The Gettysburg Journal for Public Policy

Volume 2 Article 2

2024

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Abstract

This scholarship argues that the widespread shortages resulting from the February 2022 recall of several infant formula brands following the closure of Abbott's Sturgis plant are emblematic not of an acute market hiccup, but rather of a series of anti-competitive policy measures decades in the making. Using the aforementioned punctuating event as a guidepost, this analysis reviews the critical role that quality regulations, import restrictions, and procurement protocols within the WIC program play on concentration within the market for infant formula.

Keywords

economics, policy, FDA, USDA, shortages, WIC

Cover Page Footnote

I would like to thank Professor Tozzi for his help and support during both the research project and the PP 401 capstone course. I would also like to thank the staff at Musselman Library for their assistance in retrieving data.

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Executive Summary:

This scholarship argues that the widespread shortages resulting from the February 2022 recall of several infant formula brands following the closure of Abbott's Sturgis plant are emblematic not of an acute market hiccup, but rather of a series of anti-competitive policy measures decades in the making. Using the aforementioned punctuating event as a guidepost, this analysis reviews the critical role that quality regulations, import restrictions, and procurement protocols within the WIC program play on concentration within the market for infant formula.

Background

Introduction

The year 2022 proved to be difficult for many parents and caretakers as the availability of powered formula products faced nationwide disruptions. These shortages began when Abbott Nutrition, a dominant player in the market, faced an outbreak of *Cronobacter* and was forced to issue a mass recall of thousands of highly-demanded product units.[1] Within the span of several months, the market transformed from its quiet equilibrium to scenes of half-empty shelves, dazed nutrition benefits programs, and imports via U.S. military aircraft. From beneath the buzz of individual responses emerged a broad sense of disillusionment with the market. Hindsight suggests that this is rightfully so. Today, a renewed focus lends itself to understanding how one firm came to exert such a profound influence that one hiccup sent a multi-billion dollar industry into a downward spiral. A deep reading into the market for infant formula suggests a clear

through-line linking current policies at all levels of government to the concentration of all but 4 percent of market power in the hands of just four firms.

This scholarship will lend focus to the causes and effects of industry concentration with respect to infant formula. It will begin by providing a deeper study of the details of the 2022 shortages, and discuss the policy responses implemented at various levels of government. This case study will serve to contextualize discussions of relevant stakeholders, existing policies, and proposed solutions related to the problem described. Ultimately, this is intended to be a form of applied scholarship that motivates action by providing meaningful and viable recommendations that enhance trade, social benefit, and regulatory policy and mitigate the problem of concentrated market share in the infant formula industry.

Problem Definition

Building more deeply on the established background, the central claim of this scholarship is that a high concentration of market power within a small number of firms stifles competition and increases volatility in the market for infant formula. Figure 1 illustrates a 2021 breakdown of the proportions of total market sales captured by four dominant firms. Abbott Nutrition, the leader in domestic infant formula production, holds top brands like Similac®, PediaSure®, Ensure®, and EleCare®.[2] Mead Johnson Nutrition, a subsidiary of the Reckitt Benckiser Group,produces brands such as Enfamil®, Gentlease®, and Nutramigen®.[3] A smaller but not insignificant player is Perrigo Pediatrics, a primary manufacturer of private store labels by Target, Walmart, CVS, Kirkland, Aldi, and more.[4] Lastly, capturing just under 10 percent of the market is Nestlé Gerber, the producer behind the Gerber GoodStart® and Nestlé NAN® brands.[5]

