risk of cardiovascular disease." To make such a recommendation based on the adverse reactions presented in the newsletter is not scientifically rigorous. The data are not adjusted for exposure, and thus are unlikely to represent an accurate evaluation of cardiovascular risk.

The impetus behind this article appears to be a meta-analysis by Mukherjee and colleagues,[2] which is methodologically flawed[3–5] and does not form an appropriate basis for public health recommendations.

Certainly the increased rate of adverse cardiovascular events, as demonstrated in the VIGOR study for rofecoxib,[6] warrants further investigation. Clinical data available for celecoxib, however, demonstrate that patients on celecoxib are no more at risk of cardiovascular events than patients taking traditional NSAIDs such as ibuprofen, diclofenac or naproxen.[7] This observation holds true even at supratherapeutic doses, as demonstrated in the CLASS trial.[8,9]

Differences in molecular structure and metabolism may partly explain the distinct cardiovascular safety profiles of the 2 coxibs, and this hypothesis should be examined further.[10,11]

If immediate recommendations are required, perhaps Health Canada would be more justified in suggesting that caution be exercised in prescribing these agents, particularly rofecoxib, to patients at high risk of cardiovascular disease. The implementation of such a policy should be individualized at the discretion of the treating physician in light of each patient's risk factor profile, the presence (if any) of diabetes and cardiovascular history.

John C. Peterson
Cardiologist
Toronto, Ont.

Competing interests: Dr. Peterson has spoken for the last 2 years at continuing medical education events for Novartis, Merck, Pharmacia and Abbott.

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In their report in the *Canadian Adverse Reaction Newsletter*,[1] Duc Vu and coauthors present their data in a table suggesting a comparison between the COX-2 agents without accounting for patient exposure or the fact that these drugs came onto the market at different times.

From this crude longitudinal data, the authors suggest that "caution should be exercised in prescribing these agents to patients at risk of cardiovascular disease." This recommendation is made even though the authors state that the "data cannot be used to determine the incidence of adverse reactions because neither patient exposure nor the amount of time the drug was on the market has been taken into consideration."

Although I recognize that Health Canada is attempting to take responsible measures for reporting adverse drug reactions, it is critical that inferences not be made when the data are provided without appropriate perspective. Reports such as these can do more harm than good by unnecessarily raising concern among physicians to the detriment of patient care. If Health Canada wants to improve adverse reaction reporting, it should look to evaluation procedures that combine information from postmarketing surveillance, epidemiologic research and clinical trials. The result will be a more comprehensive representation of data and one that appropriately reflects a therapy's safety profile and provides useful information to prescribing physicians.

Jean-Pierre Raynauld
Rheumatic Diseases Unit
Centre hospitalier de l'Université de Montréal
Hôpital Notre-Dame
Montreal, Que.

Competing interests: Dr. Raynauld received an honorarium and travel assistance to attend a meeting held by the Canadian Rheumatology Association. He has also received fees to speak about COX-2 inhibitors from Pharmacia, Pfizer, Merck and Genzyme.

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[The editors of the *Canadian Adverse Reaction Newsletter* respond:]

The Marketed Health Products Directorate of Health Canada agrees that comprehensive risk–benefit evaluations should include information from postmarketing surveillance, epidemiologic research and clinical trials. However, in the absence of complete evidence, it is well recognized that spontaneous adverse reaction reports are nonetheless valuable in signalling a potential problem. Our newsletter is meant to provide observational results from the database. The safety of new drugs cannot be known with certainty until a drug has been marketed for many years.[1]

Although a relation between the cardiovascular findings and the use of rofecoxib and celecoxib has not been established at this time, Health Canada, as a precaution, deems it necessary to inform health professionals and advises patients with a medical history of hypertension, fluid retention or heart fail-

ure to discuss their medical condition with their physician. Since the newsletter article,[2] "Dear Healthcare Professional" letters, prepared in collaboration with Health Canada and the manufacturers, were issued for rofecoxib and celecoxib on Apr. 15 and May 13, 2002, respectively. Health Canada also released public advisories for these drugs in April and May 2002 (available at www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/advhp_e.html). Ongoing evaluations and expert consultations are being conducted by Health Canada, and any new safety information will be reflected in the product monographs of these drugs.

Ann Sztuke-Fournier
Marielle McMorran
Editors
Canadian Adverse Reaction Newsletter
Ottawa, Ont.

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Blood alcohol limit: the CMA is right on

I agree with the CMA's recommendation to lower the legal blood-alcohol concentration (BAC) for driving from 0.08% to 0.05% and with Henry Haddad's response.[1] It should be noted what currently occurs in forensic practice regarding the 0.08% limit.

Police do not routinely charge a drinking driver for an offense of over 0.08% unless one of the results of the evidential breath-alcohol instrument is 0.1%.[2] In field use, the evidential breath-alcohol instruments used by the police have been found to read approximately 12% lower than the actual BAC.[3] In addition, the Criminal Code allows for a 2-hour presumption, whereby it is presumed that no alcohol has been eliminated from the body during that period of time, even though the average rate of alcohol elimination found in drinking drivers is approximately 0.02% per hour.[4]

Taking these factors together, it is possible that a drinking driver who had a BAC of 0.152% at the time of an accident may not be charged with over 0.08% when an evidential breath alcohol test is conducted 2 hours later. For this and other reasons indicated by Haddad,[1] the CMA's recommendation of a lower BAC limit is well justified.

James G. Wigmore
Forensic Toxicologist
Centre of Forensic Sciences
Toronto, Ont.

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Quality of care in for-profit hospitals

What are the implications of allowing for-profit delivery of health care? Although I admire the courage of P.J. Devereaux and coauthors[1] in attempting a meta-analysis of this literature, as they noted there is enormous variability within each category. Not all hospitals are alike. In addition to the distinction the authors accurately make between private for-profit and private not-for-profit hospitals, the literature also suggests there are major differences between for-profit firms that are investor owned and those that operate as small businesses. Differences may also exist between organizations because of varying degrees of control by health professionals. Further compounding the difficulty in making comparisons, the for-profit hospitals included in the studies that Devereaux and coauthors reviewed tended to occupy niche markets, serving different target populations (and often performing different mixes of services) than did the not-for-profit organizations. Comparisons therefore often depend on what and how various factors are controlled for, making precise point estimates even more tenuous.

Regardless of the implications for costs (which are subject to similar apples-to-oranges difficulties), quality differences between for-profit and not-for-profit organizations appear to be less pronounced when clinicians are able to influence the care they give without direct pressure to balance their clinical judgement against shareholder returns.

Raisa B. Deber
Professor
Department of Health Policy, Management and Evaluation
University of Toronto
Toronto, Ont.

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[Ten of the authors respond:]

Raisa Deber states that "quality differences between for-profit and not-for-profit organizations appear to be less pronounced when clinicians are able to influence the care they give without direct pressures to balance their clinical judgement against shareholder returns." This may be the case. However, our systematic review demonstrated that private for-profit hospitals employed less highly skilled health professionals, and there is a demonstrable association between health professionals' skill level and patient mortality. Therefore, even if the private for-profit hospitals do not pressure their health professionals to balance their clinical judgement against the return to shareholders, the lower skill level provides one explanation for