Market Factors Relevant to Infant Formula Supply Disruptions

- 2022 -

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FEDERAL TRADE COMMISSION

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Executive Summary

In 2022, millions of American families were negatively affected by infant formula supply disruptions.[1] These disruptions serve as another reminder that modern American life depends on an uninterrupted supply of goods that must be manufactured, transported, distributed, and sold to retail consumers across the United States. This Report describes the long-term features of the U.S. infant formula market that rendered it vulnerable to supply disruptions in 2022, and outlines considerations for policymakers to help create a more resilient infant formula supply going forward.

This Report is written from the perspective of the Federal Trade Commission ("FTC"). The FTC is tasked by Congress to promote fair and robust competition in markets.[2] Open, fair, and competitive markets tend to reliably deliver high quality, affordable products and can also promote resiliency. By contrast, highly consolidated markets can create fragility, with a single shock or disruption having cascading and outsized effects on the entire supply chain. In other words, concentrated production can also concentrate risk. When a single disruption has an industry-wide effect, it is worth examining whether structural factors contributed to the fragility. Pursuant to this mandate, and in accordance with President Biden's whole-of-government approach to competition announced in the July 2021 Executive Order on Promoting Competition in the American Economy,[3] the FTC considered whether certain features of the infant formula market contributed to the industry-wide disruptions in 2022, and whether certain competition-based reforms could promote greater resiliency going forward.

Federal programs that significantly impact the U.S. infant formula market are the U.S. Department of Agriculture's ("USDA") Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC Program" or "WIC") and WIC's use of single-supplier infant formula rebate contracts, as well as the U.S. Food and Drug Administration's ("FDA") regulatory review framework for infant formula products.[4]

Under Congressional mandates, both the USDA and FDA have serious and important policy objectives that affect not just competition, but also consumer safety and wellbeing for an essential product for many of the most vulnerable Americans.[5] The Report describes the WIC Program and the use of single-supplier rebate contracts, the relevant FDA framework, the potential competitive impact of these programs, and considerations for policymakers.

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[1] There are approximately 3.4 million infants under the age of one in the U.S. as of 2019, with more than half of infants receiving some infant formula. Kaiser Family Foundation, *Key Characteristics of Infants and Implications of the Recent Formula Shortage* (June 9, 2022), https://www.kff.org/medicaid/issue-brief/key-characteristics-of-infants-and-implications-of-the-recent-formula-shortage.

[2] Federal Trade Commission Act, 15 U.S.C. §§ 41-58.

[3] White House, Executive Order on Promoting Competition in the American Economy (July 9, 2021), *available at* https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy.

[4] The FTC acknowledges the existence of additional elements that may impact the U.S. infant formula market, including tariffs and agricultural subsidies. A comprehensive review of all factors that may have contributed to the shortage of formula in 2022 is outside the focus of this Report.

[5] *Supra* note 3. The USDA's legal authority regarding the federal WIC Program is codified in the Child Nutrition Act of 1966 and subsequent legislation. 42 U.S.C. § 1771 et seq. The FDA's legal authority has been broadened over the years and includes regulation of food products such as infant formula. The Food, Drug, and Cosmetic Act and subsequent amending statutes are codified in 21 U.S.C. Ch. 9, with regulations on infant formula found in various sections therein.

Section I of this Report describes the 2022 infant formula supply disruptions and relevant portions of the FTC's Request for Information ("RFI"), which solicited comments from members of the public, industry, trade groups, as well as the views of academics on a variety of issues related to the disruptions and the infant formula market more broadly.

Section II describes the history of persistently high levels of concentration in the U.S. infant formula industry, identifies the major manufacturers, and notes the significance of specialty infant formula products.

Section III describes the major features and potential effects on competition of WIC's rebate contracts, which affect more than half the infant formula purchased in the United States.

Section IV of this Report describes the current FDA regulatory framework for infant formula products in relation to other FDA-regulated products, the Syntex infant formula scandal of the late 1970s as historical context, and the FDA regulatory structure over infant formula products.

I. Background

A. Formula Shortage

Widespread supply disruptions for infant formula began shortly after Abbott Nutrition voluntarily recalled several powdered infant formulas manufactured at its facility in Sturgis, Michigan in response to reports of bacterial contamination on February 17, 2022.[6] The FDA advised consumers that same day not to use the recalled formula.[7] In turn, the USDA provided guidance to WIC State agencies and offered program flexibilities to support WIC participants' access to infant formula.[8] Supply chains would continue

[6] Abbott voluntarily recalled Similac, Alimentum, and EleCare powdered infant formulas due to concerns about Cronobacter and Salmonella contamination. *Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant*, FDA.GOV, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-recalls-powder-formulas-manufactured-one-plant (updated Feb. 17, 2022). Prior inspections beginning around the fall of 2021 by the FDA of the Sturgis facility had raised concerns regarding manufacturing conditions and inadequate product quality testing procedures. Form FDA 483 (Sep. 2019), *available at* https://www.fda.gov/media/156748/download?utm_medium=email&utm_source=govdelivery; Form FDA 483 (Sep. 2021), *available at* https://www.fda.gov/media/156747/download?utm_medium=email&utm_source=govdelivery; ESTABLISHMENT INSPECTION REPORT OF ABBOTT NUTRITION (Sep. 20, 2021), *available at* https://www.marlerblog.com/files/2022/04/APPLIED-FOI-II-BR-Abbott-Nutritions-FEI-1815692-9-2021-EIR.-1.pdf (originally created by the FDA and produced pursuant to a FOIA request); U.S. FOOD & DRUG ADMIN. INSPECTION REPORT (March 2022), *available at* https://www.fda.gov/media/157073/download. These concerns were corroborated in an October 2021 whistleblower report. *See* CONFIDENTIAL DISCLOSURE RE ABBOTT LABORATORIES' PRODUCTION SITE IN STURGIS, MICHIGAN, *available at* https://www.marlerblog.com/files/2022/04/Redacted-Confidential-Disclosure-re-Abbott-Laboratories-10-19-2021_Redacted-1-1.pdf (whistleblower report produced pursuant to a FOIA request).

[7] *FDA Investigation of Cronobacter Infections: Powdered Infant Formula (February 2022)*, FDA.GOV, https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022 (updated Aug. 1, 2022); *FDA Warns Consumers Not to Use Certain Powdered Infant Formula Produced in Abbott Nutrition's Facility in Sturgis, Michigan*, FDA.GOV, https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutritions-facility (updated Aug. 1, 2022).

[8] *See, e.g.,* U.S. DEPT. OF AGRICULTURE, REQUEST FOR ADDITIONAL WIC FLEXIBILITY IN RESPONSE TO THE IMPACT OF THE ONGOING CORONAVIRUS DISEASE 2019 (COVID-19) PANDEMIC ON NATIONWIDE INFANT FORMULA SUPPLY CHINA ISSUES AND 2022 ABBOTT

to be stretched in subsequent months amidst the global pandemic,[9] with existing inventories being depleted at increased rates due to consumer purchasing behavior reported as "panic buying" or "pantry loading."[10] Nationwide shortages of formula were reported throughout 2022.[11]

To alleviate the impact on production facilities and retailers, the FDA announced in May 2022 its guidance offering greater regulatory flexibility for infant formula, including for international formula to gain access to the U.S. market.[12] Concurrent efforts by the White House expedited the supply of formula, including Operation Fly Formula,[13] the Access to Baby Formula Act of 2022,[14] and the use of the Defense

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RECALL – VENDOR EXCHANGES (May 24, 2022), *available at* https://fns-prod.azureedge.us/sites/default/files/resource-files/wic-infant-formula-recall-waivers-vendor-exchanges-052422.pdf.

[9] In addition to the COVID pandemic and the Russia-Ukraine conflict exacerbating supply issues, Abbott's Sturgis facility was again shut down due to flooding on June 13, 2022, further postponing production at the facility until July. Wynne Davis, *Abbott's baby formula plant closes again after severe storms and flooding*, NPR (June 16, 2022), https://www.npr.org/2022/06/16/1105488061/baby-formula-plant-abbott-closed-flooding; Shauneen Miranda, *Abbott reopens Michigan baby formula plant after flooding*, NPR (July 10, 2022), https://www.ctpublic.org/2022-07-10/abbott-reopens-michigan-baby-formula-plant-after-flooding.

[10] *See, e.g.*, Eloise Barry, *Why It's So Hard to Find Baby Formula in the U.S. Right Now*, TIME (May 13, 2022), https://time.com/6175211/baby-formula-shortage ("Panic buying has added to the crisis in recent weeks. In response, retailers like Walgreens are limiting consumers to buying three cans at a time, the BBC reported. One 12.4 ounce container of formula typically produces around 15 bottles, which would only last for a few days."); Soniya Billore and Tatiana Anisimova, *Panic buying research: A systematic literature review and future research agenda*, INT'L J. OF CONSUMER STUDIES (Mar. 18, 2021), *available at* https://onlinelibrary.wiley.com/doi/10.1111/ijcs.12669.

[11] The FDA's testimony to the House Subcommittee on Oversight and Investigations reported a dip in supply volumes as well as variety of formula product supplied. *Formula Safety and Supply: Protecting the Health of America's Babies Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 117th Cong. 8 (May 25, 2022) (statement of Robert M. Califf, MD, Commissioner of Food and Drugs, et al.), *available at* https://www.congress.gov/117/meeting/house/114821/documents/HHRG-117-IF02-20220525-SD003.pdf ("Data from IRI show nearly 80 percent in-stock rates for the week ending May 15, 2022 []compared to 89 to 90 percent in-stock rates before the Abbott Nutrition recall . . . This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate translates to 40 of those 50 product types being available.").

