FTC's Quack Attack

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Miracle cures for cancer, Alzheimer's disease and arthritis.Pills for bigger breasts, weight loss, enhanced libido and supercharged immune systems. All are just a mouse click away on the Net. And though many of the come-ons are outright illegal, they proliferate in cyberspace with little regulatory oversight.

Both the Federal Trade Commission (www.ftc.gov) and the Food and Drug Administration (www.fda.gov) are well-armed with regulatory authority to deal with the age-old problem of bogus medicines and health fraud. The challenge is resources: Only 16 employees in the federal government track sales of unsubstantiated therapies and remedies on the Internet on a full-time basis.

At the same time, anecdotal evidence suggests that the problem is growing. While admitting they lack precise figures, federal officials estimate there are "thousands" of snake-oil scams going down on the Net at any given time. The FTC identified more than 800 such sites in its last two organized online sweeps.

And the cyber con artists are unusually brazen.

"We consistently find that claims being made on the Net are more egregious than those being made in print," says Lee Peeler, associate director for the division of advertising practices at the FTC.

Late last month, the FTC announced a $1 million settlement with Lane Labs USA and Cartilage Consultants Inc. on charges of making unsubstantiated claims online about the efficacy of using shark cartilage to cure cancer.

Earlier this year, the FTC announced four settlements with errant site operators. These included Natural Heritage Enterprises, which claimed its "Essiac Tea" was a "well-known" alternative remedy for cancer, and two distributors of a product called CMO, which sellers said was effective in treating arthritis, asthma and emphysema. The fourth settlement was with Gordon Josephs, an Arizona doctor who practiced intravenous peroxide therapy and claimed it could cure "virtually every disease," according to the FTC.

These victories aside, federal regulators and consumer advocates who fight medical fraud voice suspicions that the growing popularity of the Web is fueling an explosion in bogus or misleading health information.

"The Internet is adding another dimension to the problem," says Stephen Barrett, a retired psychiatrist who operates the site Quackwatch.com. "There is no question that people are being exposed to information they wouldn't otherwise find. The Web enables people to put far more information up for less money." John Taylor, acting director of the Office of

Compliance at the Center for Drug Evaluation and Research at the FDA, describes the myriad unapproved health products being sold via the Net as "a growing problem."

Rule of law

The people who buy all this snake oil don't readily make their identities known, because they either truly believe in a remedy that they know is illicit or are too embarrassed to admit their gullibility. For that reason, the FTC and FDA receive very few complaints in this area, but the laws are written in such a way that neither agency needs a victim to prosecute an offense. Either can bring suits based strictly on the nature of the product and on how it is being marketed.

The FDA's labeling rules are unequivocal: If a product says it can cure an illness, it is considered a drug and can only be approved for sale after extensive clinical testing has proven its effectiveness. The FTC gives slightly more leeway, but not much. It requires that any curative claim be supported by at least two well-controlled clinical studies.

But bogus remedy sites aren't beyond manufacturing their own "evidence," or liberally sprinkling pseudoscientific blather through their pages to give the appearance of legitimacy. A favorite ruse is a claim of ongoing European clinical studies that often don't exist, are poorly designed or are blatantly misrepresented. In general, the FTC advises Netizens to be on the lookout for such key words as "scientific breakthrough," "miraculous cure" or "ancient remedy" as likely signs that all is not right. U.S. organizations with treatment centers in Mexico or South America are also caution signs, as the drugs or therapies most likely have not been approved in the U.S.

"Often, there is quite a bit of truth and reference material, but the bottom line is that this is artificial bait," says Dr. John Renner, chief medical officer at Healthscout.com. "Some people think the more information you get, the better it is."

Renner also runs the National Council for Reliable Health Information (www.ncrhi.org), a watchdog group that keeps a close eye on potential online quacks. Its list of suspect sites includes Urinet (www.utopia.knoware.nl/users/cvdk/urinetherapy), which espouses the medicinal benefits of drinking one's own urine; Bustingout.com, which promises bigger breasts in a little pill; and a Web page promoting and selling Cancell (www.best.com/~handpen/Cancell/cancell.htm), an "anti-cancer" drug that the National Cancer Institute (www.nci.nih.gov) and the FDA have declared totally ineffective. "There are just plain dishonest purveyors out there who are very good at what they do," Renner says. "And the scientific literacy of the public is not what it should be."

Nor is the oversight. With resources at a minimum, the FTC runs two Web monitoring programs, called "surfs," under the name Operation Cure.All. The surfs, which include personnel from the FDA and state attorneys general offices, are a coordinated effort to identify bogus health sites. Last year's effort netted 400 problem sites. The FDA sends some of the sites warning letters, and moves to shut down others.

But the system offers irregular enforcement at best and tends to pick up only the worst offenders, critics say. In the end, the responsibility for deciding if a Web-advertised remedy is effective and safe is almost entirely the consumer's.

"[The feds] don't have an enforcement staff. They run sting operations," says Allen Montgomery, chief executive of the American Nutriceutical Association. "If you state on the Net that you can cure cancer, you'd better watch out. Meanwhile, there are thousands of [other] sites making ludicrous claims."

Similarly, state attorneys general offices typically track online snake oil only during organized surfs or when a case drops in their lap. Even when they have a hot case, catching the culprit is more difficult in cyberspace.

"On the Internet, it is harder to track a company or an individual because they can hide,"

says Jack Norris, an assistant attorney general in Florida.

