

Court ruling may open door to more drug marketing

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A decision by a federal appeals court this week could have a dramatic impact on the marketing of prescription drugs in America, potentially affecting patient care and everything from TV drug advertising to future government prosecutions - prosecutions that have in the past yielded billions of dollars in settlements - doctors and attorneys said Tuesday.

"This risks taking us back to an era when people could promote [snake oil](#) without restrictions - a situation I would hate to see," said Richard Deyo, a professor of [family medicine](#) at Oregon Health & Science University.

However, others say the ruling is a victory for free speech, one that could become the drug industry equivalent of Citizens United, the 2010 U.S. Supreme Court decision that gave corporations and unions the right to spend unlimited sums on political ads.

Like the Citizens United case, the ruling Monday by the U.S. Court of Appeals for the 2nd Circuit in New York involved the right of commercial free speech, applying it to the complicated world of pharmaceutical industry promotion of prescription drugs.

How wide-ranging the decision becomes likely will depend on whether it gets to the U.S. Supreme Court, [attorneys](#) said.

For years, it has been illegal for drug companies to promote their products for uses not approved by the Food and Drug Administration, what is known as off-label marketing. But [doctors](#) are free to prescribe

approved drugs for whatever purpose they want.

The case involves Alfred Caronia, a sales representative with Orphan Medical, who was criminally prosecuted for making off-label promotional statements about Xyrem, a drug approved in 2002 to treat narcolepsy patients with a condition known as cataplexy. Cataplexy involves weak or paralyzed muscles.

The FDA had put a black box warning on the drug stating its safety and effectiveness had not been established in people under 16. The active ingredient in Xyrem is GHB, a powerful medication that acts on the central nervous system and also is known as the "date rape" drug.

In 2005, the federal government began investigating Orphan Medical for its alleged off-label promotion of Xyrem.

In a taped conversation Caronia had with a doctor who was cooperating with the government, he said the drug could be used for other muscle conditions such as fibromyalgia, restless leg syndrome and Parkinson's.

He also said it could be used in patients under 16.

Caronia had claimed his off-label promotion was constitutionally protected free speech, saying the First Amendment does not permit the government to prohibit or criminalize a drug company's truthful, non-misleading off-label promotion to doctors.

The appeals court essentially agreed, noting that Caronia never conspired to put false or deficient labeling on the drug.

"The government clearly prosecuted Caronia for his words - for his speech," the court said.

"This could be a watershed moment for the pharmaceutical industry," said Michael Buchanan, a former federal prosecutor who now works for a New York law firm that represents drug companies.

He said the decision will be good for consumers and doctors because it will allow drug companies to disseminate more information about their products, allowing for more informed decision-making.

It is likely the decision, if upheld, will make it much more difficult for the Department of Justice to bring cases against drug companies for off-label drug promotion, he said.

Over the last decade or so, the Justice Department has obtained billions of dollars from drug companies after accusing them of promoting their products for off-label uses.

In its most recent prosecution in July, the department obtained a record \$3 billion settlement from GlaxoSmithKline for its marketing of several drugs, including Wellbutrin, Paxil and Advair.

Tamara Piety, an expert on commercial speech and the First Amendment and a professor of law at the University of Tulsa, said the decision could open the door to off-label television advertising of drugs if it is upheld by the Supreme Court, which she predicted would be sympathetic to the ruling.

She said the pharmaceutical industry has been trying to get off-label promotion overturned for years.

"It looks like they finally succeeded," she said.

Steven Nissen, a cardiologist with the Cleveland Clinic, said the decision was shortsighted and could result in patients being exposed to

unnecessary risks.

"Off-label promotion is not about free speech - it is the medical equivalent of yelling fire in a crowded auditorium," he said.

Andrew Kolodny, a New York psychiatrist who has been trying to reform the use of narcotic painkillers in the U.S., said the decision was terrible for public health.

A large portion of Americans already are taking drugs with serious risks that outweigh the benefits, he said.

"This is going to get much worse," he said. "It's a safe bet that health outcomes will decline from medication side effects, while spending on [prescription drugs](#) will continue to rise."

Ed Silverman, who operates the popular Pharmalot blog, said drug companies had been pushing off-label promotion as a free-speech issue for years.

"It (the decision) is vindication for the pharmaceutical industry," he said.

In a statement, the Pharmaceutical and Research Manufacturers of America said it was pleased the court found that the FDA's ability to regulate communication about [medicine](#) is circumscribed by the First Amendment.

"PhRMA believes that truthful and non-misleading communication between biopharmaceutical companies and health care professionals is good for patients, because it facilitates the exchange of up-to-date and scientifically accurate information about new treatments," PhRMA spokesman Matthew Bennett said in a statement.

Sidney Wolfe, a doctor with the watchdog group Public Citizen, said the decision will further weaken the FDA.

Caronia, the defendant in the case, was accused of conspiring with a psychiatrist who was a hired drug company speaker.

In overturning his conviction, the appeals court cited a 2011 U.S. Supreme Court decision involving a Vermont law that said "speech in the aid of pharmaceutical marketing ...," is a form of expression protected by the First Amendment. The law had barred [drug companies](#) from obtaining and using prescriber information for marketing purposes when a range of others such as private and academic researchers could acquire the information.

The Court of Appeals said the government's view of the law essentially legalized off-label prescribing but prohibited the free flow of information about that.

Arnold Friede, a former FDA and drug company attorney, said the next step may be for the government to ask the entire appeals [court](#) to rehear the case. This week's decision was made by a three-judge panel.

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