

## Voluntary recall of ephedra products not enough, MD says

Health Canada has announced a voluntary recall of some products containing ephedra and ephedrine, even though their sale has long been prohibited in this country. In Canada, ephedra is authorized for use only as an over-the-counter nasal decongestant. "None of these products should have ever been allowed," says Dr. Stephen Jones of West Elgin, Ont., who helped compile a herbal database for Health Canada in 1990. Ephedra is traditionally used to treat colds, asthma and hay fever, and has been linked to at least 60 adverse events in Canada and 81 deaths in the US. Ephedra refers to several species of herbs; ephedrine is one of the many chemical derivatives.

Although Jones is pleased with the voluntary recall, he says it doesn't go far enough. "Ephedra has to be regulated as a drug," he says.

Several American organizations, including the 135 000-member Public Citizen Health Research Group, agree. It has asked the Food and Drug Administration (FDA) to ban dietary supplements containing ephedra. And the US Association of Food and Drug Officials wants the FDA to limit sales of ephedra, either by making it a prescription drug or by restricting its use as an ingredient.

On Jan. 9, Health Canada issued a voluntary recall of products containing more than 8 mg of ephedrine per dose, as well as products that combine ephedra or ephedrine with stimulants such as caffeine, and products with labels that make claims concerning weight loss, body-building or euphoria.

In November, Health Canada officials told *CMAJ* that "many ephedrine-containing preparations that are not approved for sale are being used by Canadians." Phillip Waddington, head of Health Canada's Natural Health Products Directorate, said then that the government has to crack down on these sales.

Waddington's directorate may consider making ephedra a controlled substance, which would force manufacturers to report how much they purchase and sell. But a ban isn't in the works. "We don't ban products because there's potential to misuse them," he says. "We don't ban glue because some people sniff it."

Ephedra has been linked with 1 death and 2 suicides in Canada. Other reported adverse events range from dizziness, tremors, headaches, irregular heart rates and seizures to myocardial infarctions and strokes. In June 2001, Health Canada issued an advisory warning con-

sumers not to use products containing ephedra to lose weight or increase energy, or for body-building. Health Canada also warned that ephedrine may cause "serious, possibly fatal, adverse effects" when combined with caffeine or other stimulants.

Waddington says problems arise when ephedra's impact is compounded by the use of caffeine or acetylsalicylic acid (ASA). He says 80% of adverse events reported in the US have involved its concomitant use with caffeine, 17% with ASA; only 3% involved ephedra used alone. Still, Waddington insists the risks are small, citing a recent review article (*Obesity Reviews* 2001;2:199-211). It concluded that "the benefits of caffeine and ephedrine in treating obesity appear to outweigh the small associated risks."

But researchers at the University of California (San Francisco) say the FDA must develop safe-dosing recommendations and demand proper labelling. Their recent study (*N Engl J Med* 2000;311:1095-7) assessed 140 adverse-event reports and determined that 31% of the people involved "definitely" or "probably" experienced an adverse effect after using ephedrine to lose weight. Of those, 3 died, 7 suffered permanent injury and 4 required ongoing medical treatment. Lead author Christine Haller, an assistant adjunct professor of medicine and clinical pharmacology, told *CMAJ* that several healthy young people have experienced adverse events linked to ephedra and "we need more understanding of why some people have problems. Perhaps we should ban it until then."

The FDA is also considering banning "herbal ecstasy" — a combination of ephedra, caffeine and ASA that is supposed to mimic the effects of an illegal street drug, ecstasy. It was banned in Florida in 1996 when a student died after taking a similar product containing ephedra. Health Canada is also looking at ways to control the sale of herbal ecstasy, Waddington said. —

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Health Canada has issued a voluntary recall for some products containing ephedra.