## Correspondance

we employed both sample and longitudinal weights for the analyses in this cycle. However, only cross-sectional and longitudinal weights are calculated in the NLSCY file; bootstrap methodology is not used. In a forthcoming follow-up study of hunger in NLSCY families we compared adjusted prevalence rates of hunger in 1994 and 1996. The population estimates of child hunger in Canada using weights were 1.4% (53 995 children) and 1.6% (75 615 children) for 1994 and 1996 respectively.

Bruce Leistikow's argument is based on the presumption that the associations observed are causal; of course, such a relationship cannot be inferred from cross-sectional data. We offer another analysis: smoking in the primary caregiver is associated with hunger in the primary caregiver. Smoking is a coping mechanism for the physical and psychological stress of hunger.2 That being said, high tobacco taxes can be viewed as regressive taxes that target the tobacco-addicted poor,3 reducing family resources for food and other essentials. We can all agree on one thing: sensitive supports for tobacco cessation must be offered to low-income caregivers who smoke. Cessation will improve health and reduce the financial stress on households.

#### Lynn McIntyre

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#### James Warren

Department of Physiology and Biophysics Dalhousie University Halifax, NS

#### Sarah K. Connor

Applied Research Branch Human Resources Development Canada Hull, Que.

#### References

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## The environmental impact of war

Although the principles mentioned in the *CMA7* editorial commemorating Remembrance Day are certainly commendable, the article in the same issue by Jennifer Leaning reads like an apology for the real instigators of the miseries inflicted on the world since 1939.

Leaning writes about the death toll resulting from the bombing of Tokyo and various German cities without a word about the slaughter of the civilian populations in London, Coventry, Portsmouth and other areas by the Nazis, who started this abominable escalation, and the list of references leans heavily toward pro-Soviet apologists.

#### LCol Emile Berger (retired)

Canadian Forces Medical Services Montreal, Que.

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- Remembrance of things present [editorial]. CMAJ 2000;163(9):1121.
- Leaning J. Environment and health: 5. Impact of war. CMAJ 2000;163(9):1157-61.

#### [The author responds:]

By nature of its focus, a review of the most serious recent impacts of war on environment and health will deal with a very particular set of concerns. Many of the worst atrocities of recent wars have not been associated with specific environmental effects or specific environmental causes. Hence the topics I covered in my article did not include gross human rights abuses or violations of international law (such as torture, rape and mass killing of civilians, or even genocide) where environmental destruction was not also at issue.

A review of the impacts of war on environment and health must cross all political boundaries to follow environmental consequences rather than seek ideological motivation. During World War II, the death toll and physical damage resulting from aerial bombardment in urban areas were on a scale of magnitude greater for bombardments

launched by the Allied forces than for those launched by other forces. In my article I sought to search for greatest impact, not to assign blame.

Finally a review of the recent impacts of war on environment and health must work with the evidence that has been compiled. Countries that have more open political systems and more competent record keeping and that offer greater latitude to diligent investigators will have more information available about the environmental effects of their military production and testing enterprise. In my article I pointed out that the effects I cited are about the United States because we know more about the US system than the Soviet one.

I wrote my review for a medical and public health audience, for whom issues are traditionally raised in terms of available data on health impacts rather than analyzed in terms of political alignments or lingering nation-state enmities. I could certainly have written the article with greater attention to these sensitivities but I thought that not only unnecessary but significantly off the point. In my view, the readers of CMA7, and health professionals everywhere, must face the fact that even the countries they love and would fight for have contributed mightily to the environmental calamities we all must now address.

#### Jennifer Leaning

Professor of International Health Harvard School of Public Health Boston, Mass.

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 Leaning J. Environment and health: 5. Impact of war. CMA7 2000;163(9):1157-61.

# Cisapride and patient information leaflets

To measure the quality and usefulness of patient information leaflets distributed in Canadian pharmacies, we compared the information contained in 3 leaflets distributed in Canada for cisapride monohydrate (Prepulsid in Canada, Propulsid in the United States)

with that in the leaflet approved by the US Food and Drug Administration (FDA). Cisapride has been withdrawn from the US and Canadian markets.

We obtained 3 patient information leaflets from southern Ontario pharmacies. One was produced by Janssen-Ortho Inc. and another was produced by First DataBank (a US company); the publisher of the third one is unknown. We looked for 5 types of information: a statement of the most serious risk associated with use of cisapride; drugs with which cisapride use is contraindicated; medical conditions with which cisapride use is contraindicated; the safety and effectiveness of the drug in children; and explicit instructions on contacting the prescriber if specific adverse effects are experienced. We found substantial variability in the quality of the leaflets.

