

## FDA, Congress move to counter expansion of prescription drug ads

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**WASHINGTON** — The advertisement for an athlete's foot drug depicted attacks on a giant fungus alongside the words Crush, Kill and Destroy in bold type.

But after looking at clinical studies related to the drug, the Food and Drug Administration in August sent a letter to the distributor, Johnson & Johnson, warning that the ads "greatly overstate" claims that the prescription drug, Ertaczo, wipes out infections.

The FDA was similarly troubled by a testimonial video featuring former professional basketball star Earvin "Magic" Johnson describing his "normal life" while taking the HIV drug Kaletra. The FDA wrote to Illinois-based Abbott Laboratories, Kaletra's manufacturer, in July warning about unsubstantiated claims of long-term effectiveness.

"The personal experience of a Kaletra patient such as Magic Johnson does not constitute such evidence," the letter read.

The letters were among about three dozen sent to pharmaceutical manufacturers so far this year warning of violations and ordering the ads to stop, correspondence shows. In all of 2008, the federal agency sent out just 22 warning letters, similar to the FDA's regulatory pace during much of this decade.

Stung by the recent scrutiny, major drug makers are pushing for online advertising flexibility in hopes of launching a new wave of Internet marketing.

But Congress is watching and preparing to take up new advertising curbs, including an end to corporate tax deductions for drug promotion.

Rep. Jo Ann Emerson, R-Cape Girardeau, is one of Washington's chief critics of pharmaceutical ads and intends to play a lead role in the emerging debate.

Emerson said that she is working with Democratic co-sponsors on legislation to impose advertising restrictions, including a prohibition on marketing new drugs until their safety is proved.

"It's gotten so outrageous," she said, recalling a recent television program in which she counted a half-dozen ads for prescription drugs. "All of the money spent on advertising and marketing causes us to spend much more on drugs than we need to, money that could be better spent on research and development. Better yet, it could be spent on lowering the price people pay for drugs."

Emerson and other critics question the extent of the drug industry's direct appeals to consumers and the increasing price of those drugs.

Already, drug companies are spending more than \$4 billion yearly on advertising, and a recent study sponsored by AARP reported that the cost of prescription drugs had jumped 9.3 percent in a recent 12-month period even as the nation suffered through recession.

The Government Accountability Office, the investigative arm of Congress, concluded in 2006 that the FDA had minimal success stopping ads that inflate the benefits of drugs and minimize their risks. Consumer groups argue that little has changed since then.

"It's like the early 1900s when they were selling snake oil," asserted William Vaughn, a health care expert with Consumer's Union, publisher of Consumer Reports. "We hope that the new energy (at the FDA) is going to make a difference, because this has been a serious ongoing issue that has not been managed well."

The pharmaceutical industry defends its promotions.

Marketing "brings patients into their doctors' offices and helps to begin important doctor-patient conversations about previously undiagnosed or untreated conditions," Ken Johnson, senior vice president of the Pharmaceutical Research and Manufacturers of America trade association, said in response to Post-Dispatch questions.

## **TOUGH ENFORCEMENT**

While the FDA's drug marketing division monitors claims of prescription drug makers, another FDA unit has been keeping a closer eye on over-the-counter products that don't live up to their billing.

In September, the agency's compliance office gave a thumbs-down to claims by a hand-sanitizer billed as "the first line of defense in the war against the H1N1 swine flu epidemic." On at least seven occasions this year, the FDA sent letters contending that such ads themselves threaten public health by giving people a false sense of security.

Last spring, Mallinckrodt Inc., a St. Louis drug maker, was among at least a half-dozen manufacturers that received letters from the compliance office warning that they were marketing an unapproved new drug, morphine sulfate, in violation of federal law. Mallinckrodt was given 90 days to stop shipping the painkiller in order to avoid enforcement actions.

Mallinckrodt said in a statement last week that the company believed the drug fell into a category that would not subject it to FDA regulatory scrutiny. The company said it stopped producing the painkiller after receiving the letter and is considering options, among them applying for approval for the drug.

The FDA has backed up its recent scrutiny with some tough enforcement: In September, drug giant Pfizer agreed to pay a record \$2.3 billion to settle civil and criminal allegations that stemmed from illegal marketing of the painkiller Bextra, which has been withdrawn. That case began during the administration of President George W. Bush.

Because of the growth of the Internet, the public policy questions are growing thornier. On Nov. 16, the FDA's compliance office sent letters to 22 Internet marketing firms and individuals from around the world — including in Australia, Turkey and Gibraltar — warning about the unapproved marketing of drugs such as Viagra and Prozac. The drugs "may not be safe and effective," letters warned.

But it was a batch of 14 warning letters from the FDA's division of drug marketing to some of the giants in the drug industry that has triggered a new and contentious debate about Internet advertising. Those warnings last April about the lack of risk information in sponsored links prompted some companies to suspend their Web ads until they could be assured they were legal.

Last month, major drug manufacturers, aligned with Google, Yahoo and other Web companies, asked the FDA to change its rules for reporting the risks of drugs in Internet marketing. The corporations also want the FDA to lend a government logo to their online advertising that links viewers to more detailed information on dangers of drugs.

Jeffrey Francer, assistant general counsel for the pharmaceutical trade group, said that manufacturers want a system in which "comprehensive information is one click away."

Consumer advocates like Allan Coukell, who directs the nonprofit Pew Prescription Project in Boston, are wary. "Before the FDA provides a pathway for companies to do a whole new kind of marketing, I think they should be looking for evidence of health benefits," he said.

FDA officials say they have added 20 people to monitor drug advertising over the past three years. They declined to signal how they will respond to the industry's proposals for online advertising. But Rachel Behrman, the FDA's new acting director of its medical policy office, said her agency is aware of the need to adapt.

"The technology is changing," she said. "The mechanisms, the means of communication and the generations are changing. My four teens get all of their information on cell phone and computer. The challenge is living in an era of information explosion."

## **LEADING OPPONENT**

Emerson is among those who believes the FDA needs to bring more scrutiny to drug marketing, no matter the forum. Her immersion in the issue dates back a decade, when she was left to care for her mother-in-law after the death of her husband, Rep. Bill Emerson, in 1996.

Jo Ann Emerson, who would take over her husband's seat in southeast Missouri, was stunned to learn that her mother-in-law's income did not add up to her \$1,200 monthly prescription tab.

"She was older and lonely and watched TV a lot and was susceptible to all these ads," Emerson recalled last week.

Emerson began doing research, which led to her becoming a champion in Congress of reimporting prescription drugs from Canada and other FDA-approved nations as a means to provide seniors with inexpensive drugs. That legislation remains bottled up amid opposition from manufacturers.

Early next year, with health care legislation presumably gone from the Washington agenda, Emerson intends to proceed with bipartisan legislation aimed at prohibiting ads for newly approved drugs for a period of three years — similar to a bill she co-sponsored previously that failed to advance.

She said she is hopeful but not confident given the certainty of an industry campaign against it. "We're going to try very hard," she said.