

01 Aug 2024 | Analysis

VP Harris 'Marches In' To Presidential Campaign: Will Policy Change?

by Ramsey Baghdadi

The shake up in the US presidential campaign line up could have implications for future drug pricing policies. VP Kamala Harris has been an advocate for "march in" rights and could push that policy harder than incumbent President Joe Biden.

The change at the top of the Democratic presidential campaign ticket could mean that the next administration takes a more assertive approach to using "march-in" rights as a mechanism to address high drug prices.

Vice President Kamala Harris is set to become the Democratic Party's presidential nominee following President Biden's decision to end his campaign. The nomination won't formally be resolved until later in August ahead of the Democratic party convention, but Harris has secured the support of more than enough delegates to replace Biden atop the ticket.

As a presidential candidate in 2019, Harris endorsed the idea of patent "march-ins," telling the Washington Post that if drug manufacturers would not lower their prices, the US government could "snatch their patents" and all that was lacking was "the will" to do so. (Also see "*Patent*"

Key Takeaways

- Kamala Harris could be more assertive with march-in rights to deal with drug pricing concerns should she become the next US president.
- While running for president in 2019, she supported the idea of using the authority to help lower drug prices.
- During her tenure in the Senate, she also sponsored multiple bills intended to fight price gouging.

"March-In" As Price Control Draw Little Support At US National Academies Meeting" - Pink Sheet,



21 Aug, 2019.)

President Biden has not been as vocal on the topic, focusing on other pricing priorities, including signing the Inflation Reduction Act Medicare "negotiation" law in 2022. During his tenure, the National Institutes of Health continued declining requests to convene "march in" proceedings on specific products like <u>Astellas Pharma, Inc./Pfizer Inc.</u>'s Xtandi. (Also see "<u>After Xtandi, Will Government Ever Seek March-In Rights Over Drug Pricing?</u>" - Pink Sheet, 22 Mar, 2023.)

However, the Biden Administration also blocked a Trump era rule that would have removed "march-in" as a price control tool. Instead, the National Institutes of Standards and Technology, which oversees the Bayh-Dole technology transfer agreement process for the federal government, released a draft guidance in December 2023 that proposed a "framework" for federal agencies to use when considering whether to exercise the "march-in" authority. (Also see "*US NIH And Drug Pricing: Still Seeking A Balance*" - Pink Sheet, 13 Jun, 2024.)

The "march-in" final guidance most likely will arrive some time in 2025 after the election. However, accelerating that timeline in the coming months to signal an even tougher stance on drug prices is not out of the question and could be an opportunity for Harris to reassert her position on the issue.

That said, any more activist approach to "march-in" is certain to face judicial review. The current conservative majority of the US Supreme Court is not likely to endorse any broad interpretation of the government's right to "snatch" patents based on pricing concerns.

Still, the primary threat of "march in" authority is in the headlines. And it could emerge as a theme of a Harris campaign to build on the headlines coming from the first round of lower drug prices negotiated via the IRA provisions.

While in the Senate, Harris co-sponsored two drug price gouging bills: the CURE High Drug Prices Act (2018) and the FLAT Prices Act (2019).

CURE High Drug Prices would have required manufacturers to justify any price increase of 10% or more to the Health and Human Services Department, and given HHS the authority to require companies to reimburse consumers and payers, lower the price back to the level before the price gouging for up to one year, or pay a civil penalty up to three times the excessive amount the manufacturer received.

FLAT Prices would have tied inflationary price increases to reductions in intellectual property protections.

In 2019, Harris also introduced the PrEP Access and Coverage Act that would require all public



and private health insurance plans to cover HIV pre-exposure prophylaxis without a copay and would fund a grant program to help states facilitate access.