Biden's looming prescription drug pricing dilemma

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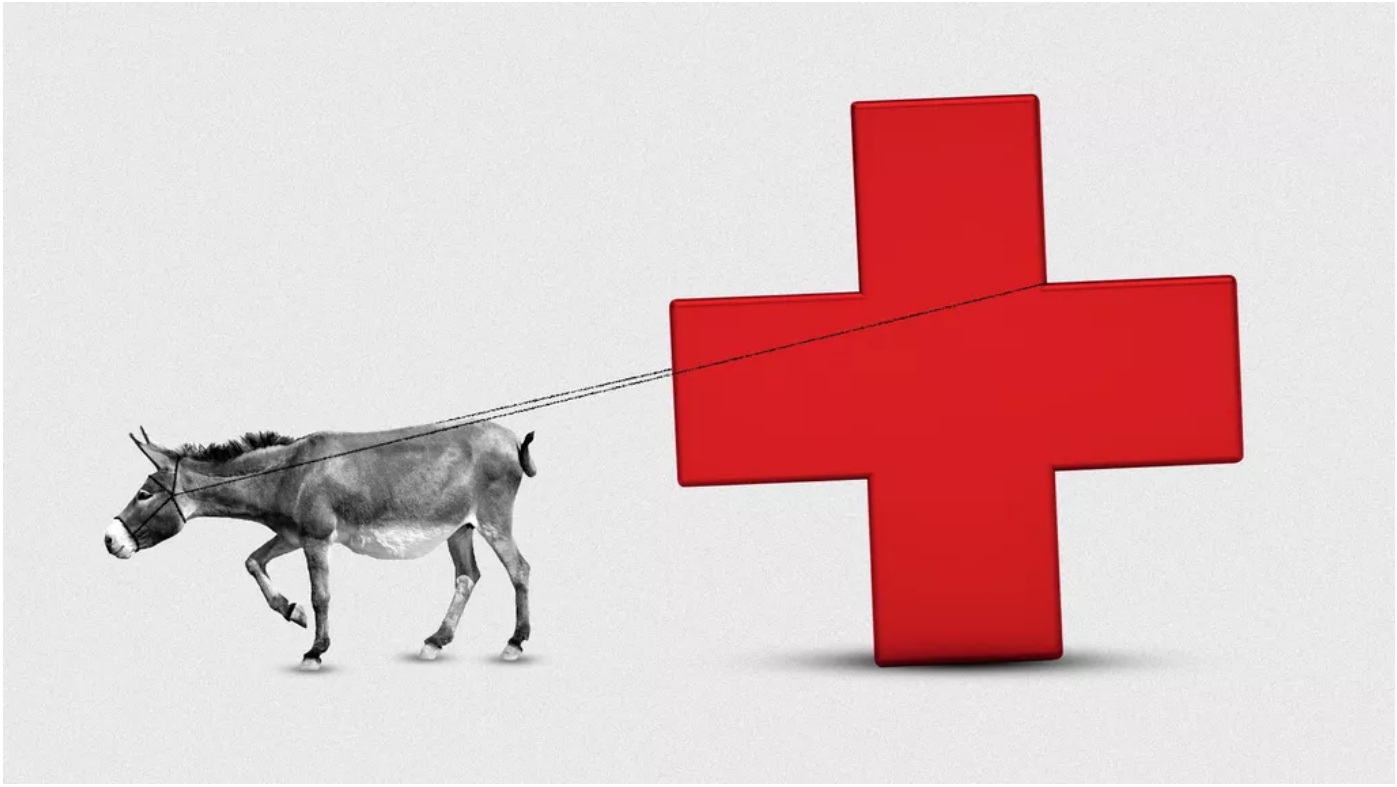

Illustration: Aïda Amer/Axios

The decades-long debate over whether the federal government can and should use its legal muscle to lower prescription drug prices may be reaching an inflection point, especially with President Biden's drug pricing agenda stalled on Capitol Hill.

Why it matters: Democrats would love to be able to show voters they've acted to lower drug prices before the November midterms, and progressive groups are urging them to so both legislatively and administratively. But taking on pharma through executive action risks uncertain legal outcomes, and opponents say that it could have a chilling effect on innovation.

State of play: Democrats' dreams of sweeping drug pricing proposals — including Medicare negotiations, which is hugely popular with their base — are being dashed in the Senate with the rest of Biden's domestic agenda.

- If the stalemate continues, that would put pressure on the administration to find ways to lower prices administratively. In a drug pricing plan that HHS released in September, the agency said that using legal authorities to circumvent drugmakers' patents on medicines developed with the government's help is still on the table.
- "HHS, NIH, and other agencies have been petitioned to take action under these provisions, and HHS will continue to give such petitions due consideration," the plan states.

The intrigue: A test case of how far the administration is willing to go is already teed up. The NIH is currently reviewing a request for it to lower the price of Astellas and Pfizer's prostate cancer drug Xtandi by using "march-in" rights, which allow federal agencies to remove exclusive patent rights on drugs that were developed using federal funding. The drug has an annual cost of about $160,000.

- March-in rights — which have existed for decades but have never actually been used — only apply in certain circumstances, per the law. The primary legal debate is over whether exorbitantly high prices count as justification for the government taking control of rights. The NIH has previously said that it doesn't believe they do.
- But the retirement of former NIH director Francis Collins, who was opposed to using march-in rights to lower prices, may create an opportunity for change.
- "Director Collins has been a major figure, so like any agency transition, there's an opportunity now to think differently about how the U.S. government is going to relate to the medical breakthroughs that it has

pioneered and financed, and what sort of return is due to the American people for those taxpayer investments," said Public Citizen's Peter Maybarduk.

What we're watching: Groups both for and against using federal authority to circumvent drug patents have become increasingly vocal on the issue.

- A petition sent by progressive advocates to HHS last week outlined how the Biden administration could use its power to lower the prices of six drugs, including Xtandi and Paxlovid, Pfizer's COVID antiviral.
- A separate group, including leading pharmaceutical industry groups, recently sent a letter asking the agency to reject the pending petition, arguing that "as the agency correctly and consistently concluded, using march-in rights to involve the NIH in drug pricing is a clear misapplication of the law."

What they're saying: Despite all of the activity, administrative patent challenges may not be in the offing, at least until there's some clear indication that Congress won't pass drug pricing reform.

- The petition advocating for the use of march-in rights "makes clear Xtandi is not a one off item that by moving forward with will appease progressives even if the courts eventually strike it down," writes Raymond James analyst Chris Meekins.
- "Instead, this shows progressives will go after more drugs resulting in the agency spending inordinate amounts of time dealing with these and likely result in the Administration having to alienate progressive[s] by not granting all of them."