Insight

Baby Formula Update 2023: Inadequate Competition, FDA Reshuffle, and Congressional Legislation

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Executive Summary

- Competition in the baby formula marketplace remains severely limited, a consequence of restrictive formula sourcing regulations, poor federal oversight, and prohibitive trade barriers.
- Among other problems, Special Supplemental Nutrition Program for Women, Infants and Children beneficiaries, who account for half of all baby formula sales, are unable to purchase non-contracted formulas; moreover, the Food and Drug Administration still lacks critical capabilities to oversee the manufacturing of baby formula or issue industry best-practice guidelines, and tariffs limit the importation of foreign products.
- Policymakers have proposed a variety of bipartisan proposals to improve the availability of baby formulas, some of which have real promise to restore and foster competition in the formula market.

Introduction

Competition in the baby formula marketplace remains severely limited, a consequence of restrictive formula sourcing regulations, poor federal oversight, and prohibitive trade barriers.

Among other problems, Special Supplemental Nutrition Program for Women, Infants and Children (WIC) beneficiaries, who account for half of all baby formula sales, are unable to purchase non-contracted formulas; moreover, the Food and Drug Administration (FDA) still lacks critical capabilities to oversee health and safety guidelines, and tariffs limit the importation of foreign products.

There are several problems with WIC's sourcing of baby formula. With only three manufacturers providing formula for 90 percent of the market, WIC funds continue to reward a system vulnerable to supply chain disruptions with little urgency from policymakers to reform the WIC state-based contracting requirements to encourage competition. The American Action Forum has previously explored the challenges facing the U.S. baby formula marketplace following the Abbott 2022 recall.

Recent congressional hearings have demonstrated lawmakers' continued frustrations with the FDA's response to the nationwide baby formula shortage. While the agency has extended certain exemptions so that specific foreign formula producers can continue to sell their product in the United States, the agency seems otherwise unwilling to acknowledge its regulatory contribution to the shortage. Notably, the agency's recently published COVID-19 "lessons learned" statement omitted the 2022 baby formula shortage altogether.

Separate from availability and competition concerns, safety concerns persist. The FDA is reshuffling the Human

Foods Program (intended to advance food safety and nutrition), and it's unclear whether its new Office of Critical Foods, which has "responsibility for the oversight, coordination, and facilitation of activities related to critical foods," will be able to effectively oversee infant formula and medical foods safety.[1] Thus far, FDA's continue reorganizing of its Human Foods Program seems to be shifting the agency away from executing its core mission of food safety.

High tariffs, alongside additional FDA nutritional requirements specific to the U.S. market, have traditionally discouraged imports of baby formula from foreign manufacturers.[2] Abbott's 2022 recall revealed the weakness of the U.S. baby formula supply chain's reliance on three large manufacturers. During the baby formula crisis, Congress temporarily suspended tariffs on baby formula imports by passing the Formula Act and the Bulk Infant Formula Retail Shelves Act. Yet most of these tariffs resumed in early 2023 and the United States remains vulnerable to another baby formula shortage.

Policymakers across the aisle have proposed bipartisan solutions to improve the oversight, quality, and availability of baby formulas. On May 11, the House Oversight Subcommittee on Health Care and Financial Services held a hearing to investigate the FDA's response to the 2022 baby formula shortage. This insight reviews various legislative proposals, including bills that would remove tariffs, extend WIC contracting, and expand program eligibility.

Marketplace Failure and Poor Manufacturer Competition

In May 2023, the Federal Trade Commission (FTC) launched an investigation into the baby formula crisis to address the ways in which the sole-source contracting model may have limited domestic competition. The FTC has the authority to address "any anticompetitive, unfair, or deceptive acts or practices that have contributed to or are worsening" the supply of baby formula.

The United States Department of Agriculture (USDA) announced three new grants delivered through the USDA's Food and Nutrition Service to improve the WIC program in October 2022.[3] Currently "less than 60 percent of eligible individuals and less than 50 percent of eligible children participate in WIC." It is important to note that none of these grants or initiatives has focused on encouraging new baby formula manufacturers to enter the marketplace. The agency's focus on participant access may thus be overlooking the core problem of limited product distribution and consistent availability of a product.

The remaining WIC flexibilities for specialty imported formula products are set to expire June 30, 2023. It is premature for USDA to end WIC flexibilities as the baby formula recalls continue to exert additional strain on the limited supply chain.[4]

FDA Reshuffle: Unlikely to Improve Baby Formula Oversight

The FDA's process by which the public and medical professionals alert the agency of suspected baby formula borne illness is complex.[5] Even more unclear is how the FDA internally escalates whistleblower complaints. Yet the agency has yet to clarify how it will escalate complaints to appropriate action to remove potentially contaminated baby formula products from the marketplace.[6] Moreover, how the Office of Regulatory Affairs at the FDA (responsible for food safety investigations) will work with the Office of Critical Foods, a new office to be launched as required by the 2023 Consolidated Appropriations Act (CAA), with the "responsibility for the oversight, coordination, and facilitation of activities related to critical foods", on the oversight of baby formula remains to be seen.[7] The CCA defines a critical food as "an infant formula…or…a medical food, as defined in section 5(b)(3) of the Orphan Drug Act

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Following on the FDA's 2022 report on the FDA Evaluation of Infant Formula Response, Congress should consider clarifying expectations around the FDA's new Office of Critical Foods including the escalation of consumer complaints related to baby formula. Currently, the FDA will escalate complaints based on product that "caused or may cause a serious illness, injury, or a life-threatening situation." But this may not be sufficient to survey for contamination caused by cronobacter, a pathogen that thrives in powdered formula and can cause serious illness in infants, as FDA would have to actively track data related to the disease to determine the impact on infant health.[8]

Proposed Bipartisan Legislation 2023

General Changes to WIC

Senators Kirsten Gillibrand (D-NY) and Roger Marshall (R-KS) introduced the More Options to Develop and Enhance Remote Nutrition in WIC Act (MODERN WIC) which would permit enrollees to receive program certification or recertification through teleconference or phone, as well as mailing WIC benefits directly to participants.

