

Influence of industry on scientific reports

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Dear Editor,

The staff report on Medtronic's influence on Infuse clinical studies published in October 2012 is very interesting to read [1]. Especially, the magnitude of the influence of a sponsoring industry is surprising. Of course, Medtronic did not agree with the findings [2]. However, if only half was true it still remained amazing.

I am convinced that these findings were not restricted to Medtronic. I assume that the results of the investigation of the Committee on Finance can be extrapolated to many companies dealing with medical devices, implants or drugs. The main goal of every company is to make profit to regain at least the investments to develop a new product, and preferentially to meet the expectations of the investors.

The findings of the Committee on Finance of the United States Senate were clearly summarized. I quote parts of them and also the reply, in which I replace the name of the company by "the company":

"The company was heavily involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from the company. The significant role of the company in authoring or substantially editing these articles was not disclosed in the published articles."

The company paid a significant amount of money to the physician–authors. In an appendix the names and the

amount of money paid were represented. In their reply, the company stated that:

"The vast majority of such payments were royalty payments made to compensate physicians for their intellectual property rights and contributions, not consulting payments. In general, royalty and consulting payments are a commonplace and appropriate practice in the medical device industry."

"An e-mail exchange shows that an employee of the company recommended against publishing a complete list of adverse events possibly associated with InFuse in a 2005 *Journal of Bone and Joint Surgery* article."

"Officials of the company inserted language into studies that promoted InFuse as a better technique than taking a bone graft from the pelvic bone (autograft technique) by emphasizing the pain of the autograft technique."

"Documents indicate that the company prepared remarks of a physician author to the U.S. Food and Drug Administration (FDA) advisory panel meeting prior to InFuse being approved. At the time, he was a private physician but was hired as a vice president at the company in 2007."

"Documents of the company show the company unsuccessfully attempted to adopt weaker safety rules for a clinical trial studying InFuse in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck."

It seemed logical that this attitude was a product of positive experiences in the past. This knowledge in

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combination with the possibilities to the known (and apparently used) ways to cheat on statistical tests when writing up results combined with the also known tips to present a medical product in the best light [3] make the results of studies sponsored by industries at least questionable.

It is also a confirmation of the fact that studies published by authors with a financial disclosure are biased [4]. Although paid for intellectual property, nobody will claim a negative result when a large amount of money is involved.

Another recent example for these practices is the introduction and promotion of disc prostheses. First, a logical and theoretical advantage was promoted: maintaining mobility to prevent adjacent disc disease. Before the introduction of the arthroplasty nobody mentioned adjacent disc disease [5], a radiological phenomenon. This is the first rule to sell a product [3]. Then studies were published reporting all kinds of statistical effects without mentioning clinical relevance. Many of the studies were sponsored by an industry and some of the author groups had financial disclosures. Studies with less positive results were not published (publication bias). Meanwhile arthroplasty has become standard care in some countries and many devices have been sold. Many other examples can be given, for example interspinous devices, or posterior dynamic stabilization.

The report of the Committee on Finance clearly disclosed the huge influence of companies on the scientific presentation of new devices or drugs. This was even more than many of us thought. It should be kept in mind when interpreting studies sponsored by the industry or reported by an author group of which some have a financial disclosure. New procedures for the development, testing and reporting of new devices, implants or drugs should be developed.

Ideally all new devices or drugs should be tested in selected centers across the world. If the results are satisfactory according to an independent board without any financial relation to the industry at the moment or in the future, the product can be released for the market. As stated this would be an ideal situation.

It would be a fantasy to think the influence of the industry will ever vanish. However, readers of journals

should be aware of the relation of the industry and the publication on a product. As suggested by the Committee on Finance, medical journals should ensure industry role contributions be fully disclosed. Most journals already request full financial disclosure of the authors. However, at the moment of publication, they can have no relationship, but after the paper is published some money could be paid for the intellectual property. Perhaps, financial relationships of companies and physicians should be stored in a public database. If a paper is retrieved through a search system, the actual financial disclosures of all authors can be disclosed at once.

The last suggestion was perhaps also idealistic. The importance of reporting clinical relevance instead of focusing on statistical significance should explicitly be stressed. The use of obscuring expressions like *reached nearly statistical significance*, or *seems to* in the conclusion, while a clear benefit was not shown should be prohibited. If a clear and relevant clinical benefit was not shown, it should be stated without any assumption of a possible positive effect. In this way, the reader will be informed in a fair way.

Conflict of interest None of the authors has any potential conflict of interest.

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