[12] *FDA Encourages Importation of Safe Infant Formula and Other Flexibilities to Further Increase Availability*, FDA.GOV (May 16, 2022), https://www.fda.gov/news-events/press-announcements/fda-encourages-importation-safe-infant-formula-and-other-flexibilities-further-increase-availability; U.S. FOOD & DRUG ADMIN. GUIDANCE FOR INDUSTRY: INFANT FORMULA ENFORCEMENT DISCRETION POLICY, MAY 2022, FDA-2022-D-0814, *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-infant-formula-enforcement-discretion-policy; *Enforcement Discretion to Manufacturers to Increase Infant Formula Supplies*, FDA.GOV, https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies (updated Jan. 18, 2023) (replacing the May 2022 guidance).

[13] On May 19, 2022, the Biden Administration announced Operation Fly Formula in which the Department of Defense (DOD) resources would be used to transport additional formula supplies into the United States. THE WHITE HOUSE, *Biden Administration Approves First Operation Fly Formula Mission, White House Briefing* (May 19, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/19/biden-administration-approves-first-operation-fly-formula-mission.

[14] On May 21, 2022, President Biden signed the bipartisan "Access to Baby Formula Act of 2022" (H.R. 7791), which allows the waiver of various WIC requirements in cases of supply chain disruption or emergency. THE WHITE HOUSE, *Bills Signed: H.R. 7691 and H.R. 7791* (May 21, 2022), https://www.whitehouse.gov/briefing-room/legislation/2022/05/21/bills-signed-h-r-7691-and-h-r-7791.

Production Act.[15] Moreover, USDA provided flexibility to WIC State agencies to support access to imported and noncontract infant formula products that met minimum nutrition standards by WIC participants.

B. The FTC's Request for Information

On May 24, 2022, the FTC issued an RFI seeking public comment on various factors that may have contributed to the then-ongoing infant formula supply disruptions.[16] The FTC sought information about families' experiences with fraud, deception, or scams; online reselling at exorbitant prices; and difficulties purchasing through WIC.[17] The FTC also asked about retailers' experiences with customer stockpiling; retailers' experiences transitioning to different brands; and whether small and independent retailers faced particular difficulties obtaining formula as compared to large chains.[18] In addition, the FTC sought input from experts, academics, and the public regarding the history of mergers and acquisitions in the infant formula industry, the impact of WIC State contracts on the infant formula industry, and the impact of FDA regulations or any other regulatory requirements that potentially discourage entry into the U.S. infant formula market.[19]

In response, the FTC received comments from members of the public, state attorneys general, and representatives of the infant formula industry and broader food industry, as well as policy experts and academics.[20] Public commentors expressed a variety of concerns about the infant formula market and the then-ongoing supply disruptions. Areas of particular focus included the WIC Program and FDA regulations. Several commentors expressed concern that the current FDA regulatory regime is overly burdensome and unnecessarily impedes potential competitors in the infant formula market.[21] Other commentors remarked on the current WIC structure and single-supplier rebate mechanism, which many

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[15] On May 22, 2022, the Biden Administration announced the use of the Defense Production Act to allow infant formula manufacturers to demand their suppliers prioritize infant formula production over competing orders. THE WHITE HOUSE, *President Biden Announces First Two Infant Formula Defense Production Act Authorizations* (May 22, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/22/president-biden-announces-first-two-infant-formula-defense-production-act-authorizations.

[16] *Federal Trade Commission Launches Inquiry into Infant Formula Crisis* (May 24, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/05/federal-trade-commission-launches-inquiry-infant-formula-crisis (last visited March 13, 2023).

[17] FED. TRADE COMM., SOLICITATION FOR PUBLIC COMMENTS ON FACTORS THAT MAY HAVE CONTRIBUTED TO THE INFANT FORMULA SHORTAGE AND ITS IMPACT ON FAMILIES AND RETAILERS (May 24, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Baby%20Formula%20RFI_final.pdf.

[18] *Id*.

[19] *Id*.

[20] *Solicitation for Public Comments on Factors that May Have Contributed to the Infant Formula Shortage and its Impact on Families and Retailers*, REGULATIONS.GOV, Docket ID FTC-2022-0031, https://www.regulations.gov/docket/FTC-2022-0031/comments.

[21] *See, e.g.,* Bobbie, Comment Letter on Solicitation for Public Comments on Factors that May Have Contributed to the Infant Formula Shortage and Its Impact on Families and Retailers, 1 (June 24, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0072 [hereinafter *Bobbie Comment Letter*]; Serenity Kids Baby Food, Comment Letter on Infant Formula Shortage, 1 (June 17, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0016 [hereinafter *Serenity Kids Comment Letter*].

see as a highly effective cost-containment mechanism[22] while others see it as an impediment to new competition[23] or an unnecessary restriction on WIC parents' choice between brands.[24] Still other commentors were generally concerned about concentration and lack of competition in the industry,[25] which some attributed at least in part to tariffs on imported infant formula blocking foreign competition.[26]

II. History of Concentration in the U.S. Infant Formula Market

A. Market Suppliers

As shown in Table 1 below, the U.S. infant formula market for several decades has been highly concentrated among relatively few manufacturers, including as of early 2022 Abbott, Mead Johnson (owned by Reckitt Benckiser), Nestlé (Gerber), and Perrigo. The most recent publicly available data on WIC supply shows that only three infant formula manufacturers—Abbott, Mead Johnson (Reckitt Benckiser), and Nestlé (Gerber, now owned by Perrigo in North America)—bid on WIC contracts between 2003 and 2013.[27]

[22] National WIC Association, Comment Letter on Infant Formula Shortage (June 24, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0073 ("For more than three decades, WIC's competitive bid process for infant formula has worked efficiently to generate federal savings and secure a strong deal for taxpayers.") [hereinafter *National WIC Association Comment Letter*].

[23] Bobbie Comment Letter at 1 ("As it remains a vital program for families, the WIC competitive bidding process places significant hurdles for small-to-medium infant formula manufacturers that ultimately hurts millions of infants. . . . Unfortunately, the WIC bidding process is stacked against small-medium manufacturers and allows for giant companies to consume the majority of the market.").

[24] *See, e.g.,* Anonymous WIC Dietician, Comment Letter on Infant Formula Shortage (June 27, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0071 ("Market competition is healthy for the economy. Market options should be available for formula companies with high quality practices and innovation rather than just market dominance and profitability. . . . The consumer has the right to choose what they would like to feed their infant, not the competitive bidder.") [hereinafter *Anonymous WIC Dietician Comment Letter*].

[25] *E.g.,* National Consumers League, Comment Letter on Infant Formula Shortage, 2 (June 24, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0064 [hereinafter *NCL Comment Letter*].

[26] *See, e.g.*, Mary Sullivan, Comment Letter on Infant Formula Shortage (June 27, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0069 ("The most obvious step [to eliminate barriers to entry in the U.S. infant formula market] is to eliminate tariffs.") [hereinafter *Sullivan Comment Letter*].

[27] *See* David E. Davis and Victor Oliveira, *Manufacturers' Bids for WIC Infant Formula Rebate Contracts, 2003-2013*, USDA ERS BULLETIN No. 142, 7–9 (July 2015), https://www.ers.usda.gov/webdocs/publications/43996/53266_eib142.pdf?v=3991.8 ("Mead Johnson won 21 contracts, Nestlé/ Gerber won 16, and Abbott won 18."). The absence of post-2013 bid data is a limitation of this analysis.

Table 1 – Reported Estimated Share of U.S. Infant Formula Market Over Time

Current	**Historical**	**1987**[28]	**1994**[29]	**2000**[30]	**2008**[31]	**2021**[32]	**2022**[33]
Abbott	Ross	55	53	35	43	40	27
Mead Johnson/ Reckitt Benckiser	Mead Johnson	35	27	52	40	31	39
Nestlé/ Gerber	Carnation	-	7	12	15 (Nestlé)	17	18
	Gerber	-	3	-			
	Wyeth	9	9	-	-		
Perrigo[34]	PBM	-	-	1[35]	<2	11[36]	13
Other		~ 1	~ 1	~ 0	<2	1	3

[28] U.S. DEPT. OF AGRICULTURE ECON. RESEARCH SERVICE, INFANT FORMULA PRICES AND AVAILABILITY: INTERIM REPORT TO CONGRESS, 10 (April 2001), *available at* https://www.ers.usda.gov/webdocs/publications/42958/32016_efan01006_002.pdf?v=6475.2 [hereinafter *USDA ERS 2001 Interim Report*].

[29] *Id*.

[30] *Id.*

[31] Victor Oliveira, et al., *The Infant Formula Market: Consequences of a Change in the WIC Contract Brand*, USDA ERS REP. No. 124, 7 (Aug. 2011), https://www.ers.usda.gov/webdocs/publications/44900/6918_err124.pdf?v=0 [hereinafter *USDA ERS 2011 Report*].

[32] U.S. FOOD & DRUG ADMIN., U.S. FOOD AND DRUG ADMINISTRATION'S IMMEDIATE NATIONAL STRATEGY TO INCREASE THE RESILIENCY OF THE U.S. INFANT FORMULA MARKET, 6 Fig. 3. (March 2023), *available at* https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/immediate-national-strategy-increase-resiliency-us-infant-formula-market.

