Committee on Energy and Commerce

Opening Statement as Prepared for Delivery of Chairman Frank Pallone, Jr.

Hearing on "Formula Safety and Supply: Protecting the Health of America's Babies"

May 25, 2022

Today, because of the baby formula shortage, parents and caregivers are seeing empty store-shelves, astronomical prices online, or having to drive hours for the formula they need to feed their children. This is simply unacceptable, and this hearing will explore how this dire situation occurred, the steps taken to address it, and, crucially, how we prevent it from ever happening again.

Our solutions will undoubtedly include legislation. The Energy and Commerce Committee has jurisdiction over the Food and Drug Administration (FDA) and will initiate any authorizing legislation.

The data on the extent of the shortage varies based on where a family lives, or whether a child needs a specialty formula or specific type or brand. Some regions have been hit harder by the shortage than others. And, disturbingly, low-income women and children who rely on the Special Supplemental Nutrition Program for Women, Infants, and Children—better known as the "WIC" program—for their infant formula, have been particularly impacted by the shortage.

Shortage rates began to rise in late 2021 due to pandemic-related strains on the supply chain, but there is no question that the February recall of Abbott products and the shutdown of its Sturgis, Michigan plant is responsible for the supply crash we face today.

The impact from just one infant formula plant closing in the United States shows the power one single manufacturer has to influence the nation's supply of formula when just three companies control roughly 95 percent of the market. We are too reliant on too few companies to do the right thing—and when just one of those companies cuts corners, we spiral into an emergency. There needs to more competition, so that these few manufacturers don't have a monopoly.

This Committee will examine the circumstances surrounding the recall and shutdown. We will ask questions about the FDA's investigation of the foodborne illnesses that sickened four infants and led to two of their deaths. We will also ask about issues at Abbott's Sturgis facility, and the questionably slow timeline of action to address safety risks.

At the same time, we must address the current shortages and prevent future supply strains by hearing from FDA, Abbott, and other manufacturers about the supply challenges they face and the steps they are taking to increase the availability of safe infant formula.

These officials and executives need to answer some tough questions. Babies' lives are at stake, and this Committee, Congress, and the American people demand answers and solutions.

Fortunately, the Biden Administration has taken important responsive actions to increase the supply of formula for American families. It worked with manufacturers to increase production at other facilities and encouraged importation of safe infant formula. The President also invoked the Defense Production Act and launched "Operation Fly Formula" to increase domestic production and bring safe imported formula to store shelves. The FDA has also eased import restrictions for 180 days to allow international manufacturers to help address the shortage, while ensuring the formula meets our national safety and nutrition standards.

Congress has also taken swift action, passing legislation, which the President signed into law, that grants flexibility to the WIC program to increase the supply of formula available to families. The House also passed the Infant Formula Supplemental Appropriations Act providing FDA with immediate resources to resolve the current baby formula shortage and lay the foundation to ensure this never happens again.

We must do more though. I've said for years FDA's food safety efforts have been chronically underfunded, under resourced, and understaffed. Last week, this Committee took a step to help address that by advancing a FDA user fee bill that will strengthen FDA's ability to recruit and retain highly qualified staff across the agency, including in areas overseeing infant formula and baby food. The bill will head to the floor in the coming weeks.

Additional legislation will be necessary to improve transparency and reporting requirements, and to empower FDA to set limits more quickly on contamination. Industry must also do its part to ensure robust internal controls are in place and are being followed to prevent contaminated products from ever reaching a single child.

Put simply, it shouldn't take the direct intervention of FDA and the President to keep infant formula on the shelves. The manufacturers have to take responsibility.

Now, we must all work together to guarantee the safety and supply of baby formula to ensure the health of our nation's children.

The Energy and Commerce Committee will act, as always, on a bipartisan basis to enact the necessary authorizing legislation.