



# Herbal Roulette

Does it work? Is it safe? Don't ask the government.

BY DAVID SCHARDT

**N**ostalgic for the good old days? Looks like Health Canada is, too. It's trying to roll back the calendar to the 19th century and the era of snake oil.

Over the last few years, Health Canada's Natural Health Products Directorate (NHPD) has authorized more than 300 new—sometimes astonishing—claims for the benefits of some 60 herbs and other botanicals. Manufacturers are now free to use the claims to market their products in Canada.

Thanks to the NHPD's generosity, companies can peddle catnip for colds, cornflower to strengthen "weak eyes," frankincense to relieve "nervous problems," rosemary to "improve mental clarity and memory," and eleuthero to "increase longevity" (just don't take it for more than three months, the NHPD cautions).

But it's hard to beat the herb called "heal-all." A cup of heal-all tea has been traditionally effective, says the NHPD, for relieving sore throats, backaches, coughs, colds, stomach cramps, shortness of breath, diarrhea, vomiting, and fevers. Heal-all can also stop spasms, reduce inflammation, and "strengthen the womb," among other things.

The NHPD has approved these claims as part of a new regulatory scheme for natural health products that's being phased in over the next four years. The idea is to assure consumers that they can buy their vitamins, minerals, and herbs in confidence because the products have been "reviewed and approved by Health Canada for safety and efficacy."

Safety? Efficacy? Hardly.

## The Granny Factor

It sounds great...at least in theory. Companies can't make claims for herbs or other natural health products unless the Natural Health Products Directorate has evaluated and approved the claims.

But the new regulatory system is being guided largely by people whose careers depend on the products they're supposed to be regulating. Although the NHPD insists that it retains final responsibility for its decisions, it relies on a 13-member Expert Advisory Committee to review both health claims and the safety and effectiveness of herbs.

Of the 13, six are practicing herbalists and a seventh runs a wholesale herb import business. Two others have done scientific research on herbs, and two more have built academic careers promoting botanicals for health. Not exactly an impartial crew.

That may explain why 292 of the 303 claims the NHPD has so far approved for herbs are based on "traditional use." To qualify, two independent sources—say, a compilation of herbal cures and a textbook of herbal medicine—have to agree that the herb has been used for at least 50 consecutive years within a "cultural belief system or healing paradigm."

Only 11 claims for herbs rest on "scientific evidence." That's supposed to mean well-designed studies in people. Yet one of the claims (garlic) relies on outdated studies, while two others (black cohosh and St. John's Wort) rely on little or no good evidence. (The NHPD has also approved some 70 claims for vitamins, minerals, amino acids, and other "non-botanicals," but those are mostly textbook statements like iron "helps to prevent iron



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anaemia" or vitamin C is "a factor in the maintenance of good health.")

According to Health Canada's Nathalie Lalonde, so many claims are based on tradition because "well-documented traditional uses" were "the easiest to find and document." As the monographs are revised, she says, "many other uses supported by different types of evidence will be added."

That's good to hear...because so far, the NHPD's assessments haven't exactly been what you'd call rigorous. Take what is arguably the most ridiculous claim the NHPD has approved: European pennyroyal, taken orally, is "traditionally used to reduce giddiness."

The NHPD based its approval on a 1931 compilation of herbal folklore that mentions that European pennyroyal "was deemed by our ancestors valuable in headaches and giddiness." The reference goes on to say, "We are told: 'A garland of Penny-royale made and worn about the head is of great force against the swimming in the head and the pains and giddiness thereof.'"

Our advice: the next time you feel "the swimming in the head" coming on, follow the 1931 compilation and wear your pennyroyal; don't listen to the NHPD and swallow it.

Allowing health claims based on traditional use is "quackery," says Meera Thadani, an assistant professor of pharmacy at the University of Manitoba. "It's not scientific."

Thadani was a member of the Natural Health Products Advisory Committee, which was convened by Health Canada in 1997 to examine the need for regulation.

"Traditional use can mean that my grandmother used it. But so what? Granny never kept track of things.



Thousands of years of use? Well, who was keeping track thousands of years ago? The people who died using the product, who weren't saved by it, don't have a voice in any of this."

Thadani fought against the "traditional use" health claims. She was outvoted.

## Tradition Rules

Pennyroyal may be the most bizarre example of how the Natural Health Products Directorate is opening up labels to outrageous claims, but it's far from the only one.

■ **Saw palmetto.** The saw palmetto bush, which grows in the Southeastern U.S., produces berries that have long been used as an herbal medicine. The NHPD authorized a claim that the herb "helps to relieve the urologic symptoms associated with benign prostatic hyperplasia." The evidence: more than a dozen studies that show that men with enlarged prostates who take saw palmetto average one less visit to the bathroom every two nights than similar men given a placebo.

But the NHPD also okayed a claim that saw palmetto is "traditionally used to promote weight gain."

"I am not aware of any evidence for an effect of saw palmetto on weight," says Timothy

Wilt of the Minneapolis VA Center for Chronic Disease Outcomes Research in Minnesota.

