

# How to Spot Health Fraud

by Paula Kurtzweil

You don't have to look far to find a health product that's totally bogus--or a consumer who's totally unsuspecting. Promotions for fraudulent products show up daily in newspaper and magazine ads and TV "infomercials." They accompany products sold in stores, on the Internet, and through mail-order catalogs. They're passed along by word-of-mouth.

And consumers respond, spending billions of dollars a year on fraudulent health products, according to Stephen Barrett, M.D., head of Quackwatch Inc., a nonprofit corporation that combats health fraud. Hoping to find a cure for what ails them, improve their well-being, or just look better, consumers often fall victim to products and devices that do nothing more than cheat them out of their money, steer them away from useful, proven treatments, and possibly do more bodily harm than good.

"There's a lot of money to be made," says Bob Gatling, director of the program operations staff in the Food and Drug Administration's Center for Devices and Radiological Health. "People want to believe there's something that can cure them."

FDA describes health fraud as "articles of unproven effectiveness that are promoted to improve health, well being or appearance." The articles can be drugs, devices, foods, or cosmetics for human or animal use.

FDA shares federal oversight of health fraud products with the Federal Trade Commission. FDA regulates safety, manufacturing and product labeling, including claims in labeling, such as package inserts and accompanying literature. FTC regulates advertising of these products.

Because of limited resources, says Joel Aronson, team leader for the nontraditional drug compliance team in FDA's Center for Drug Evaluation and Research, the agency's regulation of health fraud products is based on a priority system that depends on whether a fraudulent product poses a direct or indirect risk.

When the use of a fraudulent product results in injuries or adverse reactions, it's a direct risk. When the product itself does not cause harm but its use may keep someone away from proven, sometimes essential, medical treatment, the risk is indirect. For example, a fraudulent product touted as a cure for diabetes might lead someone to delay or discontinue insulin injections or other proven treatments.

While FDA remains vigilant against health fraud, many fraudulent products may escape regulatory scrutiny, maintaining their hold in the marketplace for some time to lure increasing numbers of consumers into their web of deceit.

How can you avoid being scammed by a worthless product? Though health fraud marketers have become more sophisticated about selling their products, Aronson says, these charlatans often use the same old phrases and gimmicks to gain consumers' attention--and trust. You can protect yourself by learning some of their techniques.

The following products typify three fraudulent products whose claims prompted FDA to issue warning letters to the products' marketers, notifying them that their products violated federal law. Two of the products also were added to FDA's import alert list of unapproved new drugs promoted in the United States. Products under import alert are barred from entry onto the U.S. market.

Take a look at these products' promotions. They are rife with the kind of red flags to look out for when deciding whether to try a health product unknown to you.

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# Tip-Offs to Rip-Offs

## Product No. 1: Pure emu oil

FDA determined that a pure emu oil product marketed to treat or cure a wide range of diseases was an unapproved drug. Its marketer had never submitted to FDA data to support the product's safe and effective use.

### One Product Does It All

"... extremely beneficial in the treatment of rheumatism, arthritis ... infections ... prostate problems, ulcers ... cancer, heart trouble, hardening of the arteries, diabetes and more. ...."

"completely eliminating the gangrene ..."

"... antibiotic, pain reliever ... ."

Be suspicious of products that claim to cure a wide range of unrelated diseases--particularly serious diseases, such as cancer and diabetes. No product can treat every disease and condition, and for many serious diseases, there are no cures, only therapies to help manage them.

Cancer, AIDS, diabetes, and other serious diseases are big draws because people with these diseases are often desperate for a cure and willing to try just about anything.

### Personal Testimonials

"Alzheimer's Disease!!! My husband has Alzheimer. On September 2, 1998 he began eating 1 teaspoon full of ... Pure Emu Oil each day. ... Now (in just 22 days) he mowed the grass, cleaned out the garage, weeded the flower beds, and we take our morning walk again. It hasn't helped his memory much yet, but he is more like himself again!!!"