Infant Formula Market-Specific

Representatives Mike Turner (OH-10) and Elise Stefanik (NY-21) introduced the Improving Newborn Formula Access for a Nutritious Tomorrow (INFANT) Act, which would require states to contract with two baby formula manufacturers, rather than just one.

Senators Mike Lee (R-UT) and Bob Menendez (D-NJ), alongside Representatives Adrian Smith (R-NE) and Don Beyer (D-VA), introduced the Formula 3.0 Act to permanently remove tariffs and trade barriers on imported baby formula. The removal of these barriers would stabilize the supply chain of baby formula and increase competition as new products enter the U.S. market.

President Biden's Budget Proposal and Appropriations Activity

Following the Abbott scandal, the FDA requested additional authority in President Biden's Fiscal Year 2024 budget to compel baby formula manufacturers to "report to FDA final product positive [cronobacter] test results." Whenever a positive test occurs, the FDA would be informed so that it could begin an escalation process to reduce the time between a positive notification and, when appropriate, product recall.

The president's budget proposes"$6.3 billion to fully fund the 6.5 million individuals expected to participate in [WIC]." The current text of the Fiscal Year 2024 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Budget would provide WIC with $6 billion until the end of September 2025.

Conclusion

While competition in the baby formula market remains severely limited, lawmakers' proposed reforms to target the regulatory sources of such dysfunction offer real promise to stabilize and improve the market. Bills offering targeted reforms to WIC's contracting model, an overhaul of the FDA's formula-specific health and safety

oversight capabilities, and the reduction and removal of trade barriers, including tariffs, to the importation of formula present workable solutions to prevent future crises.

[1] 2023 Consolidated Appropriations Act (CAA) in Subtitle D states that "…the Secretary shall establish within the Center for Food Safety and Applied Nutrition an office to beknown as the Office of Critical Foods. The Secretary shall appoint a Director to lead such Office…. [the] Office of Critical Foods shall be responsible for oversight, coordination, and facilitation of activities related to critical foods, as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)(2)."

[2] Congressional Research Service "Tariffs and the Infant Formula Shortage" 2022.

[3] The first grant provided $20 million to the Food Research & Action Center to improve outreach to potential beneficiaries. The second grant of $23 million was awarded to the 66 WIC state agencies to improve "technology and service delivery in WIC." The third grant of $10 million was awarded to 19 WIC state agencies to "improve the shopping experience through modernizing in-store shopping" for WIC beneficiaries to be able to purchase formula online.

[4] The Food and Drug Administration (FDA) was aware of a contamination incident in November 2022 but the manufacturer did not issue a recall until February 2023. Another recall occurred in May 2023.

[5] The FDA states that "If a consumer has a general complaint or concern about a food product including an infant formula, FDA is the appropriate agency to contact. These problems, complaints, or injuries can be reported in writing or by telephone, or by the Internet at Report a Problem. If you think your infant has suffered a serious harmful effect or illness from an infant formula, your health care provider can report this by calling FDA's MedWatch hotline at 1-800-FDA-1088 or by using Reporting by Health Professionals. The MedWatch program allows health care providers to report problems possibly caused by FDA-regulated products such as drugs, medical devices, medical foods, dietary supplements, and infant formulas. The identity of the patient is kept confidential. In addition, health care providers should report infectious diseases in infants associated with use of infant formula to CDC's Division of Healthcare Quality Promotion (1-800-893-0485). Consumers may also report an illness, injury or other problem they believe to be related to the use of an infant formula by calling FDA at 1-800-FDA-1088 or using Reporting by Consumers. FDA would like to know when a product may have caused a problem even if you are unsure the product caused the problem or even if you and the baby do not visit a doctor or clinic. Infant formula manufacturers provide toll-free telephone numbers on the labels of their products and should be notified about problems, complaints, or injuries caused by their products. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002."

[6] The FDA states that "Reports from across the nation are forwarded to the appropriate headquarters offices whenever the problem involves a baby food, drug reaction, or any illness, injury, or life-threatening situation related to an FDA-regulated product."

[7] *eFoodAlert*, a website run by author Phyllis Entis, published 128 consumer complaints the FDA received between December 1, 2021 and March 3, 2022 related to baby formula following a Freedom of Information Act request. Within these complaints are nine reports of infant deaths.

[8] Currently, the Council of State and Territorial Epidemiologists (CSTE) is considering recommending that cronobacter as a national notifiable disease to that the Centers for Disease Control and Prevention. It is reported that CSTE will hold a vote on recognizing cronobacter as a national notifiable disease.