

New FDA Approach to Drug Prices Adds Uncertainty to Drug Approval Process

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Key Points

- FDA’s focus on playing a direct role in lowering drug prices may provide opportunities for some pharmaceutical companies to seek a regulatory advantage. But it also places enormous pressure on manufacturers to stay on the agency’s good side by lowering prices.
- Companies that do not give in to demands for price cuts could face regulatory delays and obstacles, and risk bad publicity.
- The agency’s interest in influencing drug prices marks a dramatic shift for a regulator that has prided itself on only carrying out its science-backed public health mission.

In the first year of the second Trump administration, we have seen the Food and Drug Administration (FDA) take an unprecedented role in drug pricing policy. While standards for drug approvals are certainly within FDA’s purview, drug pricing and coverage has traditionally been left to the Centers for Medicare and Medicaid Services or private insurance plans.

In the past, FDA has suggested that drug prices might be considered a condition for obtaining or maintaining approval of a drug but had never directly tied its regulatory approval authority to the price of the drugs it approves. Under the current administration, the agency has taken direct actions aimed at lowering drug prices, potentially exceeding its regulatory authority.

A May 2025 executive order on drug pricing stated that FDA could “review and potentially modify or revoke approvals granted for drugs” if manufacturers refused to explore “most-favored-nation” (MFN) pricing strategies.

When the executive order was first published, it seemed unlikely, given past FDA practice, that FDA would consider withdrawing approval of a drug based on price alone. But agency actions over the second half of 2025 clarified that FDA does have a role in the current administration’s drug pricing strategy, and that it is willing to take bold action to achieve the administration’s goals in this regard.

FDA Commissioner Martin Makary has been vocal about the price of drugs, speaking about the issue at a number of major press conferences and indicating that FDA may take more extreme measures to influence drug pricing if traditional means do not have the desired effect.

In response to the May 2025 executive order, many companies have adopted creative strategies to avoid agreeing to across-the-board MFN pricing. We have seen a significant increase in direct-to-consumer (DTC) sales for drugs, and the administration itself is getting in on the game: It has plans to launch a government DTC portal, TrumpRx.gov, in 2026.

A DTC model drops the rebates that pharmacy benefit managers have historically negotiated on behalf of insurance plans and passes the discounted price directly to the consumer. But DTC sales are not an option for every drug, and not all consumers are able to pay out of pocket rather than relying on insurance.

The clearest example of FDA’s hands-on role in the administration’s efforts to lower the prices of prescription drugs is the Commissioner’s National Priority Voucher (CNPV) pilot program. This allows manufacturers of drugs that meet certain criteria to apply for and potentially receive a “voucher” for an extremely fast, one- to two-month drug approval review.

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One of the criteria to qualify for the voucher program is “increasing affordability.” Indeed, when the program was announced in June 2025, the commissioner noted that a company may qualify for a CNPV for one product by lowering the prices of other drugs in its portfolio. FDA has made clear that, if companies are willing to make a deal on drug pricing, reciprocal regulatory efficiencies are on the table.

This arrangement was reflected in the first tranche of CNPV recipients announced on October 16, 2025. One recipient made a coordinated announcement with the White House about bringing down the cost of fertility treatments throughout its portfolio in exchange for the speedy review of a new fertility treatment.

Another company said publicly that it was surprised to learn that it had received a CNPV because FDA thought it would give its treatment away “for free.”

Similarly, the second set of announced CNPV participants included two companies that agreed to lower the price of their already-marketed GLP-1 products in exchange for faster reviews of pending submissions.

FDA’s October 2025 announcement on eliminating comparative efficacy study requirements for biosimilars also made

clear that FDA expects a streamlined pathway to lead biosimilar manufacturers to materially lower the cost of their products.

In remarks at the Association for Accessible Medicines’ October 2025 GRx+Biosims conference, Commissioner Makary said, “Once a biosimilar comes to market, I do ask that you lower the price significantly beyond the biologic price. Sometimes, when there’s one or two biologics on the market, we don’t see the prices come down that much. There’s sometimes an implied price collusion that goes on. We want to see lower drug prices for everyday Americans.”

These remarks were particularly notable given that an FDA commissioner has never spoken to industry so directly about how products are priced, and certainly not in the context of streamlining the approval process.

Early 2026 will also bring the announcement of the results of the Inflation Reduction Act (IRA) negotiations for selected drugs as well as the next tranche of drugs selected for negotiation. The administration has used these negotiations to push its MFN priorities and tout lower drug prices paid by Medicare.

What We’re Watching

The past year has made clear that the agency is not afraid to apply public pressure to drive manufacturers to change their marketing practices, including the way they price their products. And many manufacturers have responded by announcing significant changes to their pricing strategy.

It remains to be seen how the threats of FDA reprisal will ultimately play out if manufacturers do not lower prices in the context of IRA negotiations. On the one hand, FDA’s focus on drug pricing may bring opportunities for manufacturers that have room to negotiate and want to gain a regulatory advantage.

On the other, it places enormous pressure on manufacturers to stay out of FDA’s crosshairs, either by agreeing to the administration’s demands to lower prices or by trying to not get caught up in a public shaming related to drug pricing.

At a minimum, unprecedented agency activity in 2025 created a new set of challenges for manufacturers in 2026 who were used to working with a regulator that long prided itself on predictability.