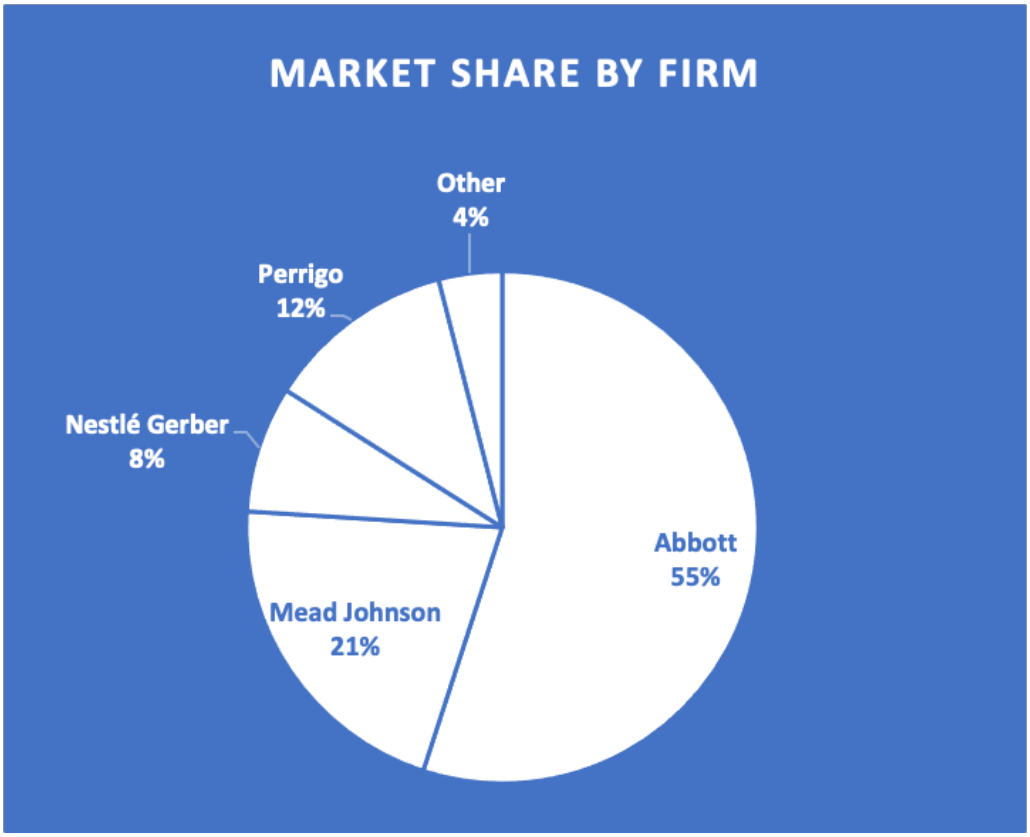

Figure 1: IBISWorld (2021)

Together, these dominant brands capture 96 percent of the market. The 4 percent leftover is captured by emerging brands and small specialty diet brands, most of which occupy niche market positions but face slim odds of gaining market share from existing infant formula giants.

Concentration has become a problem of growing concern in food supply chains across the United States. From a microeconomic perspective, consolidated markets tend to produce deadweight losses when firms gain the power to begin price-setting and collecting rents rather than accepting rates as set by supply and demand forces. Market analysis from the Federal Reserve Bank of Kansas City reveals a wealth of implications of food market concentration, including but not limited to efficiency losses, instability risks, and losses in consumer and intermediary welfare.[6] Although lower prices may sometimes be passed down due to economies of scale, overall market health from policy-induced market concentration will likely worsen as a

result of stunted innovation and centralized supply source risks. As this scholarship will continue to highlight, the small number of players in the infant formula market is not a consequence of dominant firms achieving extraordinarily high levels of efficiency and innovation but rather stems from policy structures that allow existing players to crowd out potential market entrants. The case study that follows will describe in depth one result from market structures that lack resilience and possibilities for entrance.

Case Study

On September 20th, 2021, the United States Food and Drug Association ("FDA") received a complaint from the Minnesota Department of Health alleging the development of *Cronobacter* illness onset in an infant 14 days prior.[7] This infection, caused by a naturally occurring germ commonly found in dry foods, is potentially fatal for infants who are younger than two months or were born prematurely.[8] Within days, the FDA began planning for an inspection of Abbot Nutrition's infant formula production facility in Sturgis, Michigan.[9] In the subsequent inspection spanning from January 31st to March 18th, 2022, the FDA found "significant, fundamental sanitation, building, and equipment issues" indicating the potential presence of *Cronobacter*.[10] Abbott Nutrition ceased production by February 15th and, within two days, initiated a voluntary recall in light of an FDA advisory.[11]

In the months following Abbott Nutrition's decision to recall millions of units of formula from Similac®, Alimentum®, and EleCare® brands, domestic markets experienced widespread shortages and unprecedented out-of-stock ("OOS") rates. Figure 2 illustrates the notable upward trend in OOS rates beginning at around 18 percent in January 2022 and reaching 43 percent in

May 2022. Public responses varied from retailers imposing purchase quantity limits to distraught consumers seeking out recipes for homemade formula substitutes.

