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Key Issues for FDA in a Biden Administration

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Food, Drugs, and Devices

Now that former Vice President Biden has been projected to win the 2020 U.S. Presidential Election, expect the transition to commence from the Trump Administration to a Biden Administration. Control of the U.S. Senate remains in the balance with two runoff elections in Georgia on January 5, but either way, the Senate majority will be razor thin and hence less likely to allow for major health policy and Food and Drug Administration (FDA) overhauls, particularly if a divided government. Here is our outlook for FDA in a Biden Administration.

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Transition

President Trump has not yet stated publicly what level of support he intends to provide for the transition. FDA officials – both political and career – will likely assist the Biden Transition Team, particularly given the importance of FDA’s mission and ongoing work around the pandemic response. 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 before President Trump took office (e.g., a “white paper” on the regulation of Lab Developed Tests (LDTs), 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 response might mean less last-minute policymaking this time, but still watch for the Trump Administration to consider advancing some traditionally Republican-leaning policies in its final days, such as policies around federal

preemption and reducing/eliminating regulations and regulatory burdens. We've already seen a few proposals floating around, which have been 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 (APA) 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 administration change 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. Covington's administrative law experts soon will be offering a CLE presentation providing a comprehensive overview of these issues, which will be made available on Covington's [2020 U.S. Election Toolkit](#).

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Priorities for a Biden Administration FDA

Science-based Decision-making: We have seen both Vice President Biden and Senator Harris express a desire to highlight career scientific staff and support science-based regulatory decision-making, in an attempt to rebuild what the former Vice President 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. 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 federal 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, and ensuring the federal government is working as expeditiously as possible toward ending the pandemic. Also expect attention on 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 FDA (and Health and Human Services (HHS)). Once a new Biden team is at 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 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 also 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 FDA, but with both of those prior confirmations, some Democratic Senators raised questions along these lines.

Medical Product User Fee Negotiations: The medical product user fee program negotiations are already underway, with a legislative package for PDUFA, MDUFA, GDUFA and BsUFA due to the Senate Health, Education, Labor, and Pensions (HELP) and House Energy & Commerce (E&C) Committees in January 2022, roughly one year after Biden takes office. Expect new leadership at 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 the ongoing operations at FDA. That said, with control of the Senate still an unknown, a 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 (FDASIA) in 2012.

Health Disparities: A 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. A Biden 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, where 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 a Biden Administration also will understand that several key Members of Congress share these priorities, such as Sen. Patty Murray (D-WA) who holds a top Democratic spot at the HELP Committee and recently issued a [report on racism and inequality in the U.S. healthcare system](#).

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Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER)

Generic and Biosimilar Competition: Expect the Biden Administration to redouble FDA’s efforts to promote generic and biosimilar competition in an effort to reduce drug prices. The Biden Administration likely will continue the initiatives that Commissioner Gottlieb launched under his Drug Competition Action Plan and Biosimilars Action Plan. Under the Biden Administration, FDA may take additional steps, such as reviewing the Agency’s approach to patent and exclusivity issues and seeking to address the alleged abuse of the citizen petition procedure.

Supply Chain/“Buy American”: Vice President Biden has campaigned on a platform of improving the self-sufficiency of the pharmaceutical and medical product supply chain, and has pledged to increase domestic manufacturing capacity to avoid future shortages of critical goods. While release of a comprehensive strategy is pending, likely priorities of a Biden Administration include: making greater use of authorities under the Defense Production Act (DPA) and Procurement Act of 1949, using Biomedical Advanced Research and Development Authority (BARDA) to make science-based purchasing decisions and strengthen federal stockpiles, the possible use of compulsory licensing, implementing some form of “Buy American” requirement for federal drug purchases, enacting tax and other incentives to encourage on-shoring of pharmaceutical manufacturing, establishing requirements for companies to develop plans to address shortages/disruptions, and promoting surge manufacturing capacity.

