

The \$10,000 Solution: What is "Significant?"

Donald M. Petersen Jr., BS, HCD(hc), FICC(h), Publisher

In the June 13, 2002 issue of the prestigious *New England Journal of Medicine (NEJM)*, the editors announced that they were modifying their policy on the publication of reviews and editorials.¹ Reviews of the literature involve selection of relevant papers and interpreting them; editorials provide authors the opportunity to make a broader range of comments about research findings.

The new policy involves the addition of a single word to the old policy statement:

"Because the essence of reviews and editorials is selection and interpretation of the literature, the *Journal* expects that authors of such articles will not have any "significant financial interest in a company (or its competitor) that makes a product discussed in the article." (Emphasis added)

By adding the word "significant," the editors of the *NEJM* set "an upper limit on the annual sum that a person may receive before a relationship is automatically considered significant (the limit, currently \$10,000, is referred to as the *de minimis* level)."

Why was this policy change necessary? Who does it benefit? The rationale for the change in policy is an interesting one:

"We have concluded that our ability to provide comprehensive, up-to-date information, especially on recent advances in therapeutics, has been constrained. For example, in the past two years we have been able to solicit and publish only one drug therapy article on a novel form of treatment. Certainly, if we publish nothing on a given subject we run no risk of promulgating a biased opinion, but our silence does not serve our readers. Without authoritative review articles written for scholarly journals by the best possible authors, physicians may find that pharmaceutical companies become their chief source of information about new therapies."

So here we have the ultimate irony. One of the most prestigious medical journals in the world admits that in the past two years (104 issues) it could find only one drug therapy article that wasn't authored by people who were unduly financially influenced, according to the previous policy as explained by the editors:

"...the *Journal* expects that authors of such articles will not have any financial interest in a company (or its competitor) that makes a product discussed in the article." (Emphasis added)

The *NEJM* (and most other medical journals) rely on the authors of papers to reveal any and all financial conflicts of interest:

"During the editorial process, we ask authors for details of their financial relationships with biomedical companies, such as consulting fees, service on advisory boards, ownership of equity (or options thereon), patent royalties, honorariums for lectures, fees for expert testimony, and research grants. In a statement in such articles, we report all relevant financial relationships; if an author has reported no relevant financial relationships, there is no statement." Add to this the editors' position that:

"We consider interactions that occur within two years before the publication date of an article to be pertinent."

So let's put it all together and see what we've got:

There is probably at least a six-month waiting period between the time a paper is submitted to the *NEJM* and its publication date. Therefore, as long as the financial "interaction" occurred 18 months before the paper was submitted to the *NEJM*, it would not be included by the authors or considered "pertinent" by the editors. Of course, during that 24-month period, authors could still be paid an additional \$9,999 as needed for their services, whatever those might be.

This leaves the drug companies in the perfect position. They can extend their influence over medical physicians via the *New England Journal of Medicine*, in addition to the influence of the pharmaceutical sales force and its various "free" office products to doctors, and the drug advertising directed to influence patients. The only thing the drug companies haven't done is to supply office staff for doctors. Maybe that's next.

With custom-made "research" in one hand and an enormous advertising budget in the other, the drug companies will continue to close their stranglehold on the health of unsuspecting consumers. And the list of those unwilling to assist them in their conquest has decreased by one more.

Some probably see this as a small concession, but think again. Rest assured that the value of this latest victory by the drug companies has already been calculated in terms of billions of revenue dollars amortized over the next few years.

In the end, there is only money or integrity. The *NEJM* has made its choice.

Reference

1. Drazen JM, Curfman GD. Financial associations of authors. *N Engl J Med* 2002;346:1901-1902. <http://content.nejm.org/cgi/content/short/346/24/1901>

Donald M. Petersen Jr.,
BS, HCD (hc), FICCC(h)
Editor / Publisher of Dynamic Chiropractic
don@mpamedia.com

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