

Publications

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The Trump Administration Announces Price Targets as It Takes a Second Swing at “Most Favored Nation” Drug Pricing Model

At a Glance

- **MFN Pricing Returns:** The EO revives effort to link U.S. drug prices to those in peer countries, calling for voluntary industry action.
- **Aggressive Action on the Table:** If progress on voluntary price cuts stalls, the Administration may pursue rulemaking, FTC enforcement and FDA actions.
- **DTC Emphasis:** It supports direct-to-consumer drug purchasing.
- **Broad Scope:** Announced price targets cover brand products without generic/biosimilar competition in “all markets.”

On May 12, 2025, President Donald J. Trump signed an Executive Order (EO) titled “Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients,” and the Department of Health and Human Services (HHS) quickly followed up with an announcement of related pricing targets on May 20, 2025. According to the announcement, “HHS expects each manufacturer to commit to aligning U.S. pricing for all brand products across all markets that do not currently have generic or biosimilar competition” with the most-favored-nation (MFN) target price. The announcement describes that target price as the lowest price in any Organisation for Economic Co-operation and Development (OECD) country with a Gross Domestic Product (GDP) per capita of at least 60% of the U.S. GDP per capita.

The EO follows the April 15, 2025, release of EO No. 14273 titled “Lowering Drug Prices by Once Again Putting Americans First” (April 15 EO), discussed in our previous Client Alert, and further emphasizes the Administration’s focus on reducing U.S. drug costs. Notably, the EO does not call for legislative reforms or immediate rulemaking to require MFN pricing. Instead, it seeks voluntary pricing changes and specifies additional steps the Administration will take if “significant progress” toward MFN pricing does not occur. In a statement issued shortly after the EO, however, Senator Bernie Sanders indicated that he will soon introduce legislation to ensure people in the U.S. pay no more for prescription drugs than those in other major countries.

This alert provides a brief overview of the EO and identifies key takeaways and issues to watch going forward.

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- Claire Davies
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Key Provisions of the Executive Order

The EO directs three initial actions aimed at aligning U.S. drug prices with those paid by similar countries:

1. **Direct-to-Consumer (DTC) Drug Purchasing:** The EO calls for the HHS Secretary to facilitate DTC purchasing programs that allow consumers to purchase drugs directly from manufacturers offering an MFN price.
2. **Foreign Practices:** The EO directs the Secretary of Commerce and the United States Trade Representative to ensure that foreign countries do not engage in practices that may be unreasonable or discriminatory or impair U.S. national security and that result in U.S. patients shouldering a disproportionate amount of global drug research and development costs.
3. **MFN Price Targets:** The EO instructs the HHS Secretary to communicate MFN price targets to pharmaceutical manufacturers. As noted above, HHS announced information regarding price targets on May 20, 2025.

If “significant progress” toward achieving MFN pricing is not delivered, the EO directs the following additional actions:

- **Rulemaking:** The HHS Secretary must “propose a rulemaking plan” to require MFN pricing, but the EO does not address the statutory authority for or scope of this rulemaking.
- **Personal Importation:** The HHS Secretary shall “consider” certifying that personal importation under section 804(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) will pose no additional risk to public health and safety and will significantly reduce the cost of prescription drugs to Americans. (This certification must occur before the U.S. Food and Drug Administration (FDA) can use the authority in section 804(j) to waive prescription drug import restrictions for individuals.) If such certification is given, the EO further directs the FDA Commissioner to issue guidance describing circumstances under which waivers will be consistently granted.
- **Federal Trade Commission(FTC) Enforcement:** The Attorney General and the Chairman of the FTC must, to the extent consistent with applicable law, take enforcement action against anticompetitive practices by manufacturers identified in a report to be issued under the April 15 EO.
- **Drug Exportation:** The Secretary of Commerce and other relevant agency heads shall review and consider all necessary action regarding the export of pharmaceutical drugs that may be fueling global price discrimination.
- **Potential Drug Approval Modifications/Revocations:** The FDA Commissioner must “review and potentially modify or revoke approvals” for drugs that may “be unsafe, ineffective, or improperly marketed.”