Canadian Drug Importation: During the campaign, Biden has supported letting states import Canadian prescription drugs, which means that FDA’s final rule on importation of prescription

drugs from Canada, covered in our alert [here](#), could be left in place. The rule provides for the commercial importation of prescription drugs from Canada through time-limited importation programs, which will be authorized by FDA and managed by state and tribal governments. Numerous states, including New Mexico, Colorado, and Florida, are in the process of preparing their importation proposals. Drug manufacturers, pharmacists, and the Canadian government generally oppose drug importation.

Regenerative Medicine: FDA continues to focus resources and attention on regenerative medicine products, as the number of INDs and BLAs submitted for gene therapies, cell therapies, and other regenerative medicine products rises dramatically. FDA has signaled its desire to have increased funding for this work as part of the next round of PDUFA, as reported [here](#). Meanwhile, as we previously discussed [here](#), FDA extended its enforcement discretion policy regarding investigational new drug (IND) and premarket approval requirements for certain regenerative medicine products from November 2020 to May 2021. FDA's choice to extend its enforcement discretion policy while agency resources are focused on battling the pandemic may signal an intent by the Agency to engage in meaningful enforcement in this area after May 2021.

Decentralized Clinical Trials: FDA had already been making progress this year toward issuing guidance on the "Use of Digital Health Technologies for Remote Data Acquisition in Clinical Investigations." The pandemic has only increased attention to and use of remote trial techniques by industry given the need to conduct trials during the public health emergency. FDA issued several guidance documents during the pandemic, which we discussed [here](#) and [here](#). Expect this trend of using digital health technologies in clinical trials to continue, including for remote trials.

Continued Focus on Ongoing Priorities: We also expect FDA to continue to focus on priorities established by the Obama Administration and carried forward through the Trump Administration. These include addressing challenges associated with opioid abuse, the regulation of prescription drug promotion, and the approval and regulation of combination products. Also see our discussion below regarding FDA's digital and technology initiatives, such as use of real world evidence for regulatory decision-making.

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Center for Devices and Radiological Health (CDRH)

Medical Device User Fee Amendments (MDUFA): With MDUFA negotiations underway with the device industry, a good part of CDRH's focus will be around developing the legislative package and MDUFA commitments for HHS delivery to the Hill in January 2022. Expect some Democratic Members of Congress to seek to advance additional device and diagnostic reforms as part of the MDUFA V package. Expect to see activity around the safety of medical devices and attention to issues at the intersection of women's health and device safety.

Quality/CDRH Enforcement: We have seen a downshift in quality system and promotional warning letters during the Trump administration, and there could be a return to warning letter levels from prior years. We expect the Biden Administration will likely continue the industry collaboration through Medical Device Innovation Consortium (MDIC) on medical device manufacturing quality improvement initiatives. In terms of inspections, the Biden Administration may be concerned with the rigor of Medical Device Single Audit Program (MDSAP) inspections and increase the level of scrutiny in FDA's review of MDSAP audit reports.

Premarket Review: We do not expect significant changes in the premarket review context. Most of the related guidance documents are technical in nature and driven by CDRH career staff, with little political involvement. See our discussion below about FDA's evolving software policies, including around the Pre-Cert Pilot.

Diagnostics / LDTs: Given the ongoing significance of the pandemic, the Biden Administration will likely focus on making COVID-19 tests (including molecular, antigen, and antibody/serology tests) available to the public. As part of this focus, the Biden Administration may review and revoke the August 2020 LDT [policy](#) announced by HHS. Under that policy, HHS determined that FDA must engage in notice-and-comment rulemaking before requiring premarket review of LDTs (laboratory developed tests), including requiring an Emergency Use Authorization (EUA) for certain COVID-19 tests. The HHS policy reversed decades of FDA policies issued through guidance and other mechanisms. At the same time, the Biden Administration will likely continue to support ongoing efforts to enact comprehensive legislation for diagnostic regulation, particularly as Congress considers MDUFA reauthorization in the upcoming session.

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Center for Food Safety and Applied Nutrition (CFSAN)

Food Safety and Innovation: We expect FDA to continue its implementation of the agency's [New Era of Smarter Food Safety](#) blueprint that was established under the Trump Administration, and would generally expect to see increased enforcement efforts, particularly as Food Safety Modernization Act (FSMA) continues to be implemented. FDA will also be working towards a safety framework for the production of alternative proteins through cellular agriculture, and will be engaged in establishing naming and other labeling requirements for such innovative products.

