IRP, HTA, AND AFFORDABLE HEALTHCARE:

How Does the Biden Administration Want to 'Take on Pharma?'

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PRICENTRIC ONE
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PRICENTRIC BRIEF

- Democratic President-elect Joe Biden and his administration are poised to take the reins from President Donald Trump, who had just begun to more stringently address prescription drug prices in the U.S. via Executive Orders (EOs) aimed at introducing an American version of reference pricing
- Throughout his campaign, Biden has promised to expand access to health care through the "Biden Plan," an evolution of former President Barack Obama's Affordable Care Act, dubbed "Obamacare," while "taking on big pharma" and reining in "runaway" drug prices
- Biden has also announced intentions to set up a government-run, Institute for Clinical and Economic Review (ICER) -style Health Technology Assessment (HTA) body, as ICER is currently an autonomous body to the U.S. government

THE DETAILS

WASHINGTON D.C., United States - Over the weekend following the election, former Vice President and Democratic nominee Joe Biden was projected as the winner of the 2020 United States Presidential Election by the Associated Press.

Now, Biden and his administration are poised to take the reins from President Donald Trump, who had been trying to address prescription drug prices in the U.S., most recently via Executive Orders (EOs) aimed at introducing an American version of reference pricing. In addition to the new pricing mechanism, Trump's orders focus on allowing prescription drugs to be imported from Canada to help Americans save at the pharmacy.

Throughout his campaign, Biden has promised to, once in office, expand access to health care through the "Biden Plan," an evolution of former President Barack Obama's Affordable Care Act, dubbed "Obamacare," while "taking on big pharma" and reining in "runaway" drug prices. As with Trump, Biden seeks to leverage the negotiating power of Medicare when determining drug prices, and as detailed on his campaign website, Biden has expressed support for previous legislative efforts to benchmark drug prices against those found in economically similar countries around the world.

Newly elected Vice President Kamala Harris is also in favor of adopting a reference price scheme in the U.S., as while running for President against Biden, Harris introduced her "People Over Profit" plan to regulate U.S. pharmaceutical prices. The plan would allow the Department of Health and Human Services (HHS) to set a price for any drug when the responsible company hikes the price by more than inflation or when the drug is sold at a lower price in economically comparable countries, a list that includes many nations outlined in Trump's plan. In addition, Harris is on board with importing drugs from Canada.

Republican Groundwork

Trump had initiated a radical departure to U.S. drug pricing policy with his reference pricing plan, first proposed in 2018. His latest drug pricing plan moved the reference price point from an average to a "Most-Favored Nations" Clause EO, which took the minimum of a basket of countries. While the details of the various Republican and Democratic proposals for reference pricing differ, Trump has likely increased bi-partisan support for the potential of US reference pricing and paved the way for the new Democrat administration to follow through on some form of reference pricing.

Pharmaceutical Research and Manufacturers of America (PhRMA) President and CEO Stephen J. Ubl condemned Trump's plan, commenting, "Yet, in the middle of a global pandemic, when nearly 145,000 Americans have lost their lives and millions of others have suffered untold economic hardships, this administration has decided to pursue a radical and dangerous policy to set prices based on rates paid in countries that he has labeled as socialist, which will harm patients today and into the future."

Politico reported that pharmaceutical company CEOs put forth a counteroffer to the President's plan. Their proposal sought to save Medicare in excess of $100 billion over a decade and avoid rulemaking by relying on voluntary demonstration programs within Medicare.

Dr. Wayne Winegarden of the California-based Pacific Research Institute, a free-market think tank, suggested that implementing Trump's Order could potentially "harm patients, innovation, and could ironically increase overall healthcare spending," because Trump "fails to understand the drivers of the drug affordability problem."

