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US FDA Board Formed To Manage Increasingly Complex Pharmaceutical Supply Chain Oversight

by Bowman Cox

High-level board will bring together information from across FDA drug center and work to increase supply chain transparency, CDER's Jacqueline Corrigan-Curay, who will chair the group, tells the *Pink Sheet*.

A Pharmaceutical Supply Chain Governance Board that the US Food and Drug Administration's Center for Drug Evaluation and Research is establishing in September will advance the agency's efforts to increase the transparency of pharmaceutical supply chains and protect them from emergencies like the coronavirus pandemic.

Building on the activities of the agency's drug shortages program and other efforts already in place, the board will facilitate and coordinate supply chain initiatives across CDER and provide strategic guidance, center director Patrizia Cavazzoni, explained in a 20 August email to center staff.

The board was formed to support the center's role in strengthening supply chains for pharmaceuticals and active pharmaceutical ingredients as part of a governmentwide initiative outlined in an 8 June White House *report*.

The White House document compiled reports on 100-day reviews the Health and Human Services Department and three other departments conducted in response to Executive Order 14017 on strengthening supply chains, which President Biden signed on 24 February. A more in-depth one-year report is slated for February 2022. (Also see "*Public-Private Consortium To Strengthen Essential Medicines Supply Under White House Initiative*" - Pink Sheet, 9 Jun, 2021.)

Jacqueline Corrigan-Curay, recently promoted to principal deputy CDER director, will serve as

the board's chair, with Matt DeFina, a CDER health policy analyst, serving as vice chair. The center's senior leadership will serve on the board, as will subject matter experts as needed, Cavazzoni said. (Also see "*Cavazzoni Begins Putting Her Mark On FDA Drug Center With New Principal Deputy Position*" - Pink Sheet, 6 Jul, 2021.)

The board will facilitate decision-making, provide guidance and communicate recommendations, decisions and actions related to major supply chain issues with CDER-regulated products, Cavazzoni said.

It will serve, she wrote, "as a unified center-level body that will ensure seamless alignment for supply chain activities among offices."

Responsibilities will include coordinating the development, already underway, of a drug supply chain surveillance system.

Pandemic Challenges Led To Recognition of Need

"We've always had a very strong drug shortages program," Corrigan-Curay said in an interview with the *Pink Sheet*, and during the pandemic "we had to reach out to just hundreds of drug manufacturers to manage supply, and make sure that we had adequate drugs to serve the American public."

As pandemic-related demand and supply fluctuations occurred, the agency was communicating more closely with hospitals to anticipate challenges, while the Health and Human Services Department's Assistant Secretary for Preparedness and Response, which manages the Strategic National Stockpile, also was monitoring the situation. "We were using our regulatory tools to coordinate with them and to get new generic drug applications or manufacturing supplements, all with the goal of increasing access to medications and preventing shortages," she said.

This effort involved bringing data together from different parts of CDER, "and it certainly gave us the sense that we really needed to make sure that we were unifying these efforts and bringing them together and making decisions with the best information."

Within the center, there is a lot of relevant information developed by the drug shortages staff, but there also is information elsewhere, for example drug utilization data in the center's Office of Surveillance and Epidemiology.

Corrigan-Curay also noted that applications identify drug product and active pharmaceutical ingredient manufacturing facilities and provide other supply chain related information that can be aggregated and updated as applications are approved "in a way that allows you to really see the bigger picture."

A Role In CARES Act Implementation

The board will also play a key role in a related effort to bring greater transparency to the global pharmaceutical supply chain that was advanced in the 27 March 2020 Coronavirus Aid, Relief and Economic Security Act and further articulated in the 100-day review.

The agency is developing guidance to implement CARES Act provisions for:

- Expanded notification requirements related to manufacturing discontinuances or interruptions for certain drugs;
- Requirements for manufacturers of certain drugs, APIs or associated medical devices to develop and maintain redundancy risk management plans; and
- Requirements for manufacturers to report on the amount of every drug they manufacture each year.

The annual reporting requirement was supposed to take effect on 23 September 2020 but is on hold while the agency develops an electronic submission data portal.

The 100-day review goes further in calling for greater supply chain transparency and providing incentives to increase the resiliency of supply chains.

The report discusses the possibility of empowering the FDA to collect additional information on drug manufacturing volume and any increases in demand, and to require clearer labeling as to the original manufacturers of APIs and finished drug products.