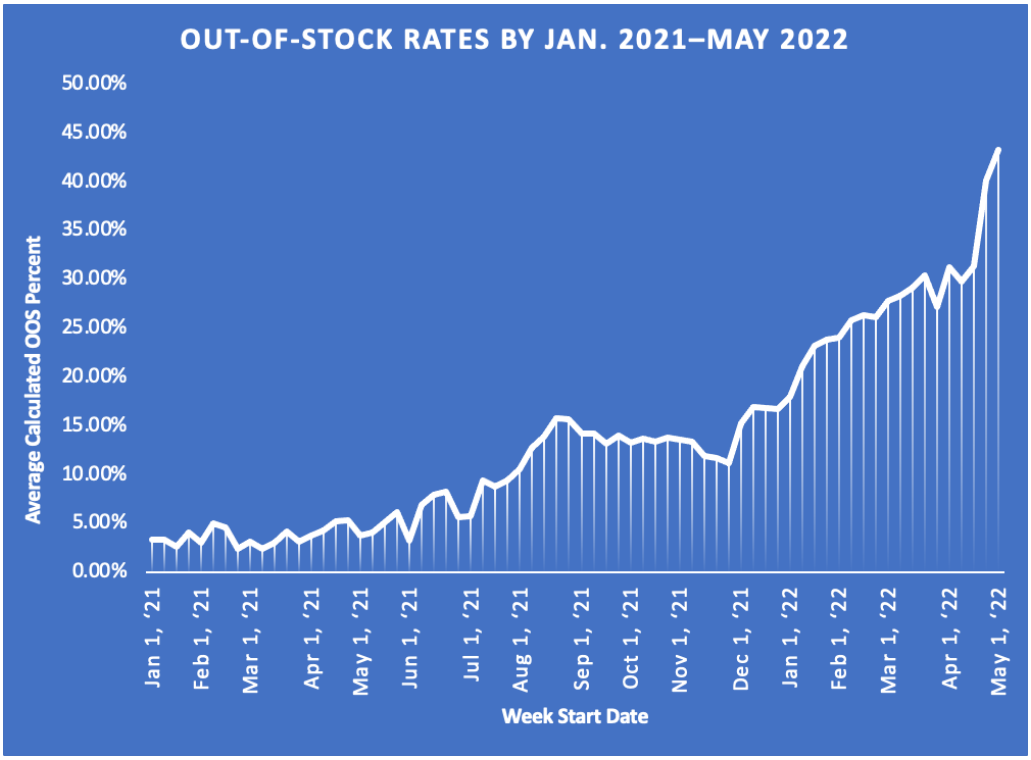

Figure 2: Datasembly (2022)

Policy Response

Several policy measures were swiftly passed to increase the domestic supply of infant formula. On May 18, 2022, the United States House of Representatives authorized $28 million in emergency spending to increase supply and support the Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC").[12] These funds were directed at supporting state WIC agencies as they sought out temporary emergency contracts to compensate for the sudden drop in supply. Additionally, Congress passed two policies temporarily suspending tariffs and caps on imports of infant formula and its necessary inputs.

Simultaneously, the Biden Administration introduced two authorizations under the Defense Production Act ("DPA") to aid the remaining domestic formula manufacturers in

boosting production. [13] According to these authorizations, applicable manufacturers of infant formula could incorporate legally-binding language in supplier orders that grant the manufacturers priority over other customers.[14] Although this measure could not remedy production capacity limits, it aimed to at least reduce delays in manufacturers' raw material procurement. The administration also initiated "Operation Fly Formula," designed to take a direct approach to ramp up the importation of foreign-held, domestically-produced infant formula.[15] These orders included hundreds of pallets of formula from Gerber and others, transported via Department of Defense-contracted commercial aircraft.[16] [17] It is worth noting that the formula covered under Operation Fly Formula was confined to that which was compliant with U.S. health and safety standards.[18]

Within the FDA, efforts began to loosen restrictions on a case-by-case basis to raise shelf capacity. Ultimately, the agency authorized 28 foreign-produced formula labels from nine companies to be sold in U.S. markets.[19] A similar relaxation characterized actions taken by the Department of Agriculture, which focused on loosening state-level administration of the WIC program's product purchasing requirements.[20]

Faced with supply chain deficiencies, efforts were taken at all levels of government to remove barriers to production and encourage a rapid rebound of national infant formula supply. The existing policies targeted were not coincidental and offer valuable insights into what changes might be permanently adopted to prevent the next crisis.