The first paragraph in the FDA-approved patient information leaflet for cisapride begins as follows: "Propulsid may cause serious irregular heartbeats that may cause death." None of the 3 patient information leaflets distributed in Canada that we looked at contain a statement on potentially fatal cardiac arrhythmia, the most serious risk associated with cisapride.

The FDA-approved patient information leaflet for cisapride lists 21 generic names and 25 brand names for drugs whose use is contraindicated with cisapride, followed by a caution

that "This is not a complete list of medications that you should not take. Therefore, tell your doctor about all other prescription and nonprescription drugs you are taking, including herbal supplements." The First DataBank patient information leaflet lists 8 drugs and provides brand names for 7 of them. The Janssen-Ortho patient information leaflet lists 24 drugs, but brand names are given for only 9 of them. The patient information leaflet from the unknown publisher lists no drugs whose use is contraindicated with cisapride.

The FDA-approved leaflet lists 12 medical conditions for which cisapride use is contraindicated. The patient information leaflets from the unknown publisher and from First DataBank do not list any of these. The Janssen-Ortho leaflet lists 11 of these 12 contraindications.

The FDA-approved patient information states that "the safety and effectiveness of Propulsid in children younger than 16 years have not been demonstrated for any use." The Janssen-Ortho patient information leaflet does indicate that cisapride should not be used in children, but no age range is given. The other 2 patient information leaflets distributed to Canadian patients make no reference to the use of cisapride in children.

The FDA-approved leaflet places

the risks of the drug in a useful context for patients, in stating that it may cause serious irregular heartbeats that may cause death. It also gives explicit instructions on the steps a patient should take if the symptoms of cardiac toxicity develop, including stopping use of the drug immediately. None of the leaflets being distributed to Canadian patients that we assessed contained both information on the most serious risk associated with the use of the drug and explicit instructions on the actions that should be taken if the symptoms of toxicity occur. The Janssen-Ortho leaflet instructs patients to stop taking the drug and get medical help if they experience dizziness or irregular heartbeats. The only advice the First DataBank leaflet provides to patients is to "contact your doctor immediately" if any of a long list of adverse effects are experienced, including irregular heartbeats. This leaflet does not instruct patients to stop taking the drug if these symptoms occur. The leaflet from the unknown publisher contains no information of this type.

Patients or their caregivers may think that the drug information leaflet is all they need in order to understand how to use a drug safely and effectively. If the leaflet omits important information it is thus potentially dangerous. We suggest that the federal government regulate the patient information leaflets distributed by pharmacists for all drugs marketed in Canada. The contents of patient information leaflets should meet regulated standards and should be derived from or consistent with a drug's approved labelling.

#### Sana R. Sukkari

Oncology - Palliative Care Pharmacist Joseph Brant Memorial Hospital Burlington, Ont.

Larry D. Sasich

Public Citizen's Health Reseach Group Washington, DC

#### [Two of the companies respond:]

C ana Sukkari and Larry Sasich raise Some important issues that need to be addressed, but their letter obscures a very important distinction between patient leaflets created by the company that discovered and developed a medicine and those distributed by commercial pharmacy information companies.

Janssen-Ortho's patient leaflets are submitted to and reviewed by Health Canada and form part of the official product monograph. Leaflets provided by commercial pharmacy information companies may or may not be considered with the monograph and are not controlled by the drug's manufacturer.

Sukkari and Sasich do not indicate whether the patient leaflets they compared were all in use in the same time period. As additional information becomes available to manufacturers and Health Canada, changes may be made to monographs and manufacturers' patient leaflets.

Sukkari and Sasich seem to imply, incorrectly, that because the Canadian patient leaflet is different from that used in the United States, it is somehow inferior. Patient leaflets often vary in different countries because of differences in the conditions of use approved by local regulatory authorities. For example, the Canadian Janssen-Ortho leaflet for Prepulsid (cisapride) includes fewer contraindicated drugs than the US one for Propulsid because some drugs mentioned in the US leaflet are not available in Canada or are more commonly referred to by their generic names.

We, like other manufacturers, provide physicians and pharmacists with more detailed information, through product monographs and periodic updates, that allow them to weigh the benefits and risks of a drug for any particular patient. The patient leaflet is not intended to supplant the patientphysician discussion or the detailed information provided to medical professionals in the product monograph.

We agree that some form of additional controls over commercial pharmacy information and other third-party publications should be considered. The accuracy of patient information is an important issue for the pharmaceutical industry. Janssen-Ortho would be pleased to participate in the discussion of this subject.

#### Wendy Arnott

Vice-President Regulatory and Medical Affairs Janssen-Ortho Inc. Toronto, Ont.

The primary source of patient drug ■ information has traditionally been the point of care: the patient's physician and pharmacist. Patient education materials prepared by manufacturers and information services, however, are a useful adjunct.

