

# Commercial conflict of interest and medical publication: What should the practising physician do about it?

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I read with interest the comment by Mark Wilson (1), which deals with possible conflict of interest (Col) affecting publications in academic medical journals. This comment has specifically targeted the *New England Journal of Medicine (NEJM)* and its editor-in-chief Jeffrey Drazen on the "Vioxx scandal" which broke 15 years ago. Wilson's comment seems to be in response to a blog by Natarajan on Col in medical publications (2). In the blog Natarajan writes of commercial Col biasing publication of clinical trials and cites, among other examples, a publication in the *NEJM* on trials of voriconazole.

The VIGOR trial on the gastrointestinal effects of a selective non-steroidal anti-inflammatory drug (NSAID) rofecoxib (Vioxx) versus naproxen in patients with rheumatoid arthritis was published by the *NEJM* in 2000 (3). It reported superior gastrointestinal safety of rofecoxib. Later, it transpired that the article had not reported all the cardiovascular events that occurred in the trial. There was a higher incidence of myocardial infarction in the rofecoxib arm. Subsequently, the drug was withdrawn from the market. Wilson analyses this controversy in detail, quoting from the press and from internal memos on the role of the *NEJM* and also of the US Food and Drug Administration, and concludes that there was an attempt to hush up this effect due to commercial reasons and Col.

As a practising clinician and clinical researcher, although a regular reader of the *NEJM*, I am not privy to the rarefied world of board room financial deals between the pharmaceutical industry and academic journals. I cannot comment on the veracity of Wilson's conclusions but it seems not unlikely that some Col does occur and may affect what we as physicians read. How does this impact the practising physician in India? The examples given by Wilson refer to journals published in the USA and UK (*British Medical Journal* and *Lancet*). There is little information on the situation in India. Col probably exists in India as most medical journals carry advertisements from the pharmaceutical industry. Indeed, they would not be viable in the absence of such advertisements, which permit them to be distributed free to all members of their respective associations who pay a nominal fee. As an example, the *Journal of the Association of Physicians of India (JAPI)* regularly publishes

supplements or reviews on topics in issues which also carry advertisements from the companies producing the very product discussed in the supplement/review. A recent example is a review on azilsartan suggesting that it is superior to other angiotensin receptor blockers (4) in an issue that carries on its back cover a full page advertisement from the manufacturers of this very product. Will such practice not affect the content of the review? Professional associations are themselves not free of suspicion. While individual physicians are prohibited from advertising, the Indian Medical Association (IMA) has endorsed fruit juice and cereals produced by Pepsico (for a fee of Rs 1.56 crore) (5) besides endorsing water purifiers, soaps and toothpaste (6). In the USA, the American Association of Family Practice (AAFP) received funds from the Coca Cola Company for obesity research. Studies have shown that sugary soft drinks such as made by Coca Cola are important contributors to obesity. This arrangement was stopped six years later in 2009 under public protest (7,8).

I wonder how relevant this issue is in India where so many physicians "stay up-to-date" by listening to the hard sell of medical representatives, reading the literature provided by pharmaceutical companies, and attending sponsored "CMEs" over dinners and cocktails. Could there be any doubt that such "educational" activity is biased? The question is how should busy practising physicians in India get the required information? Traditionally, textbooks have been the main repository of knowledge, and are probably free from major Col. But in the present era of rapid change and information overload, textbooks may be insufficient to deal with current practice and changing guidelines. The more adventurous physicians will read journals and the internet. Most of us believe that whatever is published in standard journals is reliable and genuine. We need to remember that even "genuine" publications may have errors due to inadequate design, sample size, follow-up, or misinterpretation of data. Despite a stringent review and editorial process, invalid studies may still be published and do not necessarily indicate that the journal concerned is tainted with Col. A single article rarely should be the basis for change of practice. Before physicians change their practice it would be wise to wait for a body of evidence to develop and analytical reviews to be done. A safe way would be to wait for updated guidelines to be developed by learned societies. Such guidelines are or should be prepared by a group of experts from a detailed and transparent review of clinical trials and meta-analyses. Is such a process devoid of Col? Probably more so than individual publications although controversies may arise on how that group has interpreted the literature – recent examples are the 2014 8th Joint National Committee (JNC 8) Guidelines on hypertension (9) and 2013

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American College of Cardiology Guidelines on lipid control (10). What about Indian guidelines? Unfortunately, because of a lack of valid clinical trial data on Indian subjects, Indian guidelines generally are a consensus opinion of a group of experts based on US/UK guidelines. That is why such guidelines have not really gained wider acceptance.

So what should conscientious physicians who want to stay up-to-date in the best interest of their patients do in the light of Wilson's comment? Should they give up reading journals? I think not. They should try to read between the lines, read accompanying editorials, meta-analyses when available and other sources of information. It is not wise to change one's practice in a hurry and almost never based on a single article. When a patient and physician are comfortable with a line of treatment and the patient's medical condition is under control, it is wise to wait for a body of evidence to develop from different sources. This approach is not because publications are fraudulent but because such a body of evidence needs to develop to be convincing about the need for change either because of greater efficacy, greater safety or lower cost. New information (or protocol or treatment) should encourage physicians to reflect on how their patients are doing and whether they could benefit from a change in treatment. As evidence develops, I personally would probably start patients who are not fully controlled or satisfied with their present medication to the new one, observe how they fare, and if convinced, start to change over to a new protocol or treatment. Before making changes in the medication, I would discuss the new evidence with the patient in the light of better health outcomes, safety and/or cost. Many patients have clear opinions on such matters and are more likely to comply with treatment if they are heard and decisions taken jointly.

In conclusion, it is possible that even hallowed journals like the *NEJM* are tainted with Col. However, Wilson has not produced sufficient evidence to call into disrepute the *NEJM* which has over the years built a reputation of reasonable integrity. Sensible and conscientious physicians should know how to gather new knowledge and not be hasty in drawing conclusions or changing established practice unless convincing evidence emerges from more than one source or is

recommended by guidelines, while always using their common sense, scientific knowledge, and keeping patient interest foremost.

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