Health Policy and Legislation Alert

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FDA Preparedness Reforms Come into Focus as the PREVENT Pandemics Act Advances in the Senate HELP Committee

April, 19, 2022

Last month, the Senate Health, Education, Labor and Pensions (HELP) Committee voted 20 to 2 to advance S. 3799, the Prepare for and Respond to Existing Viruses, Emerging New Threats and Pandemics Act (the "PREVENT Pandemics Act"). The Senate HELP Committee Chair Sen. Patty Murray (D-WA) and Ranking Member Sen. Richard Burr (R-NC) have led the Committee's work on this bipartisan legislation, which includes provisions related to medical products and U.S. Food and Drug Administration (FDA) activities as part of their focus on strengthening our nation's medical and public health preparedness and response frameworks. This alert outlines the bill's current FDA-related reforms, including a number of policies that would have applicability and impact beyond pandemics. While there is no companion bill in the House, these reforms could potentially be adopted as policy riders in the drug and device user fee reauthorizations Congress is considering this year. However, regardless of the legislative vehicle, these various FDA reforms are worth monitoring by medical product developers, industry partners and stakeholders as the legislative process continues to unfold.

General FDA Reforms

Clinical Trials and Real-World Evidence

Section 502 of the PREVENT Pandemics Act aims to modernize and improve clinical trial design by requiring FDA to issue several guidance documents addressing the use of digital health, decentralized trials and seamless, concurrent and other innovative clinical trial designs. The guidance on digital health would include recommendations on how these technologies may be used to collect data remotely from trial participants, increase recruitment and participation, optimize data quality and facilitate the inclusion of diverse and underrepresented populations. This guidance would also address the protection of trial data collected using digital health technologies, including compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and general recommendations for protection against cybersecurity threats. The guidance on decentralized clinical trials would provide recommendations for decentralized trial designs, including information on how digital technologies, telemedicine, local

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laboratories and providers, home visits and direct-to-participant shipping of drugs and devices could facilitate such trials.

The guidance on seamless and concurrent trial designs would give recommendations on seamless trials, in which expansion cohorts and other designs are used to assess different aspects of product candidates in one trial; and concurrent trials in which multiple clinical trial phases are conducted at the same time. Similar to those recommendations regarding decentralized trials, the seamless and concurrent trial guidance would also be required to contain recommendations regarding patient safety and maintaining compliance with good clinical practice. Importantly, this guidance would also include recommendations regarding early engagement with FDA, with respect to the development of these trials.

Section 505 of the bill is intended to facilitate the use of real-world evidence to support regulatory decision making with respect to both drugs and devices. The bill directs FDA to issue or revise existing guidance on the use of real-world data and real-world evidence, including with respect to evidence from drugs and devices authorized for emergency use.

Platform Technology Designation and Advanced Manufacturing Pilot Program

Section 506 would create a new platform technology designation to streamline the development and review of new therapies and countermeasures that use adaptable platforms. In order to be eligible for a platform technology designation, the technology must already be used by an approved drug or biologic and have the potential to be incorporated in or utilized by more than one drug without an adverse effect on quality, manufacturing or safety. Data submitted in reference to the platform technology must also indicate that use of the platform technology has a reasonable likelihood of creating significant efficiencies to the drug development or manufacture process as well as the review process. This section also includes a provision allowing the Secretary to designate a platform technology as a designated platform technology either in conjunction with or after a submission under the investigational provisions at Section 505(i) of the Federal Food, Drug and Cosmetic Act (FDCA) or Section 351(a)(3) of the Public Health Service Act (PHSA).

Once a platform technology designation is granted, FDA may take actions to expedite the development and review of any subsequent application for a product that uses or incorporates the platform, such as engaging in early interactions with the sponsor to discuss the use of the designated technology. This section requires FDA to issue draft guidance on the implementation of the platform technology designation. The legislation provides that this guidance shall include examples of drugs that can be manufactured using platform technologies, as well as information about the Secretary's review of such technologies, and considerations for individuals making a designation request.

Section 518 would create a new pilot program under which FDA may designate certain methods of manufacturing drugs, biologics and active pharmaceutical ingredients as advanced manufacturing technologies. FDA would expedite the development and review of applications for drugs and biologics manufactured using a designated advanced manufacturing technology. A method of manufacturing would be eligible for designation if it incorporates a novel technology or uses established technologies or techniques in a novel way to enhance drug quality or improve the manufacturing process for a drug while maintaining drug quality. Such improvements may include

reducing the development time for a drug or ensuring the supply of a critical drug or a product that is in shortage.

This section requires FDA to hold a public meeting to gather input from relevant stakeholders and to issue guidance on implementation of the pilot program. The pilot and FDA's authority to consider advanced manufacturing designation requests would sunset after October 1, 2029.

Good Guidance Practices and Agency Communications

Section 508 of the legislation aims to improve FDA's guidance practices and communication with external stakeholders. This section requires FDA to develop and publish a report identifying best practices for prioritizing, developing and issuing guidance documents, along with a plan for implementing these best practices. The implementation plan must address (1) streamlining development and review of guidance documents; (2) the use of guidance documents to streamline processes for regulatory submissions to FDA; and (3) implementing innovative guidance processes and transitioning or updating guidances during the COVID-19 public health emergency (PHE).

This section also directs FDA to publish a report on the agency's practices for communication with external stakeholders, including medical product sponsors. The report would include, among other things, plans for using innovative forms of communication to provide increased regulatory clarity to stakeholders. FDA is directed to consult with stakeholders in developing and publishing this report and implementation plan.