Robert Reyna, director of the Consumer Protection Division at the New Mexico Attorney General's Office, agrees, adding: "We're really in the training stage of how to use the Net as an investigative tool."

State attorneys general have been much more proactive in targeting illegal prescription sales, but that pretty much is the limit of their organized health fraud efforts, say those familiar with the situation. The American Medical Association (www.ama-assn.org) does not monitor online health fraud, nor does the National Fraud Information Center (www.fraud.com). Law enforcers aren't entirely alone, however. A rag-tag posse of snake-oil vigilantes occasionally helps identify culprits and even contributes to investigations.

Quackwatch's Barrett falls into this category. His latest target is Florsheim Shoes, which sells a line of footwear called Magneforce. The shoes contain magnets that the company claims on its Web site "increase circulation, reduce foot, leg and back fatigue and provide natural pain relief and improved energy level."

Barrett is dubious: "I predict the FTC will flatten them like a pancake - it's brazen."

Florsheim officials counter that they are within the law, and they cite several clinical studies supporting the health benefits of magnets.

Ludnil Chotkowski, a retired internist, is another self-proclaimed online quack buster. His primary beef is with chiropractic medicine, which he calls "a hoax from start to finish." Chotkowski is a doubting Thomas when it comes to alternative remedies. "Just because they're natural doesn't mean a damned thing. Show me the [scientific] proof," he says.

Opening Pandora's box

Nearly everyone involved in the cyber snake-oil issue agrees that the present state of affairs is largely a result of the Dietary Supplement Health and Education Act of 1994 - the legislation that gave birth to the booming $15 billion dietary supplement industry.

The law created a new category of "food supplements" that do not need to be tested like drugs as long as they do not purport to "treat or cure" an illness. Critics say the act provided a dance hall of details in which the devil can frolic, giving companies new leeway to tiptoe around the drug-approval issue. "It opened the door for every scoundrel to use the law to their advantage," Reyna says.

Chotkowski agrees: "It was 'open sesame' for selling anything you wanted."

Exacerbating the situation was the fact that the FDA took six years to announce rules for supplement labeling. In January, the agency said food supplements could refer to structures and functions of the body but not claim an ability to diagnose or treat a disease outright.

The new rule states: "Although FDA believes that dietary supplements have potential benefits for consumers, dietary supplements labeled with unproven disease claims, i.e., those that have not met the requirements for health claim authorization or new drug approval, can pose serious risks."

The gray area between legal structure and function claims - for example, fish oil pills that claim to "contribute to heart and vascular health" - and illegal curative statements is subtle and has resulted in consumer confusion about the difference between supplements and drugs, critics say. Some sites carry the federally mandated labeling disclaimer: "This product is not intended to diagnose, treat, cure or prevent any disease."

But plenty don't - and are doing their best to dodge scrutiny, regulators say.

Holy war

The alternative medicine industry isn't entirely happy with the food supplement statute either. Advocates for such cures and therapies say the stringent drug testing requirements of the FDA make it impossible for most supplements ever to become drugs, because big pharmaceutical companies won't spend money on substances they can't patent.

"Nobody wants to spend $80 million on a new drug study for a vitamin," says Ralph Fucetola, a lawyer who counsels supplement companies.

And without extensive clinical proof, alternative-medicine practitioners and supporters have a hard time mollifying their critics.

Karen Hornblatt, president of Green Turtle Bay Vitamin in Summit, N.J., concedes that the huge growth of the supplement industry has led to some multilevel marketing schemes promoting products with doubtful uses but adds that they don't present much of a danger to the consumer. "In some cases you do get unreasonable claims," she says, "but the downside for natural products is limited."

While that statement may be arguable, the FTC is doing its best to stay out of the emotionally charged fray.

"When we talk about health fraud, we're not talking about differences in philosophy - we're talking about claims that are false," Peeler says.

Kal Samulonis, president of CMO Distribution Centers of America in Sarasota, Fla., says the FDA and FTC rules don't mesh because one requires extensive drug testing while the other settles for just a few studies. "Our government is currently caught in a conflict with itself. I think it's a real shame," says Samulonis, whose company settled a misleading advertising complaint with the FTC earlier this year.

Samulonis is also unhappy about the way the FTC handled his company's claims that CMO can cure arthritis. "Despite credible work at an acclaimed research facility, we didn't meet their criteria for [clinical evidence]," Samulonis says. "We're now in a situation where you just make a claim and pray."

Len Sands, director of the San Diego International Immunological Center, licenses CMO to Samulonis and offered evidence of its efficacy to the FTC. "The FTC said that we were not an authority on the subject, and would not accept the data. We've cured 100,000 patients of arthritis and that wasn't good enough," Sands says.

FTC officials respond that they're not just looking at the type of data being offered as evidence but at its quality. In the CMO case, Sands' work just wasn't convincing, says Rich Cleland, a senior attorney at the FTC and the person in charge of Operation Cure.All. "You've got to have rigorous scientific evidence to make these kinds of claims," Cleland says.

In the end, federal officials say, the only real solution to the online snake-oil problem is continued awareness coupled with improved oversight.

"The answer is a combination of good enforcement with good consumer education," Taylor says. "I don't think enforcement, in and of itself, is the answer."

While it's true that public awareness is essential in the battle against health fraud, consumers often become extremely vulnerable - and find themselves flying solo - when desperate health problems have eluded all conventional therapies.

With enforcement resources so limited, Reyna says, "the consumer is left to sift through it all."