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Clinical practice guidelines and conflict of interest

In 2003, an expert committee responsible for clinical practice guidelines of the Canadian Diabetes Association (CDA) recommended that the new long-acting agent, insulin glargine, be used as an alternative for generic long-acting insulin for the treatment of type I and II diabetes mellitus in patients with problems controlling fasting plasma glucose or with nocturnal hypoglycemia.[1] This fall, panelists for the Common Drug Review (CDR), a national advisory process that evaluates drugs for provincial formularies, recommended that the drug *not* be listed.[2] Both groups of experts evaluated virtually the same evidence from about 20 randomized controlled trials. The CDA guidelines do not disclose whether the members of their expert panel had financial links of any kind with the manufacturer of insulin glargine, and, as of press time, the association had not been able to supply us with this information. Of the 3 experts contracted by the CDR, one had been paid for giving educational lectures and writing an article for the manufacturer of insulin glargine.

In response to the CDR recommendation, the CDA issued an open letter to provincial ministries of health (see www.diabetes.ca/Section_Advocacy/adv_resources.asp) expressing "serious concerns" with the CDR recommendation; these included the fact that "no diabetes medications experts [were] included amongst the experts" on the CDR panel.

This controversy over guidelines is not unique to those developed by the CDA. There has been similar debate regarding the management of hypertension, where national guidelines recommend expensive patented drugs over proven generic compounds. Almost all consensus and guideline development panels are supported by pharmaceutical companies with vested interests, and many panelists receive research grant support and personal compensation for lectures and advice from the same companies.

There is a profound and extensive problem here. A recent report on more than 200 guidelines (from various countries) deposited in 2004 with the US National Guideline Clearinghouse found that "more than one third of the authors declared financial links to relevant drug companies, with around 70% of panels being affected."[3] Further, almost half the guidelines provided no information about conflict of interest.

To maintain that such financial conflicts exert no influence on panelists' recommendations is to ignore accumulating evidence that they do. A national guideline recommendation encumbered by money in the form of lecture and consulting fees, stocks, options, patents and royalties may be effective in increasing sales and profits for companies, but may also be harmful to patients. And it will almost always result in higher-cost drugs being prescribed. (According to the CDR, insulin glargine costs 5 times as much as generic long-acting insulin.)

Disclosure of conflicts of interest is a widely accepted policy among reputable medical journals. Although disclosure should heighten readers' skepticism, it does not unburden guideline authors from the potentially compromising effects of financial ties to industry. If such ties do not bind them, they will surely be perceived as doing so.

Are recommendations made by experts without clinical expertise also distorted, as the CDA suggests? This appears to us to be less likely, especially when these experts are assessing evidence derived from clinical trials. Although clinical expertise is important in designing a trial (especially in establishing clinically meaningful endpoints), interpretation of the resulting data requires expertise in trial design and analysis, not necessarily in clinical practice.

In the face of the growing evidence that financial conflicts of interest bias expert recommendations in favour of sponsors' products, this Journal (along with most major medical journals) will not accept for publication consensus statements, narrative reviews, commentaries and similar types of articles that recommend drugs, devices, laboratory tests or other interventions for which at least one of the authors has a significant financial conflict of interest.[4]

To date we have excluded guidelines from this policy, requiring only disclosure of financial conflicts of interest. We are now reconsidering that policy. In the interim we will ask guideline developers to send us a detailed disclosure of their conflicts of interest *before* submitting their manuscript; this information will subsequently be made available to peer reviewers, should the paper be considered.

National disease associations exist to represent the interests of patients. These societies must find a way to support guideline development that does not rely on funding from companies with vested interests. In the interim, and at a minimum, guideline developers ought to disclose to lay and professional readers the financial conflicts of interest of the experts making recommendations. Physicians, patients and taxpayers deserve no less. — *CMAJ*

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