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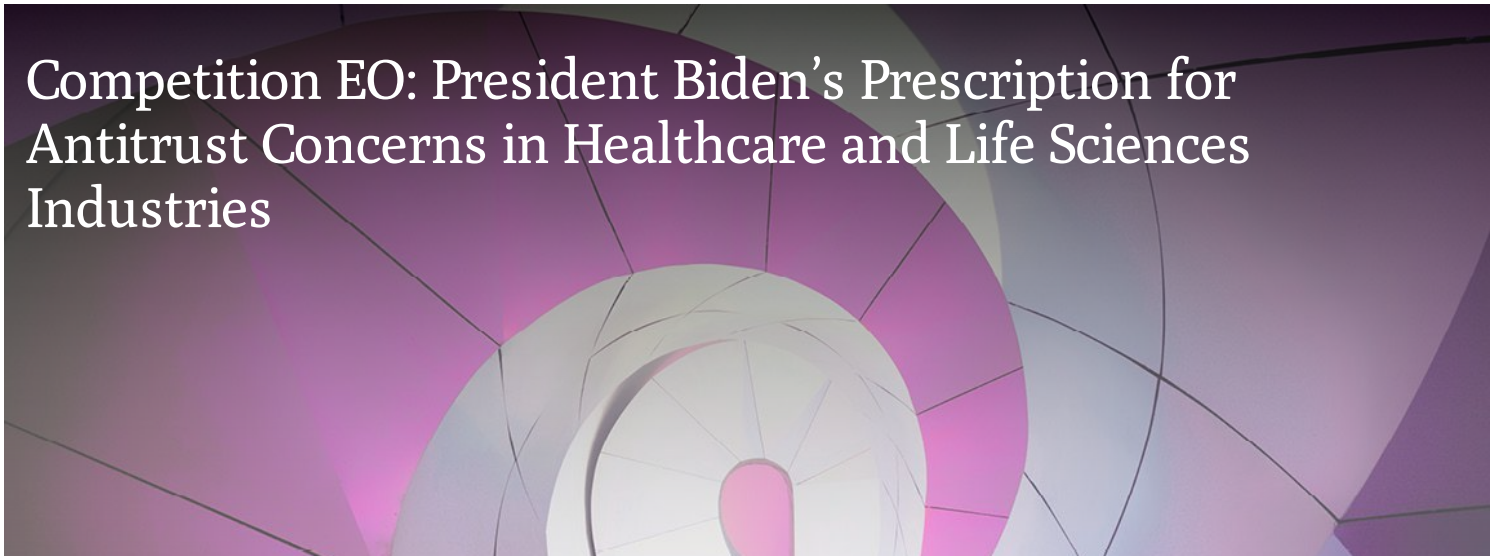

Competition EO: President Biden's Prescription for Antitrust Concerns in Healthcare and Life Sciences Industries

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On July 9, 2021, President Biden issued the "Executive Order on Promoting Competition in the American Economy" (the Order) and the White House's contemporaneous Fact Sheet with the intent to promote economic competition, rigorously enforce existing antitrust laws, and update regulations to combat practices not prohibited by existing antitrust law that may be used to anticompetitive ends. The Executive Order continues recent years' bipartisan focus on the healthcare industry, a rare area in which Democrats and Republicans have sought common ground to bring down costs.

Principally in the areas of prescription drugs and consolidation, both parties have spoken out against and introduced legislation to curtail the high cost of care in the United States. President Biden's Order aims to build upon these areas of consensus, and it specifically addresses consolidation among hospitals and health systems and allegedly anticompetitive practices of the pharmaceutical industry, and aims to improve the health insurance marketplace.

Key details of the Order's impact on the healthcare industry are below.

Mergers and Acquisitions

The Order calls out industry consolidation as leading to "excessive market concentration" and asserts that hospital consolidation, particularly in rural communities, has led to "inadequate or more expensive healthcare options." According to the White House Fact Sheet, the ten largest healthcare systems control a quarter of the market, and 138 rural hospitals have closed since 2010. The Order encourages increased scrutiny and enforcement of hospital mergers to prevent harm to patients through hospital consolidation.

The Order urges the Department of Justice (DOJ) and the Federal Trade Commission (FTC) to review and revise both vertical and horizontal merger guidelines. The agencies previously revised the Vertical Merger Guidelines in 2020 for the first time since 1984; the Horizontal Merger Guidelines were last updated in 2010.

The Order is the latest in a continued focus of the federal government on addressing healthcare industry consolidation. In May 2021, the U.S. Senate Subcommittee on Competition Policy, Antitrust, and Consumer Rights held a hearing to discuss the trend of hospital consolidation, and the alleged negative outcomes that have resulted,

including purportedly higher prices, lack of choice, and fewer incentives for hospitals to innovate. The Order highlights many of these areas of concern and seeks to remedy the purported problem.

Hospital Billing and Insurance Coverage

In addition to urging the DOJ and FTC to review and revise the merger guidelines, the Order directs the Department of Health and Human Services (HHS) to support existing hospital price transparency rules and to finish implementing bipartisan federal legislation to address so-called surprise hospital billing.[1]

The Order also aims to expand transparency in the health insurance markets with the goal of assisting Americans in choosing health insurance plans by implementing standardized options in the National Health Insurance Marketplace. According to the Order, doing so will allow Americans to compare plan offerings and choose health insurance plans that meet their specific needs. Moreover, the Order reiterates President Biden's desire to implement a public health insurance option through legislation.