Stakeholder Analysis

This scholarship lends consideration to a number of key actors with a heightened stake or interest in changes to policies surrounding infant formula. The main stakeholder groups

identified include parents and caretakers, WIC recipients, dominant infant formula manufacturers, secondary infant formula manufacturers, the Food and Drug Administration, and state-level agencies administering the WIC program.

Parents and Caretakers

Parents and caretakers (as a sort of proxy for infants) comprise the stakeholder group that tends to come first to mind when considering who is most acutely sensitive to policies surrounding infant formula. This is an ever-growing group of diverse backgrounds but with wide agreement as to the importance of affordable and accessible infant formula. Aside from this, one notable stakeholder preference is that many parents prefer to avoid switching formula brands after one has been selected.

WIC Recipients

The WIC program covers millions of Americans, a disproportionate number of whom are women and families of low income, people of color, LGBTQ+ individuals, and people with disabilities.[21] For those relying on this social safety net, gaps in coverage or access have dire consequences. The primary policy interest for this group concerning the WIC program is the continuity of benefits. This interest seeks a federal and state responsiveness to emergencies as well as the adoption of policies to increase market choice. Specifically with respect to infant formula, nearly half of national formula purchases are made using WIC funds.[22] The large voter block comprised of WIC recipients prioritizes the expansion of purchasing options beyond the constraints of the program's sole-source contracting.

Dominant Infant Formula Manufacturers

Firms with large domestic market shares like Abbott Laboratories, Mead-Johnson, and

Nestlé-Gerber have a financial interest in both preserving their current market share and maximizing profits delivered to their respective shareholders. According to 2022 Lobbying Disclosure Act disclosures, Abbott expended $1,220,000 on lobbying activities between October 2022 and the beginning of January 2023.[23] Notably, a portion of these efforts were directed at Congress and the USDA on proposals related to infant formula, Child Nutrition Programs, and implementation of the WIC program. Since these firms' market shares rely heavily on federal and state procurement, their government relations teams prioritize policies that both increase overall funding for infant formula programs and increase the likelihood of winning WIC contracts. Although these firms would likely benefit financially from a streamlined and more efficient regulatory process, the status quo is ultimately preferable because the high costs of regulatory compliance effectively limit the number of market competitors.

Secondary Infant Formula Manufacturers

Sometimes referred to as *secondary producers*, smaller domestic and international manufacturers of infant formula are defined by their lack of market share. Depending on the specifics of their situations, these groups tend to prioritize the reduction of barriers to entry and the simplification of regulatory procedures. One emerging manufacturer of specialized subscription-based infant formula, ByHeart, underwent a five-year setup time in which it completed FDA trials, purchased a facility, and sourced ingredients.[24] For smaller domestic producers like ByHeart, regulatory simplicity and ease of product sourcing are key. Further, many smaller firms have a vested interest in policies that would modify WIC sourcing procedures to allow recipients to select from a broader variety of products. International firms have yet a longer wish list as they are forced to operate within a system of high duty rates and

low import caps. These firms would champion policies that gradually reduce these barriers to allow greater global trade within domestic infant formula markets. It is worth noting that this stakeholder category has little political capital compared to more established players, suggesting that policy victories only seem likely where firm interests overlap with those held by other stakeholders.

State Administrators of the WIC Program

Individual state agencies tasked with administering the WIC program do so within the bounds set by the United States Department of Agriculture and outlined in public law. The foremost objective of these agencies is to operate in a manner consistent with federal and state regulations and requirements. Pursuant to this, agencies will favor policymaking that can provide additional resources in terms of funding, staffing, or streamlined compliance standards. Concerning how these resources are used, agencies will favor conditions within periodic federal program reauthorizations that enable cheaper procurement, heightened state rebates, and greater power over expenditures delegated to the state level.

Existing Policies

This scholarship analyzes the effect of three relevant areas of existing policy pertaining to the market for infant formula. These three areas include (1) trade policy, (2) WIC administrative policy, and (3) federal regulatory standards. It is worth noting that these areas all underwent a degree of relaxation at all levels of governance in response to the 2022 infant formula shortages. Pursuant to the objective of analyzing the role of everyday policies in influencing market concentration and, by extension, supply resilience, this reading focuses on policies as they were in the months and years before the closure of Abbott's Stergis facility.

