Unpacking President Trump's New Executive Order on "Most-Favored-Nation" Prescription Drug Pricing

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Overview

On May 12, 2025, President Trump issued an Executive Order, *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients* (the "Executive Order"), that sets forth the Administration's policy objectives to have "most-favored-nation" ("MFN") pricing for prescription drugs, along with an accompanying fact sheet, *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*.

As with President Trump's previous Executive Order regarding prescription drug pricing (issued on April 15, 2025), this proposal outlines broad policy objectives with little specificity. In addition, the Executive Order relies primarily on voluntary compliance (at least in the first instance). To the extent the administration seeks to mandate these initiatives via action by the Department of Health and Human Services ("HHS") or other federal agencies, they are likely to be subject to legal challenges. We discuss the provisions and their implications for the life sciences industry below.

The Administration's Overall Policy Objectives

The Executive Order returns to a familiar theme from President Trump's first administration: it asserts that it is unfair that the United States funds three quarters of the global pharmaceutical industry's profits—both because (i) the federal government provides support for pharmaceutical research and development and (ii) drug manufacturers "agree to other countries' demands for low prices" and allegedly charge "inflated prices" in the United States. It claims that American consumers should receive prescription drugs on the same terms as other developed nations.

Left unspoken in this narrative is that many countries impose price controls that significantly curtail the reimbursement that pharmaceutical manufacturers receive—

whereas there are no such price controls in the United States (except for the Inflation Reduction Act's provisions governing Medicare "negotiations," which caps the maximum amount that HHS can provide in reimbursement for sole-source prescription drugs that have been on the market for a specified period of time).

Addressing "Freeloading" by Foreign Countries

The Executive Order directs the Secretary of Commerce and the United States Trade Representative to take steps to ensure that foreign countries are not acting in a way that could "impair United States national security" and suppress the price of pharmaceutical products below fair market value. This provision suggests the administration may seek to encourage foreign governments to increase the amount of reimbursement they provide for price-controlled drugs—although it is unclear how the administration would accomplish that objective. The reference to national security could suggest the administration is contemplating tariffs or other retaliatory measures against countries that provide reimbursement at levels that the administration believes are too low. It is unclear, however, whether the administration plans to follow through with this threat.

Facilitating Direct-to-Consumer Sales to Patients at Most-Favored-Nation Price

The Executive Order directs HHS to "facilitate direct-to-consumer purchasing programs" for pharmaceutical manufacturers who sell their drugs to American patients at an unspecified so-called "most-favored-nation price." The Executive Order does not define "direct-to-consumer purchasing programs," indicate how HHS would (or could) "facilitate" them, or describe the scenario whereby drugs—via direct purchase—would be sold at a "most-favored-nation price."

Ordinarily, pharmaceutical companies do not sell prescription drugs directly to consumers. Instead, they typically sell drugs to distributors (i.e., licensed wholesalers), who in turn sell the drugs to a retail pharmacy (with potential additional entities inside this supply chain). The Executive Order is presumably trying to encourage direct-to-consumer programs recently implemented by a few pharmaceutical companies where consumers can be prescribed drugs through a telehealth provider, and the drugs are then dispensed and shipped through a pharmacy directly to the consumer. This model, of course, may not work for many types of drugs and indications.

Most-Favored-Nation Pricing

The Executive Order instructs HHS and others in the administration to develop "most-favored-nation" price targets and communicate them to pharmaceutical manufacturers. It does not specify how MFN prices would be determined, although it would likely be calculated based on the reimbursement provided by government-run health systems in other developed countries.

The Executive Order threatens adverse consequences (described below) if "significant progress towards most-favored-nation pricing for American patients is not delivered." It remains to be seen how (if at all) the administration will assess whether that objective has been achieved because of the complexity of the United States healthcare system. Prescription drugs are reimbursed by a wide array of payors, including government healthcare programs, commercial insurers, union benefit funds, and others. Determining the price that each payor pays is similarly complex due to rebates and incentive payments between and among the participants in the prescription drug distribution system. And the ultimate amount the patient pays out of pocket is frequently determined by the amount of co-pay or co-insurance the patient owes.

