

DC Circ. Rejects Trump's 'Far-Flung' Drug Pricing Rule

By **Kevin Stawicki**

Law360 (June 16, 2020, 7:31 PM EDT) -- The D.C. Circuit on Tuesday rejected the Trump administration's effort to force pharmaceutical companies to disclose drug prices in television ads, saying the rule's "far-flung" attempt to lower prescription costs has no legal basis.

A three-judge panel backed a lower court's decision that the U.S. Department of Health and Human Services overstepped its regulatory authority by issuing a rule in May 2019 that required pharmaceutical companies to disclose wholesale prices of drugs over \$35.

"The department acted unreasonably in construing its regulatory authority to include the imposition of a sweeping disclosure requirement that is largely untethered to the actual administration of the Medicare or Medicaid programs," the panel wrote. "There is no reasoned statutory basis for its far-flung reach and misaligned obligations."

While the agency has broad authority to issue regulations, requiring companies to disclose a drug's list price in ads was not necessary to ensure the administration of Medicare and Medicaid programs and has no relation to the price insured patients pay out-of-pocket, the panel said.

"To qualify as administering the Medicare or Medicaid statutes, a program of such intrusive regulation must do more than identify a hoped-for trickle-down effect on the regulated programs," the panel wrote.

While the rule sought to address the high cost of prescription drugs — a major problem for many Americans — the panel said Tuesday that the rule isn't the right solution because there's no basis to conclude that advertising the prices would lead to more price transparency.

Merck & Co. Inc., Eli Lilly & Co., Amgen Inc. and the Association of National Advertisers Inc. filed the suit in 2019, arguing that HHS lacks the authority to compel price disclosures and that those disclosures would violate their free speech rights by misleading consumers about their likely costs. Most patients with insurance pay far less than the list price.

U.S. District Judge Amit P. Mehta blocked the deal in July just a day before the rule was set to take effect.

On appeal, the government argued that the rule was properly issued under HHS' authority to create

regulations to efficiently administer Medicare and Medicaid and that its implementation would force manufacturers to compete on prices.

Tuesday's ruling is the latest recent setback for the administration's drug pricing agenda. In 2019, amid a ferocious lobbying campaign, it abandoned extra leeway for Medicare Part D plans to negotiate prices for prescription drugs that treat serious diseases.

Counsel and representatives for the parties did not immediately respond to requests for comment.

U.S. Circuit Judges Karen LeCraft Henderson, Patricia A. Millett and Harry T. Edwards sat on the panel for the D.C. Circuit.

The drugmakers are represented by Richard P. Bress, Daniel Meron, Caroline A. Flynn, Annie Marie Wilson and Gregory B. in den Berken of Latham & Watkins LLP.

The government is represented by Robert Phillip Charrow of the U.S. Department of Health & Human Services Office of General Counsel, Ethan Price Davis, Scott R. McIntosh and Joshua Revesz of the U.S. Department of Justice's Civil Division.

The case is Merck & Co. Inc. et al. v. U.S. Department of Health and Human Services et al., case number 19-5222, in the U.S. Court of Appeals for the District of Columbia Circuit.

--Editing by Steven Edelstone.