Trade Policy

Since its signing in November 2018, the United States-Mexico-Canada Agreement ("USMCA") has been the primary source of legislation on the import and export of infant formula products. Under this agreement, infant formula is classified as a type of dairy product and is subject to some terms that are notably different from those under the now-defunct North American Free Trade Agreement ("NAFTA"). While Mexico retains its former duty-free access to U.S. dairy products, the new agreement has phased out a number of special conditions on exports to Canada. In doing so, Canada has committed to gradually increasing its caps on formula purchased from the United States and transferred across the Northern border. This is considered to be a key achievement on the part of the White House Trade Representative, as it liberalized the markets for infant formula among other U.S. dairy exports.[28]

Contrary to the direction taken by countries like Canada, the United States has maintained a restrictive approach in its admission of foreign infant formula products. With the ratification of the USMCA, the United States imposed additional provisions on formula imports from Canada, citing concerns over Chinese investment into an Ontario-based production facility.[29] The prevailing strategy for the U.S. has been one of greater protectionism. Figure 3 illustrates the source countries of 2021 domestic formula consumption to show the dramatic effects of such a deliberate resistance to international imports.

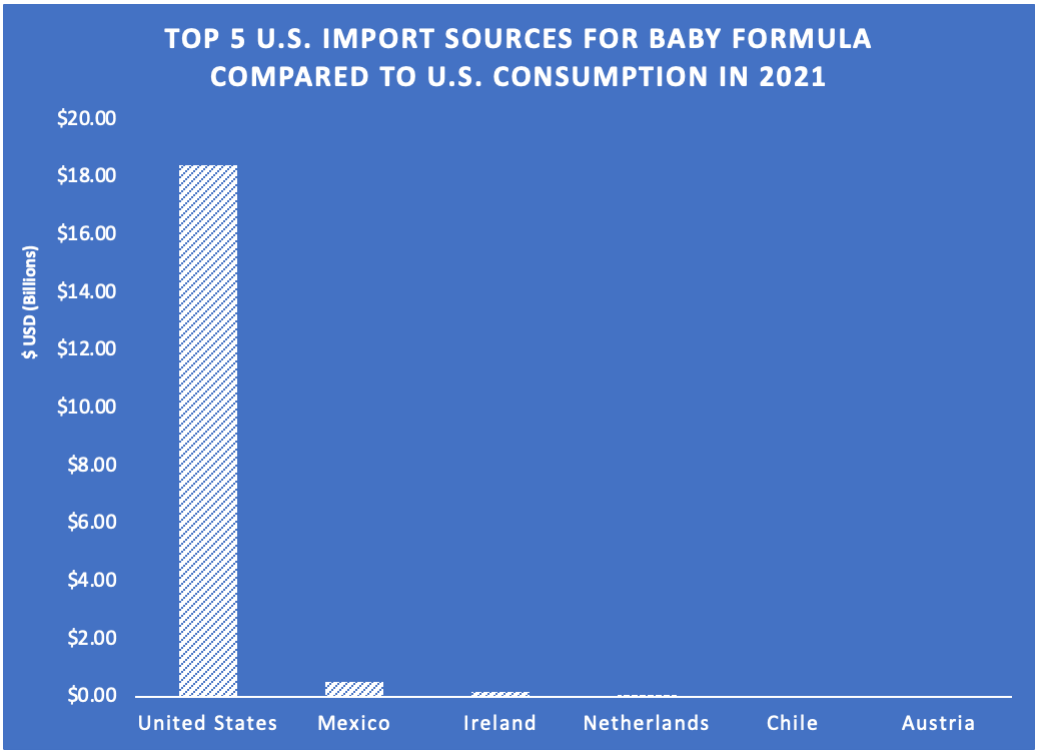

Figure 3: Cato Institute, IBISWorld

In terms of import logistics, United States Customs and Border Protection ("CBP") is tasked with enforcing admissibility requirements as defined by regulating agencies such as the Food and Drug Administration and the U.S. Department of Agriculture. One key consideration is whether the formula being imported is for personal or commercial use. In the view of CBP, infant formula products that are reasonably small and provide supply for at most several days are admissible as personal consumption products.[30] Products imported for commercial use and distribution are inspected to ensure the product's FDA registration, shipment authorization, sanitation standards, and labeling compliance with U.S. standards.[31] These powers are derived from the U.S. Federal Food, Drug, and Cosmetic Act's provisions qualifying imported food products as interstate commerce activities.

