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The Outlook For The Pharmaceutical Industry Under Trump

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Law360, New York (January 12, 2017, 1:30 PM EST) --
The 2016 election will have important consequences for the pharmaceutical industry. While President-elect Trump has now made key health care-related appointments and has issued several broad post-election statements related to health care reform, many unknowns remain.


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Immediately after the election, the price of pharmaceutical and biotech companies generally rose. Investors have been optimistic that Mr. Trump's free-market, anti-regulation approach will benefit drug and biotech manufacturers.

While there is truth to this conventional wisdom, what we do know suggests that the reality will be more nuanced. We also know that changes won't be experienced immediately or all at once. Here are some ways the pharmaceutical industry could be affected.

ACA Revisions — the Good, the Bad, and the Uninsured

Full repeal of the Affordable Care Act — which Trump called for during his campaign — seems unlikely. After a post-election meeting with President Obama, Trump said he would like to keep two of the ACA's most popular provisions: the ban on insurers discriminating based on preexisting conditions and the requirement that insurers permit adult children to be covered by their parents' policies through age 26. That being said, Trump's appointment of Rep. Tom Price, an avowed ACA foe, as the Secretary of Health and Human Services, strongly suggests that Trump is still committed to major APA revisions. As we'll discuss, likely ACA revisions could have cross-cutting implications for the pharmaceutical industry.

What's on the Chopping Block?

The 2015 bill repealing the ACA, which Congress passed but Obama vetoed, hints at which provisions of the ACA are likely targets for repeal by Trump and Congressional Republicans.

It would have eliminated:

- The individual mandate, which penalizes certain people who do not purchase health insurance.
- Subsidies to lower-income consumers to purchase health insurance.
- The "Cadillac tax" on high-cost health insurance plans.
- The annual tax on branded prescription drug industry, which was $3 billion for 2016 and was scheduled to rise to $4 billion in 2017 and 2018.
- The excise tax on medical devices.
- Taxes on high earners, which helped fund the program.
- The expansion of Medicaid to include all adults who earn less than 138 percent of the federal poverty level.

Notably for the pharmaceutical industry, the 2015 bill did not repeal the ACA provision that has gradually closed the "doughnut hole" in Medicare Part D coverage. The "doughnut hole" was a coverage gap between an initial threshold of drug costs that would be covered by Part D and much higher catastrophic maximum after which Part D coverage would resume. However, the bill also preserved the ACA provision that imposed significant discounts on the cost of prescription drugs that were dispensed to Medicaid patients.

Obstacles to Passing Repeal in Congress

A more sweeping repeal of the ACA would face at least a couple of hurdles in Congress.

For one, Republicans passed the 2015 bill through the filibuster-proof budget reconciliation process by targeting taxes and subsidies. Many provisions relating to insurance reform cannot be altered through budget reconciliation because they do not impact federal spending. A broader ACA repeal would be subject to filibuster by Senate Democrats, which the Republicans, with a slim majority, could not defeat.

In addition, Republicans passed the 2015 bill knowing it would have no actual consequences because Obama would veto it. For example, Medicaid expansion remains popular in states with large numbers of Medicaid beneficiaries, including some Republican-led states. Some Republican states, like Ohio and Indiana, adopted the Medicaid expansion. And several Republican senators opposed the repeal of the expansion in 2015. Whether Republicans have enough support within their party to roll back the expansion now is uncertain.

On November 21, Trump released a video outlining his plans for his first 100 days. He made no mention of the ACA, although he called for action in other areas like trade and national security. That being said, many Congressional Republicans want to take immediate action on the ACA. The predominant view among Congressional Republicans is that the ACA should be "repealed" immediately — but the repeal should not go into effect until at least 2019. That would give Congress and the Trump administration time to reach consensus on the divisive question of what health care measures should be implemented in place of the ACA.

What Would Replace the ACA?

Trump has identified a few features of an ACA replacement. These include:

- Allowing people to deduct premiums on their personal income tax returns.

- Expanding the availability of health savings accounts (HSAs), which allow people to set aside pre-tax dollars for health expenses.
- Permitting the purchase of insurance plans across state lines.
- Providing states with "block grants" (annual fixed amounts) to fund their Medicaid programs. States would be responsible for funding their costs exceeding the grant or would need to cut Medicaid coverage.

