

BLOG



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In a marked shift toward competition-focused healthcare policy, the latest Executive Order on drug pricing reflects the Administration's expanding use of **antitrust tools to address high pharmaceutical costs**. Framed around the "most-favored-nation" principle, this initiative is more than a pricing measure—it signals a broader regulatory agenda that targets **market power and pricing disparities** long shielded from traditional enforcement. Here's what companies across the healthcare sector need to know.

On May 12, 2025, President Donald Trump signed an <u>Executive Order</u> that seeks to align U.S. drug prices with the lowest price paid in other developed nations. The Order, titled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," comes on the heels of a **broader anticompetitive-regulation agenda** and targets what the Administration calls **"global freeloading"** and **"price discrimination"** by pharmaceutical manufacturers who sell the same products abroad for a fraction of the U.S. list price.

THE ORDER IS THE LATEST STEP AMONGST A LANDSCAPE OF RECENT REGULATORY INITIATIVES

The Order falls within broader efforts by the Administration to **dismantle anticompetitive regulations** and combat the high prices that both Americans and the government are paying for medications in particular. [1] According to the Order, Americans allegedly fund three-quarters of global pharmaceutical profits although they represent just five percent of the world's population. [2] This amounts to over \$800 billion spent by Americans on prescription drugs in 2024 alone. [3]

On February 19, 2025, President Trump signed Executive Order 14219 directing agencies to "initiate a process to review all regulations" and identify regulations that "impose undue burdens on small businesses and impede private enterprise and entrepreneurship." Shortly thereafter, a separate executive order instructed every federal agency to review and eliminate regulations that "reduce competition, entrepreneurship, and innovation—as well as the benefits they create for American consumers." Consistent with this directive, on March 27, 2025, the Department of Justice announced an Anticompetitive Regulations Task Force aimed at **identifying and eliminating "anticompetitive state and federal laws and regulations that undermine free market competition and harm consumers, workers, and businesses.**" The announcement listed healthcare as one of the target markets of the Task Force. [4] The Federal Trade Commission has also followed suit with a public inquiry into regulatory obstacles to competition.

Both the President and the FTC have shown a clear focus on high prices of prescription drugs in particular. In January, the FTC released a <u>staff report</u> detailing its views on how the pharmaceutical industry, particularly the market for specialty generic drugs, is increasingly shaped by the dominance of three vertically integrated Pharmacy Benefit Managers (PBMs)—Caremark Rx (CVS), Express Scripts (ESI), and OptumRx. The report asserts that PBMs frequently steer the most profitable prescriptions to their affiliated pharmacies, generating billions in excess revenue through significant markups and preferential reimbursement rates. These practices have led to rapidly rising costs for both plan sponsors and patients, with expenditures and out-of-pocket payments for specialty generics increasing at double-digit annual rates.

Additionally, less than a month before the issuance of the May 12 Order, President Trump signed an <u>executive order</u>, titled "Lowering Drug Prices by Once Again Putting Americans First," that outlined a comprehensive strategy to <u>reduce prescription drug costs in the United States</u>. The order directed the Department of Health and Human Services to advance policies that promote competition, improve Medicare's ability to negotiate and pay for drugs, and ensure discounted access to essential medications like insulin for low-income individuals. It also called for faster approval of generics and biosimilars, streamlining drug importation, and new regulations to address anticompetitive practices and pharmacy benefit manager fees.

THE MAY 12 ORDER PRESENTS A MULTI-PRONGED APPROACH TO LOWERING PHARMACEUTICAL PRICES

The May 12 Order lays out a multi-pronged strategy aimed at ensuring that the United States does not pay more than the price charged in any other developed country for the same product.

- 1. Within thirty days of the Order, the Secretary of HHS, together with the Domestic Policy Council and the Centers for Medicare & Medicaid Services, should transmit precise "most-favored-nation price targets" to pharmaceutical manufacturers to jump-start voluntary price concessions.
- 2. If voluntary concessions fail, HHS must produce a rulemaking plan that would formally impose MFN ceilings. The order also instructs HHS to consider certifying that drug importation under section 804(j) of the Food, Drug, and Cosmetic Act poses "no additional risk" to public health. This directive lays the groundwork to authorize waivers that would allow for the importation of drugs from developed markets where prices are lower. The Order also directs the Food and Drug Administration to modify or revoke approvals of drugs viewed as unsafe, ineffective, or "improperly marketed."
- 3. At the same time, the Attorney General and the FTC are ordered to pursue enforcement actions **against** anticompetitive practices involving pharmaceutical manufacturers through the use of sections 1 and 2 of the Sherman Act and section 5 of the FTC Act.
- 4. Additionally, the Secretary of Commerce and the heads of other relevant agencies are instructed to review "all necessary action regarding the export of pharmaceutical drugs or precursor material" that could be the cause of price discrimination globally.

