

Drug Prices Are Prime Target In Biden's Competition Order

By Adam Lidgett

Law360 (July 9, 2021, 7:59 PM EDT) -- President Joe Biden's executive order Friday to invigorate competition across the American economy focused intensely on prescription drug costs, including a demand that top health officials rapidly devise a plan to cut spending on overpriced drugs.

The order called on more than a dozen federal agencies to pursue more than 70 initiatives, but many of its splashiest initiatives involved drug prices, a perennial pocketbook concern for voters. In a **Friday signing** ceremony at the White House, Biden devoted a sizable portion of his remarks to the order's drug pricing provisions.

"Americans pay two-and-a-half times more for prescription drugs than in any other leading country," the president said. "And nearly one in four Americans struggles to afford their medication."

McDermott Will & Emery LLP partner Emily Cook, who specializes in drug reimbursement issues, told Law360 that Biden's focus on drug prices, which continues the Trump administration's same focus, is "not surprising" because of "the significant public interest and frustration."

One of the order's most intriguing initiatives told the U.S. Department of Health and Human Services to craft a plan within 45 days to combat "excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such drugs, and to address the recurrent problem of price gouging."

Cook said that the directive to create a comprehensive plan was of particular note, given that "earlier this week, what appears to be a new version of the 'most-favored nation' drug pricing rule arrived at [Office of Management and Budget] for review."

The Trump administration's "most-favored nation" policy — **under which** the U.S. would peg Medicare's reimbursement for certain drugs to lower prices in other countries — attracted lawsuits in numerous federal courts and didn't take effect.

"It will be interesting to see whether the Biden administration's take on this rule continues this international pricing approach to addressing high drug costs in the U.S., which was not previously well-received by either drug manufacturers or health care providers," Cook said.

Friday's order also told the U.S. Food and Drug Administration to find ways to get cheaper drugs from Canada into the U.S. by working with both tribes and states.

Stacie Ropka, a partner at Axinn Veltrop & Harkrider LLP, said that bringing in drugs from Canada could be beneficial.

"In my opinion, the ability to bring in the Canadian counterpart to drugs approved by the FDA in the United States can reduce prescription drug prices for U.S. citizens because these drugs are far less expensive in Canada and those savings can be passed on to patients, regardless of their insurance status," Ropka said.

The Trump administration in late 2020 finalized a rule that would allow states, tribes, pharmacists and wholesalers to import certain prescription drugs from Canada without approval from drug manufacturers. That rule was challenged by Pharmaceutical Research and Manufacturers of America and other trade groups in a lawsuit that **remains pending**.

PhRMA said in an email that the group has "long-standing concerns with importation because it risks the health and safety of patients."

"We support commonsense solutions that would lower out-of-pocket costs for patients [and] that don't risk the health and safety of patients or undermine future innovation," PhRMA CEO and President Steve Ubl said in a Friday statement.

Additionally, Biden's order recommended that the Federal Trade Commission use its rulemaking authority to address so-called pay-for-delay deals. The deals typically see brand-name drugmakers compensate generic-drug manufacturers to postpone the introduction of copycat products with smaller price tags. A White House fact sheet said the order "encourages the FTC to ban" the deals.

When HHS Secretary Xavier Becerra **was California's** attorney general, he inked eight-figure **settlements over** pay-for-delay deals, and **he successfully** defended California's ban on most pay-for-delay deals.

In his 2020 presidential campaign, Biden made a number of commitments on drug prices. As examples, he vowed to pursue **value-based** limits on drug prices, a ban on price hikes that outpace inflation, and the elimination of a statutory prohibition on Medicare's negotiation of drug prices. He also tweeted in December that "prescription drug companies are profiteering off the pocketbooks of sick individuals."

In April, he again **urged lawmakers** to allow Medicare to negotiate prescription drug prices. The same month, **Biden signed** a pair of bills meant to lower prescription drug prices by boosting generics and biosimilars.

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