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The FDA Under a Biden Administration

In January 2021, President-elect Biden will assume office and begin the transition to new leadership in the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA). Without question, a focus on Coronavirus Disease 2019 (COVID-19) vaccines, treatments, and new technologies to identify, cure, and reduce the transmission of the virus will continue to be of paramount importance to President-elect Biden, as these matters were the centerpiece of his campaign. This GT Alert will also address additional changes in the broad areas of drugs, medical devices, biologics and foods, with a special emphasis on emerging technologies (especially through the Emergency Use Authorization (EUA) process), dietary supplements, remote patient monitoring/telehealth, and vaccines.

COVID-19 FDA Efforts (Vaccines)

President-elect Biden has taken action to confront the COVID-19 pandemic. He announced a COVID-19 task force made up of physicians and health experts. The three co-chairs include: Dr. Vivek Murthy, surgeon general during the Obama administration; Dr. David Kessler, FDA commissioner under Presidents Bush and Clinton; and Dr. Marcella Nunez-Smith, associate dean for health equity research at Yale University. The early goals of the task force are to work with state and local health officials on a plan to address the virus and its racial disparities and to develop a plan for reopening schools and businesses.

The key to the strategy includes the FDA EUA authority and ensuring that products going through this process have sufficient safety and efficacy prior to use in the market. Currently, there are several vaccines, therapies, lab tests, and other products either on the market or currently subject to EUA review. President-elect Biden could extend the Public Health Emergency (PHE) (currently set to expire on Jan.

21, 2021) in order to continue work to expedite review of these FDA products to the marketplace, and until such time as vaccines have been distributed and administered and a significant reduction in COVID-19 cases.

Vaccines and COVID-19 treatments are a priority for President-elect Biden. Dr. Janet Woodcock, an experienced leader in the FDA's Center for Drug Evaluation and Research, is now working solely on accelerating vaccines and treatments for COVID-19.

Drugs

During the campaign, President-elect Biden called for greater cost transparency in the pricing of drugs – both for the government (as a purchaser) and for consumers. While these efforts are likely to be exerted through other agencies in HHS, President-elect Biden may want to continue efforts to encourage FDA and the National Institutes of Health (NIH) to find cures for cancer, as the "Cancer Moonshot" was intended to support cancer research, including prevention and treatment.

In addition, implementing the over-the-counter (OTC) provisions of the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) may be a priority, as this law permits OTC manufacturers to file labeling changes and alternative claims for review. As the OTC market is important for consumers and reduces costs of drugs that no longer require a prescription, this could result in lower costs, signaling an important initiative of President-elect Biden.

Clinical Trials

As vice president during the Obama administration, President-elect Biden made public statements on strengthening the transparency of reporting requirements in clinical trials. The requirement to report a summary of clinical trial results is not new. On Sept. 27, 2007, the Federal Food Drug & Cosmetic Act was amended to include changes requiring that all clinical trials be registered with Clinicaltrials.gov and that their results be summarized regardless of whether the drug/device product was approved or cleared. The reporting requirement is intended to increase the availability of information to the public and to communicate the risks and benefits of therapeutics so that patients, providers, and researchers can make more informed health care decisions.

In 2017, the Obama administration's finalized rules establishing the means for reporting the clinical trial results went into effect. Failing to report result summaries would subject the investigator to a $10,000 per day fine. The Trump administration interpreted the rules to apply only to clinical trials completed ***after*** Jan. 18, 2017. The administration's interpretation was set aside by the United States District Court for the Southern District of New York, but the reporting requirements have still not been enforced.

Clinical trial transparency is promoted by some as a way to spur new developments by providing drug developers the results on prior therapeutic candidates. However, others are concerned that, if clinical trial results are publicly summarized, then journals would not be interested in paying the researchers to include the results in their publications. Under the Biden administration, the penalties may snap into effect and apply to all clinical trial results after Sept. 27, 2007.

Medical Devices

Digital Health

Over the last few years, FDA has spent significant time on the policy agenda promoting digital health. This helped to advance digital health technologies and artificial intelligence/machine learning at an unparalleled pace. FDA has put forth a series of regulatory initiatives and creative approaches in reforming the agency's review of the utilization of real-world data in regulatory review process, introduction of an initial framework for artificial intelligence/machine learning products, as well as prescription drug-use-related software, a pre-certification program pilot to facilitate the development of software as a medical device, and the establishment of a Digital Health Center of Excellence within the Center for Devices and Radiological Health (CDRH).

There are also other pending regulations that exclude software functions in medical device classification in accordance with the 21st Century Cures Act, and medical device de novo classification process.

