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How Joe Biden Will Change The FDA: Part 1

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President-elect Joe Biden has won the 2020 U.S. presidential election, although the transition from the Trump administration to the Biden administration has not yet commenced, due to ongoing election litigation brought by the Trump campaign. Meanwhile, control of the U.S. Senate remains in the balance, with two runoff elections in Georgia on Jan. 5.

Regardless of the outcome of the Georgia races, the Senate majority will be razor-thin. Hence, major overhauls of health policy and the U.S. Food and Drug Administration are unlikely, particularly if Democrats do not prevail in the Senate. This two-part article offers our outlook on the FDA under the Biden administration.

Transition

President Donald Trump has not yet stated publicly what level of support he intends to provide for the transition. But FDA officials — both political and career — will likely assist the Biden transition team, particularly given the importance of the agency's mission and ongoing work around the COVID-19 pandemic.

As with any administration leaving office, the Trump administration may seek to issue new policies in its waning days. For example, the Obama administration's FDA issued a host of policies just before Trump took office — e.g., a white paper on the regulation of lab developed tests, guidance addressing communication with payors and communications consistent with FDA-approved labeling, and guidance on several biosimilar and biological product issues.

The ongoing focus on the pandemic might mean less last-minute policymaking this time. Nonetheless, watch for the Trump administration to consider advancing some Republican-leaning initiatives in its final days, such as policies around federal preemption, and reducing/eliminating regulations and regulatory burdens. We've already seen a few proposals widely reported in the press.

With the potential for a divided government, many important policy initiatives will shift from Congress to agency rulemaking proceedings, guidance documents and executive orders — thus subjecting them to judicial review under the Administrative Procedure Act and other laws.

A complex web of statutes, judicial precedents and procedural requirements governs and constrains the ability of a new presidential administration to change its predecessor's policies, and this body of law will play a key role in determining the fate of reforms advanced by the Biden administration.

The law governing a change of administrations presents significant risks and opportunities for regulated industry and other stakeholders, and there are a wide range of tools affected parties can employ as part of the process, regardless of whether they support or oppose the new policy measures.

Priorities for the Biden FDA

Science-Based Decision-making

We have seen both Biden and Vice President-elect Kamala Harris express an interest in highlighting career scientific staff and supporting science-based regulatory decision-making, in an attempt to rebuild what Biden sees as an erosion of public trust in federal health agencies. Expect a messaging push on this front, along with potential new policies that solidify the roles and voices of career staff within the federal government.

Continued Focus on COVID-19 Medical Countermeasures

Given the significance of the COVID-19 pandemic, the Biden administration will continue focus on medical countermeasures to help detect, treat and prevent the spread of the virus.

The FDA has authorized therapeutics, diagnostics and devices for emergency use during the pandemic, and has issued numerous guidance documents and enforcement policies to advance its response. Although Biden and Harris have been vocal critics of the federal response, they must immediately switch gears, as they are now responsible for that response.

Expect them to strive to find an appropriate balance: providing the space and time needed for FDA career scientific staff to do their work, while ensuring that the federal government is working as expeditiously as possible toward ending the pandemic. Also expect attention to how to best prepare for future pandemics and other threats.

Leadership and Personnel Changes

As with any new administration, expect changes in the political staff and leadership at the FDA, as well as at the U.S. Department of Health and Human Services. Once a new Biden team is in place at the FDA, career staff at the product centers and programs typically brief a new administration on existing agency priorities and ongoing work.

Given that Republicans may continue to control the Senate, and any new FDA commissioner must be confirmed by the Senate, expect Biden administration nominees to be individuals that both sides of the aisle can support. It remains to be seen to what extent the Biden administration will select leadership and political staff from industry.

Recent FDA commissioners Robert Califf and Scott Gottlieb may have proven to members of Congress and NGOs that individuals with prior experience working in or with the private sector can indeed be effective and trusted leaders of the FDA. But during both of those administrators' confirmations, some Democratic senators raised questions along these lines.

Medical Product User Fee Negotiations

Medical product user fee program negotiations are already underway. Legislative packages for the Prescription Drug User Fee Act, the Medical Device User Fee Amendments, the Generic Drug User Fee Amendments and the Biosimilar User Fee Amendments are expected in the Senate Health, Education, Labor, and Pensions Committee and the House Energy and Commerce Committee in January 2022, roughly one year after Biden takes office.

Expect new leadership at the FDA to be briefed on the ongoing negotiations — which they likely will not want to disrupt, given the negotiations are led largely by FDA career staff and are critical to ongoing operations at the agency.

That said, with control of the Senate still an unknown, the Biden administration may not have that many opportunities to advance legislative priorities, so expect consideration about whether to put forward additional legislative proposals for potential inclusion in the medical product user fee reauthorization in 2022 — similar to what the Obama administration did with Title VII of Food and Drug Administration Safety and Innovation Act in 2012.

Health Disparities

The Biden administration is likely to focus on additional steps to help address health disparities in the U.S., which the COVID-19 pandemic has further exposed. This is a broad health policy issue — from access to care and incidence/burden of disease, to participation in clinical trials and the potential for bias in health-related algorithms.

Biden's FDA could address the issue in a number of ways. Expect continued focus on ensuring diverse enrollment in clinical trials. In the context of COVID-19 vaccines, expect FDA leadership to weigh in on federal plans for vaccine distribution. The administration's plans are likely to take into account that communities of color have been disparately impacted by the pandemic.

It is worth noting that the administration also will understand that several key members of Congress share these priorities. For example, Sen. Patty Murray, D-Wash., holds a top Democratic spot at the

Health, Education, Labor, and Pensions Committee, and recently issued a report on racism and inequality in the U.S. healthcare system.

FDA Inspections and Enforcement Activity for Medical Products

Although FDA inspections have continued apace for the past four years, the FDA has recently tended to issue warning letters and use other regulatory tools to secure voluntary corrective actions, rather than seeking an enforcement action in court.

While the Biden campaign and transition team have not discussed FDA enforcement specifically, expect the Biden administration to explore the potential for more vigorous judicial enforcement, including by seeking consent decrees and making more criminal referrals to the U.S. Department of Justice.

For imported medical products, we expect that the Biden administration will continue the trend of issuing import bans — so-called import alerts — against offending firms. With an increased push to manufacture medical products domestically, there is a potential for even more import bans targeting products from foreign manufactures.

The second part of this article will discuss how the transition to the Biden administration will likely affect the FDA divisions responsible for regulating specific product areas.

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