KEY TAKEAWAYS AND PRACTICAL IMPLICATIONS

In practical terms, the Administration has given itself and the pharmaceutical industry a tight window. By June 11 HHS must dispatch MFN targets. If "significant progress" has not been achieved by then, HHS shall propose a rulemaking plan to impose MFN pricing. This means that proposed rules imposing MFN ceilings could surface as early as this summer, leaving industry players little time to negotiate concessions.

Because any final rule would almost certainly qualify as a "major rule" under the Congressional Review Act and a "significant regulatory action" under Executive Order 12866, any such rule is likely to trigger heavy review and inevitable court challenges. Drug manufacturers are likely to challenge any rule on statutory and constitutional grounds, arguing that forced price caps exceed HHS's delegated authority. In addition, the Administrative Procedure Act's requirements for notice-and-comment rulemaking, reasoned decision-making, and cost-benefit analysis create multiple procedural hurdles.

Logistics around implementation of any MFN rule also present difficulties. For example, constructing an accurate global price index will be difficult as foreign list prices are often hidden by confidential rebates and managed-entry agreements. In addition, formularies, drug interchangeability rules, and supply-chain mark-ups differ across countries, further complicating comparisons needed to inform any MFN rule.

While the implications are thus uncertain, the threat of an MFN rule may shift bargaining dynamics in the industry: manufacturers will face a choice between swift voluntary cuts or the risk of mandated parity and possible loss of market access through importation or approval revocation.

Whether the Administration's plan ultimately succeeds will depend on the availability of reliable pricing data, interagency coordination, and the result of legal challenges. However, **coupled with broader efforts to dismantle anticompetitive regulations**, the MFN framework positions drug pricing as a **central focus of federal competition policy going forward**.

Indeed, the Order is not just a policy lever—it's part of a larger antitrust playbook aimed at breaking entrenched pricing structures and reviving competition in pharmaceutical markets. By tying pricing reform to enforcement under the Sherman and FTC Acts, the Administration is redefining the boundaries of antitrust intervention. Whether through voluntary price cuts or regulatory action, industry stakeholders across the healthcare sector should prepare now for a more aggressive regulatory environment and should operate with a clear understanding: competition law is being recast as a core instrument of drug pricing reform.

Law Clerk Sofia Vescovo also contributed to this blog post.

[1] See Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients, The White House (May 12, 2025), https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/; Fact Sheet: President Donald J. Trump Announces Actions to Put American Patients First by Lowering Drug Prices and Stopping Foreign Free-riding on American Pharmaceutical Innovation, The White House (May 12, 2025), <a href="https://www.whitehouse.gov/fact-sheets/2025/05/fact-sheet-president-donald-j-trump-announces-actions-to-put-american-patients-first-by-lowering-drug-prices-and-stopping-foreign-free-riding-on-american-pharmaceutical-innovation/; Lowering Drug Prices by Once Again Putting Americans First, The White House (April 15, 2025), https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/.

[2] Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients, The White House (May 12, 2025), https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/; Fact Sheet: President Donald J. Trump Announces Actions to Put American Patients First by Lowering Drug Prices and Stopping Foreign Free-riding on American Pharmaceutical Innovation, The White House (May 12, 2025), <a href="https://www.whitehouse.gov/fact-sheets/2025/05/fact-sheet-president-donald-j-trump-announces-actions-to-put-american-patients-first-by-lowering-drug-prices-and-stopping-foreign-free-riding-on-american-pharmaceutical-innovation/.

[3] Elizabeth Guevara, *As Trump Moves to Lower Costs, Here's How Much Americans Are Spending on Prescription Drugs*, Investopedia (May 12, 2025), https://www.investopedia.com/as-trump-moves-to-lower-costs-here-s-how-much-americans-are-spending-on-prescription-drugs-11733323?utm_source=chatgpt.com#citation-2.

[4] Justice Department Launches Anticompetitive Regulations Task Force, U.S. Dep't of Just. Off. Of Pub. Aff. (Mar. 27, 2025), https://www.justice.gov/opa/pr/justice-department-launches-anticompetitive-regulations-task-force.

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Eva Cole

Lauren Duxstad

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