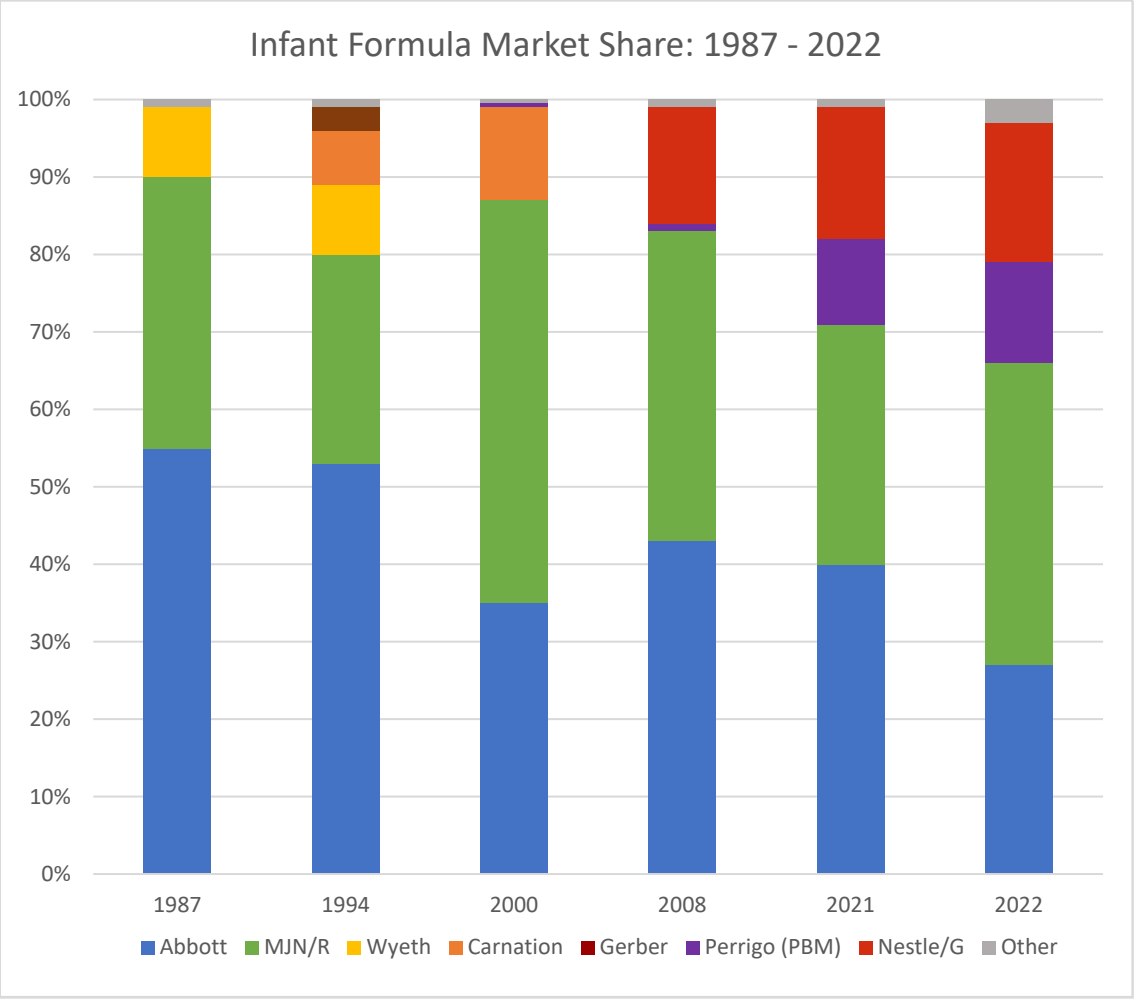
[33] Data is current as of CY 2022 and is provided by Circana, Inc. This does not account for Perrigo's purchase of Nestlé/Gerber. *Id. See also infra* note 34.

[34] In the fourth quarter of 2022, Perrigo purchased Nestlé/Gerber's primary infant formula manufacturing facility. *See* PERRIGO, *Perrigo purchases Nestlé's Gateway infant formula plant,* https://www.perrigopediatrics.com/infant-formula-investment-nestle-gateway-plant/default.aspx (last visited Aug. 24, 2023).

[35] Infant formula sold by PBM was manufactured by Wyeth. Wyeth was acquired by Nestlé in 2012, while PBM was acquired by Perrigo in 2010. USDA ERS 2001 Interim Report at 10. *See also* PERRIGO, *Perrigo Acquires Infant Formula Manufacturer PBM Holdings for $808 Million* (Mar. 23, 2010), https://investor.perrigo.com/2010-03-23-Perrigo-Acquires-Infant-Formula-Manufacturer-PBM-Holdings-for-808-Million; NESTLE, *Wyeth nutrition acquisition*, https://www.nestle.com/investors/overview/mergers-and-acquisitions/wyeth-nutrition-acquisition (last visited Aug. 24, 2023).

[36] The 2021 and 2022 estimates for Perrigo's market share include all "private label" brands, which may include manufacturers other than Perrigo. *See* U.S. FOOD & DRUG ADMIN., IMMEDIATE NATIONAL STRATEGY, *supra* note 32.

Figure 1 – Share of U.S. Infant Formula Market



Abbott

Abbott Laboratories, doing business as Abbott Nutrition ("Abbott"), was the largest powdered infant formula supplier before the shutdown of its Sturgis, Michigan facility in early 2022.[37] Abbott manufactures several varieties of Similac brand products in addition to several specialty formulas such as EleCare and related nutritional products. Abbott acquired the Similac brand in 1964 with its acquisition of M&R Dietetics Laboratories[38] (later known as Ross Laboratories or Ross Products), including its two operating formula factories in Columbus, Ohio and Sturgis, Michigan.[39]

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[37] *Explainer: What happened with Abbott baby formula that worsened a U.S. shortage?*, REUTERS (May 17, 2022), https://www.reuters.com/business/healthcare-pharmaceuticals/what-happened-with-abbott-baby-formula-that-worsened-us-shortage-2022-05-16.

[38] *ABBOTT ACQUIRING M. & R. DIETETIC; Big Drug Company Plans to Buy Specialty Food Maker Xerox Corporation And Electro-Optical Systems Glidden Company And Macco Chemical United Utilities, Inc. And Inter-Mountain Telephone The Times Mirror Co. And World Publishing*, N.Y. TIMES (Dec. 13, 1963), https://www.nytimes.com/1963/12/13/archives/abbott-acquiring-m-r-dietetic-big-drug-company-plans-to-buy.html.

[39] Ohio History Central, *M&R Dietic Laboratories*, https://ohiohistorycentral.org/w/M_%26_R_Dietetic_Laboratories (last visited Aug. 24, 2023).

Mead Johnson/Reckitt Benckiser

Mead Johnson has manufactured and sold infant formula since 1911, including the popular Enfamil brand formula since 1959.[40] Mead Johnson was owned by Bristol-Myers from 1968 until it was spun off into a standalone company in 2009.[41] In 2017, Reckitt Benckiser Group plc acquired Mead Johnson, which it now operates as a wholly owned subsidiary.[42]

Nestlé/Gerber

Nestlé, which until recently owned the Gerber Good Start brand, has a long history in the U.S. infant formula market since at least the 1870s when it introduced Nestlé's Infant Food, which was the first wholly artificial formula sold in the United States.[43] Nestlé acquired the Good Start brand as part of its 2007 acquisition of Gerber[44] and acquired Wyeth's formula brands in 2012.[45] In December 2022, Nestlé sold the U.S. and Canadian rights to the Gerber Good Start brand to Perrigo, along with its manufacturing plant in Wisconsin.[46]

Perrigo/PBM

Perrigo acquired PBM Holdings in 2010.[47] PBM was then the world's largest manufacturer of store brand infant formula.[48] It sold infant formulas under its own label as well as under private-label brands, including chain stores like Wal-Mart and Target,[49] in addition to newer brands like Bobbie, which do ordinarily participate in the WIC Program .[50]

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[40] *A concise history of infant formula (twists and turns included)*, CONTEMPORARY PEDIATRICS (Feb. 1, 2023), https://www.contemporarypediatrics.com/view/concise-history-infant-formula-twists-and-turns-included; RECKITT BENCKISER, *Our Brands: Enfa*, https://www.reckitt.com/brands/enfa/ (last visited Aug. 24, 2023).

[41] Claire M. Reckert, *Exchange of Stock Set; MERGERS DEAL SET BY BRISTOL-MYERS*, N.Y. TIMES (Aug. 25, 1967), https://www.nytimes.com/1967/08/25/archives/exchange-of-stock-set-merger-deal-set-by-bristolmyers.html.

[42] MEAD JOHNSON NUTRITION, *Mead Johnson Nutrition Merger with Reckitt Benckiser Completed* (June 15, 2017), https://www.meadjohnson.com/news/press-releases/mead-johnson-nutrition-merger-reckitt-benckiser-completed.

[43] *See* Contemporary Pediatrics, *supra* note 40; Emily E. Stevens, et al., *A History of Infant Feeding,* JOURNAL OF PERINATAL EDUCATION (Spring 2009), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2684040.

[44] NESTLE, *Nestlé completes its acquisition of Gerber* (Sep. 3, 2007), https://www.nestle.com/media/pressreleases/allpressreleases/nestl%C3%A9_completes_its_acquisition_of_gerber.

[45] NESTLE, *Wyeth nutrition acquisition*, https://www.nestle.com/investors/overview/mergers-and-acquisitions/wyeth-nutrition-acquisition (last visited Aug. 24, 2023).

[46] *Supra* notes 34 and 44. However, Nestlé is to continue to fulfill existing WIC contracts. NESTLE, *Perrigo Announces Strategic Investment to Expand and Strengthen U.S. Manufacturing of Infant Formula* (Nov. 1, 2022), https://www.nestleusa.com/media/pressreleases/perrigo-purchases-infant-formula-plant-rights-good-start; PERRIGO, *Perrigo purchases Nestlé's Gateway infant formula plant* (2022), https://www.perrigopediatrics.com/infant-formula-investment-nestle-gateway-plant.

[47] PERRIGO, *Perrigo Acquires Infant Formula Manufacturer PBM Holdings for $808 Million* (Mar. 23, 2010), https://investor.perrigo.com/2010-03-23-Perrigo-Acquires-Infant-Formula-Manufacturer-PBM-Holdings-for-808-Million.

