Biotech: Price Rule Follows Regulatory Trajectory

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Companies such as Thousand Oaks-based Amgen oppose the regulation because it excludes rebates and discounts that drug makers may offer. And the outcome of debate over drug price disclosure could affect advertising agencies, health providers and insurers as well as pharmaceutical companies.

"Not only does the rule raise serious freedom of speech concerns, it mandates an approach that fails to account for differences among insurance, treatments and patients themselves, by requiring disclosure of list price," Amgen said in a statement. "Most importantly, it does not answer the fundamental question patients are asking: 'What will I have to pay for my medicine?'"

"This may actually get consumers, or potential patients, to not go to their doctor, because they feel that the prices of these drugs are ones they would not be able to support," added **Dan Jaffe**, vice president of government relations for the Association of National Advertisers. "This is part of a much broader problem that advertisers and the business community is facing, which is a growing number of mandatory disclosure proposals that governments are trying to force on businesses."

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Advertising template

Companies such as **Johnson & Johnson** have already started listing drug prices on their advertisements as of March, with direct-to-consumer television spots for Xarelto, a blood thinner.

Xarelto's ad advises patients that they may pay between "$0 and $47 per month," and that the "maintenance dose list price" is $448 per month.

"Actual costs may vary based on dosing, site of care, insurance coverage and your eligibility for support programs," the ad states.

Drug companies were given a template by the HHS, outlined in the regulation:

"The list price for a 30-day supply of (name of drug or biological product) is (insert list price). If you have health insurance that covers drugs, your cost may be different."

The template also requires a certain font size and style at the end of the ad to allow for the information to be read easily.

The companies and trade group allege HHS does not have the authority to enforce the new regulation, being a violation of the First Amendment and the Administrative Procedure Act.

All agency action is governed by the Administrative Procedure Act to set parameters for how agencies go about making decisions, according to **Evan Zoldan**, law professor at the **University of Toledo**. It also allows courts to review decisions and make sure they're consistent with law.

"We can be fairly sure that the government will elaborate on two basic arguments: that existing statutes gave HHS authority to promulgate the new pricing rule even though they do not specifically authorize HHS to promulgate rules about advertising for drugs, and that the First Amendment does not prohibit the government from requiring the disclosure of factual information in marketing commercial products," explained Zoldan.

"I think the government will respond with survey information about the connection in consumer's minds between the wholesale acquisition price on the one hand and expenses on the other hand."

The federal government presented its argument before Judge **Amit Mehta** on July 2 in response to the complaint, essentially outlining what Zoldan said. Federal attorneys reasoned that the regulation would not drown out the speaker's message or rule out a mode of communication, essentially not being a violation of the First Amendment.

Up Front: In March, Johnson & Johnson's Xarelto ads started including a price range.

Legal counsel for the Trump administration suggested the court deny the drugmakers' motion for a stay, pending judicial review, in its response conclusion. A decision on the rule is expected by mid-July, Jaffe said.

Regulated industry

From an advertising perspective, Trump's America First initiative and regulations stemming from it aren't anything new. The specificity of this particular regulation raised some eyebrows, but direct-to-consumer requirements have always been handed down from the federal government.

"It's very common for the federal government to regulate advertising," said **Hunington Sachs**, vice president of business and legal affairs at **InterMedia Group of Cos.**, based in Woodland Hills. "The (Federal Trade Commission) enforces advertising and they want to make sure that advertising is fair and not misleading."

Direct-to-consumer advertising of pharmaceuticals has been legal in the U.S. since 1985 to reach aging baby boomer consumers at home, according to a post on the FDA's website. Advertisers and drug companies also noted that an increasing number of patients were participating in their own health care decisions.

Starting in 1997, the Food and Drug Administration eased up on broadcast regulations, which at the time ran long and expensive for drug makers. As opposed to providing a summary in the ad specific to each drug, a "major statement" was allowed to be made rather than a list of all product risks.

"Those were the regulations that required that you publish a toll-free number and that you can get additional information from your pharmacist or physician, and all of that risk language," added Sachs. "You know you've seen those ads, and they go on for 60 seconds – almost 30 seconds of the ad talks about product risks and benefits."

The list price would be tacked on to a broader list based on 1997 requirements, Sachs said.

Ultimately, it comes down to whether or not consumers would be able to take the information in the ad and apply it to their individual situation.

"It does require a little bit of sophistication on the part of the consumer," Sachs said. "These are things that consumers study. It gives them enough information to be able to calculate what their cost is going to be; I don't think that's misleading."

But the final word could rest with consumers.

"I don't think that you can just argue one way or the other without actual survey information of what consumers think when they look at the list price and what that makes them believe about their out-of-pocket expenses," added Zoldan.