Foreign Manufacturer Registration and Foreign Inspections

The PREVENT Pandemics Act also includes language intended to improve the transparency of foreign manufacturers of medical products and give FDA greater visibility into supply chains. Specifically, Section 511 amends the FDCA to clarify that foreign drug manufacturers intending to distribute a product in the United States must register with FDA and provide information on the facilities involved, including when the drug or device undergoes further processing at a separate foreign establishment prior to reaching the United States.

Section 513 of the legislation, meanwhile, requires FDA to conduct a pilot program to increase unannounced inspections of foreign drug facilities and evaluate the impact of such inspections. In particular, the program would assess (1) differences in the number and type of violations identified during unannounced and announced inspections; (2) costs and benefits associated with conducting announced and unannounced inspections; (3) barriers to conducting unannounced inspections and challenges to achieving parity with domestic inspections; and (4) approaches for mitigating the disadvantages of announced foreign inspections.

FDA would publish its findings and any associated recommendations in a report to follow completion of the pilot program.

Extending Drug Expiration Dates

Section 512 of the legislation requires FDA to issue or revise existing guidance to address recommendations for drug or biologic sponsors regarding the submission of stability data in applications and establishing the longest feasible expiration dates

supported by data. The guidance would consider ways to facilitate faster review of longer proposed expiration dates and how extended expiration dates may help prevent or mitigate drug shortages.

Every two years, FDA would be required to report to Congress on the number and type of drugs for which the agency has requested a labeling change to extend the expiration date as well as information about the drug in question and the rationale for the agency's request.

Study on FDA Hiring

Intended to respond to hiring challenges at FDA, Section 509 of the bill requires the Government Accountability Office (GAO) to prepare a report examining the agency's hiring, recruiting and retention policies and practices, and their impact on FDA's ability to carry out its public health mission.

The report would include an assessment of various issues, including hiring challenges, vacancy rates, professional development, successful hiring policies implemented during the pandemic, challenges faced by FDA's workforce with respect to, among other things, workload, diversity and morale, and the impact of related challenges on FDA's ability to meet user fee agreement performance goals and conduct inspection activities. The report would also include recommendations to address the issues identified.

Device-Specific Reforms

Combating Counterfeit Devices

Section 514 of the PREVENT Pandemics Act aims to address counterfeit medical devices by extending existing authority to combat counterfeit drugs to counterfeit devices. Specifically, the effect of this section would be to raise the cap on sentencing from three years to 10 years, allow FDA to present additional evidence at criminal trials and make possession of a counterfeit device with intent to sell a criminal act.

Medical Device Supply Chain

Section 515 of the legislation would require manufacturers of medical devices that are "critical to public health" to develop, maintain and implement a redundancy risk management plan in order to ensure more resilient supply chains. Additionally, two years after the enactment of the PREVENT Pandemics Act, and annually thereafter, the Secretary would be required to report to Congress on the use of this information from manufacturers.

Section 516 of the bill, meanwhile, would expand the circumstances in which shortage notifications are required from device manufacturers. In addition to requiring notifications during, or in advance of, a PHE, this provision would also include any circumstance that is likely to lead to a meaningful disruption in the supply of that device. The Secretary would also be required to issue or revise guidance regarding required reporting under Section 506J of the FDCA. Section 516 of the legislation also aims to facilitate additional voluntary notifications of supply disruptions of critical medical devices and would direct FDA to issue guidance to this effect.

Remote Records Assessments

Section 517 of the PREVENT Pandemics Act would require device manufacturers to comply with FDA requests for certain records in advance or in lieu of an inspection. FDA must provide to the manufacturer a description of the records requested and the rationale for requesting such information. This section also requires FDA to issue guidance on how it intends to issue these requests.

FDA and Medical Countermeasure Provisions

Accessing Specimen Samples and Diagnostics

Section 304 of the PREVENT Pandemics Act would require the Secretary of Health and Human Services (HHS) to publish policies and procedures related to facilitating public and private entities' access to specimens of pathogens for the purposes of developing and validating medical countermeasures for emerging infectious diseases. HHS is directed to issue guidance regarding the method for requesting such samples and additional considerations related to sample availability and the use of suitable surrogates or alternatives.

This section also authorizes HHS to contract with public and private entities to increase capacity for the rapid development, validation, manufacture and distribution of diagnostics tests for immediate public health response activities to address an emerging infectious disease for which a PHE has been declared or which has significant potential to cause such a PHE.

Countermeasure Development and Review

Section 503 allows FDA to expedite the development and review of medical countermeasures during future PHEs or similar threats. Such actions may include expedited review of submissions by sponsors, expedited and increased engagement with sponsors, expedited issuance of guidance and publication of other regulatory information, involvement of senior managers and experienced review staff and other steps to accelerate the development and review of a countermeasure.

Third-Party Evaluation of Diagnostics

Section 504 of the legislation clarifies that FDA may consult with or contract with third parties to evaluate in vitro diagnostic tests for which an emergency use authorization has been requested. This provision is intended to help FDA prioritize its response efforts during future emergencies. This section also would require FDA to issue guidance on such third-party consultations, including conflicts of interest and compensation arrangements.

Emergency Use Authorization Transparency

Section 507 is intended to increase transparency around products that are granted emergency use authorizations (EUAs). In particular, this section would require FDA to post notices of authorizations or revocations of authorizations on its website, in addition to publishing such notices in the *Federal Register*.

This section also would authorize FDA to publish additional summary information about EUA applications, requests and submissions even if the summary might reveal the existence of such application, etc., or data contained therein.