[48] *Id.*

[49] USDA ERS 2001 Interim Report at 11.

[50] Bobbie Baby LLC, a self-described "European style organic baby formula" manufacturer, names Perrigo as a "trusted co-manufacturer" on its website. BOBBIE, *Bobbie Formula Safety and Quality: Manufacturing*, https://www.hibobbie.com/pages/safety (last visited Aug. 24, 2023).

B. The Specialty Infant Formula Market

While often thought of as a single nationwide market, there are distinct types of infant formula and each may be uniquely affected by supply disruptions. Most healthy, term infants who are fed commercial products are given regular—also known as routine—formulas based on ingredients derived from cow's milk or soy, some of which may be marketed as particularly appropriate for sensitive stomachs or meeting other specific needs.

However, some infants require specialty formulas[51] to address allergies, metabolic disorders, and other serious medical conditions.[52] Similarly, there are also infant formulas for premature or low birth weight infants, as well as milk fortifiers and similar products.[53] The top specialty infant formula brands include Similac Special Care, Similac Alimentum, and Elecare, all manufactured by Abbott, along with Enfamil Premature, Enfamil Nutramigen, and PurAmino, manufactured by Mead Johnson. Routine infant formula cannot be substituted for specialty infant formula, and an abundance of routine infant formula does not help infants in need of specialty formula. The specialty formula industry may be even more concentrated than the routine infant formula market. Before the 2022 recall, Abbott's leading specialty infant formula products, Similac Alimentum and Elecare, held high market share in their respective categories and were produced at Abbott's Sturgis facility.[54]

III. The WIC Program

A notable feature of the U.S. infant formula market is that more than half of the routine infant formula sold in the United States—56% as of 2018—is purchased by participants in the WIC Program.[55] Since 1989, WIC State agencies have procured infant formula pursuant to contracts in which manufacturers agree to provide large rebates in exchange for single-supplier contracts. As discussed further below, manufacturers who hold single-supplier WIC State contracts also tend to dominate infant formula sales outside of the WIC Program in that state. While these contracts can significantly lower overall WIC Program costs, this approach comes with certain tradeoffs—including the risk that states become overly reliant on a single source of supply, the risks of foreclosing competition or creating barriers

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[51] Usage of the term "specialty formula" varies across government and industry usage. As used here, "specialty formula" refers to types of infant formula products that are medically required, not merely premium brands or brands with atypical qualities. *See, e.g.,* U.S. FOOD & DRUG ADMIN., *Information Regarding Medically Necessary Specialty Infant Formulas: Notice to Health Care Providers* (July 1, 2022), https://www.fda.gov/safety/medical-product-safety-information/information-regarding-medically-necessary-specialty-infant-formulas-notice-health-care-providers (describing "specialty, amino acid-based, and metabolic infant formula products").

[52] U.S. FOOD & DRUG ADMIN., *Exempt Infant Formulas Marketed in the United States by Category*, https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/exempt-infant-formulas-marketed-united-states-manufacturer-and-category (updated Dec. 3, 2019).

[53] *Id.*

[54] *See* ABBOTT, *Abbott Restarts Production of Specialty Formulas at its Michigan Plant* (June 4, 2022), https://www.abbott.com/corpnewsroom/nutrition-health-and-wellness/abbott-update-on-powder-formula-recall.html (stating that Abbott was restarting production of EleCare and other specialty and metabolic formulas before regular/routine formula types).

[55] *Infants in USDA's WIC Program consumed an estimated 56 percent of U.S. infant formula in 2018*, USDA ERS, https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=103970 (updated May 23, 2022).

to entry that prevent new manufacturers from coming to market, and the risk of unintended spillover effects on the non-WIC infant formula market.

WIC provides nutritious foods, nutrition education, breastfeeding support, and referrals to healthcare providers and other services for nutritionally at-risk pregnant participants, breastfeeding and non-breastfeeding postpartum participants, infants, and children up to age five.[56] WIC is intended to serve as an adjunct to health care during critical times of growth and development to prevent health problems and to improve the health status of participants.[57] Eligible participants receive vouchers, checks, or electronic benefit transfer cards for specific amounts of foods based on their participant category, nutritional needs, and any other relevant medical or dietary factors. Many participants redeem their food benefits, including infant formula, at authorized retail vendors free of charge.

To be eligible for WIC, an applicant must be at nutritional risk (based on criteria established by a physician or nutritionist) and have household income no greater than 185% of the federal poverty line, which translates to an annual income of $49,0225 for a four-person household in 2022, or they may be considered income-eligible for WIC if they participate in Supplemental Nutrition Assistance Program (SNAP), Temporary Assistance for Needy Families (TANF) or Medicaid.[58]

WIC is administered by the USDA's Food and Nutrition Service through state and local WIC agencies that provide services to more than 6.2 million adult participants, infants, and children in FY 2022. As shown in Table 2 below, according to USDA Food and Nutrition Service statistics, WIC served 88,000 participants when it began in 1974. The program grew to nearly 9.2 million participants in 2010, before falling to less than 6.3 million as of 2022.[59]

[56] Victor Oliveira and Elizabeth Frazão, *The WIC Program: Background, Trends, and Economic Issues, 2015 Edition*, USDA ERS BULLETIN No. 134, 1 (Jan. 2015), *available at* https://www.ers.usda.gov/webdocs/publications/43925/50999_eib134.pdf?v=8038.2 [hereinafter *USDA ERS WIC 2015 Report*].

[57] *Id*.

[58] U.S. DEPT. OF AGRICULTURE, WIC POLICY MEMORANDUM No. 2021-5 (Mar. 15, 2021), *available at* https://fns-prod.azureedge.us/sites/default/files/resource-files/WIC-Policy-Memo-2021-5-IEG.pdf#page=3.

[59] U.S. DEPT. OF AGRICULTURE, Food and Nutrition Service, WIC Data Tables, National Level Annual Summary, FY1974-2022, *available at* https://www.fns.usda.gov/pd/wic-program (last visited Oct. 19, 2023).

Table 2 – USDA Food and Nutrition Service - WIC Program Participation and Costs[60]

Fiscal Year	Total Participation	Total Annual Costs (Millions of Dollars)	Average Monthly Food Cost Per Person (Dollars)
1974	88,000	$10.4	$15.68
1975	344,000	$89.3	$18.58
1980	1,914,000	$727.7	$25.43
1990	4,517,000	$2,122.4	$30.20
2000	7,192,000	$3,982.1	$33.06
2010	9,175,000	$6,689.9	$41.43
2020	6,247,000	$5,011.7	$38.48
2022	6,260,000	$5,736.3	$47.75

A. Single-supplier WIC State Contracts

In the late 1980s, in an attempt to control costs, WIC State agencies began conducting procurement auctions in which they agreed to procure all routine infant formula from a single manufacturer in exchange for manufacturers providing post-sale rebates to the WIC State agency.

Infant formula manufacturers respond to WIC State agency solicitations by submitting a bid indicating the rebate amount they would be willing to pay to be chosen as the single supplier for all forms of routine infant formula. The manufacturer offering the lowest net price wins the contract. This system incentivizes a manufacturer to offer a large rebate (effectively, a low net price) to win the contract.

In 1986, Tennessee became the first state to implement a single-supplier WIC contract rebate program.[61] In 1989, Congress passed the Child Nutrition and WIC Reauthorization Act, which required all WIC State agencies to solicit single-supplier WIC rebate contracts unless they could find an alternative method that would produce equal or greater savings to the government.[62]

Over time, infant formula manufacturers became increasingly willing to pay large rebates to become states' sole WIC suppliers. In 2013, WIC rebates averaged 92% of the wholesale price of infant formula for brands participating in the WIC Rebate Program.[63] This meant that the infant formula manufacturer on average retained 8% of the wholesale price of WIC infant formula after paying the rebate to the state on formula purchased through WIC.

WIC State agencies in recent years have recouped a large percentage of infant formula spending in the form of WIC rebates. In 2018, WIC participants redeemed $2.23 billion worth of infant formula at

[60] *Id*.

[61] *Id. at* 17; Victor Oliveira, et al., *WIC and the Retail Price of Infant Formula*, USDA ERS REP. No. 39, 11 (May 2004), *available at* https://www.ers.usda.gov/webdocs/publications/46787/15976_fanrr39-1_1_.pdf?v=7740.2.

[62] USDA ERS WIC 2015 Report at 17.

[63] *Id.* at 14.

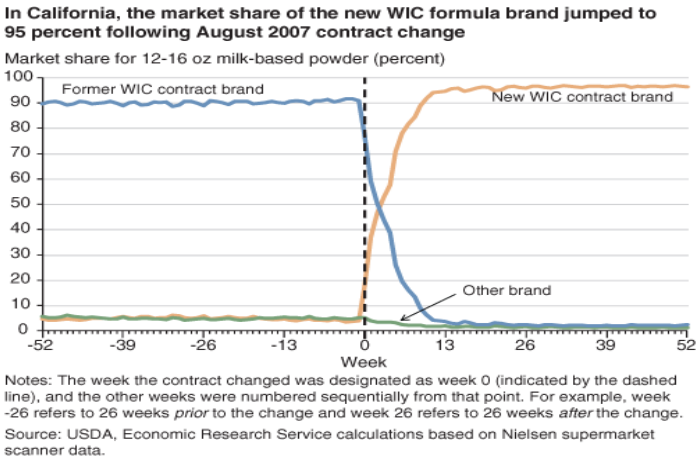
the retail level.[64] WIC State agencies then received $1.72 billion in manufacturer rebates for a net cost of $514.5 million, which reflects a 77% discount off the original retail price.[65]

B. Volume Spillover Effects

One of the most significant aspects of the single-supplier WIC contract mechanism is that infant formula manufacturers who capture such single-supplier contracts not only secure all WIC sales in the covered state but also benefit from an increased share of infant formula sales sold outside the WIC Program in that state.[66] This is commonly referred to as "spillover" sales, volume "spillover," or the "WIC halo effect."