Prescription Drug Prices

The Order aims to rein in the price of prescription drugs through its "whole-of-government" approach by urging multiple executive agencies to undertake action to address purportedly anticompetitive conduct in the pharmaceutical industry. The White House Fact Sheet asserts that drug price increases continue to far surpass inflation and that Americans are paying more than 2.5 times as much for the same prescription drugs as peer countries, leading to nearly one in four Americans reporting difficulties in paying for medication.

The Order encourages the FTC to ban so-called "pay-for-delay" agreements and similar agreements through its statutory rulemaking process. The White House alleges that so-called "pay-for-delay" agreements, in which a brand-name pharmaceutical company pays generic pharmaceutical companies in exchange for delaying the introduction of any generic medications into the marketplace, have allowed drug manufacturers to maintain monopolies and avoid competition. These arrangements between companies can be lucrative: one study conducted by Professor Scott Hemphill revealed that a one-year delay in generic entry represented a $12 billion transfer from consumers to producers,[2] and a 2010 FTC study estimated that pay-for-delay settlements cost consumers $3.5 billion annually.[3] The FTC rarely challenges such agreements; in the last decade the agency has targeted only a handful of such arrangements.[4] As a result of this Order and the actions taken as a result, the industry can expect to see an increase in enforcement against these types of arrangements and potential follow-on civil litigation.

The Order further instructs agencies to take the following action to combat the "excessive pricing of prescription drugs" and improve access to prescription drugs and biologics:

- Orders HHS to increase support for generic and biosimilar drugs and to issue a comprehensive plan within 45 days to combat high cost of prescription drugs and price gouging.
- Instructs the Food and Drug Administration (FDA) to work with states and tribes to safely import prescription drugs from Canada.
- Urges the support of biosimilar product adoption by providing access to educational materials to better understand biosimilar products among health care providers, patients, and caregivers.
- Promotes the removal of any unnecessary trade practice regulations such as bottle sizes, permitting, or labeling that may present an unnecessary roadblock to competition without serving any public health, informational, or tax purpose.

Reining in the price of pharmaceutical drugs has been one of the areas with the broadest bipartisan consensus and is a perennial campaign issue, with increased governmental focus this year on lowering the cost of prescription drugs in the midst of the COVID-19 pandemic.

In March 2021, the FTC announced the formation of an international working group in order to identify new approaches to better scrutinize pharmaceutical mergers that may raise anticompetitive concerns. While the FTC has challenged many pharmaceutical mergers in the past, the agency has largely managed only to require the divestiture of overlapping product lines between the merging parties instead of blocking the mergers altogether. At the time of the announcement, FTC Commissioner Rebecca Kelly Slaughter lamented that current agency criteria do not account for whether the merger remedy adequately ensured continued innovation.

Noncompete Clauses and Unnecessary Licensing Requirements for Workers

The Order also takes on certain issues in the healthcare market that particularly impact healthcare workers, including noncompete clauses that make it difficult for healthcare workers to change jobs. Specifically, the Order directs the FTC to use its rulemaking authority to ban or limit the unfair use of such practices. Many states already have laws governing noncompete agreements, and the extent that any new FTC rulemaking may conflict with and potentially preempt state law could lead to future litigation.

The Order urges the FTC to consider promulgating rules that curtail the use of "unnecessary" occupational licensing requirements. It remains to be seen how this would affect the healthcare industry, as many of the occupational licenses issued are specifically designed to promote patient and healthcare worker safety.

For additional detail regarding the Order's impact on labor markets, see our prior post here.

Hearing Aids

Finally, in an attempt to increase access to hearing aids, the Order also directs HHS to consider proposing rules that would allow hearing aids to be sold over the counter. According to the White House, hearing aids cost over $5,000 on average per pair, and those costs are not often covered by health insurance; driving these costs are medical evaluations by a doctor or specialist, despite experts agreeing that medical evaluations are not necessary before purchasing hearing aids. In 2017, Congress passed the bipartisan FDA Reauthorization Act, which would allow hearing aids to be sold over the counter, but the FDA did not issue rules necessary to enact it. Over-the-counter hearing aids would provide a new area of competition by manufacturers and increase access to the approximately 41 million Americans with hearing loss.

This article is part of our "Unpacking the Executive Order on Promoting Competition" series. Click here for other related articles. Please contact a member of the Winston & Strawn Antitrust/Competition Practice Group or your Winston relationship attorney for further information.

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[1] The White House, *FACT SHEET: Executive Order on Promoting Competition in the American Economy* (July 9, 2021), *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/.

[2] C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Columbia L. Rev. 629, 650 (2009).

[3] Fed. Trade Comm'n, *Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 1, 2 9 (2010), *available at* https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

[4] Robin Feldman & Prianka Misra, *The Fatal Attraction of Pay-For-Delay*, 18 Chi.-Kent J. Intell. Prop. 249, 279 (2019), *available at* https://repository.uchastings.edu/faculty_scholarship/1729.

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