warnings from recent international "Dear Healthcare Professional" letters, to distill key messages when such letters are vague and to bring debates from more specialized bodies of literature to our general medical audience. Questions about the exact frequency and risk factors for a so-called propofol syndrome in critically ill children are certainly worthy of future systematic and rigorous research. However, I believe the real issue is not whether the syndrome truly exists, but whether a single advisory from the US Food and Drug Administration (FDA) in 2001 is sufficient to put the issue to rest. We know from the cisapride story that even multiple warnings can fail to have an impact on physicians' prescribing behaviours.[2,3] In the case of propofol, postmarketing adverse events (including deaths) continued to occur in Canada, despite the 2001 FDA warning, and were the reason that Health Canada issued its own warning.[4] I felt it wise to echo these concerns, to frame the debate for those who were unfamiliar with it and to recommend that patients be kept informed.

I can appreciate the letter writers' concerns about whether or not to include "theoretical risks" in preoperative discussions with patients and their families. Although I usually choose to inform patients of all serious adverse events (including those that are rare), I admit that in writing this column I should have better emphasized the difference between concerns about propofol's use for the long-term sedation of critically ill pediatric patients and its relative safety in other contexts.

Eric Wooltorton
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Snowmobiler's hematuria

Snowmobiling is a common recreational activity in many regions of Canada and other countries with winter snow cover, but snowmobilers are at risk for traumatic injuries.[1] I describe here a healthy man who experienced gross hematuria after long-distance snowmobiling. A MEDLINE search yielded no other reports of nontraumatic gross hematuria after snowmobiling.

A 40-year-old man experienced

transient, frank, painless gross hematuria after snowmobiling a distance of almost 500 km. He denied any recent flulike illness or injury to the flanks; he also denied difficulty in passing urine and had no burning sensation during urination. No other aspects of the medical history were relevant, and the results of a physical examination were unremarkable. The prostate was not enlarged, and there was no prostate tenderness. Urinalysis revealed brownish urine, 4+ for blood on a urine dipstick (20 to 40 erythrocytes per high-power field) and traces of protein. There were no erythrocytic or granular casts. The symptoms resolved spontaneously within 24 hours. The results of urine culture were negative. Intravenous pyelography, cystoscopy performed 2 days later and abdominal ultrasonography were unremarkable. The results on follow-up urinalysis 2 weeks and 1 month later remained negative. A 24-hour urine collection for calcium, oxalate and uric acid showed no evidence of crystalluria.

Exercise-related urinary abnormalities are common in people engaging in strenuous exercise, contact sports and marathon running. Exercise hematuria occurs in 18% of marathon runners[2] and has also been described in players of contact sports and physically active servicemen, especially after severe exertion.[3] However, controversy surrounds the source of bleeding after strenuous exercise. Kincaid-Smith[4] emphasized that glomeruli are the usual source of bleeding in such cases, frank hematuria of bladder origin being less common. However, Blacklock[5] described long-distance runners who experienced profuse hematuria from erosive lesions in the bladder that had been caused by trauma. The source of bleeding in the man described here remains speculative, but it appeared to be from the bladder, as no casts were observed on microscopic examination. Snowmobilers sometimes experience some flank discomfort that is usually attributed to the frequent thrusting movements related to the bumpy ride. I believe that the repetitive impact of the man's partially filled bladder against the bladder base during each thrust caused bladder irritation leading to transient gross hematuria, similar to what has been described in marathon runners. Because snowmobiling is a common recreational activity, this association may be underrecognized.

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CRA endorsement of osteoporosis guidelines

The Canadian Rheumatology Association endorses the recently published guidelines for the treatment of osteoporosis.[1] We would like to make the readership of *CMAJ* aware that we support these important recommendations.

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Mandatory pharmacovigilance

A recent *CMAJ* editorial[1] commented on the lack of objective, user-friendly information from Health Canada and the pharmaceutical industry regarding the use and effectiveness of new therapies. However, one cannot help but perceive an element of hypocrisy on the part of *CMAJ*.

Since July 1994, *CMAJ* has provided a means of distribution for Health Canada's *Canadian Adverse Reaction Newsletter* (initially as part of the journal itself and now as an accompanying publication) without any editorial critique of the information presented there. Such critique is warranted for several reasons. In particular, the newsletter publishes information with medicolegal implications for appropriate medical practice.

However, many physicians have serious concerns about Health Canada's continuing reliance on a highly flawed approach to postapproval surveillance and the department's interpretation of the resulting data. A case in point: the October issue of the newsletter described potentially severe adverse reactions associated with leflunomide,[2] but when all patients exposed to the drug have been monitored, the rate of adverse events reported for leflunomide has been lower than for methotrexate or other commonly used disease-modifying antirheumatic drugs for rheumatoid arthritis.[3] Crude mortality rates were also lower for the patients who received leflunomide. Similar data attesting to the relative safety of leflunomide compared with methotrexate have been presented in another large study monitoring all patients exposed to leflunomide.[4]

In addition to revealing errors of ascertainment, these data highlight the serious limitations in attribution that may occur in surveillance programs that do not monitor exposure to the drug in question. Several countries have recognized and acted on these concerns by implementing surveillance programs that *do* monitor exposure (e.g., the UK National Institute of Clinical Excellence for Surveillance of Biologics). Meanwhile, as *CMAJ*'s editorialists indicated, Health Canada is only hesitantly "grasping the nettle" in addressing this issue. It is therefore all the more essential that the data it presents in its newsletter be subject to the same degree of scrutiny and peer review as any other data submitted to *CMAJ*.

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

In responding to Walter Maksymowych's letter about a recent *CMAJ* editorial[1] and an article about leflunomide[2] in the *Canadian Adverse Reaction Newsletter* (CARN), we would like to emphasize that every drug has benefits and risks. As its name implies, the CARN discusses mainly the risks associated with drugs rather than their benefits. Its purpose is to raise awareness of potential safety issues detected through the review of case reports submitted to Health Canada and to remind health care professionals of ways to minimize the risks. Publication of articles in the CARN is preceded by a comprehensive consultative process with scientific staff within Health Canada, the Regional Adverse Reaction Centres, members of the department's Expert Advisory Committee on Pharmacovigilance and the editor of *CMAJ*.

The leflunomide article[2] summarized safety information from various sources (e.g., the Arava product monograph, the *Australian Adverse Drug Reaction Bulletin* and documents on leflunomide from the European Medicines Evaluation Agency), rather than drawing conclusions based solely on the adverse reaction data presented in the article. The data in the CARN represent observational results from the Canadian Adverse Drug Reaction Monitoring Program database. Prominent caveats in the newsletter advise readers that adverse reactions to health products are considered suspicions, because a definite causal association is often impossible to determine. Spontaneous reports of adverse reactions cannot be used to estimate the frequency of such events, because adverse reactions remain underreported, and patient exposure is unknown.

Health Canada continues to enhance its postmarketing surveillance and assessment program for health products; the spontaneous adverse reaction report-