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Written by <u>Alex Newman</u> on October 7, 2009

FDA Ad Regulations Under Scrutiny

A new report released Tuesday is challenging the Food and Drug Administration's (FDA) regulation of pharmaceutical Internet ads, claiming the "1960s approach" is harming consumers.

In April of this year, the government body sent out 14 warning letters to drug companies informing them that their use of Internet advertising services was allegedly against the rules. Apparently, the ads did not contain the required information about risks, the drugs' full names, and details about limitations.

The space available in the tiny ads is minuscule, usually about 70 characters, making these disclosures impossible. But a spokesman for the FDA explained that the agency enforces the same standards in all media. In response, drug companies "virtually abandoned search ad marketing," reports <u>Advertising</u> <u>Age</u>, citing a ComScore study that showed an 84 percent decline in online search ads by the industry.

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"It wasn't surprising," said ComScore vice-president John Mangano. "A lot of the big pharma players had to pause and say, 'Hey, we have to figure out what makes the FDA happy here.'"

So to "fix" the problem, the bureaucracy that regulates about a quarter of the U.S. economy announced last month that it would host a public hearing in November to consider fashioning its first regulatory regime for online promotion of drugs. "This meeting and the written comments are intended to help guide FDA in making policy decisions on the promotion of human and animal prescription drugs and biologics and medical devices using the Internet and social media tools," read part of the FDA's announcement published in the Federal Register.

And it's about time, according to the Competitive Enterprise Institute (CEI), the Washington-based freemarket think tank that just released its damning report entitled "<u>FDA and Internet Advertising: The</u> <u>Medium is the Message</u>." The authors aim to have the agency bring its online ad regulations "into the 21st Century by acknowledging that the Internet and other new media let ads present complete risk and benefit information in unique ways," according to a <u>press release</u>.

"For over a decade, the FDA has treated the Internet as just another form of print advertising," explained CEI Senior Fellow Gregory Conko, one of the authors. "Internet ads have had to comply with rules that simply don't make sense in the Internet Age, where the amount of text available in a banner ad or sponsored link is strictly limited, but the required information can be 'one click' away on the landing page to which those ads direct the user."

Conko also highlighted the irony in FDA rules that allow television ads to guide viewers to a website for product risks, whereas sponsored links that connect directly to the site must still make full disclosure in the ad. He added that it was "absurd" to force Internet advertising to comply with regulations designed for newspaper and magazine ads when consumers know that "risk information is just one click away."





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"In other industries, the absence of an applicable statutory or regulatory policy generally means that businesses and individuals have the flexibility to innovate," the report said. "But, when it comes to the FDA's regulation of drug and device promotion, the absence of clear guidance effectively works as a prohibition on the kinds of innovation that would deliver complete risk and benefit information in ways that take advantage of the Internet's unique capabilities. It is no surprise then that drug and device manufacturers are still uncertain how to proceed with many new media tools, such as banner ads, sponsored links, email messages to physicians and patients, social media like blogs, Facebook, microblogs such as Twitter, or any other form of Internet communication."

The report concluded with some suggestions for the agency: "There is ample room, even under current law, for FDA to apply a more nuanced and flexible approach to the regulation of drug and device promotion on the Internet and other new media. The November 2009 public hearings present a valuable opportunity for the agency to take a bold first step in developing a constructive policy for Internet advertising. Bringing FDA's 1960s approach to prescription drug advertising and promotion into the 21st century is long overdue."

While the suggestions would certainly make life easier for drug marketers, there may be an even better solution: abolish the unconstitutional FDA. A basic understanding of the U.S. Constitution reveals that the federal government does not have the authority to regulate food or drugs — except perhaps those coming in from other countries — let alone regulating advertising.

There is still that cherished provision in the First Amendment that reads "Congress shall make no law ... abridging the freedom of speech." That seems clear enough — the federal government is stepping outside its lawful authority in attempting to regulate speech, regardless of what the Supreme Court has "interpreted." Contrary to what doomsayers may claim, the market and state governments are perfectly capable of policing drug advertising.



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