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Looking Ahead: FDA in 2021

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The U.S. Food and Drug Administration had a busy 2020, as detailed in **earlier blog posts**. This blog post explores politics and a few policy activities we'll be keeping an eye on in 2021 and how they might impact medical product manufacturers, particularly now that we know the U.S. Senate will be controlled, like the U.S. House of Representatives and the White House, by Democrats.

Politics

Chairmanship of the powerful House Energy & Commerce Committee, which has jurisdiction over FDA, remains with Rep. Frank Pallone of New Jersey while Senator Patty Murray of Washington is in line to helm the Senate Health, Education, Labor, and Pension (HELP) Committee. While President-elect Joe Biden has announced his picks for Secretary of Health and Human Services (California Attorney General Xavier Beccera) and Director of the Centers for Disease Control and Prevention (Rochelle Walensky, chief of the Infectious Diseases at Massachusetts General Hospital and professor of medicine at Harvard Medical School), there is still no official announcement from the Biden-Harris team about who the FDA Commissioner nominee will be.

We are bullish on either David Kessler, a former FDA Commissioner who has been advising the Biden-Harris team on COVID-19, or Joshua Sharfstein, a former deputy FDA commissioner and current vice dean at Johns Hopkins University. Experience at FDA is widely considered a must-have credential for any nominee considering the immense portfolio of work normally charged to an FDA Commissioner coupled with the ongoing pandemic. Whoever is nominated and ultimately confirmed will have the monumental task of leading the agency's COVID-19 response in addition to its routine business, and we'll be watching Senate confirmation hearings to learn more about where Congress wants the new commissioner to focus his or her attention.

Compliance

It is critical that companies stay in FDA's good graces because a Warning Letter or other enforcement action can require diverting resources to fix problems that would have cost less time and money to address up front.

Medical device manufacturers with operations in multiple countries have to comply with each of those countries' quality system requirements, or with the international medical device quality system standard known as ISO 13485. FDA has repeatedly delayed aligning its Quality System Regulation (known to many as QSR and found at 21 CFR 820) with ISO 13485, but has indicated it plans to finally issue proposed regulations in 2021 doing just that. We will be analyzing the revised Quality System Regulation to see how it aligns, and—importantly—how it differs, from ISO 13485. Medical device companies should take time to understand how the revisions will impact them.

We are also watching to see how FDA handles enforcing requirements related to the many drugs and devices that were authorized for use during the COVID-19 public health emergency. Emergency Use Authorizations (EUAs) granted during the COVID-19 pandemic are not full approvals, clearances, or licenses to market a product indefinitely, so companies who were granted an EUA will need to be sure they make the appropriate submissions to FDA to obtain full authorization or have a plan to cease distribution and withdraw their products from the market. The agency will undoubtedly continue to authorize new vaccines, therapeutics, and diagnostics as the COVID-19 pandemic continues.

With respect to regenerative medicine therapies (which includes cell and gene therapies), FDA extended its deadline for enforcing regulatory requirements from November 2020 to May 2021. Funding to support oversight of the growing regenerative medicine industry is something FDA is looking for in the current round of user fee reauthorization talks. A Democrat-controlled Congress may be less forgiving of additional delays in implementing enforcement policies for these products.

Manufacturing

The FDA in 2020 partnered with other federal agencies to evaluate methods for additive manufacturing (known to many as 3D printing) with a focus on personal protective equipment (PPE) to aid in the response to the COVID-19 pandemic. As 3D printing of medical devices has grown in recent years, we are watching to see how the America Makes program sets standards to support innovation in alternative manufacturing methods that can be used beyond pandemic applications.

Eyes are also on FDA and Congressional activities related to improving the adoption of continuous manufacturing, which can reduce the time and cost of manufacturing drugs. Rep. Frank Pallone, Chairman of the House Energy & Commerce Committee, and Rep. Brett Guthrie introduced in late 2019 the National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act, which we expect will receive renewed attention in 2021.

Speedier reviews of chemistry, manufacturing, and controls (CMC) data has also been a topic of discussion at PDUFA VII negotiation meetings.

Medical Device Servicing

FDA has for many years delayed action on fixing its laissez-faire policy related to third party servicing of medical devices. We expect the Biden administration will finally take concrete steps towards clarifying the difference between servicing and remanufacturing and, therefore, what requirements apply to servicers who are actually remanufacturing. Servicing is generally considered returning a device to its original condition (e.g., repairing it) while remanufacturing changes devices' safety and performance and therefore is subject to stricter regulatory controls.

Even though we expect FDA guidance to clarify servicing and remanufacturing policy, we think legislation will be needed to ensure FDA has the appropriate tools and resources to have effective oversight of these activities. A Democrat-controlled Congress is expected to be more focused on policies to prevent patient harm that comes from improper servicing and remanufacturing than Republicans, who have historically expressed concerned about overregulation.

Other Policies & Programs

In the first week of the new year, FDA published a final guidance document about the **Safer Technologies Program** (STeP) for medical devices. STeP provides benefits like earlier and greater interaction with FDA reviewers for device developers. The goal is to help improve access to devices that can have meaningful impacts for patients but that do not meet the stringent criteria to be considered breakthrough devices. Device manufacturers, particularly small businesses with minimal or no experience working with FDA, should take note as the program's benefits may be of value to them.

We continue to await further information about how FDA's **Digital Health Center of Excellence** will improve the review and availability of digital health medical products, including better coordination between FDA's drug and device centers. We expect a Senate health committee chaired by Senator Patty Murray, who has expressed skepticism about FDA's digital health plans, to more heavily scrutinize the agency's digital health activities.

And we await Congressional action on the **VALID Act** which would create a new type of diagnostic medical product called an in vitro clinical test (IVCT) with new regulatory requirements and user fees. This bill has bipartisan support in both houses of Congress and could be incorporated into a broader regulatory reform legislative package like 21st Century Cures 2.0. Cures 2.0 could also bring renewed focus on the Cancer Moonshot, a Biden priority when he was Vice President when the original 21st Century Cures Act was enacted. The Cancer Moonshot aims to improve cancer prevention, diagnosis, and treatment. A renewed focus on it could be a good opportunity for medical product developers to push for regulatory and reimbursement reforms or other changes in the health care ecosystem.

Lastly, we'll keep an eye on how the various medical product **user fee** reauthorization discussions are **progressing**.

2020 brought unexpected challenges to FDA and the health care ecosystem, yet FDA demonstrated it can respond to a global pandemic while still advancing many policies. This post covered only a fraction of FDA-related policies and related political considerations, so stay tuned for more information and analysis of FDA's policy activities in 2021.

Authors