One of the 3 leaflets on cisapride surveyed by Sana Sukkari and Larry Sasich contained content provided by First DataBank, a leading US provider of drug data for pharmacy and hospital information systems. We must point out that commercial content providers — First DataBank included — do not "produce" leaflets for patients. Instead, we license drug information to system developers and health care organizations for use by their customers — physicians and pharmacists — in educating their patients. Organizations that acquire our data can, at their discretion, exclude any information that they consider not relevant to or practical for their application. (First DataBank does not recommend this practice.) For example, they might not include some sections of our knowledge base if their pharmacy system automatically screens patient data for drug interactions because the caregiver can verbally counsel patients if there are any risks in using a particular drug.

Sukkari and Sasich evaluated the 3 leaflets on whether they covered 5 types of risk information on cisapride. Some of the data provided by First DataBank appear to have been deleted by the system developer or customer: our database did in fact contain most of the information sought by the authors.

We question the validity of evaluating patient information leaflets on the basis of an exhaustive list of risks. In our view, a major goal of drug information leaflets is to encourage patient compliance, which may be better achieved by a balanced presentation of the risks and the benefits of proper usage. We do agree with the authors, however, on the need for standards in patient information materials. First DataBank has been working toward full compliance with the FDA's Keystone Action Plan in all of its patient education materials.

#### Pat Muller

Vice President **Knowledge Base Operations** First DataBank The Hearst Corporation San Bruno, Calif.

#### [Health Canada responds:]

Tealth care professionals and con-H sumers must have access to highquality, easy-to-use drug information. However, some of the information provided by Canadian pharmacies is not derived from Canadian sources. In addition, the Therapeutic Products Programme (TPP) has no legislative or regulatory means of controlling the dissemination of this information: it falls under provincial jurisdiction, which means that it is a matter to be considered by the Colleges of Pharmacy.

Even though the TPP does not currently have the authority to prevent the distribution of such information, it does have risk communication strategies to provide current safety information. For example, the July 1996 and January 2000 editions of the *Adverse Drug Reaction Newsletter* provided safety information on cisapride.<sup>1,2</sup>

The only TPP-approved information on drugs in Canada is provided in the product monograph. The TPP is revising the format and content requirements for product monographs; one component of the new monographs will be specific, Canadian patient information that could be provided when a product is prescribed or dispensed. On the basis of public consultations on the product monograph held in September 2000 (www.hc-sc.gc.ca /hpb-dgps/therapeut/htmleng/consult \_monograph.html), we are planning to electronically post product monographs in both official languages.

Health Canada recognizes the importance of communicating risk information concerning therapeutic products to health care professionals and consumers alike. I therefore urge *CMAT* readers to consult our Web site to familiarize themselves with the progress on our initiative to improve the format and content of product monographs and to make their contents available to the Canadian public.

#### Robert G. Peterson

Director General Therapeutic Products Programme Health Products and Food Branch Health Canada Ottawa, Ont.

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## Fifty years at Western

Tappreciated the lists of University of Western Ontario medical school students from 1954 and 2004 that you published in your 2000 holiday issue. The changes that have taken place over the 50 years are obvious: we now have a larger number of students, more female

students and a greater ethnic mix within the student body. These differences reflect not only the increasingly multicultural nature of Canadian society but also the changing attitudes toward who should be admitted to medical school.

Women now account for 50% of Canada's medical students, compared with 5% from our class of 1954. It is worth noting that women were not accepted in any Canadian medical school just over 100 years ago.

Similarly, our schools now welcome candidates who reflect the ethnic spectrum of the population, and this range of cultural and ethnic backgrounds enriches everybody and helps ensure that our graduates will understand and respond appropriately to diversity within their patient population.

However, increased recognition of the value of inclusiveness in Canadian medical schools in no way detracts from the class of 1954, whose members have provided committed service and leadership to their profession for so many years.

#### Carol P. Herbert

Dean

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1. Fifty years at the University of Western Ontario. CMA7 2000;163(12):1581.

### Clinical examination for carpal tunnel syndrome

Thenar wasting is not mentioned in the CMA7 clinical update on carpal tunnel syndrome.¹ However, it may be obvious on one or both sides — particularly in elderly people — and it can even reduce the thenar bulk of the heavy labourer's typically more muscular dominant side so that it matches that of the other side. Thenar wasting is associated with detectable loss of muscle power. These signs are common, reliable and easily elicited at the bedside.

#### Alex MacIntyre

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#### Reference

 Myers KA. Utility of the clinical examination for carpal tunnel syndrome. CMA7 2000;163(5):605.

The clinical update on the utility of the clinical examination for carpal tunnel syndrome¹ is a review of a review. The original article highlights the pitfalls of using MED-LINE-based reviews to generate clinical practice guidelines.² The basic assumption of Kathryn Myers' clinical update is that electrodiagnostic studies represent the gold standard for di-

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