COMPLEMENTARY MEDICINE

Debate over credibility of natural health product claims

Clinical trials of natural health products are unnecessary because the existing licensing process adequately addresses the public's safety and efficacy concerns, says the director-general of Health Canada's Natural Health Products Directorate (NHPD), Phil Waddington.

Before going to market, natural products are tested for toxicity, and a monograph, including a health claim, is developed. Post-market, the products' manufacturers must provide a "safety summary report" that guarantees ample consumer protection, says Waddington.

If something untoward surfaces after the product has gone to market, "then, of course, we wouldn't allow it to go forward, or it would have to be mitigated through other means, such as limiting the dose, or putting a warning on the label."

This "safe-until-proven otherwise" policy has been entirely ineffective in the US, says Bruce Silverglade, director of legal affairs for the US Center for Science in the Public Interest (CSPI), a public advocacy group. It creates a "reverse onus" on the US Food and Drug Administration to demonstrate that a product is hazardous before the agency can demand it be pulled from the shelves. "In the case of ephedra, it took the FDA 10 years to mount the case, while people were dying."

In January, the US Institute of Medicine and the Agency for Healthcare Research and Quality urged that natural health products be subject to the same clinical testing requirements imposed on pharmaceuticals. But Waddington argues that if NHPD, which oversees licensing of an estimated 50 000 natural health products, were to rely strictly on clinical trials, it wouldn't "get as complete a picture" of a product's safety as through toxicity testing and post-market surveillance.

He rejects accusations by the CSPI that the directorate's approach is nothing less than a "mockery of the scientific review process" (*Nutrition Action Healthletter* November 2004) and that it implicitly helps to mislead consumers by allowing manufacturers to make unsubstantiated and often contradictory claims about the efficacy and benefits of their natural health products, typically by citing "traditional use."

Waddington says NHPD carefully steers for the "middle" ground between classic scientific standards and cultural demands. Allowing manufacturers to make claims of therapeutic benefit because "traditional use" is consistent with the demographics of Canada: "we want to be able to respect [its] multicultural nature."

Traditional use involves the "healing paradigm" in which a product has been used. For example, traditional Chinese medicine "has to have had at least 50 years of use within that paradigm."

But Bill Jeffery, national coordinator of the Canadian CSPI, says extended use is hardly evidence of "whether a product actually serves the purpose." Echinacea, for example, continues to be sold as a remedy for colds, despite contradictory evidence.

Canapress

A health claim based on "traditional use," such as those used for Chinese medicines, must be backed by 50 years of experience.

Health Canada is, de facto, "assisting industry in deceiving consumers" while abandoning the scientific method, which is based upon "learning from mistakes. That's not the case with traditional use," he says.

Each of the 218 products now licensed by Health Canada got a stamp of government approval regarding its safety, efficacy and quality.

The Canada Health Food Association, a trade organization, says the government's acceptance of the notion of traditional use affirms its validity. "It's a level of evidence that our government is willing to accept," says spokesperson Anne Wilkie.

That's hardly assurance of the validity of therapeutics claims, Jeffery says, given that the effects of most natural health products haven't been scientifically established. — *Wayne Kondro*, Ottawa

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