The existence of single-supplier WIC contract volume "spillover" effects has been extensively studied and documented. For instance, Figure 2 below shows how California infant formula market shares changed after a different company secured the state's WIC contract in 2007.[67] As shown, sales of the former WIC brand decreased from 90% to 5% of the 12-16 oz milk-based powder market, while the new WIC brand increased its share from 5% to 95% after securing the California single-supplier WIC contract. Dramatic changes in market share have likewise been observed across 29 other states.[68]

Figure 2 – USDA Economic Research Service – How WIC Affects the Infant Formula Market



[64] WIC State agencies reimburse retailers the full retail price of infant formula before submitting and receiving a manufacturer rebate on each WIC unit sold. *Id.* at 53. *See also* Tina L. Saitone, et al., *Cost Implications of Participant Product Selection in USDA's Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)*, USDA ERS BULLETIN No. 299, 3 n.5 (Oct. 2021), https://www.ers.usda.gov/webdocs/publications/102307/err-299.pdf?v=6307.4.

[65] Nicole Kline, et al., *WIC Participant and Program Characteristics 2018 Food Packages and Costs Final Report*, USDA, iii (Nov. 2020), https://fns-prod.azureedge.us/sites/default/files/resource-files/WICPC2018FoodPackage-1.pdf.

[66] Victoria Oliveira, et al., *The Infant Formula Market Consequences of a Change in the WIC Contract Brand*, USDA ERS REP. No. 124 (Aug. 2011), https://www.ers.usda.gov/webdocs/publications/44900/6918_err124.pdf?v=8349.4; Victoria Oliveira, *Winner Takes (Almost) All: How WIC Affects the Infant Formula Market*, USDA ERS (Sep. 1, 2011), https://www.ers.usda.gov/amber-waves/2011/september/infant-formula-market; USDA ERS 2011 Report at 18–20.

[67] Oliveira, *Winner Takes (Almost) All*, *supra* note 66.

[68] *Id.*

Similarly, a 2018 study examined WIC spillover effects using Nielsen retail data from 2007 to 2013 and concluded that securing a WIC contract increased state-level market share for WIC infant formula sales, non-WIC infant formula sales, as well as toddler formula drinks (which are not covered by the WIC program).[69] Another 2020 study examined 2006 to 2015 Nielsen retail data and concluded that winning a WIC contract was associated with a 322% increase in sales of WIC-eligible formula products in the state for the winning WIC brand and a decline of 77% in sales of the former brand.[70]

Researchers have proposed a variety of factors that potentially contribute to these volume spillover effects.[71] First, one longtime explanation is that WIC-brand products are given better shelf space and product placement as a result of the size of the WIC market.[72] Second, another potential factor is the prevalence of hospital and physician recommendations, who tend to recommend WIC-brand formulas even to non-WIC customers.[73] Third, researchers have proposed that the appearance of WIC logos on shelf labels may be viewed by some non-WIC consumers as the government's endorsement of a product by virtue of association with the WIC Program.[74] Finally, researchers have proposed that WIC participants tend to continue to purchase WIC-brand formulas when their benefits are depleted or after they leave the WIC program (including in related product categories such as toddler formula).[75]

IV. Advantages and Disadvantages of the Current WIC Rebate Program

A. Public Submissions to the RFI

The FTC received a total of 315 public comments in response to our May 24, 2022 RFI. Comments focused on the WIC Program provided viewpoints about various aspects of WIC. Some emphasized the large savings from WIC rebates and the importance of those savings in providing WIC benefits to millions of additional beneficiaries.[76] Other commentors highlighted the fact that the U.S. infant formula market

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[69] Christian A. Rojas and Hongli Wei, *Spillover Mechanisms in the WIC Infant Formula Rebate Program*, J. OF AGRICULTURAL & FOOD INDUS. ORG., 11 (Dec. 14, 2018), *available at* https://www.degruyter.com/document/doi/10.1515/jafio-2018-0019/html ("Our results indicate that, immediately after the contract change, the winning manufacturer experiences a significant increase in its market share for all three types of formula.").

[70] Yoon Y. Choi, et al., *Effects of United States WIC infant formula contracts on brand sales of infant formula and toddler milks*, J. OF PUBLIC HEALTH POLICY (Apr. 30, 2020), at 9, *available at* https://media.ruddcenter.uconn.edu/PDFs/Choi2020_Article_EffectsOfUnitedStatesWICInfant.pdf.

[71] Rojas and Wei, *supra* note 69 at 2 (reviewing existing literature).

[72] *Id*. (*citing* GOV'T ACCOUNTABILITY OFFICE, SOME STRATEGIES USED TO MARKET INFANT FORMULA MAY DISCOURAGE BREASTFEEDING: STATE CONTRACTS SHOULD BETTER PROTECT AGAINST MISUSE OF WIC NAME, GAO-06-28 (2006)).

[73] *Id*. (*citing* Oliveira, et al., *Rising Infant Formula Costs to the WIC Program Recent Trends in Rebates and Wholesale Prices*, USDA ERS Rep. No. 93 (2010) and Oliveira, et al., *The Infant Formula Market: Consequences of a Change in the WIC Contract Brand*, USDA ERS Rep. No. 124 (2011)).

[74] *Id*. (*citing* Huang and Perloff, *WIC Contract Spillover Effects*, R. OF INDUSTRIAL ORGANIZATION, 44: 49–71 (2014)).

[75] *Id*. (*citing* Oliveira, Frazão, and Smallwood, *The Infant Formula Market: Consequences of a Change in the WIC Contract Brand*, USDA ERS Rep. No. 124 (2011)).

[76] *See, e.g.*, Center on Budget and Policy Priorities, Comment Letter on Infant Formula Shortage, 4 (June 24, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0067 ("Nationwide, the competitive bidding process yields $1 billion to $2 billion a year in rebates. . . . The 2021 savings of $1.6 billion were enough to provide WIC benefits to more than 2 million low-income women, infants, and young children."); National WIC Association Comment

has been highly concentrated for decades and was even more concentrated before the introduction of single-supplier WIC contracts in the late 1980s, suggesting that single-supplier WIC contracts may not be the cause of market concentration.[77]

Conversely, other commentors were concerned about the impact of the WIC Program and state single-supplier rebate contracts on competition. One smaller infant formula brand opined that the current WIC bidding process "places significant hurdles for small-to-medium infant formula manufacturers" and allows "giant companies to consume the majority of the market."[78] Consumers and those involved in the WIC Program also pointed to how single-supplier WIC State contracts can result in a lack of consumer choice.[79]

B. Single-Supplier Rebates Reduce WIC Program Costs and Expand Access

There are advantages to the current WIC structure of awarding single-supplier contracts within each state in exchange for large manufacturer rebates. The single-supplier WIC contract mechanism creates large savings for the government, which allow WIC to provide benefits within existing budget allocations to more families than it could otherwise.[80] Unlike other federal food programs, which operate as "entitlements" to eligible beneficiaries, WIC is subject to annual appropriations. Infant formula rebates reduce a state agency's overall food benefit costs and allow a state agency to serve more people than they otherwise would be able to with their appropriated grant funding.[81] One 2017 report estimated that WIC would have served roughly 2 million fewer participants in 2016 without infant formula rebates—roughly a one-fourth reduction of the overall program.[82]

C. Single-Supplier WIC Contracts May Make Each State Dependent on a Single Manufacturer

While cost effective, the current single-supplier WIC contract mechanism may make the U.S. infant formula market more fragile. The single-supplier contract mechanism, combined with the size of WIC in the infant formula market and documented volume spillover effects, means that the manufacturer

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Letter ("For more than three decades, WIC's competitive bid process for infant formula has worked efficiently to generate federal savings and secure a strong deal for taxpayers.").

[77] Robert Greenstein, Comment Letter on Infant Formula Shortage, 2 (June 24, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0062 ("In either case, this is slightly lower than the degree of market concentration before WIC competitive bidding became widespread at the end of the 1980s. Before WIC competitive bidding, just two companies — Abbott Laboratories (now Abbott Nutrition) and Mead Johnson — controlled 90 percent of the market.").

[78] Bobbie Comment Letter at 2 (citing "the cost to compete, the required product offerings, and inconsistent federal requirements (FDA approval vs. USDA approval)").

[79] *See, e.g.*, Anonymous WIC Dietician Comment Letter ("Market competition is healthy for the economy. Market options should be available for formula companies with high quality practices and innovation rather than just market dominance and profitability. . . .").

[80] Zoë Neuberger, et al., *Infant Formula Shortage Highlights WIC's Critical Role in Feeding Babies*, CENTER ON BUDGET AND POLICY PRIORITIES (June 22, 2022), *available at* https://www.cbpp.org/research/food-assistance/infant-formula-shortage-highlights-wics-critical-role-in-feeding-babies.

[81] *Id*.

[82] Steven Carlson, et al., *WIC's Competitive Bidding Process for Infant Formula Is Highly Cost Effective*, CENTER ON BUDGET AND POLICY PRIORITIES (Feb. 17, 2017), https://www.cbpp.org/research/food-assistance/wics-competitive-bidding-process-for-infant-formula-is-highly-cost.

holding each state's WIC contract dominates that states' market with an average of 84% market share.[83] By rendering each state dependent on a single manufacturer for the vast majority of its infant formula supply, single-supplier contracts can make it more likely that a lone contaminant outbreak or incident will have cascading and outsized effects leading to serious supply disruptions.

