## Making drug data more transparent

Joel Lexchin discusses the importance of informing people about medicines so that they can be knowledgeable about the risks and benefits of various drugs.[1] Although it recognizes that there is an element of risk in all medicinal products, the Pharmaceutical Manufacturers Association of Canada (PMAC) has always advocated that information about medicines be made available to both health care professionals and patients.

As Lexchin notes, the processes and procedures of the Therapeutic Products Directorate concerning disclosure of data are less transparent than those in the US. The PMAC supports a renewal of the Canadian system, and the objective of this exercise should be harmonization with the practices in other major developed countries. The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project. It brings together regulatory authorities from Europe, Japan and the US, as well as experts from the pharmaceutical industry in these regions, to discuss scientific and technical aspects of product registration. Canada currently holds observer status within the ICH, but the PMAC believes this country should become an ICH cosponsor. We have made that request to the organization.

**Judith A. Erola**
President
Pharmaceutical Manufacturers
Association of Canada
Ottawa, Ont.

**Reference**

1. Lexchin J. Secrecy and the Health Protection Branch. *CMAJ* 1998;159(5):481-3.

## Physicians and breast examination

As a radiologist interested in breast cancer I have had the opportunity to speak on the diagnosis of this disease to a number of women's groups. These talks are usually followed by a question-and-answer period.

At one such talk, one woman, a breast cancer survivor, asked me why physicians are not taught how to examine breasts. I was taken aback by this question — I had just emphasized the important role of the family physician's regular physical examination in breast cancer detection. I was even more surprised by the chorus of confirmation from many of the other women present.

I was told that some physicians are shy or otherwise reluctant to vigorously and thoroughly examine breasts. The women reported that some doctors are obviously uncomfortable with the procedure, whereas others seem unsure or apologetic. For whatever reason, such physicians do not inspire their patients' confidence. I had stated in my talk that all physicians are taught the art of breast examination as part of their training. Unfortunately, in the opinion of many of these highly motivated and discerning women, some physicians have not put this training into practice.

This is an issue sufficiently important to warrant some action. I suspect that the reality is somewhere in the middle. There are probably some physicians who simply do not know how to examine breasts appropriately, which represents a failure of medical schools and clinical programs. But there are probably others who *are* performing adequate examinations but are unable to convey their skill and confidence in the procedure to their patients. Both failings require remedy. Any suggestions?

**Joe Zanbilowicz, MD, CM**
St. Joseph's General Hospital
Comox, BC

## Bittersweet memories of residency

Robert Patterson's recollections of residency were bittersweet,[1] particularly the entry entitled "A resident dies, take 2." I read them on the day I was supposed to attend a hospital memorial service for a gifted young intensivist who had died suddenly. After reading Patterson's article I surprised myself by deciding not to attend the service. I had realized that the service would inadvertently serve to individualize what was a collective tragedy. Instead, I retreated to ponder the decency and the pathos of a system

that commended an exhausted physician for distributing articles on DVT prophylaxis while relentless circadian and other hidden demons were consuming his soul.

**Erica Weir, MD**
PGY1
Hamilton, Ont.

**Reference**

1. Patterson R. You're the worst goddamm resident I've ever had. *CMAJ* 1998;159 (7):823-5.

## Secondhand smoke and statistical analysis

In their letter about secondhand smoke and cancer,[1] Dildar Ahmad and W. Keith Morgan correctly note that there is a lack of proof that secondhand smoke causes lung cancer. Indeed, there is growing awareness that many of the "facts" about environmental tobacco smoke have been exaggerated for what appear to be political purposes.

Publication bias is troublesome in meta-analyses based solely on the published scientific literature. The "publication threshold" for peer-reviewed journals appears to have fallen in recent years, especially for topics concerning public health and "risky" personal behaviour, because studies deemed to be "of great reader interest" are more likely to be reported in the mass media.

In addition, there is a selection bias favouring publication of positive results. Studies with no statistically significant association or a negative correlation are not published. Foreign-language publications, another wealth of material, are also frequently ignored. Responsible researchers should be urged to take the time and trouble to include these studies or to use "trim and fill" algorithms[2] to account for their absence.

A larger problem is the troubling trend toward reporting "positive correlation" for relative risks of less than 2.0 — particularly when the lower bound is less than 1.0. In a press release[3] accompanying publication of a study on breast cancer and abortion,[4] the US National Cancer Institute noted that "In epidemiological research, relative risks of less than 2 are considered small and are usually difficult to interpret. Such increases may be due to chance, statistical bias or effects of confounding factors that are sometimes not evident." Thus, the relative risk of 1.16 (confidence interval 0.93–1.44) reported by the World Health Organization regarding environmental tobacco smoke and lung cancer is meaningless.

Even the best and most rigorous calculations of risk are but shaky estimates, providing only an upper bound for the effect of a variable. Although it is possible to account for some confounders, multiple factors are often simply not recognized. Unrecognized confounders are important in the issue of environmental tobacco smoke as well as smoking itself, given that smoking or being in the presence of environmental tobacco smoke is often just one in a cluster of risky behaviours.

**Anne Fennell**
Littlewood & Fennell, P.A.
Independent Public and Health Policy Research
Austin, Tex.

Competing interests: None declared.

**References**

1. Ahmad D, Morgan WK. Secondhand smoke and cancer: Where's the proof? *CMAJ* 1998;159(5):441-2.
2. Taylor S, Tweedie R. *Trim and fill: a simple funnel plot based method of adjusting for publication bias in meta-analysis*. Denver: Department of Statistics, Colorado State University; 1998.
3. Abortion and possible risk for breast cancer: analysis and inconsistencies [press release]. Washington (DC): US National Cancer Institute; 1994 Oct 26.
4. Daling JR, Malone KE, Voigt LF, White E, Weiss NS. Risk of breast cancer among young women: relationship to induced abortion. *J Natl Cancer Inst* 1994;88(21): 1584-92.

## Smoking out the tobacco connection

Dildar Ahmad and W. Keith Morgan ask for proof of the relation between secondhand smoke and cancer.[1] Numerous respected studies have shown a clear link between the two, including lung cancer.[2,3] Granted, the link is not as strong as for smokers, but that is to be expected.

Barnes and Bero, writing in the *Journal of the American Medical Association*, have stated that "the only factor associated with concluding that passive smoking is not harmful was whether an author was affiliated with the tobacco industry."[2] In the US, situations have recently been uncovered in which the tobacco industry paid thousands of dollars to physicians in return for writing letters to the editor,[4] submissions that are not generally reviewed before publication to the same extent as many other medical articles.

I suggest that *CMAJ* should require anyone who writes a letter to the editor to state that he or she has not received anything of value from anyone for doing so.

**Roger Ellis**
Attorney at Law
Westlake Village, Calif.

Competing interests: None declared.

**References**

1. Ahmad D, Morgan WK. Secondhand smoke and cancer: Where's the proof? *CMAJ* 1998;159(5):441-2.
2. Barnes DE, Bero LA. Why review articles on the health effects of passive smoking reach different conclusions. *JAMA* 1998;279:1566-70. [Abstract available: www.ama-assn.org/sci-pubs/journals/most/recent/issues/jama/rv71060a.htm (accessed 1998 Nov 23)].
3. Skolnick AA. Draft of report on secondhand smoke released. *JAMA* 1997;277: 1026-71.
4. Hanners D. Scientists were paid to write letters: tobacco industry sought to discredit EPA report. *St. Paul Pioneer Press* 1998 Aug 4. Available: junkscience.com/news3/pioneer.htm (accessed 1998 Dec 4).