



# BOB CASEY

FIGHTING for PENNSYLVANIA FAMILIES

## **The Protect Infants from Formula Shortages Act of 2022**

*U.S. Senators Bob Casey, Sherrod Brown, Tammy Duckworth, Kirsten Gillibrand, and Elizabeth Warren*

The recent infant formula shortage in the U.S. has sent families desperately scrambling to find essential food sources for their children. Many children rely on infant formula—sometimes specific formulations—as their sole source or an indispensable supplement of nutrition during a critical period of growth. Additionally, many patients with digestive diseases, severe allergies, or inborn errors of metabolism require highly specialized medical foods to meet their nutritional needs. For them, these foods are as critical to survival as any drug or medical device, yet they can disappear from store shelves without a moment’s notice. To protect patients who rely on these critical life-sustaining products, the Protect Infants from Formula Shortages Act would authorize the Food and Drug Administration (FDA) to work with formula and other essential source of nutrition (ESN) manufacturers to avoid, adequately prepare for, and, if necessary, respond to potential supply disruptions.

### **The Protect Infants from Formula Shortages Act of 2022**

To safeguard the availability of key sources of life-sustaining nutrition, the Protect Infants from Formula Shortages Act requires manufacturers of ESN to more proactively manage risk and communicate with the FDA. It also empowers the FDA to prevent or mitigate potential shortages by enabling greater insight into ESN supply chains. This legislation:

- Requires manufacturers of ESN to provide timely notification of known circumstances that are likely to lead to meaningful disruption in their domestic supply;
- Allows the FDA to expand and accelerate notification requirements for certain foods during public health emergencies;
- Directs manufacturers of ESN to develop risk management plans for the supply of their product; and
- Gives the FDA authority to request records in advance or in lieu of an in-person inspection, and requires that manufacturers of ESN comply with these requests.

To implement these provisions and provide clarity to manufacturers, the FDA would be required to develop regulations, including a list of each category of food subject to enhanced oversight, within a year of enactment.

### **Additional Background**

The recent infant shortage was caused by a major recall of infant formula and exacerbated existing supply chain issues. In addition to hospitalizations and deaths directly related to contaminated formula, the ensuing shortages caused by the recall resulted in children being hospitalized due to lack of formula or formula intolerance upon switching to alternative available formulations, in addition to less acute weight loss and gastrointestinal complications.

The FDA is charged with overseeing infant formula and medical foods. However, their authority to collect information that could help them to avoid or mitigate shortages of ESN is limited, and manufacturers have no obligation to report anticipated supply shortages. The FDA has long recognized the inadequacy of their authorities to satisfactorily oversee foods that are ESN, and their own limits in mitigating shortages. The Agency has [requested additional authority to prevent food shortages, including infant formula and certain medical foods](#), for several years. The Protect Infants from Formula Shortages Act would address these shortcomings by more closely aligning FDA’s authorities to oversee ESN with current authorities relating to addressing and mitigating shortages of life-saving and life-sustaining drugs.