In effect, the United States has up to fifty individual state infant formula markets each dominated by a single manufacturer with market share that far exceeds the share of any manufacturer in the nationwide market.[84] This outcome is primarily the result of the Child Nutrition and WIC Reauthorization Act,[85] which requires single-supplier WIC contracts unless an alternative method can produce equal or greater savings. While this system has greatly expanded the number of WIC recipients (with attendant benefits of improved infant and maternal health), the inherent risks of state-by-state concentration became apparent during recent supply disruptions.

Even if the overall national infant formula supply is held constant, each state's reliance on a single manufacturer means that shifting products towards impacted states when disruptions arise can be a challenge. A disruption in a highly concentrated state market may require significantly modified supply chains, which may require new agreements between manufacturers, distributors, and retailers before alternate supply can physically enter the state. Additionally, all such alternate commercial arrangements must be made in compliance with state and federal WIC regulations for WIC families to ultimately access alternate brands at the retail point-of-sale.

Over the last few years, the American people have repeatedly been reminded that neglecting to invest in the resilience of our manufacturing capacity, supply chains, distribution networks, and transportation networks can render us highly susceptible to large-scale supply disruptions and shortages. Policies and programs relating to infant formula should be assessed with an eye towards promoting resilience so that when contaminant outbreaks, natural disasters, or other incidents occur, our markets are less susceptible to wide-scale shocks and large-scale supply disruptions. Policymakers may want to consider that state single-supplier WIC contracts are contributing to high levels of concentration at the state level, which can leave states extremely vulnerable to supply disruptions.

D. Single-Supplier WIC Contracts May Foreclose Competitors and Increase Risk of Collusion

In addition to increasing state-level concentration, single-supplier WIC contracts may also contribute to increased nationwide concentration by foreclosing smaller companies from competing for the entire WIC share of the market (in addition to any volume spillover sales). Smaller manufacturers generally lack sufficient scale to afford the same scale and rebates as the largest incumbent manufacturers. USDA data shows that between 2003 and 2013, only the three largest manufacturers (Abbott, Mead Johnson/Reckitt Benckiser, and Gerber/Nestlé, now Perrigo in North America) have ever bid on a single-supplier WIC contract.[86]

Single-supplier WIC contracts are expressly intended to trade the cost-savings from manufacturer rebates for exclusivity. This means that market entrants without sufficient scale or brand incumbency to

[83] USDA ERS 2011 Report at 16.

[84] Some states form multistate alliances to jointly solicit bids for WIC contracts. *Id.* at 3.

[85] USDA ERS WIC 2015 Report at 17.

[86] *See generally* David E. Davis and Victor Oliveira, *Manufacturers' Bids*, *supra* note 27.

compete for single-supplier WIC contracts are essentially foreclosed from competing for the vast majority of each state's market for the duration of each WIC contract.

A single-supplier contracting system with only a few established market participants also greatly increases the risk of tacit or explicit collusion. In 1992, the FTC charged Abbott, Mead Johnson, and American Home Products Corp. (later known as Wyeth) with an unfair method of competition in violation of Section 5 of the FTC Act for sharing their respective strategies before the Puerto Rico WIC bidding process.[87] In addition, in 1991, the Florida Attorney General brought a complaint against infant formula manufacturers alleging price-fixing in the infant formula market.[88]

E. The WIC Program May Have Multiple Spillover Effects on the Non-WIC Infant Formula Market and Non-WIC Participants

In addition to volume spillover effects—in which the winner of each state's single-supplier WIC contract also captures the majority of non-WIC infant formula sales, as described in Section III.B. above—there are several other spillover effects of the WIC Program on the non-WIC infant formula market and non-WIC participants.

Studies have found a positive spillover effect from the WIC Program in reducing childhood anemia among non-WIC children as a result of products being fortified with iron to comply with WIC Program standards.[89] Additionally, other studies have found positive spillover effects from WIC regarding access to healthy foods and improvements in the diets of WIC participants' family members.[90]

However, not all potential spillover effects from WIC may be as unambiguously positive. One longtime concern is that the WIC Program may increase retail prices for infant formula purchased outside the WIC Program. In the early 1990s, the U.S. Senate held hearings on infant formula prices,[91] which had doubled over the 1980s and appeared to exceed increased costs of inputs.[92]

One theory as to how WIC contributes to formula price increases is that the expansion of the WIC Program to approximately 50% of the overall market transformed many of the most price-sensitive purchasers (low-income WIC-eligible families) into entirely non-price sensitive purchasers by eliminating their exposure to the ordinary retail price, since WIC covers 100% of the cost of formula at the point-of-sale.[93] One 2009 study funded by the USDA Economic Research Service examined this theory and

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[87] *FTC Files Antitrust Charges Against 3 Largest Makers of Infant Formula*, AP NEWS (June 12, 1992), https://apnews.com/article/fcf10a6ea4a084cf875bcd8be75911a4.

[88] *Florida v. Abbott Laboratories*, No. 91-40002, *In re Infant Formula Antitrust Litigation*, MDL 878 (N.D. Fla, 1991); 1993-1 Trade Cas. (CCH) ¶ 70,241 (N.D. Fla. 1993).

[89] USDA ERS WIC 2015 Report at 33.

[90] *Id.*

[91] SENATE JUDICIARY COMMITTEE, SUBCOMMITTEE ON ANTITRUST, MONOPOLIES, AND BUSINESS RIGHTS, COMPETITIVE ISSUES IN THE INFANT FORMULA PRICING (May 29, 1990), *available at* https://books.google.com/books?id=4ZcTAAAAIAAJ&printsec=frontcover&source=gbs_ge_summary_r&cad=0#v=onepage&q&f=false.

[92] David Betson, *Impact of the WIC Program on the Infant Formula Market*, USDA ERS CONTRACTOR AND COOPERATOR Rep. No. 61, 3-4, 10 (Jan. 2009), *available at* https://naldc.nal.usda.gov/download/32816/pdf ("Over the 1980s, the real price of formula continually rose and the existing three companies appeared to adjust their prices in lock step. . . It was not until the late 1990s that the real price of formula appears to have stabilized at a level that is roughly twice the real price of formula in 1981.") [hereinafter *Betson Report*].

[93] *Id.* at 3–4.

estimated that the expansion of WIC coverage was a primary factor in the increase in the real wholesale price of infant formula from 1980 to 2002. The report notes:

> "When the government provides formula to these families, the effect is to increase the total demand for formula and create a total demand for formula that is less sensitive to price [c]onsequently allowing firms with market power to charge a higher price for infant formula".[94]

In other words, roughly 50% of infant formula purchases in the United States are made by WIC participants whose purchases are subsidized by the program. This sizeable population with decreased price sensitivity may allow manufacturers to raise their wholesale prices above what they would be in the absence of the WIC Program.

The possibility that WIC increases retail prices for non-WIC infant formula purchasers is worthy of attention from policymakers. At first blush, it may seem to be a reasonable tradeoff given that more affluent purchasers who do not qualify for WIC are better positioned to pay more. But given that the WIC cut-off for benefits corresponds to an annual income of $32,227 for two-person household, or $49,025 for a four-person household as of 2022, it may still prove concerning.[95] An unintended result of the WIC Program, as currently designed, may be that it exposes many non-affluent families who purchase infant formula outside the WIC Program to higher prices.

V. FDA Regulation of Infant Formula

As Justice Felix Frankfurter of the United States Supreme Court stated in 1943, food regulations concern "the lives and health of people which, in the circumstances of modern industrialism, are beyond self-protection."[96] This sentiment may ring even truer today. Apart from breastmilk, infant formula is the sole source of nutrition for newborns.[97] Accordingly, the FDA has an extensive regulatory process in place to ensure that infant formula is safe and provides infants with all nutrition necessary for healthy development at a vulnerable stage of life. Some commentators, however, have argued that certain FDA regulatory procedures and requirements, some of which were established by Congress, can also create entry barriers and impede the government's response to supply disruptions.

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[94] *Id. See also* Victor Oliveira and Elizabeth Frazão, *Painting a More Complete Picture of WIC: How WIC Impacts Nonparticipants*, USDA ERS (Apr. 6, 2015), https://www.ers.usda.gov/amber-waves/2015/april/painting-a-more-complete-picture-of-wic-how-wic-impacts-nonparticipants/ ("Together, these studies suggest that WIC and its infant formula rebate program result in higher formula prices for non-WIC consumers, thereby impacting the food budgets of non-WIC families with formula-fed infants.").

[95] U.S. DEPT. OF AGRICULTURE, WIC POLICY MEMORANDUM No. 2021-5, *Publication of the 2021-2022 Special Supplemental Nutrition Program for Women, Infants and Children (WIC) Income Eligibility Guidelines* (Mar. 15, 2021), *available at* https://fns-prod.azureedge.us/sites/default/files/resource-files/WIC-Policy-Memo-2021-5-IEG.pdf#page=3.

[96] *United States v. Dotterweich,* 320 U.S. 277, 281 (1943).

[97] U.S. FOOD & DRUG ADMIN., FDA EVALUATION OF INFANT FORMULA RESPONSE, 7 (Sep. 2022), *available at* https://www.fda.gov/media/161689/download [hereinafter *FDA Evaluation of Infant Formula Response, September 2022*].

