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# How Joe Biden Will Change The FDA: Part 2

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(November 24, 2020, 4:25 PM EST)-- President-elect Joe Biden has won the 2020 U.S. presidential election, and the transition from the Trump administration to the Biden administration has now commenced. 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.

The first part discussed the transition period, likely priorities for the Biden FDA, and the future of the agency's inspections and enforcement activities for medical products. This installment focuses on the stronger regulatory focus that can be expected at the FDA divisions responsible for regulating specific product areas.

**Center for Biologics Evaluation and Research, and Center for Drug Evaluation and Research**

***Generic and Biosimilar Competition***

Expect the Biden administration to redouble the FDA's efforts to promote generic and biosimilar competition, in an effort to reduce drug prices. The administration likely will continue the initiatives that former FDA Commissioner Scott Gottlieb launched under his Drug Competition Action Plan and Biosimilars Action Plan.

Under the Biden administration, the 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 and Buy American Policies***

Biden 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 and Procurement Act of 1949;
- Using the Biomedical Advanced Research and Development Authority to make science-based purchasing decisions and strengthen federal stockpiles;
- The possible use of compulsory licensing;
- Possible implementation of some form of Buy American requirement for federal drug purchases;
- Enacting tax and other incentives to encourage onshoring of pharmaceutical manufacturing;
- Establishing requirements for companies to develop plans to address shortages and disruptions; and
- Promoting surge manufacturing capacity.

***Canadian Drug Importation***

During the campaign, Biden supported letting states import Canadian prescription drugs, which means that the FDA's final rule on importation of prescription drugs from Canada could be left in place. The rule provides for the commercial importation of prescription drugs from Canada through time-limited importation programs, to be authorized by the 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***

The FDA continues to focus resources and attention on regenerative medicine products, as the number of investigational new drug and biologic license applications submitted for gene therapies, cell therapies and other regenerative medicine products has risen dramatically.

The agency has signaled its desire for increased support for this work as part of the next round of Prescription Drug User Fee Act funding. Meanwhile, the FDA has extended its enforcement discretion policy regarding investigational new drug and premarket approval requirements for certain regenerative medicine products, from November 2020 to May 2021.

The 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***

The FDA made 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. The agency has issued several guidance documents on this subject during the pandemic. 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 the 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 the FDA's digital and technology initiatives, such as use of real world evidence for regulatory decision-making.

**Center for Devices and Radiological Health**

***Medical Device User Fee Amendments***

With Medical Device User Fee Amendments, or MDUFA, negotiations underway with the device industry, the Center for Devices and Radiological Health, or CDRH, will be focused on developing the legislative package and MDUFA commitments for delivery to Congress by the U.S. Department of Health and Human Services 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 and CDRH Enforcement***

We have seen a downshift in quality system and promotional warning letters during the Trump administration. Under Biden, there could be a return to warning letter levels from prior years.

We expect the Biden administration will likely continue industry collaboration through the Medical Device Innovation Consortium 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 inspections, and may increase the level of scrutiny in the FDA's review of the program's 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 Center for Devices and Radiological Health career staff, with little political involvement. See our discussion below about the FDA's evolving software policies, including around the Precertifcation Pilot.

***Diagnostics and Laboratory Developed Tests***

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 administration may review and revoke the August laboratory developed test policy announced by the HHS.

Under that policy, the HHS determined that the FDA must engage in notice-and-comment rulemaking before requiring premarket review of laboratory developed tests, including requiring an emergency use authorization for certain COVID-19 tests. This 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 Medical Device User Fee Amendments reauthorization in the upcoming session.

**Center for Food Safety and Applied Nutrition**

***Food Safety and Innovation***

We expect the FDA to continue implementation of its New Era of Smarter Food Safety blueprint established under the Trump administration, and we expect to see increased enforcement efforts, particularly as the Food Safety Modernization Act, or FSMA, continues to be implemented.

The FDA will also be working toward 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 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 at the Office of Management and Budget for nearly a year. We think it is 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. One critical question is whether they will be released before the inauguration, or be delayed until the Biden administration is in place. For context, the 2015-2020 dietary guidelines were issued on Jan. 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 process, label transparency, environmental considerations and bioengineered food labeling.

***Dietary Supplements***

The FDA may push to modernize the Dietary Supplement Health and Education Act, to expand the agency's

authorities over dietary supplements. Industry should be prepared to consider what it would like to see as part of such legislative change.

***CBD***

The FDA's efforts to find a pathway toward allowing CBD in food and dietary supplements will likely continue at their current slow pace.

But we note that a guidance document on the agency's CBD enforcement policy has been at the OMB for a few months, and a change in administration could influence both the timing and content of that document.

**Center for Veterinary Medicine**

On the animal products front, the Center for Veterinary Medicine 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.

We can also expect, in cooperation with state regulators, more rigorous enforcement under the FSMA, as animal food facilities become more experienced with FSMA requirements in their establishments. And we can 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.

**Consumer Products: Cosmetics and OTC Drugs**

The Center for Drug Evaluation and Research will continue to focus efforts on implementing the over-the-counter monograph reform legislation that was passed this year as part of the Coronavirus Aid, Relief, and Economic Security Act.

This will include a number of anticipated guidance documents, including guidance on the safety and efficacy data that the 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 the Center for Food Safety and Applied Nutrition on cosmetic legislative reform efforts that have persisted for a number of years. And we could see increased regulatory and enforcement activity regarding cosmetic safety, including a focus on allergenic ingredients in cosmetics and other potential contaminants.

**Digital Health, Real-World Evidence and Technology Initiatives**

We've seen the 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 framework; the New Era of Smarter Food Safety; and the establishment of a Digital Health Center of Excellence at the Center for Devices and Radiological Health.

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 Capitol Hill have raised questions in the past about the FDA's Precertification 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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