Focus on Access:

How Most Favored Nation Could Fail Patients

The rising cost of prescription drugs in the United States (U.S.) has become a significant concern for policymakers and patients. The U.S. often pays more for the same medications when compared to other developed nations, leading to proposals aimed at lowering these costs. One concept under consideration is the "Most Favored Nation" (MFN) pricing model for pharmaceuticals. The MFN approach, recently revived through an Executive Order (EO) signed by President Trump in May 2025, proposes that the U.S. should pay no more for prescription drugs than the lowest price paid in other comparable developed countries.[i]

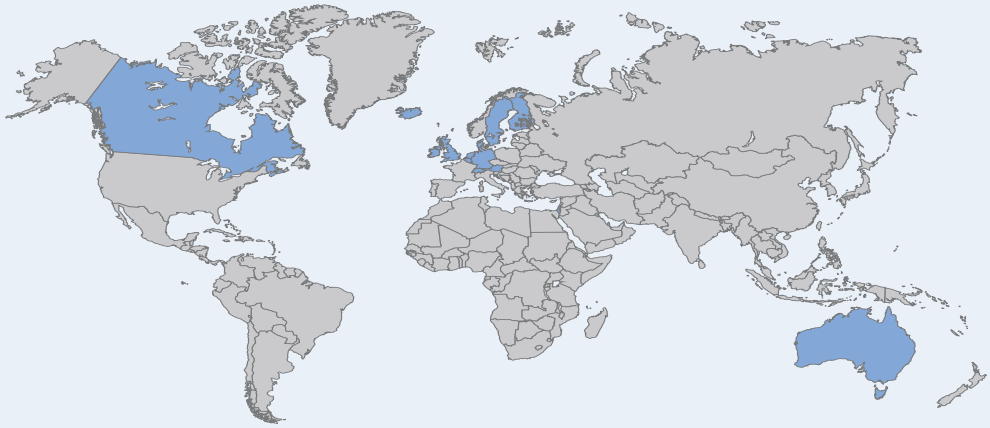
While the MFN concept sounds like a straightforward solution to high drug prices, it potentially does little to improve patient affordability. Furthermore, the implementation of MFN pricing carries potential risks for patient access, the future of biosimilar medications, and pharmaceutical innovation. Finally, it is crucial to recognize that the cost of drugs in the U.S. is intertwined with a unique, and more expensive, healthcare system overall, encompassing higher costs for hospitals, providers, and administrative processes.

Understanding MFN

The core idea behind the MFN pricing is to benchmark U.S. drug prices against those in other developed countries, ensuring that the U.S. does not pay more than other countries. While the hope is that U.S. prices will "equalize" with other countries paying more and the U.S. paying less, it seems unlikely that prices in other countries will increase quickly enough to satisfy the current political climate and desire for change.

In response to the MFN EO, the Department of Health and Human Services (HHS) has said they will look at 38 countries in the Organization for Economic Co-operation and Development (OECD) as a comparator set. HHS has indicated they include countries with a gross domestic product (GDP) per capita of at least 60% of the U.S.[ii]

COUNTRIES LIKELY TO BE INCLUDED[iii]



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Once the comparator countries have been selected, the lowest price for specific brand-name drugs within those reference countries would need to be determined. This lowest international price would then be the maximum price the U.S. would pay for the same drug. Thus far the Administration has not published these maximum prices despite saying they would do so within 30 days.

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The specifics of how MFN would be implemented are still to be determined. Most recently 17 pharmaceutical companies received letters demanding that they provide MFN pricing to every Medicaid patient, establish a mechanism for selling direct to patients at MFN pricing and ensure newly launched drugs are not priced higher in the U.S. than in other developed nations.[iv]

Previously, HHS said that MFN will apply to all brand products across all markets that do not currently have generic or biosimilar competition. It also implied that MFN would apply to all types of insurance coverage including Medicare, Medicaid and commercial coverage. It is unclear how the letters to the pharmaceutical manufacturers square with, if there is one, a larger MFN effort with formal rulemaking.

Patient Affordability

MFN may lower the overall cost of drugs in the U.S.; it does not inherently guarantee improved affordability for patients at the point of sale for several reasons.

1. Most Americans rely on health insurance to cover prescription drug costs. Even if the list price of a drug decreases due to MFN, there is no guarantee that these savings will be directly passed on to patients through lower out-of-pocket expenses. MFN savings could be shared through adjusted premiums or perhaps not at all.

2. Payers often prefer high cost, high rebate drugs and use the rebate to reduce premiums but also pay intermediaries like pharmacy benefit managers (PBMs). Without the rebate from high-cost drugs, payers will need to find new ways to secure revenue like higher premiums or higher patient cost sharing.

