When Abbott Nutrition stopped operations at a Michigan facility that was producing about 20% of infant formula in the US, it demonstrated how vulnerable that industry is to shortages, despite tight regulation meant to ensure a safe and adequate supply. That oversight has been a factor in creating an oligopoly (limited competition) for infant formula, with about 80% of the US market controlled by Abbott and 1 other manufacturer. This has left the market vulnerable to a disruption at any of the large, domestic facilities that manufacture infant formula. However, such oversight was not stringent enough to ensure that there would not be a snafu and ensuing shortfall at any one of these plants—leaving the market excessively shaky.

Abbott halted production after a series of contaminations at the Michigan facility that were initially implicated in the deaths of 2 infants and infections in at least 2 others from Cronobacter sakazakii, which is a bacterium found naturally in the environment. This pathogen can live in dry foods, such as powdered infant formula, and is especially risky to infants younger than 2 months and those with weakened immune systems. It is a known and closely monitored risk in infant formula manufacturing. When Cronobacter outbreaks do occur, they are unlikely to be large even if the infant formula is a source of the contamination; cases are more likely to be isolated and sporadic, making it difficult to identify them, to trace them to a source, and to know if infant formula might be a common link. Infant Cronobacter infections should be a nationally notifiable disease so they can be properly investigated. However, the US Centers for Disease Control and Prevention and most states currently do not require cases to be reported.

The US Food and Drug Administration (FDA) is unlikely to confirm or exclude whether the contamination at the Abbott plant led to the infections. Although genetic analysis of the strains isolated in 2 available samples from affected infants did not match those found in the plant, recent FDA inspections found that the plant had different species of Cronobacter contaminating various surfaces, perhaps for a long time. Abbott disclosed to FDA inspectors earlier this year that the company’s testing in the facility had identified Cronobacter going back to 2019, including in the finished product. Complicating matters, a 34-page whistleblower report (from a former plant employee) was sent to FDA leaders in October 2021, alleging that the plant’s personnel falsified data about safety operations and withheld findings from FDA inspectors, charges that Abbott disputes. But once the cases emerged in the 4 infants, in concert with action from the FDA, Abbott issued a recall of the product produced at the plant in February 2022 and subsequently shut down its facility.

Based on past findings and the existence of many strains of Cronobacter in the plant, the FDA will not be able to easily and definitively conclude that one of the implicated strains could not have been present in the plant earlier, resulting in a transient contamination. Likely owing to all these concerns, and without a single and clearly identified source for the bacteria found in the plant, the FDA placed Abbott under a consent decree requiring the facility, which recently restarted manufacturing, to operate under close federal supervision.

The US has high regulatory barriers to new infant formula approvals and rigorous standards on how it is manufactured—higher standards compared with those in Europe, where regulations are closer to the requirements applied to dairy products. Some point to Europe as a more successful market, with a greater variety of choices and new product entrants in Europe than in the US because of a lower regulatory burden on manufacturing. However, Europe also has far more infant formula recalls and frequent contamination with bacteria such as Salmonella, which is seldom seen in the US.
Control over infant formula manufacturing in the US is more like oversight of drugs than the regulation applied to food products because the FDA requires careful premarket review of new ingredients or changes in formulations. However, the infant formula group at the FDA is underresourced, with only 9 people assigned to oversee the manufacturers and review infant formula premarket submissions for safety and nutrition for the entire industry. As a result, review of product notifications is slow when existing manufacturers want to make ingredient or production changes or when new companies want to enter the market, thereby adding to costs and creating barriers to new entrants.

Under current regulations, US manufacturers can go to market with new ingredients if the FDA has not responded to their notifications within 90 days. More detailed notices to the FDA—that an ingredient is also "generally regarded as safe" under conditions of its intended use and does not require premarket approval—are sometimes also required. In practice, companies do not go to market with their products until the FDA has reviewed their notices; however, the agency can take months to years to respond to these submissions. During the past 15 years, only 1 company, ByHeart, has entered the market with a new infant formula product based on a new clinical study and a new manufacturing site, which was cleared by the FDA earlier this year.

Congress and many consumers have favored the FDA’s high standards for infant formula. But to maintain tight controls and the assurance of safety, it is essential to ensure that the oversight prevents problems at existing manufactures and does not unduly impede the path for new entrants and more competition. For incumbents that may mean tightening existing regulatory standards, such as increasing the frequency of inspections (now typically performed annually) and the environmental monitoring that firms do to identify bacteria. Congress can also require infant formula makers to notify the FDA when production problems may lead to shortages and provide the agency with data on production levels and the supply of ingredients so the agency can identify impending shortfalls.

In addition, Congress should take steps to encourage more competition and innovation from new entrants that bring additional domestic manufacturing facilities into the US infant formula market. Another step to help lower barriers to entry and reduce the cost of capital needed to advance safe, new products would be to ensure that notifications for new formulations or manufacturing facilities receive a prompt review by the FDA with clear, efficient, and immutable timelines. This will require a larger review staff, and the agency must be held to deadlines for responding to submissions. Such an approach (clear review deadlines that are adhered to and priority designations giving new entrants timely and predictable reviews) has promoted investment in areas of medical need on the drug side of FDA's house.

Many of the newer manufacturing facilities built in recent years have been constructed outside the US because of lower labor costs or preferable tax jurisdictions. The federal government could use the large contracts it awards for infant formula through the Special Supplemental Nutrition Program for Women, Infants, and Children program to favor companies that develop new products or invest in building new manufacturing facilities in the US.

The US currently has the worst of both worlds for infant formulas. Regulation meant to ensure safety is stringent enough to stymie new investment and competition, but not effective enough to ensure that the infant formula oligopoly that it helps preserve is not prone to risk, contaminations, and perilous shutdowns.
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REFERENCES