The Bottom Line for Pharma and Biotech

During the negotiations that led to the ACA, the pharmaceutical industry and President Obama reached an agreement — the industry would receive the benefits of millions of people that could now afford prescription drugs, but in return agreed to billions of dollars of taxes and discounts to government drug purchasers. If the 2015 bill is now enacted, the deal would only be partially unwound and the ultimate impact is difficult to assess. Branded manufacturers would be freed of the annual tax and would still benefit from the closure of the doughnut hole, meaning that seniors would have access to greater subsidies to purchase prescription drugs. But both branded and generic manufacturers could lose out on drug purchases by non-seniors that formerly received free or subsidized insurance through Medicaid or the exchanges but no longer can afford coverage. Notwithstanding these potential developments, pharmaceutical companies would remain saddled with the ACA's significant drug discounts for prescription drugs that are dispensed to Medicaid patients.

Pressure on Prescription Drug Pricing

Conventional wisdom is that a Trump administration and continued Republican majorities in Congress will permit greater flexibility in drug pricing. In Hillary Clinton, the industry had faced an alternative leader who had actively called for controlling the price of prescription drugs.

However, while Trump is regarded as business-friendly, he has expressed support for introducing more competition into the health care marketplace, which could lower the price of certain prescription drugs. He has proposed:

- Letting the Centers for Medicare & Medicaid Services (CMS) negotiate discounts for the price of drugs covered by Medicare Part D.
- Allowing American consumers to import cheaper prescription drugs from overseas.

Neither proposal has broad support among Congressional Republicans. Trump has not mentioned either proposal since the election. Trump recently expressed concern about high drug prices but did not say what, if anything, he plans to do about the issue. In any event, price increases by the pharmaceutical industry will likely remain under fairly intense scrutiny from the media, Congress and the public at large.

Tax Reform Could Facilitate Repatriation of Foreign Earnings and U.S. Involvement

Trump and Congressional Republicans are eager for significant corporate tax reform. In June 2016, House Republicans wrote a tax policy paper (known as the "blueprint"), which could be the starting point for legislation. Many of Trump's tax plans are consistent with the blueprint.

Its most important provisions are:

- The corporate tax rate would be a flat 20 percent (Trump's plan proposed 15 percent).
- Businesses could immediately expense 100 percent of the costs of business investment (including in plants and equipment, but excluding land).
- Offshore earnings held in cash or cash equivalents would be immediately taxed at an 8.75 percent rate. Offshore earnings held in other forms would be taxed at a 3.25 percent rate (payable over 8 years).
- Prospectively, foreign earnings and distributions from foreign subsidiaries would be exempt from U.S. tax.
- Interest expense that exceeds interest income would be non-deductible.

The net impact of these proposals could stimulate the repatriation of foreign earnings, which have been moored overseas by companies that do not want to pay the high U.S. corporate tax rates. This has long been an objective of the pharmaceutical industry and would likely result in increased investment activity in the U.S.

Less Federal "Red Tape" for Drug Development

In his plan for his first 100 days in office, Trump said he would "reform" the U.S. Food and Drug Administration. He emphasized the need to "cut red tape" and approve "new and innovative medical products." This could include:

- Accelerating the process to approve new drugs.
- Approving new uses for already-approved drugs.
- Lowering the bar to approve generic drugs.

FDA reform could shorten the approval process and reduce development costs. But it could also introduce more competition into the marketplace and exert downward pressure on drug prices. There is some indication that Congress may be on board with Trump's initiatives. The lame-duck Congress just passed, with bipartisan support, the 21st Century Cures Act. This bill would, among other things, allow the FDA to expedite approval of certain drugs.

Free Trade Agreements Might Get the Boot

Opposition to free trade agreements has been a pillar of Trump's platform. This could be a challenge for the pharmaceutical industry, which operates globally and relies on manufacturing conducted outside of the U.S. For example:

Trans-Pacific Partnership (TPP). Trump strenuously opposes the TPP, and since the election, the TPP has effectively died. The treaty's demise might have mixed results for the pharmaceutical industry. The treaty would have expanded patent protections and market exclusivity for new pharmaceutical products, and it would have created a framework for third-party challenges to intellectual property, modeled on the Hatch-Waxman Act. These provisions were generally supported by makers of branded pharmaceutical products but were not advantageous to generics companies. The treaty would also have created a period of exclusivity for biologics that was shorter than the period granted under U.S. law. Some industry players lobbied against the shortened period, while others, like generics companies, lobbied in favor of further shortening those periods.

North American Free Trade Agreement (NAFTA). Trump may seek to renegotiate or withdraw from NAFTA. Doing so could jeopardize pharmaceutical companies' operations in Mexico and Canada and roll back the intellectual property protections under the treaty. However, Congress may need to approve withdrawal from NAFTA, which could hinder Trump in his efforts.

More will be known in the coming months about the Trump administration's plans and how they will affect the health care industry. One thing is clear: Change is coming, and it will present both benefits and challenges for players in the pharmaceutical industry.

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