

Trump Administration Appeals Decision on Drug Pricing in TV Ads (1)

By Valerie Bauman

Posted Aug. 21, 2019, 1:19 PM Updated Aug. 21, 2019, 2:26 PM

- Administration rule required TV drug ads to reveal list prices
- A federal judge struck down the rule in July

The Trump administration is appealing a court decision that struck down a federal rule that would have required drugmakers to include the list prices for drugs in TV advertising.

The federal government filed the appeal in the U.S. Court of Appeals for the District of Columbia Circuit on Aug. 21.

“President Trump and Secretary Azar are committed to providing patients the information they need to make their own informed healthcare decisions and to lower the high cost of prescription drugs,” Health and Human Services Department spokeswoman Caitlin Oakley said. “It’s time for drug companies to level with American patients about the cost of their drugs: If the drug companies are embarrassed by their prices or afraid that the prices will scare patients away, they should lower them.”

Judge Amit P. Mehta struck down the rule in a July 8 decision after Merck & Co., Eli Lilly and Co., and Amgen Inc. challenged the policy. The Centers for Medicare & Medicaid Services issued the final rule May 8.

“To accept the agency’s justification here would swing the doors wide open to any regulation, rule, or policy that might reasonably result in cost savings to the Medicare and Medicaid programs, unless expressly prohibited by Congress,” Mehta wrote in his opinion for the U.S. District Court for the District of Columbia.

“This case is not just about whether [the HHS] can force drug companies to disclose their list prices in the name of lowering costs,” he added. The “disclosure rule represents a significant shift in HHS’s ability to regulate the health care marketplace. Congress surely did not envision such an expansion of regulatory authority when it granted HHS the power to issue regulations.”

Merck, Eli Lilly, Amgen, and an advertising trade association filed the lawsuit June 14, alleging the HHS and the CMS violated their right to free speech. They also argued that the agencies lack the statutory authority to impose such a requirement.

The case has raised questions about what authority the government has to regulate and compel commercial speech, which historically has fewer legal protections under the First Amendment than other types of speech, though Mehta instead focused on the agency’s statutory authority.

Useful Information?

Another challenge ahead for the government is that few people pay the list price for medication, and the actual cost for drugs varies dramatically depending on a patient's health coverage. The lawsuit argues that the government has a "heavy evidentiary burden" when compelling commercial speech to show that the mandate will advance the government's intended goal—in this case, price transparency.

The CMS acknowledged when it published the rule that the requirement could lead to consumer confusion and even deter patients from seeking out medications that would benefit them.

But the government said that could be offset if drug companies include a disclaimer or language explaining that if "you have health insurance that covers your drugs, your cost may be different."

Uphill Battle

"The Trump administration is going to have an uphill battle to try to convince an appeals court to come out differently," said Jeffrey A. Greenbaum, a partner in the advertising and marketing group at New York City-based Frankfurt Kurnit Klein & Selz PC.

"The lower court—which was faced with a rule that appeared not to be accomplishing any of the objectives that the Trump administration said it would achieve—pretty easily struck down the rule," he added.

However, the drug companies face challenges of their own, as federal agencies "are given a fair amount of deference in their rulemaking," Greenbaum said.

Officials with the drug companies did not immediately respond to requests for comment.

Meanwhile, global drugmaker Johnson & Johnson has already taken the step of putting list prices directly in TV ads, in addition to on websites, in a move that aligned the company with Trump's blueprint.

"The data shows that consumers want simply presented information on what they can expect to pay," spokesman Ernie Knewitz said in April. "It's the right decision for us."

The case is *Merck & Co., Inc. v. Department of Health and Human Services*, D.C. Cir., 1:19-cv-01738, appeal filed 8/21/19.

(Updates throughout with additional detail and comment.)

To contact the reporter on this story: Valerie Bauman in Washington at vbauman@bloomberglaw.com

To contact the editors responsible for this story: Fawn Johnson at fjohnson@bloomberglaw.com; Randy Kubetin at rkubetin@bloomberglaw.com

Related Articles

[Merck Scores Win as Judge Strikes Down TV Ad Price Disclosures \(2\)](#) (July 8, 2019, 6:27 PM)

© 2019 The Bureau of National Affairs, Inc. All Rights Reserved