wants a larger market share, meaning money; and an article at this time is of no commercial value. The bias here was the enormous investment Dr X had in positive results. Anyone can make or steal money, but not everyone can take claim for revolutionary advances in medical understanding. The problem, of course, is in actually making the advance, not the claim.

— JOSEPH H. FRIEDMAN, MD

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Addendum

Since this was written, a formulation of the manuscript was reached that seemed to be an accurate reflection of the results, suggesting but not claiming a potentially revolutionary advance.