The Executive Order threatens the following consequences if the administration's MFN objectives are not met voluntarily:

- HHS is supposed to impose MFN pricing via rulemaking. It is unclear what authority HHS would have to implement such rules, as the reimbursement mechanisms for federal healthcare programs are set via statute and reimbursements for non-governmental payors are governed by private contractual arrangements. The first Trump administration proposed a rule (addressed here) that would have created a payment model that sought to gradually impose MFN prices on unspecified costly Medicare Part B drugs, but the rule was blocked by the courts for procedural reasons and was not revived by the Biden Administration. If HHS engaged in rulemaking, it would likely again seek to use its authority to develop payment models as the basis for limiting reimbursements for certain Medicare drugs to what the administration deems the MFN amount. Any such rule could be subject to challenge for a number of reasons, including on the basis that the administration lacks the statutory authority to implement an entirely new reimbursement regime for Medicare drugs. Such rulemaking may also implicate the Supreme Court's "major questions" doctrine—which precludes agencies from issuing rules with major political or economic implications without explicit authorization from Congress.

- HHS is to consider certifying to Congress that the importations under Section 804(j) of the Federal Food, Drug, and Cosmetic Act would not risk public health and would

result in a significant reduction in prices to be paid by consumers. This statutory provision, however, enables only states to import prescription drugs from Canada under limited circumstances. Although regulations by the Food and Drug Administration ("FDA") enabling importation under this program have been in place for five years, only Florida has received FDA approval to import drugs from Canada under this program. Moreover, according to public reports, Florida has not yet implemented the program. It seems improbable that the administration will facilitate widescale state importation of prescription drugs from Canada—and there is no mechanism to allow for state importation of prescription drugs from any other country.

- The Department of Justice and the Federal Trade Commission should take action to combat any anti-competitive practices. As a practical matter, antitrust regulators are likely to maintain their traditional areas of scrutiny, including anticompetitive Orange Book listings and reverse payment settlements. It is unclear how antitrust enforcement would lead to most-favored-nation pricing.

- The Secretary of Commerce should consider "action regarding the export of pharmaceutical drugs or precursor material that may be fueling the global price discrimination," which appears to suggest an effort to block the export of prescription drugs or active pharmaceutical ingredients. The Executive Order, however, does not specify what authority (if any) the federal government has to block such exports. Moreover, this threat is inconsistent with the administration's trade policies, which aim to facilitate exports.

- The FDA should review drug approvals and revoke or modify approvals to the extent the drugs are "unsafe, ineffective, or improperly marketed." This appears to be a threat to the pharmaceutical industry that the FDA may consider attempting to revoke approvals of drugs sold by manufacturers at prices the administration appears to believe are too high. The FDA's authority to revoke drug approvals is limited to a narrow set of circumstances—and FDA has no statutory authority to withdraw a drug approval based upon drug prices.

- Administration officials should take "all action available" to "address global freeloading and price discrimination against American patients." The Executive Order provides no further specificity regarding what authority, if any, the administration could exercise. Presumably the administration would want to convince other countries to pay more for prescription drugs, but it would be challenging to convince another country to voluntarily pay more for their drugs.

Although President Trump claimed this Executive Order would result in the prices of prescription drugs dropping "almost immediately, by 30% to 80%,"[1] the actual terms of the Executive Order do not suggest such objectives are likely to be achieved in the near or long term. Instead, it seems more likely that the administration will attempt to use its regulatory authority to issue new regulations related to the sale of prescription drugs to the federal healthcare programs (including both pharmaceutical manufacturers and/or intermediaries in the pharmaceutical supply chain). Such actions will likely trigger regulatory challenges by stakeholders that are adversely affected.

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[1] Donald J. Trump (@realDonaldTrump), TRUTH SOCIAL (May 11, 2025, 6:22 PM), https://truthsocial.com/@realDonaldTrump/posts/114491534347862682.

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