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# Biden's Pharma Plans Keep Industry Fighting On All Fronts

by Sarah Karlin-Smith

President's State of the Union address doubled down on his desire to expand on the IRA. While the agenda poses no near-term threat, it will keep pharma on its toes as industry juggles implementation of the new Medicare prices with fighting the IRA in court and trying to reform the original law.

US President Joe Biden took a strong swing at the pharmaceutical industry in his State of the Union address on 7 March by reupping his desire to expand Medicare's government price controls and apply some of the Inflation Reduction Act's prescription drug cost reforms to more Americans.

"We finally beat big pharma" Biden said. "This year Medicare is negotiating lower prices for some of the costliest drugs on the market that treat everything from heart disease to arthritis. Now it's time to go further and give Medicare the power to negotiate lower prices for 500 drugs over the next decade. That will not only save lives it will save taxpayers another \$200 Billion."

Biden also called out pharma in a portion of his speech focused on tax policy, putting the industry in pretty unpopular company.

"I also want to end the tax breaks for Big Pharma, Big Oil, private jets, and massive executive pay," the president said.

The industry did get one positive shout out as Biden mentioned the successful COVID-19 vaccine development and the current efforts to use mRNA technology to treat cancer. Biden also reiterated his support for ARPA-H, the Advanced Research Projects Agency For Health. (Also see "[ARPA-H, US FDA Discuss Incentives For Game-Changing Health Projects](#)" - Pink Sheet, 9 Oct, 2023.)

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In a statement released after the speech, Pharmaceutical Research and Manufacturers of America CEO Stephen Uhl said, “The IRA is stifling lifesaving research – like the very research needed to get the president’s Cancer Moonshot off the ground – and creating access barriers for patients. There is bipartisan support for fixing some of the flaws of the IRA, yet the administration is rushing to make this bad law worse.”

There’s little threat of near-term follow through on Biden’s agenda given the divided Congress and election year politics – not to mention Democrats themselves couldn’t reach unanimous agreement to create a stronger IRA on its first go round. (Also see "[Medicare Price Negotiation Lite? Congress Targets Post-Exclusivity Drugs, Preserves Launch Price Discretion](#)" - Pink Sheet, 4 Nov, 2021.)

“Bottom line is I think it’s mostly noise at this point, and I suspect most people know it. As the last few weeks have shown, this Congress has an exceedingly difficult time passing even general consensus items or traditionally ‘must-pass’ bills like appropriations, so the odds of them successfully relitigating the IRA – before the November elections no less – falls somewhere between slim and none,” John Leppard, who covers the industry for Washington Analysis, told the *Pink Sheet*.

But the existence of this aggressive agenda still forces pharma to stay on its toes, exerting energy against another political battle when it already has quite a few tasks to keep it busy.

The current (and certainly not exhaustive) list includes pharma’s efforts to challenge the existing Inflation Reduction Act in court (*see sidebar*), working Capitol Hill for changes to particularly disliked IRA measures, pressing for pharmacy benefit management (PBM) reform, dealing with the implementation of current IRA measures, and now once again pressuring lawmakers to not grow the law.

Drug manufacturers still have unanswered questions about the current IRA implementation such as what evidence the Centers for Medicare and Medicaid Services is considering when determining a price for a drug, said John O’Brien, CEO of the National Pharmaceutical Council.

“If I’m a manufacturer, I won’t know what evidence CMS valued until it releases what they call a ‘concise justification’ early next year – after manufacturers of

## ***IRA Litigation: NJ Judge Looks For Own Path In Evaluating Medicare Price Negotiation Program***

By **Brenda Sandburg**

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During oral argument in four cases challenging the IRA, Judge Zahid Quraishi suggested he may find that Medicare

the next batch of drugs have already submitted their evidence before the next round's deadline," O'Brien said.

"Drug development is risky business, and layering more uncertainty on top of the uncertainty caused by the IRA will make it even harder."

participation is voluntary but takings claim would still need to be considered. On question of whether the program is hurting innovation, Quraishi seemed skeptical.

[Read the full article here](#)

There was a time when industry analysts thought pharma should be quiet and take what many said would be a relatively small hit with the pared back IRA and get itself off policy makers agenda for a bit. The problem is pharma has never quite fallen off the agenda.

Biden's current asks are not novel and nearly mirror his State of the Union address and budget requests from a year ago in March 2023. (Also see "[President Biden's Proposal To Expand Medicare Price Controls A Sign Of Things To Come](#)" - Pink Sheet, 8 Mar, 2023.)

The president wants to let Medicare negotiate drug prices for at least 50 drugs every year instead of the eventual 20 drugs/year limit. He also wants to let the government negotiate the prices of these drugs earlier in their lifecycle.

Further, Biden wants to expand the IRA's out-of-pocket cap on prescription drugs to all private insurance and require that the IRA's inflation rebates for drugs that raise their prices beyond the inflation rate be paid for commercial drug sales as well.

The drug industry would likely support expanding the out-of-pocket cap.

These policies have polled well in the past, one pharma industry lobbyist said, but without a prospect of Congressional passage, this is all about political messaging.

"While pharma will undoubtedly issue statements against it, I don't think they're particularly nervous about it," the lobbyist said.

Biden's plans were well received by industry critics.

The IRAs reforms "are modest compared to big pharma's avarice and undue influence, and to the onerous burden of high medicine prices on American families," said Public Citizen's Access to Medicines program director Peter Maybarduk. "Therefore, the president is powerfully right to call for negotiating the price of many more drugs and broadly penalizing price spikes to protect people outside of Medicare. Do not go small when the problem is so large."

How far Democrats can go likely depends on the outcome of the November elections. But even a Republican White House doesn't mean safety for the industry.

“From a sector level, I'm not really sure there's a 'win' for biopharma that's available, irrespective of who wins in November,” said Leppard.

“If Biden/Democrats win, the narrative will be the continued implementation of the IRA as they've outlined to this point, though I suspect most investors have come to terms with that. If Trump wins, however, we know that he's no friend of industry, and he has already pledged to reintroduce his Most Favored Nation policy for physician-administered drugs,” which would impact prices more than the IRA.

“I suppose the risk I suspect most people don't necessarily appreciate at this point is the potential for Trump to try to outflank Biden *from the left*,” Leppard said.