Personal testimonies can tip you off to health fraud because they are difficult to prove. Often, says Reynaldo Rodriguez, a compliance officer and health fraud coordinator for FDA's Dallas district office, testimonials are personal case histories that have been passed on from person to person. Or, the testimony can be completely made up.

"This is the weakest form of scientific validity," Rodriguez says. "It's just compounded hearsay."

Some patients' favorable experiences with a fraudulent product may be due more to a remission in their disease or from earlier or concurrent use of approved medical treatments, rather than use of the fraudulent product itself.

### Quick Fixes

"... eliminates skin cancer in days! ..."

Be wary of talk that suggests a product can bring quick relief or provide a quick cure, especially if the disease or condition is serious. Even with proven treatments, few diseases can be treated quickly. Note also that the words "in days" can really refer to any length of time. Fraud promoters like to use ambiguous language like this to make it easier to finagle their way out of any legal action that may result.

## **Product No. 2: Over-the-counter transdermal weight-loss patch**

FDA issued a warning letter to the marketer of the weight-loss product described here because it did not have an approved new drug application. Because of the newness of the dosage form--skin-delivery systems--FDA requires evidence of effectiveness, in the form of a new drug application, before the product can be marketed legally.

### **'Natural'**

**"Healthy, simple and natural-way to help you lose and control your weight."**

Don't be fooled by the term "natural." It's often used in health fraud as an attention-grabber; it suggests a product is safer than conventional treatments. But the term doesn't necessarily equate to safety because some plants--for example, poisonous mushrooms--can kill when ingested. And among legitimate drug products, says Shelly Maifarth, a compliance officer and health fraud coordinator for FDA's Denver district office, 60 percent of over-the-counter drugs and 25 percent of prescription drugs are based on natural ingredients.

And, any product--synthetic or natural--potent enough to work like a drug is going to be potent enough to cause side effects.

### **Time-Tested or New-Found Treatment**

**"This revolutionary innovation is formulated by using proven principles of natural health based upon 200 years of medical science."**

Usually it's one or the other, but this claim manages to suggest it's both a breakthrough and a decades-old remedy.

Claims of an "innovation," "miracle cure," "exclusive product," or "new discovery" or "magical" are highly suspect. If a product was a cure for a serious disease, it would be widely reported in the media and regularly prescribed by health professionals--not hidden in an obscure magazine or newspaper ad, late-night television show, or Website promotion, where the marketers are of unknown, questionable or nonscientific backgrounds.

The same applies to products purported to be "ancient remedies" or based on "folklore" or "tradition." These claims suggest that these products' longevity proves they are safe and effective. But some herbs reportedly used in ancient times for medicinal purposes carry risks identified only recently.

### **Satisfaction Guaranteed**

**"... Guarantee: If after 30 days ... you have not lost at least 4 pounds each week, ... your uncashed check will be returned to you ... ."**

Here's another red flag: money-back guarantees, no questions asked.

Good luck getting your money back. Marketers of fraudulent products rarely stay in the same place for long. Because customers won't be able to find them, the marketers can afford to be generous with their guarantees.

## **Product No. 3: Unapproved weight-loss product marketed as an alternative to a prescription drug combination**

FDA issued an import alert for a Canadian-made weight-loss product whose claims compared the product with two prescription weight-loss drugs taken off the market after FDA determined they posed a health hazard.

## Promises of Easy Weight Loss

**"Finally, rapid weight loss without dieting!"**

For most people, there is only one way to lose weight: Eat less food (or fewer high-calorie foods) and increase activity.

Note the ambiguity of the term "rapid." A reasonable and healthy weight loss is about 1 to 2 pounds a week.