WIC Administrative Policy

WIC is a federally-funded program that is administered on the state level to provide food, healthcare referrals, and nutrition education to select populations.[32] These often include at-risk children in addition to low-income pregnant, breastfeeding, or postpartum women. Per this mission, the WIC program has long been a major purchaser of infant formula in the United States. This process is largely carried out by WIC state agencies, which are required by law to competitively bid infant formula rebate contracts with infant formula manufacturers.[33] Within this cost-minimizing procurement system, state agencies collect rebates from manufacturers for each unit of product sold through the program.[34] In the process of obtaining contracts, manufacturers operate in an auction-like format to submit sealed bids for the most competitive rebate deal with the administrative agency. Often, manufacturers will be willing to meet this competitive offer and sustain slimmer profit margins in return for the security of an exclusive contract for all WIC procurement in the state for on average about four years at a time. In response to the infant formula shortages seen in 2022, Congress recently passed a notable exception to this policy that grants the USDA and state agencies the option to pursue secondary procurement contracts outside of pre-established WIC terms in the event of acute shortages.[35]

While delivering lower operating costs to WIC state agencies, this sole-source contracting procedure contributes substantially to the concentration of market power. Reports by the USDA seem to reveal tension by contrasting the mechanism's effectiveness in delivering billions of dollars in annual rebates with a detailed quantitative analysis of the market effects of WIC procurement procedures. This report found that all contracts in the decade leading up to 2013 received multiple bids, and larger states with more WIC recipients tended to receive slightly lower bids than less populated states offering smaller markets.[36] In other words, although

only three firms engaged in the bidding process (Abbott, Mead Johnson, and Nestlé/Gerber), downward price competition did still occur between these players.

A different USDA report offers insights into why contract bidding becomes such a high-stakes practice. This found that the manufacturer holding a sole-source WIC contract accounts for over 80 percent of all milk-based formula sales within the state or region awarding the contract.[37] Although three manufacturers primarily compete for these contracts, those without a winning bid are left to compete for a small portion of the remaining sales. This same effect is observed in the magnitude of market share transfer observed when a state or partnership awards a sole-source contract to a manufacturer different from the current holder. On average, the state market share of a manufacturer awarded a new contract tends to increase by 74 percentage points.[38] This makes WIC contracts a lucrative pursuit for the three legacy firms while also raising the barriers to entry for emerging or international firms that do not hold political capital or specialized knowledge about government procurement.

Federal Regulatory Standards

The Infant Formula Act of 1980 is largely responsible for federal regulations on infant formula in their modern structure and form. This act amended the Federal Food, Drug, and Cosmetic Act to include infant formula as a sub-classification of food. In doing so, the statute set forth requirements with which all formula products must comply to be considered unadulterated products. These requirements include the obligation of manufacturers to adhere to specified nutrient levels, maintain records of frequent inspections, and report compliance to the Secretary of Health and Human Services.[39] This also began the existence of labeling requirements specific to infant formula, which would play a role in the product's status as an adulterated or

unadulterated product.

Pursuant to these objectives of ensuring the safety and quality of infant formula, the FDA operationalizes much of the legal authorization process for brands in addition to providing guidance for the industry.

Last updated in 2014, Title 21 CFR 106 sets forth infant formula requirements concerning manufacturing, quality control, and reporting.[40] Subpart B lists a series of controls to be put in place to prevent adulteration by workers, facilities, equipment, ingredients, packaging, and microorganisms. The lattermost consideration refers specifically to the *Cronobacter* bacterium. Control practices include complying with handling procedures for thermally processed low-acid and acidified foods, conducting sample tests at the final product stage, and retaining reportable records on microorganism testing. For testing to conclude that a batch is unadulterated by *Cronobacter*, 30 samples of 10 grams of the product must return negative results.[41]

On the topic of infant formula labeling, the FDA provides guidance related to statements of identity, exemptions, nutrient claims, health claims, and general labeling requirements. Consistent with broader federal requirements for food identification, the FDA upholds a requirement that the principal display label of infant formula products must bear a statement of product identity expressed in the form of the product's legal, common, or descriptive, name.[42] An additional class of "exempt" products exists for formulas that are represented or labeled for use by infants with medical conditions or unusual dietary problems. The FDA holds that applicable brands may deviate from some labeling and nutrient requirements but must be subject to an assessment of whether public health will remain adequately protected.[43] This standard is similarly applied to evaluating claims about the relationship between specific nutrients and a

disease or health-related condition. Within 21 CFR part 101 subpart E, the FDA is instructed to confirm that health claims meet validity requirements in addition to enabling the public to comprehend the information in the context of a total daily diet.[44] Often health claims are regulated based on the appropriateness of the claim's wording and the inclusion of key safety disclaimer information. Some more general labeling requirements include the inclusion of directions for preparation and use in both written and illustrated forms.[45] The FDA also requires standard labeling elements that include a water statement, warning statement, and physician's recommendation.[46]