However, Trump's proposal was not the only one to come under fire. U.S. Speaker of the House Nancy Pelosi's earlier proposal (H.R. 3) was forecasted to similarly impact the industry. Pricentric Analysts found the impact of H.R. 3 would be significant, with price reductions for the costliest drugs for Medicare – Celgene's Revlimid (lenalidomide), Sanofi's Lantus (insulin glargine), AbbVie's Humira (adalimumab), and EMD Serono's Januvia (sitaglipin), for example – ranging between 62% and almost 89%.

A similar impact would be seen by Trump's EO, which would see the most-favored-nation price as the lowest price among select member countries of the Organization for Economic Co-operation and Development (OECD) with comparable per-capita gross domestic product to the U.S. This list could've included Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Ireland, Israel, Japan, the Netherlands, New Zealand, Norway, Sweden, Switzerland, and the United Kingdom, according to Forbes.

Now, though less concrete, Biden's plan intends to stop "runaway" drug prices, specifically for medicines not facing any competition, and reduce drug costs by nixing the current exception allowing drug companies to avoid negotiating with Medicare. He has gained support from Congressional Democrats to pass such legislation, which the Congressional Budget Office found could cost the industry more than US$30 billion by 2029.

Further, Biden's proposal suggests that as a condition of participation in the Medicare program, all brand, biotech, and "abusively" priced generic drugs will be prohibited from increasing their prices more than the general inflation rate, including a tax penalty on drug manufacturers that flout this rule.

Medicaid has increased rebates if prices increase too fast. Also, there is the Federal Upper Limit (FUL), the maximum reimbursement amount allowed for certain drugs to ensure Medicaid is a "prudent purchaser." Moreover, it's important to note that the U.S. government has had reimbursement policies that generally take their pricing cue from privately negotiated prices, rather than directly making drug pricing decisions. Examples of this include the Department of Veterans Affairs (VA), which negotiates its own drug prices, and Medicaid, which allows special exceptions to negotiate contracts for Hepatitis C treatments.

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U.S. Looks to Europe for HTA Inspiration

Perhaps one of Biden's biggest changes would be to set up, as he intends, a government-run, Institute for Clinical and Economic Review (ICER)-style health technology assessment (HTA) body. The details of the organization are yet to be finalized and unveiled, but it has been suggested that Biden will look to European HTA systems, in particular Germany's, as an influence for the U.S.'s own.

As it stands, the U.S. does not have an overarching national HTA agency, primarily due to a historically large private insurance marketplace that sets its own reimbursement. It has been suggested that Biden's plan would enable the government to negotiate for "ceiling prices" applicable for all payers. However, it has not been disclosed whether the ceiling price would be the final price or whether negotiated discounts would apply to bring prices lower, according to Bernstein analyst Ronny Gal.

Tipping the Balance

This year, the majority of pharma-backed funding over the course of the election went to Biden, who received $11,305,975 in total, compared to $2,192,233 for Trump. This could be in part because of the largely negative reception of Trump's EOs. The Orders fell short on his initial promises of an immediate cut to drug prices, lowering patients' out-of-pocket costs. Rather, it would just start the process to test the impact of this change.

Interestingly, the funding amounts are a stark contrast to the usual pharma cash-flow during elections, as in 14 of the past 16 elections – which takes us all the way back to 1990 – the pharmaceutical industry has given more money to Republicans than to Democrats.

Here to Help

EVERSANA uniquely has the people, methods, and tools to assist businesses in navigating any changing pharmaceutical policies, even in such unsure times. This expertise is built on our combined decades of experience solving problems in and building tools for global pricing intelligence, global visibility, and product launch expertise, which puts us in a trusted position to advise clients on how to handle these changes.

At the same time, Pricentric Insights strives to deliver accurate, comprehensive insights on major policy and regulatory changes, as well as HTA decisions and drug approvals, in over 100+ markets around the world. Our team of researchers checks a database of over 700+ reliable sources, including everything from government databases to local newspapers, to provide readers with in-depth updates on the ever-changing pricing and reimbursement landscape. In addition, we provide conference coverage and utilize our team of consultants to detail how major policy changes, such as those proposed by Biden, can impact market access and the global pricing landscape.