FDA chief: COVID, mail mix-up delayed action on baby formula

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Michelle Saenz of Santee, Calif. buys baby formula at a grocery story across the border, Tuesday, May 24, 2022, in Tijuana, Mexico. As the baby formula shortage continues in the United States, some parents are opting to cross the border into Mexico, where the shelves are still stocked with options to feed their babies. Credit: AP Photo/Gregory Bull

The head of the Food and Drug Administration said Wednesday that efforts to investigate problems at a baby formula plant linked to the nationwide shortage were slowed by COVID-19, scheduling conflicts and even a missing piece of mail.

FDA Commissioner Robert Califf laid out a series of setbacks in congressional testimony that slowed his agency's response by months, including a whistleblower complaint that didn't reach FDA leadership due to a "mailroom failure."

Califf testified before a House subcommittee probing the shortage, which has forced the U.S. to begin airlifting products from Europe while many parents still hunt for scarce supplies in stores.

Califf told lawmakers FDA's response was: "Too slow and there were decisions that were suboptimal along the way."

The FDA and President Joe Biden face mounting pollical pressure to explain why they didn't intervene earlier to try and address the supply problems. The oversight subcommittee's ranking Republican quickly zeroed in on the slow response.

"Why did it take an onslaught of national media attention for the Biden administration to act with a sense of urgency required to address an infant formula shortage?" asked Rep. Morgan Griffith, R-Virginia. The panel will also hear from three formula manufacturers, including Abbott Nutrition.

The shortage mostly stems from Abbott's Michigan plant, the largest in the U.S., which the FDA shut down in February due to contamination.

"We knew that ceasing plant operations would create supply problems but we had no choice given the insanitary conditions," Califf said in

opening testimony.

Califf gave the first detailed account of why his agency took months to inspect the plant despite learning of potential problems as early as September.

FDA staff began honing in on Abbott's plant last fall while tracking several bacterial infections in infants who had consumed formula from the facility. The four cases occurred between September and January, leading to hospitalization and two deaths.

Califf told lawmakers the FDA began planning to visit the Sturgis, Michigan, plant in early December, with inspectors set to arrive on Dec. 30. But Abbott said that about a dozen of its employees had recently tested positive for COVID-19 and requested a delay. As a result, the FDA didn't begin its inspection until Jan. 31.

After detecting positive samples of bacteria in multiple parts of the plant, the FDA closed the facility and Abbott announced a massive recall of its formula on Feb. 17.

Abbott and the FDA have reached an agreement to reopen the plant next week, requiring the company to regularly undergo outside safety audits.

Califf also laid out the agency's months-long timeline responding to an October whistleblower complaint alleging numerous safety violations at Abbott's plant, including employees falsifying records.

Several FDA staffers reviewed the complaint in late October, but officials didn't request an interview until early December. Because of conflicts with the whistleblower's schedule, the interview didn't take place until Dec. 22, according to the FDA testimony.

Senior FDA officials eventually received emailed copies of the complaint, but not until February due to "an isolated failure in FDA's mailroom, likely due to COVID-19 staffing issues," according to the prepared remarks. A mailed copy addressed to then-acting commissioner Dr. Janet Woodcock has still not been located, according to the FDA.

Political fury over the shortage has landed squarely on the FDA and Califf, the only administration official who has testified thus far on the issue. The problems have quickly snowballed into a political firestorm for President Joe Biden, who has invoked the Defense Production Act and emergency flights to shore up supplies.

Califf is also facing questions about why his agency didn't anticipate the shortage, given that Abbott's plant supplies roughly one-sixth of the U.S. formula supply. FDA regulators did not contact the U.S. Department of Agriculture about impacts to the formula supply until Feb. 11. Califf's testimony states that his agency does not have the "authority, resources, or dedicated staff" to track supply chain disruptions. He asked lawmakers for new powers and resources to monitor the information.

Behind the shortage are other distinct factors, including industry consolidation that's made the U.S. formula market vulnerable to disruptions at individual companies.

An Abbott executive is expected to tell the committee that his company will invest in additional capacity and supply chain safeguards. After the company restarts production next month it will be able to produce more formula than before the recall, according to prepared remarks from Abbott's senior vice president, Christopher Calamari.

The company will restate its contention that there is no direct link between its formula and the infant infections investigated by the FDA. Agency regulators have said the small number of cases and incomplete

testing data make it hard to draw a direct connection between the illnesses and Abbott's plant.

Executives from Reckitt and Gerber are also scheduled to testify.