3. Adding an MFN discount may not significantly change the cost-sharing burden for patients or make drugs affordable. For example, a patient with a high-deductible plan may still face significant upfront costs for their medications, even if the overall price of the drug has fallen. Or, even with a lower cost, the drug may still be out of reach for patients, especially if plans move to coinsurance to try and recoup lost revenue from rebates. Payers may also adjust the cost-sharing amounts and/or switch copayments to coinsurance, increasing the burden on patients.

A singular focus on MFN pricing risks undermining pharmaceutical innovation and market dynamics without guaranteeing meaningful relief for American patients struggling to afford their medications.

Shattering Current and Future Access

Beyond its limited impact on patient affordability, MFN pricing could lead to several unintended negative consequences for patient access to pharmaceuticals:

- **Changing Formularies and Utilization Management:** It is likely that use of MFN would force insurers to reconsider formularies and what drugs should be covered, particularly if there are therapeutic alternatives available. This means that even if a drug's price is lowered under MFN, it might not be included in a patient's formulary, forcing them to pay a higher price for an alternative or face access barriers through prior authorizations or step therapy requirements.

Limiting Future Treatment Options

- **Harm to Biosimilar Pipeline:** While MFN policies will target brand products without generic or biosimilar competition, the overall downward pressure on prices could affect the market for future biosimilars. There may not be enough predictable profitability for a biosimilar to spend money on the research needed for Food and Drug Administration (FDA) approval and to compete with an established branded product that offers an MFN price. MFN combined with Medicare negotiation in the Inflation Reduction Act could decimate the long-term outlook for biosimilars because it is too unstable a market.
- **Reduced Pharmaceutical Innovation:** The U.S. market provides revenue that incentivizes pharmaceutical companies to invest in research and development. If U.S. prices are significantly reduced, we could see a slowdown in the development of new drugs, particularly for less common diseases or those requiring significant investment or more risk. Smaller biotechnology firms, which rely on investor confidence and future revenue projections, might find it harder to secure funding. If investors believe that the pharmaceutical manufacturers will have to rely more heavily on the U.S. market to succeed, it is likely we would see less competition in therapeutic areas because there would not be enough volume to support multiple therapeutic alternatives.

Apples and Oranges, the U.S. Healthcare System is Different

It is essential to acknowledge that the cost of drugs in the U.S. is embedded within a fundamentally different healthcare system compared to the countries used for MFN benchmarking.

Many MFN reference countries have single-payer or heavily regulated healthcare systems where the government directly negotiates drug prices or sets reimbursement rates. These systems often offer less patient/provider choice in treatment options and can have significant delays to treatment.

Studies consistently show that hospital and physician fees are significantly higher in the U.S. compared to other developed nations. These higher costs contribute substantially to the overall healthcare expenditure in the U.S., far outweighing the difference in drug spending in many cases. Essentially the price of drugs in the U.S. could be seen as aligning with the value they provide in the context of overall healthcare spending. While some medications in the U.S. may cost more, the savings that they bring are also higher in relation to the overall U.S. healthcare system.

In addition, the administrative complexity of the U.S. healthcare system, with its numerous payers, intricate billing processes, and extensive insurance regulations, results in significantly higher administrative costs compared to more streamlined systems in other countries.

The U.S. relies on a multi-payer system with private insurance playing a dominant role, leading to a more fragmented and less price-controlled market. These payers do negotiate for prescription drugs, but the savings may not be shared directly with the patient and may not be transparent to others. It should be noted that the U.S. often pays less for generic drugs than other countries because of the competition among drug manufacturers once a brand name drug's patent expires. The Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) of 1984 facilitated the entry of generic drugs into the market. More competitors typically lead to price reductions as manufacturers compete for market share and utilization.

Overall, it is critical to look at the fundamental differences between countries and not just import systems without considering the reasons for the variances.

Addressing the Bigger Picture

A deeper look at the concept of MFN reveals its significant limitations in addressing the core issue of patient affordability and access. Prescription drugs in the U.S. are aligned with the value they provide in relation to other healthcare costs, and we are right in line with other countries: 9% of United Kingdom's National Health Service budget goes to medicine compared to 17% in Germany and Italy and 15% in France.[v]

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To truly address patient affordability, policymakers need to consider more comprehensive reforms that tackle all aspects of healthcare costs including enhancing transparency in the drug pricing and insurance system and ensuring that any savings achieved are directly passed on to patients at the point of sale. A singular focus on MFN pricing risks undermining pharmaceutical innovation and market dynamics without guaranteeing meaningful relief for American patients struggling to afford their medications.

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