A. History of FDA Regulation: The Legacy of Syntex

The history of FDA regulation of infant formula follows the pattern of corporate scandal and public outcry.[98] In the early 1970s, infant formula was relatively unregulated. The leading manufacturer of soy-based baby formula, Syntex Corporation, changed its infant formula ingredients in 1978 after one of its nutritionists proposed removing salt, an ingredient providing electrolyte chloride that is key for infant growth.[99] The change went unnoticed, as it was not on packaging and advertising and Syntex's scientists no longer tested chloride levels.[100]

Over a hundred cases of Bartter's Syndrome, a rare disease caused by a chemical imbalance in the blood, were reported by October of 1978 in infants fed Syntex formula.[101] Syntex recalled the affected formula products,[102] though some low-chloride products remained on store shelves by year's end.[103] Syntex's president defended the decision to remove salt as well-intentioned, stating that "the medical profession, strongly supported by consumer groups, has taken the position that having salt in baby food is bad for children. Many companies removed salt from their products and were praised for it."[104] Government investigations and private lawsuits followed.[105]

Carole Laskin and Lynne Pilot, two Washington-based mothers whose infants had consumed Syntex formulas, launched an advocacy group calling for reform in baby formula testing.[106] In September of 1980, the milestone Infant Formula Act was passed and became part of the Federal Food, Drug, and Cosmetic Act.[107] In 1986, amendments passed as part of the Anti-Drug Abuse Act increased the

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[98] For instance, the original Food and Drugs Act was passed in 1906 following public concern regarding food handling industries. *History of FDA, 1906*, FDA.GOV, https://www.fda.gov/about-fda/fda-history/milestones-us-food-and-drug-law (updated Jan. 20, 2023).

[99] *Infant Formula Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Interstate and Foreign Commerce*, 96th Cong., 1st Sess. 63 (1979) (testimony of Paul E. Freiman, President, Syntex), *available at* https://www.google.com/books/edition/_/VnMmAAAAMAAJ?hl=en&gbpv=1&bsq=salt%20in%20baby [hereinafter *1979 Subcommittee Hearings*].

[100] Randal D. Shields, *Food and Drug Law: The Infant Formula Act of 1980*, 15 AKRON L. R., 752, 755–56 (1982) *available at* https://ideaexchange.uakron.edu/akronlawreview/vol15/iss4/7. *See also* David Kurlander, *'The Sole Source of Nutrients': The Syntex Scandal and Federal Regulation of Baby Formula*, CAFE (July 28, 2022), https://cafe.com/article/the-sole-source-of-nutrients-the-syntex-scandal-and-federal-regulation-of-baby-formula.

[101] Symptoms were later diagnosed to be metabolic alkalosis. *See* Shields, *supra* note 100 at 753 (*citing Infant Metabolic Alkalosis and Soy-Based Formula*, MORBIDITY WEEKLY REP. 358 (Aug. 3, 1979); Roy and Arant, *Alkalosis From Chloride-Deficient Neo-Mull-Soy*, 301 NEW ENG. J. MED. 615 (1979); Greenberg, et al., *Withdrawal of Two Soy-Based Infant Formulae*, THE LANCET 462 (Sep. 1979)).

[102] *See* Shields, *supra* note 100 at 755, 762–63 ("Late on August 1st, Syntex made the decision to voluntarily recall the formulas. The FDA concurred with the recall documents prepared by Syntex, and the announcements were made on August 2, 1979.").

[103] *Id*. at 762–63.

[104] *See* 1979 Subcommittee Hearings, *supra* note 97.

[105] *See* Shields, *supra* note 100 at 756 n.86; Kurlander, *supra* note 100.

[106] Kurlander, *supra* note 100; Linda Greenhouse, *Consumer Saturday; Safeguards on Baby Formula*, N.Y. TIMES (May 31, 1986), https://www.nytimes.com/1986/05/31/style/consumer-saturday-safeguards-on-baby-formula.html.

[107] *Milestones in U.S. Food and Drug Law*, FDA.GOV, *available at* https://www.fda.gov/about-fda/fda-history/milestones-us-food-and-drug-law.

frequency and breadth of FDA oversight into the formulation and production process.[108] In 2014, FDA rulemaking implemented the remaining provisions of the 1986 amendments and established the quality factor requirements along with updated manufacturing practices and quality control procedures.[109]

B. Current Regulatory Framework

Supply Timeline

Current infant formula regulations cover formulation, the regulatory submission process, manufacturing and marketing, and ongoing monitoring requirements. New infant formulas must meet the FDA's two "quality factors," which generally require weeks of clinical testing to determine if, first, the formula contains proteins of "sufficient biological quality"[110] and, second, supports normal physical growth.[111] Satisfying these factors generally requires the manufacturer to run a specific preclinical study measuring protein efficiency[112] and conduct a "well-controlled growth monitoring study,"[113] which typically requires a minimum of fifteen weeks, with enrolled infants no older than two weeks, collecting detailed data including weight, length, and head circumference at frequent, scheduled intervals.[114] Analysis of collected data and any adverse events during the study must be reported.[115] For formulas that are not new or are formulated for infants with specialized needs (such as premature or low-weight newborns), similar clinical testing requirements exist.[116]

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[108] "[Reagan administration loyalists] had a little different idea about government regulation and never promulgated them," commented an aide to Ohio Senator Howard Metzenbaum in October 1986. "It was basically thrown back to the manufacturers." Kurlander, *supra* note 100. *See also* Greenhouse, *supra* note 106 ("In the waning months of the Carter Administration, the Food and Drug Administration developed highly detailed regulations to implement the new formula law. But the Reagan Administration never put those regulations into effect."); Federal Register, "Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula," Final Rule, June 10, 2014, *available at* https://www.federalregister.gov/documents/2014/06/10/2014-13384/current-good-manufacturing-practices-quality-control-procedures-quality-factors-notification [hereinafter *June 2014 Final Rule*].

[109] *See* June 2014 Final Rule, *supra* note 108.

[110] 21 C.F.R. § 106.96.

[111] Exemptions and regulatory procedures for using alternative study designs are provided. *See, e.g., infra* note 116.

[112] *Id.* § 106.96(e)-(f). This Protein Efficiency Ratio Rat Bioassay (PER test) has been required since 1982. *See* U.S. FOOD & DRUG ADMIN., FDA-2014-D-0033, GUIDANCE FOR INDUSTRY, DEMONSTRATION OF THE QUALITY FACTOR REQUIREMENTS UNDER 21 C.F.R. 106.96(I) FOR "ELIGIBLE" INFANT FORMULAS (June 2014), *available at* https://www.fda.gov/media/88686/download [hereinafter *FDA Guidance June 2014*]. Modifications are allowed and updates to the procedure are an active area of scrutiny for the FDA. U.S. FOOD & DRUG ADMIN., PROTEIN EFFICIENCY RATIO (PER) RAT BIOASSAY STUDIES TO DEMONSTRATE THAT A NEW INFANT FORMULA SUPPORTS THE QUALITY FACTOR OF SUFFICIENT BIOLOGICAL QUALITY OF PROTEIN: GUIDANCE FOR INDUSTRY, DRAFT GUIDANCE (Feb. 2023), https://www.fda.gov/media/165173/download (last visited Aug. 24, 2023) [hereinafter *FDA Draft Guidance February 2023*].

[113] *Id.* § 106.96(b).

[114] *Id.*

[115] *Id*.

[116] *See id.* § 106.96(i). Separate from the category of new formulations of infant formula is "eligible infant formula," defined in 21 C.F.R. § 106.3 as formula that could be lawfully distributed in the United States on December 8, 2014. The quality factors are the same, and testing requirements also include a protein study and growth study, though

The FDA may exempt a manufacturer from the protein quality study or the growth monitoring study, although the exemption process takes time and resources. The manufacturer must gain FDA concurrence in any proposed alternative testing for the infant formula,[117] taking care that procedures follow scientific guidance for clinical practice.[118] For the formulation's contents, the FDA specifies minimum levels for thirty nutrients (macronutrients, vitamins, and minerals) and maximum levels for ten nutrients.[119] Should any manufacturer fail to submit proof of its formula meeting the quality factors or nutritional content specifications, the formula is deemed adulterated.[120]

Before the infant formula may go to market, the manufacturer goes through a months-long process of submissions to the FDA. At least 90 days before the formula can be marketed, the manufacturer must submit a "notice of intent" containing details as to the formula's contents, directed use, and "quality" as shown in its studies.[121] As such, a manufacturer typically spends a minimum of 195 days (fifteen weeks of clinical study plus 90 days after the notice submission) in an evaluation phase prior to sale of its new formula. Should FDA evaluators require additional information—and that information be evaluated as a "substantive amendment"—the 90-day period will restart.[122] After, the manufacturer must make an additional "verification submission" to the FDA[123]

Upon receiving the FDA's green light after the verification stage, the manufacturer may market and sell the new infant formula. Detailed product labeling requirements specify nutritional content, directions for use, and shelf life.[124] Formula must meet strict quality control standards laid out in 21 C.F.R. § 106.5 through § 106.92, which require multiple layers of checks on the manufacturing, processing,

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with slightly different terms. For instance, the growth study should be no less than four months in duration, enrolling infants no more than one month old at time of entry into the study. *Id.* § 106.96(i)(1)–(2). *See also* FDA Guidance June 2014, *supra* note 112 ("The quality factors for an eligible infant formula are the same as for a new infant formula.").

[117] A limited carveout from new formula studies exists for a specific type of minor change, such as changing the type of packaging from metal cans to plastic pouches, *id.* § 106.96(c)(1) and § 106.96(g)(1) for growth monitoring and protein quality studies, respectively. . . . Otherwise, changes must be submitted to the FDA with data as if supporting a reformulation. *See, e.g.*, 21 U.S.C. § 350a(d)(3); 21 C.F.R. § 106.140.

[118] *Id.* § 106.96(c), (g). Both the protein quality and growth studies must follow "sound scientific principles." In the case of the growth study, FDA guidance further instructs manufacturers to follow "regulations of human subject protection, additional safeguards for children in clinical investigations of FDA regulated products, and institutional review boards (see 21 CFR 50, and 21 CFR 56)" whose protocols "may be submitted for agency comment" but "does not guarantee that the data generated will be sufficient to meet the requirements for the quality factor of normal physical growth." U.S. FOOD & DRUG ADMIN., *Regulations and Information on the Manufacture and Distribution of Infant Formula*, FDA.GOV, https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/regulations-and-information-manufacture-and-distribution-infant-formula (updated May 16, 2022).