Nutrition Policy: In the nutrition space, we think increased focus and efforts on advancing nutrition policy is likely, including with respect to sodium reduction and potentially heightened enforcement, which would continue a theme that we saw in the Obama Administration. This could include the Biden Administration taking a fresh look at the proposed rule for the nutrient content claim, "healthy," which has been sitting with OMB for nearly a year; we think it seems likely that such a proposal will ultimately be issued. In addition, the 2020-2025 Dietary Guidelines for Americans are due to be published in the coming months, and one critical question is whether they will be released before inauguration or whether they will be delayed until the Biden Administration is in place (for context, the 2015-2020 Dietary Guidelines issued on January 30, 2016). Further, we think consumer advocacy groups will find a far more receptive audience in a Biden Administration, so it seems advisable for stakeholders to be mindful of their priorities, including with respect to the Generally Recognized as Safe (GRAS) process, label transparency, environmental considerations, and bioengineered food labeling.

Dietary Supplements: The Agency may push to modernize the Dietary Supplement Health and Education Act of 1994 (DSHEA) to expand FDA's authorities over dietary supplements, so industry should be prepared to consider what it would like to see as part of such legislative change.

CBD: FDA's efforts to find a pathway toward allowing cannabidiol (CBD) in food and dietary supplements will likely continue along the current slow pace, though we note that a guidance document on the agency's CBD enforcement policy has been at OMB for a few months, and a change in administration could influence both the timing and content of that document.

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Center for Veterinary Medicine (CVM)

On the animal products front, CVM can be expected to focus on antibiotic resistance associated with dose form animal antimicrobials (the earlier antibiotic resistance initiatives focused on drugs dosed in animal feed), and, in cooperation with state regulators, more rigorous enforcement under the Food Safety Modernization Act (FSMA) as animal food facilities become more experienced with FSMA requirements in their establishments. We can also expect to see evolution in the regulation of hemp-derived pet food/animal feed products, as the first application for approval of hemp as an animal feed ingredient is expected to be filed with the Association of Animal Feed Control Officials imminently.

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Consumer Products: Cosmetics and OTC Drugs

CDER will continue to focus efforts on implementing the [OTC monograph reform legislation](#) that was passed as part of the CARES Act. This will include a number of anticipated guidance documents, including guidance on the safety and efficacy data that FDA will expect to support industry-initiated proceedings on new active ingredients or new dosage forms. We also expect continued, and perhaps heightened, engagement by CFSAN on cosmetic legislative reform efforts that have persisted for a number of years, and could see increased regulatory and enforcement activity regarding cosmetic safety, including a focus on allergenic ingredients in cosmetics and other potential contaminants.

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Digital Health, RWE and Technology Initiatives

We've seen FDA launch a number of digital and technology initiatives over the last several years, including around use of "[real world evidence](#)," the [Pre-Certification Pilot](#), the framework for [AI/ML-based software](#), the [Prescription Drug Use Related Software](#) (PDURS) framework, the [New Era of Smarter Food Safety](#), and establishment of a Digital Health Center of Excellence at CDRH. While the digitalization of FDA-regulated products and activities is happening at a rapid pace, particularly in light of the pandemic, expect a Biden Administration to take a fresh look at some of these ongoing initiatives. For example, some Democrats on the Hill have [raised questions](#) in the past about FDA's Pre-Cert Pilot, as well as around the acceptance of real world evidence, so a Biden Administration may want to put its own mark on these policies heading into the medical product user fee reauthorization in 2022 where Congress will be considering legislative change.

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FDA Inspections and Enforcement Activity for Medical Products

Although FDA inspections have continued apace for the past four years, in recent years FDA has 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 has not discussed FDA enforcement specifically, expect a Biden Administration to explore the potential for more vigorous judicial enforcement, including by seeking consent decrees and making more criminal referrals to the Department of Justice (DOJ). 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.

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