Key Takeaways and Issues to Watch

- **The Administration’s focus for MFN pricing appears to be broad:** Neither the EO, nor its accompanying Fact Sheet, describes the scope of drugs subject to MFN pricing, but the HHS announcement refers to “brand products across all markets,” indicating that innovator drugs without generic or biosimilar competition—regardless of their cost to federal healthcare programs or indications—are within scope.
- **What happens if voluntary price reductions fail to materialize?** Many actions described in the EO come into play only if there is a failure to make “significant progress” toward MFN pricing. In most cases, the EO offers little detail on the authority and timeframe for those actions (such as the kinds of measures the Administration might pursue to address drug exports contributing to global price discrimination). Without a set deadline for “significant progress” to occur, the EO

appears to provide manufacturers and other stakeholders a window to propose changes to current pricing. Whether any voluntary changes will convince the Administration to hold off on rulemaking to implement a mandatory MFN model, enforcement actions, or other activities described in the EO remains to be seen.

- ***A new MFN rule will be a likely target of legal challenges.*** During President Trump's first term, Centers for Medicare & Medicaid Services (CMS) issued an interim final rule that would have tied Medicare Part B payments for 50 single source drugs to the lowest GDP-adjusted price paid in economically similar countries. Multiple organizations swiftly challenged the rule, and three federal courts temporarily blocked its implementation, citing the likely insufficiency of notice and comment rulemaking procedures under the Administrative Procedure Act (APA). The rule was later withdrawn by the Biden Administration. This time around, the Trump Administration may seek to reduce the likelihood of an APA procedural challenge by issuing a proposed rule for public comment before implementing any mandatory MFN pricing. However, it is reasonable to expect that any final rule issued on this topic will prompt litigation.
- ***Pharmacy benefit managers (PBMs) may face increased pressure.*** In his remarks at the EO signing, President Trump was clear that one of the aims is to "cut out the middlemen"—a likely reference to the pharmacy benefit managers (PBMs) that, among other things, negotiate with drug manufacturers and pharmacies to set prices. The EO's directive to facilitate DTC purchasing programs reflects this goal but is short on specifics that will be key to the impact of such programs. For example, it's unclear if manufacturers will be required to participate and if patients will ultimately pay more out of pocket for drugs offered through the DTC programs than they would by obtaining drugs through their insurance. Nonetheless, the EO, along with April 15 EO calling for regulations to improve PBM fee transparency may increase pressure on PBMs to change their pricing practices.
- ***The impact of any personal importation waivers may be limited.*** During the first Trump Administration, FDA expressed significant concerns about implementing the personal importation waiver authority under section 804(j) of the FDCA. Even if thinking at HHS and FDA has changed, and the HHS Secretary makes the required certification to implement the authority under section 804(j), the waivers described in the EO must be issued to individuals on a case-by-case basis to permit them to import unapproved drugs from other countries. Such waivers, which would not facilitate large-scale commercial drug imports, seem unlikely to result in significantly increased access to lower cost drugs.
- ***Should manufacturers expect FDA scrutiny if they don't reduce prices?*** The EO's reference to potential modification or revocation of existing drug approvals is puzzling. While the FDA has authority to withdraw the approval of a drug or revoke a biological product license, those actions must be based on certain findings, and none of the bases for withdrawal or revocation refers to drug pricing. The EO makes no express link between drug manufacturer pricing actions and FDA review of existing drug approvals, but it could be read to imply that those manufacturers who do not voluntarily reduce prices will see additional FDA examination of their approved products.

While significant questions remain about the authority for and impact of several directives in this new EO, the Trump Administration is clearly focused on drug pricing reforms. The EO also appears to be another piece of the Trump Administration's approach to tariffs on pharmaceuticals and biologics. (See our previous client alerts on Section 232 investigations of pharmaceutical imports and President Trump's May 5, 2025 Executive Order to Promote Domestic Production of Biopharmaceuticals). Pharmaceutical and biologics industry stakeholders should closely monitor additional developments in this area.

If your business needs strategic legal advice or anticipates potential impacts resulting from these announcements, contact Claire Davies, Suzanne Bassett, Polsinelli's Executive Action Working Group or your Polsinelli contact.