[119] 21 C.F.R. § 107.100.

[120] *Id.* § 106.1; 21 U.S.C. § 350a(a)(1)-(2).

[121] *Id.* § 106.120.

[122] *Id.* § 106.120(f).

[123] This submission requires, among other things, summaries of nutrient test results and certifications of good manufacturing practices. *Id.* § 106.130.

[124] *Id.* §§ 107.10-107.20.

packing, and storage of the formula. The FDA maintains oversight of these supply stages through manufacturer recordkeeping obligations and government audit rights.[125]

Relative Regulatory Processes

Infant formula is categorized as a food by the FDA. Yet, aspects of its stricter regulatory oversight—specifically that of product research and development, including generating data and documentation—approach regulation for pharmaceuticals. Specialized pre-clinical protein assays and weeks-long human clinical growth studies are particularly costly in terms of time and capital, with some manufacturers spending more than $190 million and five years of time in an evaluation phase prior to beginning sales.[126] Standard review timelines built into the regulations require over half a year for a formula's research and development to undergo FDA review.[127] As a general reference point, compared to the standard minimum of three months (in addition, after the required 15 weeks of clinical testing) for review prior to sale of formula, the standard timeline for FDA approval of a drug is ten months (although post R&D FDA drug approval procedures vary greatly[128]), with accelerated, priority approval processed within six months.[129] In contrast to infant formula, baby food has no specialized set of regulations beyond that of other foodstuffs for human consumption,[130] though there is recent research into levels of heavy metals found in certain baby foods.[131] The FDA also recently announced rulemaking efforts are underway to limit amounts of specific harmful chemicals in baby food.[132] This difference in approach between formula and baby food can be understood given that infant formula is considered to be "the sole source of nutrition" for many newborns and "pose[s] unique challenges" when "unavailable due to a shortage."[133]

[125] *See, e.g., id.* §§ 106.90-106.100.

[126]), https://bit.ly/39vSfj9 (; State Attorneys General, Comment Letter on Infant Formula Shortage, 4 (June 24, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0074 [hereinafter *State AGs Comment Letter*].

[127] *See supra*, Section V.B, Current Regulatory Framework, Supply Timeline.

[128] This comparison is an imperfect one due to overarching distinctions in the regulatory structure of infant formula, which the FDA does not "approve" but "reviews", and drugs, which the FDA does approve. Drug approval timelines provided here do not generally include timelines for drug "sponsors" (often, but not always, the manufacturer) to design, conduct, analyze and report on the pre-clinical and clinical studies and other scientific and technical information required to support an application for FDA approval of the drug. *Development & Approval Process | Drugs*, FDA.GOV, https://www.fda.gov/drugs/development-approval-process-drugs (updated Aug. 8, 2022).

[129] *Id.*; *Accelerated Approval*, FDA.GOV, https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval (updated Feb. 24, 2023)

[130] Malic acid and polydextrose are regulated specifically for baby food. 21 C.F.R. § 184.1069, § 172.841.

[131] Kevin Loria, *Are There Still Heavy Metals in Baby Food?,* CONSUMER REPORTS (June 27, 2023), https://www.consumerreports.org/babies-kids/baby-food/are-heavy-metal-levels-in-baby-foods-getting-better-a1163977621/.

[132] *Closer to Zero: Action Plan for Baby Foods*, FDA.GOV, https://www.fda.gov/food/environmental-contaminants-food/closer-zero-action-plan-baby-foods (updated Aug. 10, 2023).

[133] See *FDA Evaluation of Infant Formula Response, September 2022*, *supra* note 97.

C. Public Submissions to the RFI

Among the public's submissions to the FTC, some commentors highlighted the regulatory structure as a challenge for expanding the supply of infant formula. In particular, some commentators raised concerns that current FDA requirements for formula development and for quality control have increased costs to enter the market, concentrating the market, decreasing overall manufacturing capacity, and leading innovation to stagnate.[134] Although detailed instructions on formulation, processing, and marketing limit room for error, some commentors have suggested that a more flexible guidelines-based approach would afford the same benefit while lowering costs, which could spur additional entrants to the market and result in greater product selection.[135] Some comments further discussed whether the United States should further open itself to an international supply of formula.[136]

Commentors noted that a significant contributor to the cost of bringing infant formula product to market is the regulatory review timeframe.[137] Scientific review and regulatory processing at times requires almost half a year.[138] As commentors observe, a months-long waiting period is a significant investment for manufacturers and is especially risky for new market entrants with a limited product portfolio.[139] Suggested solutions in the comments include to change the standard wait time to less than 90 days, to increase FDA resources to evaluate and process formula, and to allow the FDA to exercise greater discretion to lessen its enforcement burden and allow the agency to prioritize between duties.[140]

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[134] *See, e.g.*, Bobbie Comment Letter at 1 ("As it stands, the economics do not support the innovation of specialized ingredients and products to address certain infant health need."); Sullivan Comment Letter at 2 ("In addition to regulating infant formula nutrient content and product labeling, the regulatory process involves waiting periods and regular plant inspections."); State AGs Comment Letter at 5–8.

[135] *See, e*.g., Bobbie Comment Letter at 1; Serenity Kids Comment Letter at 1.

[136] *See, e.g.,* Katheryn Russ and Philip Baker, Comment Letter on Infant Formula Shortage, 1, 4 (June 24, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0075 (US tariffs, trade agreement provisions, and complex regulatory requirements are barriers for international producers to enter the U.S. market); National WIC Association Comment Letter at 6 ("NWA urges FTC to . . . explore the long-term feasibility of imports"); Nicole R., Comment Letter on Infant Formula Shortage (June 22, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0049; Sonya Genesius, Comment Letter on Infant Formula Shortage (June 21, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0042.

[137] *See, e.g.,* Sullivan Comment Letter at 2; State AGs Comment Letter at 5–6.

[138] Bobbie Comment Letter at 1 ("Over the last couple years, the industry has seen the timeframe of these reviews extended from 90 days to 180 days. This additional time slows innovation and significantly delays the entry of new products into the market, especially for new market entrants with small product portfolios.").

[139] *See, e.g., id.* at 1; Serenity Kids Comment Letter at 1 ("The infant feeding study requirement is the single biggest barrier to entry for innovative formula makers like us to launch infant formulas in the U.S."); Andrew Adjan, Comment Letter on Infant Formula Shortage (June 21, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0044.

[140] *See generally, e.g.,* Bobbie Comment Letter; Serenity Kids Comment Letter. *See also* The Food Industry Association, Comment Letter on Infant Formula Shortage 2 (June 24, 2022), https://www.regulations.gov/comment/FTC-2022-0031-0065 ("It is also important to understand the stresses already on the market . . . due to requirements of the program, legal issues, lack of clarity in certain areas, organized retail crime and consumer confidence concerns.").

D. Potential Reforms

The FDA has recently identified certain areas of existing regulations or guidance that may lend themselves to updates[141] and is continuing to work with industry experts and scientists to refine procedures such as the pre-clinical trials for formula testing.[142]

Some voices have called for the FDA to create a new office that would specifically oversee infant formula.[143] The Consolidated Appropriations Act of 2023 directed the creation of an Office of Critical Foods within FDA's Center for Food Safety and Applied Nutrition.[144] This office is tasked with oversight, coordination, and facilitation of activities related to critical foods which includes infant formula. Supporters note that such an investment in FDA capabilities could not only shorten routine processing,[145] but also allow a more effective response to supply disruptions.[146]

VI. Conclusion

This Report was written from the perspective of the FTC, which is an agency tasked with promoting fair, competitive markets that deliver high quality, affordable, reliable supplies of products. Pursuant to this mandate, the FTC analyzes high levels of concentration in the infant formula market and explores whether certain policy changes could promote greater competition and resiliency, thereby rendering the market less susceptible to serious supply disruptions. We recognize that concerns about competition and resiliency must be balanced against other policy priorities, and that any attendant tradeoffs will require thoughtful and careful analysis.

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[141] *See FDA Evaluation of Infant Formula Response, September 2022*, *supra* note 97.

[142] The FDA is currently considering updates to Protein Efficiency Ratio pre-clinical assay methodology and has issued recent guidance to the industry to explain appropriate modifications to testing procedures. *See* FDA Draft Guidance February 2023*, supra* note 112*.*

[143] *See, e.g.,* NCL Comment Letter at 2 ("NCL also recommends that the U.S. create a single food safety agency and designate an office to oversee the safety and supply of infant formula. This must include the appointment of a baby formula safety and supply chain expert."). The FDA suggested a similar specialized resource growth strategy. *See FDA Evaluation of Infant Formula Response, September 2022*, *supra* note 97 at 7 (stating in Evaluation Finding 8: "The FDA's shortage of investigators, subject matter experts, and compliance personnel with infant formula expertise hinders the agency's ability to comprehensively inspect infant formula manufacturing facilities, review and evaluate new products, and respond to product concerns or complaints in a rapid manner.").

[144] Consolidated Appropriations Act of 2023, Pub. L. No. 117-328, § 3401, Subtitle D, 1380 (2022), *available at* https://www.congress.gov/117/plaws/publ328/PLAW-117publ328.pdf.

[145] The FDA has identified that investments in the agency's technology and staffing are important aspects of preventing future supply chain volatility. *See FDA Evaluation of Infant Formula Response, September 2022, supra* note 97.

[146] Consumer groups expressed concern about the timing of FDA's response to whistleblower complaints sent about the Abbott facility in Michigan. NCL Comment Letter at 2.