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Don't panic, it's organic: dispute over natural health products regulations continues

Critics of Health Canada's proposed regulatory framework for natural health products say that its standards of evidence for safety serve manufacturers and complementary care providers, not the people who use the products.

The proposed regulatory framework (**www.hc-sc.gc.ca/hpb/onhp**), which will likely go before Parliament early next year, states that standards of evidence for safety and health claims will "not be limited to double-blind clinical trials."

According to the latest framework, the directorate will use 3 levels of evidence: randomized controlled trials (RCTs), existing (traditional) use and initial evidence (products for which the collection of evidence has just begun).

"Consumers don't want to wait 20 years," says Philip Waddington, head of the Natural Health Products Directorate (NHPD). Waddington, a naturopath, says his directorate will try "to provide access while ensuring safety and effectiveness. Clinical trials are one way to gain evidence on whether it works. Years of usage is another way. We will look at the whole body of evidence."

Barbara Sibbald

Are standards of evidence for natural products too weak?

However, Canadians for Rational Health Policy (CRHP), a national association of 60 scientists and physicians, wants pre-market efficacy testing for all natural health products. "Dropping standards will only protect the interests of the producers and providers, not the public," says Dr. Lloyd Oppel, the Vancouver emergency physician who heads CRHP. He describes the traditional-use argument as "astoundingly weak."

Waddington says his office will attempt to educate consumers if other standards of evidence are allowed. For example, there isn't an RCT demonstrating that echinacea is useful in preventing colds and flu, but this is a traditional use. The NHPD may end up requiring labelling such as: "Traditionally used for…," Waddington says.

The recommendation not to limit standards to RCTs was first suggested by the NHPD's transition team in 1999, and the view was reinforced during cross-Canada consultations last year, says Waddington.

However, Oppel takes "a very dim view" of the consultation process, which he described as a "PR exercise, not an effort to get scientific information." Members of his group were refused a spot on the NHPD advisory panel, and their presentation to Health Canada asking for more rigorous standards was ignored. "It's clear the government wants to placate the public, its voters," says Oppel.

There is no international consensus on how to regulate natural health products. The US lists them as dietary supplements, with the onus on manufacturers to have data supporting their claims. At the other extreme, Germany regulates the products as drugs.

Although the Therapeutic Products Program requires manufacturers to pay for the drug-approval process, the same cost-recovery rules won't be applied to makers of natural health products.

"The impact on small manufacturers is one of the prime drivers behind the NHPD," said Waddington. "They're smaller businesses, therefore [the regulations] have to be appropriate." — *Barbara Sibbald*, CMAJ

No public voice in genetics research?

As medical researchers march into genetics laboratories, it is essential that members of the community march alongside them, the past president of the Canadian Bioethics Society says. "Clinical trials are going to be in big trouble if there isn't more honesty and more transparency in transmitting the legitimate goals of DNA research," Dr. Bartha Maria Knoppers told participants attending a recent meeting in Halifax.

In an earlier paper written for the *McGill Law Journal*, Knoppers explained why DNA research is raising concerns in the community that other types of research do not. "These developments have raised a certain sense of public unease with the deciphering of the genomes of all living organisms … and a perceived transgression of our humanness, if not humanity, in this new technocracy."

Knoppers says a critical first step in overcoming this unease is to promote the active involvement of community members in the research. "We need a [bigger] public voice," says Knoppers, a law professor at the Université de Montréal. "The first place to go is the research ethics review board. There is a real mandate here for patients' organizations to get involved."

In 1978, the Medical Research Council of Canada (MRC) released its Ethics in Human Experimentation Guidelines, which called for the addition of lay members to ethics review committees. "[Lay members] are essential to ethics review committees and might form a majority," the guidelines stated. Twenty years later, a policy statement released by the MRC, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada (**www.nserc.ca/programs/ethics/english**) called for "at least one member with no affiliation with the university be recruited from the community."

Knoppers said that the hope that community members would comprise the majority of committee members has now transformed into the need for committees to have at least one community member. — *Donalee Moulton*, Halifax