

## Full Disclosure—Nothing Less Will Do

It is with some trepidation that I offer a counterpoint to such a distinguished editor and Harvard cancer professor. In his editorial in this issue, Thomas Stossel (2007) writes cleverly, although predictably (Stossel, 1999, 2005) and, as I shall argue, speciously. His commentary is to be welcomed because conflicts of interest (COI) are rarely discussed in the dermatology literature (Williams *et al.*, 2006), and I thank the *Journal of Investigative Dermatology* for allowing me an opportunity to explore some of Stossel's key concerns.

I strongly urge *JID* readers to read the original article for themselves (Williams *et al.*, 2006), because Stossel misunderstands two crucial points. He begins by obfuscating the differences between a circumstance and a behavior (Smith, 2006). We defined a competing interest as one in which professional judgment concerning a primary interest (such as the care of patients) could be influenced by a secondary interest (such as financial gain). This does not mean that everyone with such a secondary interest then sets out to deliberately deceive their audience about their research—most do not and some might overcompensate for such COI. A COI simply means that a set of conditions is operating that could have a marked influence on behavior. It is for the audience and not the researcher to make a judgment on whether such conflicts are relevant and whether the condition could have resulted in a specific behavior. Most journals restrict their declaration of conflicts to financial ones simply because they are clear and easier to describe (Smith, 2006; Caplan, 2007). Here I completely agree with Stossel that it makes little sense to include only financial interactions that involve drug or device companies—the *JID* certainly makes no such distinction on financial conflicts in its COI policy ([http://www.nature.com/jid/author\\_instructions.html](http://www.nature.com/jid/author_instructions.html); accessed 24 April 2007). Nor does the *Journal of Clinical Investigation*—a leading journal of which Stossel was formerly Chief Editor and one that has recently undertaken stringent measures to develop clear and

comprehensive policies on COI that extend to editors and referees as well as authors (Neill *et al.*, 2007).

Stossel then polarizes the debate into one of clinicians versus industry—a dichotomy that we strove to avoid, given that conflicts of interest can occur for all sorts of reasons, such as ambition, rivalry, and envy (Caplan, 2007). But since he has mentioned the pharmaceutical industry, it is an uncomfortable fact that some of the most obscene conflicts and behaviors have come from that sector, as summarized in a detailed House of Commons enquiry (House of Commons Health Committee, 2005). Just recently I read the gory details of the rofecoxib (Vioxx) affair stemming from the VIGOR study—of a promising new drug that resulted in serious cardiovascular harm—and how conflicting interests among Merck's board members had complicated matters (Krumholz *et al.*, 2007). The head of the VIGOR trial board, for example, had family ownership in Merck shares worth \$70,000, which was not a matter of public record when the trial was conducted or published. Perhaps the conflict had nothing to do with the concealed cardiovascular risk in the publication—the main point is that it was not declared. What surprised me most was not that the Vioxx scandal occurred but how little the medical community seemed to react. Winston Churchill described the phenomenon aptly: "Men occasionally stumble over the truth, but most of them pick themselves up and hurry off as if nothing ever happened." I also do not agree with Stossel that most advances in medicine and dermatology are due to "products developed by private companies." Of course, our patients have benefited greatly from some treatments, such as topical corticosteroids, oral and topical retinoids, and (possibly) the new biologics for psoriasis, but other advances, such as identifying the causative agents for infectious and non-communicable skin diseases, studies of disease definition, outcome assessment, and prognosis, treatments such as ultraviolet light, and prevention of skin diseases such as melanoma, have not come primarily from private companies.

Stossel then dismisses the *BMJ* surveys of the effects of declaring COI, but does not suggest

a better scientific way to explore such effects. The literature is replete with clear evidence of the potential harms of COI, including reporting outcomes that were not part of the original protocol (Chan and Altman, 2005), selective reporting of positive results and positive studies (Melander *et al.*, 2003), duplicate publication (von Elm *et al.*, 2004), and ghost writing (Gotzsche *et al.*, 2007)—what more do we need to convince us that steps need to be taken to ensure that trial protocols are registered and reported properly with full declarations of COI? Stossel also dismisses the contribution of “unconflicted” researchers and equates them with being less competent based on one anecdote, yet there are plenty of examples of “unconflicted” individuals working in independent organizations such as the UK National Institute for Health and Clinical Excellence (<http://www.nice.org.uk>) and the US Agency for Healthcare Research and Quality (<http://www.ahrq.gov/>) who produce excellent, insightful, and accurate research summaries that minimize bias.

The question remains as to whether COI is a problem in dermatology. I cannot think of any logical reason why those of us in dermatology should be exempt from human nature. Money makes the world go round, and the sums of money involved in drug-company research are vast. I agree with Rees, who commented recently in this journal on “how easily our quest for truth is subverted” (Rees, 2007). The point is that the extent and effects of COI in dermatology have been studied very little to date (Williams *et al.*, 2006). Perlis *et al.* (2005) have documented that 43% of 179 dermatological clinical trials reported financial conflicts for at least one author and that such studies were more likely to report positive results than others. Schemes that allow pharmaceutical funding of U.S. dermatology trainee programs have also raised concerns that they might lead to significant conflicts of interest (Kuehn, 2005). Katz and Bartus have drawn attention to misleading advertisements in dermatology journals and inconsistent or absent policies governing such advertisements (Katz, 2005; Bartus and Katz, 2006). Others have tried to develop voluntary codes of practice to manage COI in dermatology (Prendergast *et al.*, 2004). We may not have any Vioxx scandals yet, but maybe it is only a matter of time—the story of evening primrose oil for atopic eczema came quite close (Williams, 2003).

So where do I stand in all this? It is important that we remember what the whole debate is about—it is not about me or Stossel or doctors or industry, but about patients’ welfare. Distortions of the scientific record result in wasted time for patients and doctors (Chalmers, 2006). Scarce resources can be misspent denying others appropriate treatments, and sometimes bias results in downright harm, as in the Vioxx affair (Krumholz *et al.*, 2007). If, as Stossel suggests, start-up companies in his area of the United States are genuinely stifled because of overregulation, then he has my sympathies. As noted in Lowell Goldsmith’s recent *JID* editorial about COI (Goldsmith, 2006), we need a balance in such matters, and maybe regulation has swung too far in Stossel’s patch. I also have some sympathies with Stossel’s view that declaring COI can be perceived as a discredit rather than honor of sponsorship, yet I fail to see how any scientist can argue

against full disclosure in this day and age. So, do I encourage investigator-led studies with industry colleagues? Yes. Encourage interactions between universities and industry that lead to better health and wealth? A resounding yes. But as for the failure to permit readers and editors access to original trial protocols in the public domain (Dellavalle *et al.*, 2007), failure to disclose potential conflict of interest in dermatology presentations and publications, and failure to report all the data honestly and completely—no compromises.

**CONFLICT OF INTEREST**

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