Wilt and colleagues have reviewed trials that tested saw palmetto as a treatment for urinary symptoms due to enlarged prostates for the Cochrane Collaboration, an international network of scientists and others who evaluate medical therapies.

Where does the evidence on weight gain come from?



**Good for what ails ya'.** Canadians can't rely on claims approved by the Natural Health Products Directorate.

In 1879, a physician in Savannah, Georgia, noticed that deer that had become scrawny over the summer would fatten up in the fall by eating saw palmetto berries, which ripen in October and November. The good doctor decided that something in the berries was stimulating the deers' appetites. It apparently didn't occur to him that the berries may have been the only tasty food around. So the physician and his colleagues began adding saw palmetto berries to the tonics they prescribed for their ailing patients.

By the 1920s, according to some accounts, the use of saw palmetto as an appetite stimulant, along with most of its other uses, had fallen out of favour. Apparently, it's still *in* favour at the NHPD.

■ **Echinacea.** Echinacea doesn't prevent colds. Study after study, including the best one to date—a trial sponsored by the National Center for Complementary Medicine of the U.S. National Institutes of Health—shows that (see p. 8). Yet the NHPD lets labels say that the herb is "traditionally used to fight off colds, flus and infections."

Bottom line: when science trumps tradition, the NHPD sticks with tradition. But even when it talks science, it doesn't always tell the whole story.

There may not be any evidence that echinacea prevents colds, but can it make them milder or shorter?

Yes, said the NHPD, when it approved a claim, based on "scientific evidence," that echinacea "acts as supportive therapy in the treatment of colds, flus, upper respiratory infections and urinary infections."

But the NHPD's guidelines require that "the favourable evidence must outweigh the unfavourable evidence." In this case, it doesn't. For every study that finds that echinacea helps cold symptoms, there's a study that finds that it's worthless. (And no studies show that the herb does anything for urinary tract infections.)



■ **Horehound.** The NHPD approved a claim that black horehound is "traditionally used as a sedative." It also approved a claim that the herb is "traditionally used as a stimulant." Clearly, someone at NHPD headquarters needs to wake up (or go to sleep).



■ **Garlic.** The NHPD approved a "scientific evidence" claim that garlic "helps maintain cardiovascular health." It cited research from the early 1990s showing that garlic lowers blood cholesterol and blood pressure, even though most good studies carried out since then show that garlic has little or no impact on blood cholesterol or blood pressure.

■ **Horseradish and fenugreek.** The NHPD approved claims that horseradish is traditionally used as "an anti-scorbutic" (meaning it treats



scurvy) and that fenugreek is traditionally used as an "antipellagral" (it treats pellagra). Scientists now know that scurvy is caused by a vitamin C deficiency and pellagra is caused by a niacin defi-

ciency. It makes no sense—and it could be dangerous—to take anything other than vitamin C to treat scurvy or niacin to treat pellagra.

The NHPD has quickly fallen behind in approving natural health products for sale, let alone approving claims for them. By the middle of this summer, it had

dealt with just 522 of the 8,180 requests. Companies are expected to submit more than 30,000 products for approval over the next year or two. The natural health products industry is grumbling that the process is taking too long and that the new regulations should be loosened up.

Could they get any looser? 🍀

## Cold Comfort



According to the Natural Health Products Directorate, consumers can tell whether a claim is based on solid science simply by reading the product's label. Yet the most recent example of a natural health product label that the NHPD has published on its Web site confuses traditional use with scientific evidence.

### WHAT DOES NEW LABELLING MEAN FOR YOU?

Informed Choice  
Assurance of the Product's Safety, Quality and Claim  
Confidence in knowing that what is on the label is in the bottle

**Product Safety**  
A kit number and contact information will facilitate reporting on concerns and assist with recall action in the event of a product safety issue.

**Health claim**  
All natural health products will display their recommended use or purpose which is appropriate and truthful.

**Natural Product Number**  
The Natural Product Number indicates that Health Canada has assessed this product for its safety, quality and claim and has authorized it for sale in Canada.

**A complete listing of all ingredients.**  
A complete listing of all medicinal and non-medicinal ingredients will help you make an informed choice allowing you to include and/or avoid ingredients which are important to you.

**Complete conditions for use**  
Complete conditions for use, in both official languages, including any warnings and/or cautions will assist you in using the product in a safe and appropriate manner.

**FOR ILLUSTRATION PURPOSES ONLY**

"Relieves sore throats due to colds," says the large print on the front of the hypothetical box of echinacea tablets. That's the way a claim would be worded if it were based on *scientific* evidence. Yet the Natural Health Products Directorate approved the claim based on *traditional* use. The large print should say: "Traditionally used for the relief of sore throats due to colds."

If this were a real box, it would be illegal.

Natural Health Products Directorate: home page ([www.hc-sc.gc.ca/dhp-mps/prodnatur/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index_e.html)), monographs ([www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/mono\\_list\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/mono_list_e.html)).