Some natural scepticism about the Natural Health Products Directorate

The word "natural," applied by marketing departments to everything from shampoo, foods and fabrics to (perhaps with some relevance) pine caskets, implies a claim that such products are a wise and wholesome choice. With respect to herbal remedies and food supplements, manufacturers have until now been able to imply what they liked, as long as they made no explicit promise of therapeutic benefit. But now we have a means of keeping a sharper regulatory eye on the arcane array of "natural" products that occupy an increasing share of shelf space in pharmacies and health food stores. The mission of the recently created Natural Health Products Directorate (see page 679)[1] is to "ensure that all Canadians have ready access to natural health products that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity."[2] Much as we welcome the extension of food and drug regulation into the nebulous terrain of the natural, we cannot help asking: Safety and efficacy are one thing, but since when have "philosophical and cultural diversity" been a guarantor of either?

For the moment it's not entirely clear where the category of natural health product begins or ends. Ripped Force, a cocktail of natural substances, contains ephedra alkaloids; a 22-year-old man who used it while lifting weights suffered a cardiac arrest.[3] Are such products, which fall within the NHPD's purview, more "natural" than penicillin? The current definitional framework appears to be that the NHPD will regulate products that "are generally used and best managed within the context of a wellness, holistic medical paradigm that optimizes health."[2] Whatever that means.

It seems to mean that while penicillin will continue to be regulated by the Therapeutic Products Programme, the nominally natural will be subjected to a softer, gentler scrutiny, one that is not "limited to double blind clinical trials, but may also include other types of evidence such as generally accepted and traditional references ...." The government appears to believe that when it comes to safety and efficacy there are "other ways of knowing."

The NHPD will be powered by an Expert Advisory Committee whose members are "agreeable to [industry] stakeholders." One could reasonably expect this requirement to blunt the Directorate's milk teeth. Even major pharmaceutical companies, with extraordinary depth of resources, abundant traditional scientific expertise, and extensive premarket evaluations of short-term safety, have a patchy record when it comes to postmarketing surveillance for severe but rare side effects (see page 684).[4] Some companies have demanded retractions of scientific reports of adverse effects (see page 621)[5] and others have required gag clauses in legal settlements with stroke victims.[6]

The NHPD may be stillborn, unless critical changes are made that result in effective, unbiased evaluations and monitoring systems that lead to active reporting. Safety is not a holistic concept of wellness and a new paradigm. Hemorrhagic strokes happen. They are part of an old paradigm and an intensely scientific one. There are no other ways of knowing. — *CMAJ*

References

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