## Paranoid Accusations

**"Drug companies make it nearly impossible for doctors to resist prescribing their expensive pills for what ails you . . ."**

**"It seems these billion dollar drug giants all have one relentless competitor in common they all constantly fear--natural remedies."**

These claims suggest that health-care providers and legitimate manufacturers are in cahoots with each other, promoting only the drug companies' and medical device manufacturers' products for financial gain. The claims also suggest that the medical profession and legitimate drug and device makers strive to suppress unorthodox products because they threaten their financial standing.

"This [accusation] is an easy way to get consumers' attention," says Marjorie Powell, assistant general counsel for the Pharmaceutical Research and Manufacturers of America. "But I would ask the marketers of such claims, 'Where's the evidence?' It would seem to me that in this country, outside of a regulatory agency it would be difficult to stop someone from making a claim."

Think about this, too: Would the vast number of people in the health-care field block treatments that could help millions of sick, suffering patients, many of whom could be family and friends? "It flies in the face of logic," Barrett says on his Quackwatch Website.

## Meaningless Medical Jargon

**"... Hunger Stimulation Point (HSP) ..."**

**"... thermogenesis, which converts stored fats into soluble lipids ..."**

**"One of the many natural ingredients is inolitol hexanicontinate."**

Terms and scientific explanations such as these may sound impressive and may have an element of truth to them, but the public "has no way of discerning fact from fiction," Aronson says. Fanciful terms, he says, generally cover up a lack of scientific proof.

Sometimes, the terms or explanations are lifted from a study published in a reputable scientific journal, even though the study was on another subject altogether, says Martin Katz, a compliance officer and health fraud coordinator for FDA's Florida district office. And chances are, few people will check the original published study.

"Most people who are taken in by health fraud will grasp at anything," he says. "They're not going to do the research. They're looking for a miracle."

## **Truth or Dare**

The underlying rule when deciding whether a product is authentic or not is to ask yourself: "Does it sound too good to be true?" If it does, it probably isn't true.

If you're still not sure, check it out: "Look into it--before you put it in your body or on your skin," says Reynaldo Rodriguez, a compliance officer and health fraud coordinator for FDA's Dallas district office.

To check a product out, FDA health fraud coordinators suggest:

- Talk to a doctor or another health professional. "If it's an unproven or little-known treatment, always get a second opinion from a medical specialist," Rodriguez says.
- Talk to family members and friends. Legitimate medical practitioners should not discourage you from discussing medical treatments with others. Be wary of treatments offered by people who tell you to avoid talking to others because "it's a secret treatment or cure."
- Check with the Better Business Bureau or local attorneys generals' offices to see whether other consumers have lodged complaints about the product or the product's marketer.
- Check with the appropriate health professional group--for example, the American Heart Association, American Diabetes Association, or the National Arthritis Foundation if the products are promoted for heart disease, diabetes or arthritis. Many of these groups have local chapters that can provide you with various resource materials about your disease.
- Contact the FDA office closest to you. Look for the number and address in the blue pages of the phone book under U.S. Government, Health and Human Services, or go to <http://www.fda.gov/AboutFDA/ContactFDA/FindanOfficeorStaffMember/FDAPublicAffairsSpecialists/default.htm> (<http://www.fda.gov/AboutFDA/ContactFDA/FindanOfficeorStaffMember/FDAPublicAffairsSpecialists/default.htm>) on the FDA Website. FDA can tell you whether the agency has taken action against the product or its marketer. Your call also may alert FDA to a potentially illegal product and prevent others from falling victim to health fraud.

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## **Joining Forces to Fight Fraud**

Health fraud isn't confined to the United States only. It's worldwide, and to help combat it in North America, the United States has joined with Canada and Mexico to share knowledge and coordinate enforcement activities related to fraudulent health products, services and devices.

In announcing their decision in December 1998 to adopt the Joint Strategies Agreement, the countries agreed to:

- share information on current trends in health fraud
- cooperate in detecting health fraud along borders
- share information about significant investigations in their country
- consider each others' requests to investigate domestic activities and coordinate related enforcement activities
- develop and distribute joint consumer and business education messages about health fraud.

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