One notable labeling requirement is outlined in 21 CFR 101.15(c)(1), specifying that all words, statements, or other required information must appear in English.[47] An exception to this regulation applies in Puerto Rico and other territories where the predominant language is not English. Although the FDA exercises some discretion with products bearing a separate label in a foreign language, the agency maintains a requirement that all labeling components also appear in English.[48] Under these standards, infant formula products that are wholly compliant with all health and safety standards but bear non-English labeling are considered adulterated products in the United States.

Policy Proposals

The recommendations offered by this scholarship are directed at reducing firm concentration within the market for infant formula while maintaining effective regulatory standards capable of providing for public health by ensuring physically safe and unadulterated formula products. These solutions are targeted at three levels of government, each involving a distinct set of policymakers with the power to enact change.

Trade Policy

One key recommendation aimed at reducing industry concentration and opening consumer markets to a greater variety of products is to gradually reduce general duty rates on infant formula products. The current 17.5% general rate is prohibitively high for many would-be trade partners. This current rate applies to both final consumer products and intermediate forms of powders that are essential inputs for domestic producers. By pursuing gradual reductions in both of these rates, domestic consumers would see expanded access to a wider array of products while domestic producers would enjoy greater access to competitive markets for lower-cost production inputs.

This scholarship recommends pursuing tariff reductions at a modest 2.5 percent annual rate with a sustained duty floor of 10 percent. This recommendation is reflected in Figure 4. If implemented in Q1 of 2024, this plan would prescribe an immediate general rate of 15%, reducing over two years and locking in indefinitely at a rate of 10 percent in 2026. This target rate is deliberately set at a level consistent with the local maximum of similar powdered and processed milk solids, which consistently receive rates between 8.5–10 percent.[49]

