



fact that health care never became a hot election issue last June says nothing about its priority for the new government.

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Spirometric testing and the breathalyser

Our recent criminal court experience supports the caution to physicians contained in "Don't use medical excuses to escape breathalyser, MDs warn" (*Can Med Assoc J* 1997;156:157).

A 61-year-old man was arrested for operating a motor vehicle while impaired by alcohol. At the police station he did not provide a suitable breath sample for the breathalyser, citing "shortness of breath" from smoking and work in a dusty area that day. The breathalyser technician noted that the accused did not blow hard enough to raise the piston, and no exhalation or venting was detected after several attempts.

A physician wrote that the accused had "a degree of chronic destructive [sic] lung disease," and with no objective spirometric data concluded that it would be difficult for the accused to provide a breath sample for the breathalyser.

At trial, a videotape of the accused taken at the police station showed he had no apparent breathing problems while walking or talking. The physician testified that the accused had some degree of chronic obstructive pulmonary disease (COPD), but upon cross-examination admitted it was not severe enough to warrant spirometric testing.

In a study of 10 patients with known COPD, all were able to provide an adequate sample for the breathalyser. These patients (aged 56 to 78 years) had a forced expiratory volume in 1 second (FEV₁) between

0.46 and 1.86 L and a ratio of FEV₁ to forced vital capacity of from 0.19 to 0.53.¹

Our experience is that objective spirometric testing, showing significantly diminished values, is required for reliable testimony in these types of cases. In this case, the accused was convicted of failing to provide a breath sample.

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Reference

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Drug- and caffeine-induced headaches

The article "Guidelines for the diagnosis and management of migraine in clinical practice" (*Can Med Assoc J* 1997;156:1273-87), by Dr. William E.M. Pryse-Phillips and associates, is an excellent overview. On the basis of my personal and practice experience, I would like to see more emphasis on the importance of drug-induced and caffeine-induced headaches. Anyone with frequent headaches (more than 2 per week) should be carefully questioned about intake of caffeine and use of over-the-counter and prescription drugs.

Acetaminophen and NSAIDs are the drugs least likely to cause headaches. Anything else needed to relieve headache pain (including sumatriptan) is prone to causing rebound headaches when withdrawn.

The initial management should involve identification and avoidance of triggers, careful and sensitive provi-

sion of information, the simplest single analgesic, rest, ice and massage. An appropriately informed patient can then be his or her own headache expert, detective and healer.

Philip E. Shea, MD
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[The principal author responds:]

I certainly agree with Dr. Shea that there are several areas to do with migraine that require emphasis for their optimal management in Canada.

Our article was written according to the strict requirements for guidelines based on randomized controlled trials. Very few of the nonpharmacologic therapies have been subject to such analyses; as a result, they could not be included. As we mentioned in the article, we have decided to perform a separate review of all such therapies, including acupuncture, biofeedback and hypnosis.

The whole problem of drug-induced headache is a very important one. We referred to it briefly in our article but, to my knowledge, no firm guidelines for diagnosis have yet been constructed and agreed upon, although this work is in progress.

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Feverfew products

The article "Herbal products begin to attract the attention of brand-name drug companies" (*Can Med Assoc J* 1996;155:216-9), by Kate Cottrell, contains some errors.

The Health Protection Branch (HPB) of Health Canada regulates botanical products under its Food and Drug directorates. If a product is classified as a drug, usually after a manufacturer makes a therapeutic



claim or the Drug Directorate decides it has pharmacologic activity, it must have a drug identification number (DIN) in order to be marketed legally. However, many products with widely recognized pharmacologic activity are sold in Canada with and without a DIN.

Tanacet, a feverfew-based product highlighted in the article, is correctly identified as the first modern herbal product accorded a DIN for a specific therapeutic application based on orthodox clinical data. However, the article states incorrectly that a DIN was needed "because it exceeds an HPB-specified level of parthenolide, the active ingredient." The DIN is based entirely on the therapeutic claim. As an employee of the Drugs Directorate for 20 years and the official spokesperson on herbal science, I was instrumental in establishing, along with Dr. Stan Heptinstall of the University of Nottingham's Queen's Medical Centre, the criterion of a minimum content of 0.2% parthenolide for feverfew leaf's sesquiterpene lactones in inhibiting *in vitro* release of serotonin from blood platelets. This theory of the mechanism of migraine is simply the best hypothesis so far and has not been demonstrated to be relevant to the prevention of migraine.

Further, the assertion that "before launching the product, McNeil identified which species of feverfew had the highest level of parthenolide" is false. McNeil was not involved in the DIN application, which was obtained by Herbal Laboratories in the UK. Although 34 species in 2 plant families have been identified as containing parthenolide, so far only feverfew (*Tanacetum parthenium*, dried leaf) has been clinically tested.

Finally, the statement that "Life Brand . . . products are tested to ensure standardization and shelf life of the active ingredients" displays a lack of appreciation of 2 major areas of contention in herbal medicine sci-

ence today. The active constituents of a herbal medication that are responsible for its pharmacologic effects are rarely known to the degree that dose-response relations can be meaningfully established, making expiry dates a problem. The standardization claimed by many manufacturers often has more bearing on quality control and batch-to-batch consistency than on intensity and reliability of effect and is the subject of intense debate within the industry and certain regulatory agencies.

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[The author responds:]

Clearly, despite considerable efforts to clarify the conditions under which a herbal product requires a DIN, I have not managed to fully grasp the intricacies of the process. Dr. Awang says a product may be classified as a drug requiring a DIN when "the Drug Directorate decides it has pharmacologic activity"; yet he goes on to say that "many products with widely recognized pharmacologic activity are sold in Canada . . . without a DIN." Perhaps I am not alone in failing to understand under what circumstances a product's pharmacologic activity warrants drug classification and thus requires a DIN.

McNeil stressed that Tanacet contains a consistent percentage of parthenolide, the active ingredient, and that the company had chosen to use a type of feverfew known to produce it in high enough levels for its product. I erred in inferring that the company had been active in identifying the species of plant; it was active only insofar as it made use of existing research that identified that plant, some of which must be credited to Awang.

Regarding my statement about the testing of Life Brand products to ensure standardization and shelf life of the active ingredients: I was clearly mistaken to take what I was told at face value. I should have asked for a more specific definition as to whether their standardization and shelf life referred to quality control and batch-to-batch consistency or to reliability of effect, as was implied.

Herbal medicine is indeed fraught with contention, and there are many grey areas surrounding the manufacture, regulation and control of these products that need to be addressed. I apologize for any confusion I may have inadvertently caused, and I hope that Awang's criticisms will help shed light on a complex subject.

Kate Cottrell, BA
Consecon, Ont.

Epidurals and fever: association or cause?

The Research Update item "Epidurals and fever" (*Can Med Assoc J* 1997;156:1262) was certainly newsworthy for *CMAJ* readers; however, the analysis was inaccurate and misleading. The statement that "epidural analgesia during labour *can cause* [our emphasis] fever in mothers

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