Challenges in Supply, Market Competition, and Regulation of Infant Formula in the United States

Role of the U.S. Department of Health and Human Services

Infant formula is the primary or sole source of nutrition for many infants in the United States. Consequently, disruptions to the supply or safety of infant formula can have a severe impact on infants’ health and well-being. In late 2021 and early 2022, a recall and pause in production of specific infant formula products resulted in a widespread, national shortage that created hardships for many families. Those receiving infant formula through the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) were particularly adversely impacted. This incident demonstrated that more action is needed to protect U.S. infants from the consequences of potential future supply chain disruptions.

With funding provided by the 2023 Consolidated Appropriations Act, the U.S. Food and Drug Administration (FDA) contracted with the National Academies of Sciences, Engineering, and Medicine to convene an expert committee to examine and report on the challenges in supply, market competition, and regulation of infant formula. The resulting consensus study report explains policy and marketplace vulnerabilities that were exposed by examining the infant formula landscape before, during, and after the 2022 shortage. The report also describes the extent to which actions taken by relevant groups addressed these vulnerabilities, identifies remaining gaps in the system, and recommends actions to address the gaps. The U.S. Department of Health and Human Services (HHS) can play an important role in addressing three major vulnerabilities in the infant formula supply chain: risk management planning, the ability to support a speedy supply recovery, and management of adverse effects on consumers.

RISK MANAGEMENT PLANNING

Risk management planning and the implementation of such plans are key elements of a preparedness strategy for potential supply disruptions. Proper risk management needs to be conducted by the federal government and infant formula companies on the sector level, firm level, facility level, and product level. The committee found that FDA lacked a sector-wide assessment of vulnerabilities in the infant formula supply chain, as well as preparedness plans for what actions it would take should supply disruptions occur. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), critical foods facilities, including infant formula facilities, must develop redundancy risk management plans (RRMPs), subject to inspection by FDA under its authority to inspect production facilities. Under the Food Safety Modernization Act, FDA has the authority to promulgate regulations establishing evidence-based standards and a review process for RRMPs as a component of required written food safety plans. If risk mitigation plans are costly for firms to implement, firms may not implement those plans unless they are funded or incentivized to do so.
The committee recommends that **HHS and FDA, including the Office of Critical Foods, should conduct sector-wide risk management planning**. When conducting sector-wide risk management planning, other agencies could be consulted for input on risk management scenarios (e.g., Administration for Strategic Preparedness and Response or the Federal Emergency Management Agency), supply chain vulnerabilities (e.g., Department of State), or potential solutions to risk scenarios (e.g., Office of the United States Trade Representative or Centers for Medicare & Medicaid Services). It will be important to consider the vulnerability of the upstream supply chains as well. The results of these risk assessments could be used to develop standards for the RRMPs. As a component of sector-wide preparedness efforts, it will be important for FDA to address not only what companies should do when a supply or demand shock to supply chains occurs but also how to minimize the likelihood and magnitude of potential shocks. The committee also recommends that **FDA should develop evidence-based RRMP regulatory standards, a process for reviewing RRMPs, and a mechanism for monitoring implementation of the RRMPs.** The committee proposes two options to accomplish this recommendation:

- **Legislative option:** Congress should amend the Infant Formula Act to require all manufacturers to submit RRMPs for each product, while recognizing capacity constraints, and direct FDA to promulgate regulations specifying evidence-based regulatory requirements for RRMPs and an RRMP review process to provide feedback on compliance with the evidence-based standards.

- **Administrative option:** FDA should use its authority under the Food Safety Modernization Act to promulgate regulations that require RRMPs for critical food facilities as part of their required food safety plans and establish evidence-based standards and a review process for RRMPs.

**SPEEDY SUPPLY RECOVERY**

FDA regulatory requirements may present a barrier to importing infant formula during supply chain disruptions. During the shortage, FDA determined some infant formula regulations could be temporarily relaxed through enforcement discretion without compromising safety. Rules also restrict which U.S. businesses are eligible to import infant formula, preventing some retailers from buying additional stocks from abroad during a shortage. To maintain the safety and quality of infant formula in the event of another shortage, FDA should collect information on nutrient and labeling requirements used by other countries and use this information to develop a database to be updated every 4 years, consistent with FDORA, of the requirements in other countries to facilitate the use of enforcement discretion in case of a shortage. In addition, the information in the database can be used by FDA to evaluate evidence to determine if an update is needed to U.S. regulations. FDA could also consider collecting information on how other regulations, such as those on emulsifier and contaminants, differ across countries. During the shortage, some hospitals and WIC retailers experienced uneven supply of infant formula because of opaque distribution by distributors and/or wholesalers. Additionally, the government was unable to obtain information about where infant formula was in the supply chain, which hindered its ability to adequately coordinate a whole-of-government response. HHS, including the HHS Supply Chain Coordinator and FDA, should work with the appropriate wholesalers and distributors of infant formula to develop risk management and disaster plans to prepare for a shortage of critical foods.

**ADVERSE CONSUMER IMPACT**

During the 2022 shortage, professional organizations, government agencies, and WIC offices provided consumer education on how to prepare infant formula and avoid unsafe feeding practices. However, caregivers had limited guidance on how to find infant formula, substitute alternate infant formula brands or other foods without causing gastrointestinal issues, or read labels and instructions on imported infant formula containers. Health care providers were also underprepared to provide this guidance to caregivers. FDA and the Centers for Disease Control and Prevention should work with infant
nutrition experts and infant formula manufacturers to jointly develop guidance on how caregivers can substitute infant formula (based on ingredients) and guidance for providers and caregivers on how to feed their infants when no breast milk or safe infant formula is available, to address ongoing challenges and to prepare for any future recall or supply disruption.

While FDORA now requires FDA to provide information on its website on appropriate substitutes for infant formula products in shortage for infants with inborn errors of metabolism or other serious health conditions, it does not address other types of infant formula such as hypoallergenic or non-exempt formulas. FDA should maintain a public list of all infant formulas currently marketed and registered in the United States, indexing formula name, whether the formula is exempt or non-exempt, and the registered list of ingredients that appear on the label.

Users of exempt infant formulas have a particularly limited set of feeding options because use of other infant formulas or even breast milk can lead to severe health problems, even if used in the short term. Because of the much more restrictive set of options faced by users of most exempt infant formulas, special considerations are needed to ensure steady supply of those infant formulas, including protecting the supply against demand spillovers. The Centers for Medicare & Medicaid Services should issue a rule requiring hospitals that accept Medicaid to have a plan for a meaningful disruption of nutrition support for hospitalized infants.

### AREAS FOR ADDITIONAL RESEARCH

HHS could conduct additional research to address vulnerabilities in the infant formula supply chain as described below:

- Model scenarios other than a recall, of varying levels of severity and duration, that could lead to an infant formula shortage (e.g., lack of a key ingredient or packaging component because of a weather event or geopolitical problem) and their effect on the availability of infant formula.
  - This should include separate estimates for WIC costs associated with a shortage caused by factors other than a recall.

- Examine additional strategies to protect infant formula users with additional medical needs from shortages of exempt infant formula.

- Identify ways to restrict access to exempt infant formulas to those with medical necessity at the first sign of a potential shortage.

- Analyze the criteria, time, and resources needed to assess various types of new infant formula notifications, based on the categories of infant formula products that are required to submit a 90-day notification to FDA.

To access the full report and other supporting materials, visit www.nationalacademies.org/infant-formula-supply-study.