The Biden administration may revisit the critical issues underlying the current digital health policy framework. For example, there are strong concerns raised by Democrats in Congress regarding the pre-certification program and the acceptance of real-world data in the approval or clearance of the medical products for both of their potential compromises of public health. Both of the concepts of pre-certification and utilization of real-world data reflect a new, if not revolutionary, mindset for the regulator's approach to a quickly evolving technology. It is worthwhile to pay close attention to find out how a new administration and Congress will reshape their approach to modern technology. The Biden administration may prefer to author its own by having an approach that reflects Democrats' perspectives.

Laboratory Developed Tests

Regulatory process changes occurred at FDA during the Obama administration. The Obama administration issued a white paper on issues governing Laboratory Developed Tests (LDTs), but the Trump administration has not made any rules to reflect the visions articulated in the white paper. Recently, HHS further announced that FDA will not require premarket review of LDTs absent notice-and-comment rulemaking. There has been a longstanding debate surrounding the regulation of LDTs. The Biden administration may try to establish a comprehensive framework for regulating LDTs. The Biden administration may choose to reverse the recent HHS announcement.

Medical Device User Fees

In addition, ongoing Medical Device User Fee Amendments (MDUFA) negotiations with the device industry may spur Congress to seek to advance additional reforms in the device sector. The Biden administration may seek to take advantage of MDUFA as a critical vehicle to interpret or modify laws governing emerging technologies, including digital health and diagnostics.

Regulation of Food and Dietary Supplements

There may be a substantial increase in federal governmental regulation of food, beverage, and dietary supplements under the Biden administration. Substantial funds were diverted from federal governmental agencies like the FDA, the Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA) under the Trump administration. As a result, personnel were reduced at these federal agencies, and many programs initiated by President Obama were put on hold or extinguished. With less personnel, the number of inspections decreased, and the frequency of overall agency action was

diminished. The Biden administration may redirect funds to governmental agencies like the FDA, the USDA, and the EPA, among others.

There are already reports that President-elect Biden plans, through the use of Executive Orders, to "undo" many of the Trump policies implemented over the last four years. The Biden administration may well reverse President Trump's policy of decreasing governmental oversight by limiting the effect of agency guidance and slowing the implementation of new rules and regulations. In fact, since President-elect Biden may have to work with a divided U.S. Congress to implement policies, more direction of policy through agency action and guidance may be seen. FDA guidance and proposed rules initiated under President Obama and frozen under President Trump, like formalizing a definition of "natural" and redefining "healthy," could be rehabilitated under President-elect Biden. Formal guidance and regulations pertaining to the manufacturing and sale of products containing hemp and CBD have also been pending for over a year; with the expected renewed deference to agency action and guidance, some movement in that area could be seen in 2021.

As President-elect Biden was a key part of the Obama administration that ushered in the Food Safety Modernization Act, there may be a renewed focus on food safety. With the indication that President-elect Biden is already working on formulating a robust COVID-19 task force, the COVID-19 pandemic may be stabilized on a quicker time frame. Once the COVID-19 pandemic has been stabilized, FDA and USDA on-site inspection of food facilities may increase.

Further, the Federal Trade Commission (FTC) may take less of a "pro-business" stance and become more aggressive in its enforcement of advertising laws against businesses in all areas, including the food, beverage, and dietary supplement industries. As the five FTC commissioners were reset in 2018 by President Trump, there may be several changes to FTC seats, to usher in people willing to implement the goals and policy direction of the Biden administration.

Biologics

The numbers of Investigational New Drug Applications (INDs) and Biologics License Applications (BLAs) for regenerative medicine or cell/gene therapy has grown significantly. FDA's Center for Biologics Evaluation and Research (CBER) director slated 75% of his time on cell and gene therapy matters prior to the COVID-19 pandemic. Under the Biden administration, FDA may continue reviewing regenerative medicine applications and progressively foster the agency's expertise in cell therapies after its initial emphasis on gene therapy. The utmost challenge for the agency may be to secure sufficient resources. Even before COVID-19, the exponential growth in cell and gene therapy development may have caused CBER staff to limit sponsor interactions, to convert many meetings to written responses only, and to limit external interactions.

In the Biden administration, Regenerative Medicine Advanced Therapy (RMAT) designation could gain dedicated funding as part of cell and gene therapy program enhancements. In the past, FDA would only review RMAT designation requests if there was an active IND in the United States. The FDA may consider such designation application when sponsors have collected scientifically valid preliminary clinical evidence outside of the United States. There have been several robust and active regenerative medicine clusters in China and Japan, where many companies have advanced their regenerative medicine developments. If changed, this approach could help accelerate U.S. patients' access to those innovations originated outside the United States and other countries.

In addition, the bipartisan concern on the urgent need to reduce drug prices may motivate the Biden administration to promote competition between brand name drug/biologics and generic/biosimilars.

Closing

President-elect Biden is focused on a strong government and a renewed reliance on federal agencies as important partners to implement his administration's policy directives. Therefore, there may be robust activity as the Biden administration works to address COVID-19 and the other areas regulated by HHS and FDA.

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