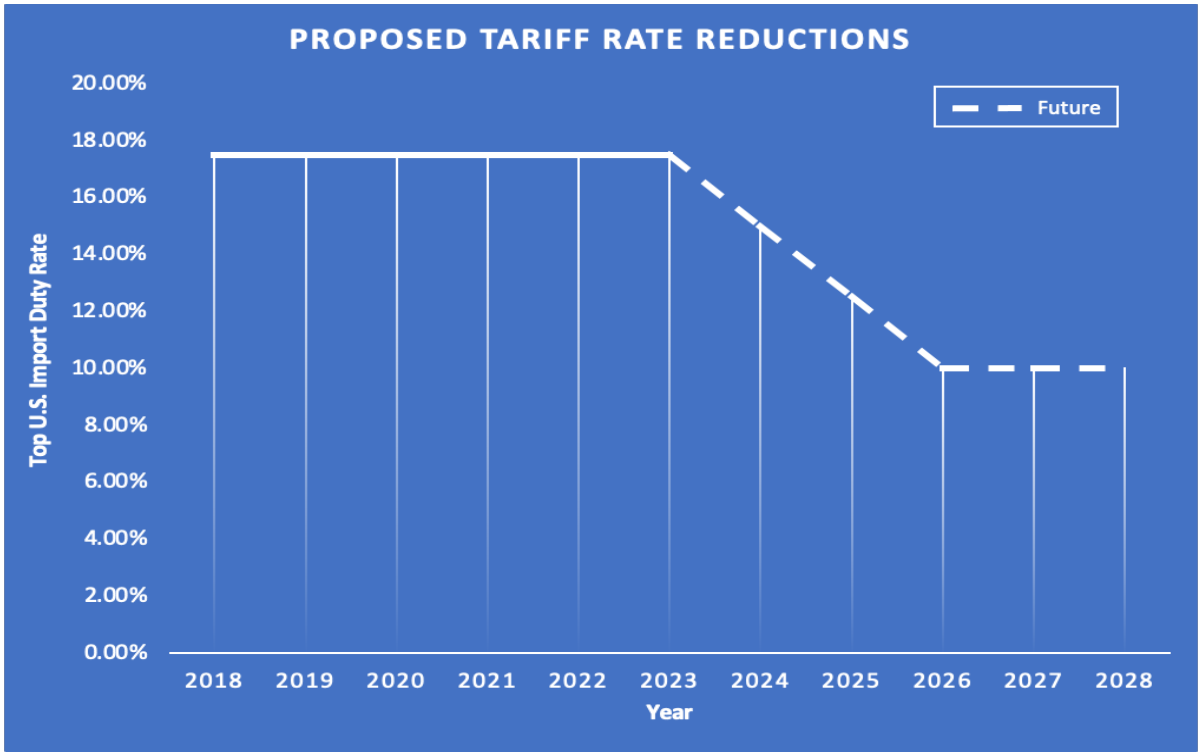

Figure 4

Reductions in duty rates alone cannot provide a fully effective trade policy remedy to the problem at hand; even a free entry policy would usher in little change without the simultaneous expansion of import caps. The United States has long established maximum tolerable import amounts quotas for foreign firms that could pose an undue threat to the market share of domestic manufacturers. For infant formula, this level has remained rigid at 100,000 metric tons since even before the transition from NAFTA to the USMCA.

This scholarship recommends that U.S. International Trade Commission commits to a 3-year variable increase schedule, thereafter followed by sustained rate increases. If implemented alongside tariff reform in Q1 of 2024, this schedule would prescribe an initial hike of 5,000 metric tons. This would be followed by additional increases of 15,000 metric tons in 2025 and

2026, until the rate of increase tapers to an annual level of 10,000 metric tons from 2027 onward.

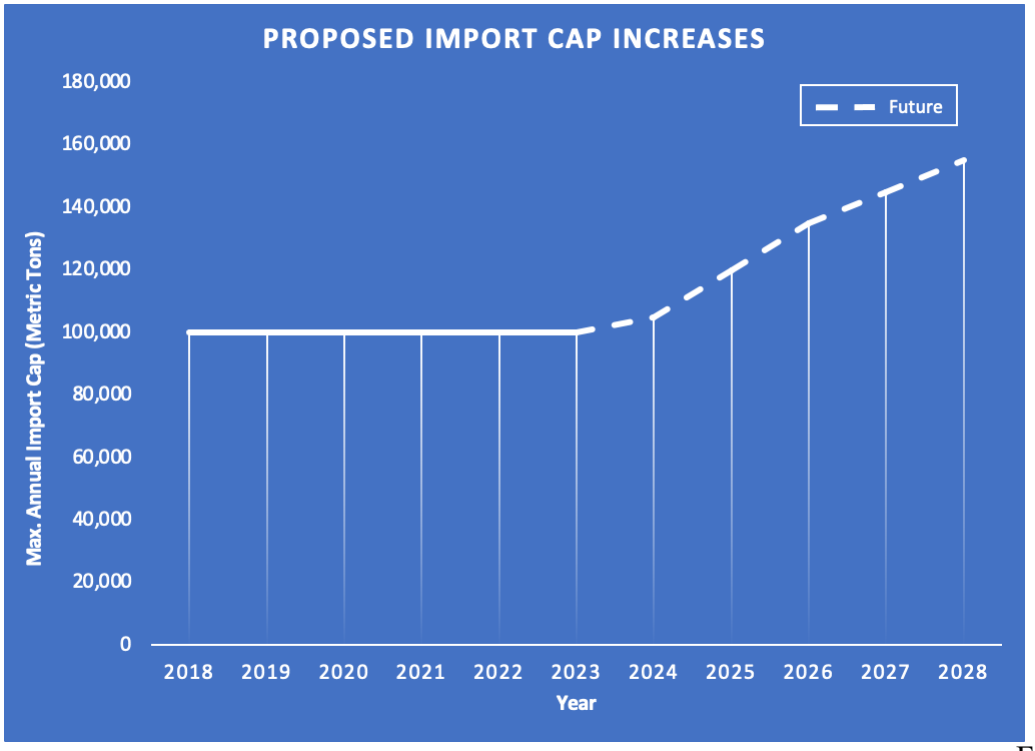

Figure 5

Figure 5 reflects this proposal. Under this plan, the United States would effectively double its allowable formula import levels (compared to 2023 levels) by the year 2031. These are ambitious rates, although it is important to take into account that the current import cap has remained stagnant for years and is overdue for reconsideration. The proposed schedule of increases is designed to ease into effect in 2024 before picking up the rate of increase and ultimately settling at a steady growth rate in 2027. The gradual process toward the import cap's obsolescence is designed to temporarily insulate domestic producers, allowing them to adjust to a more competitive market.

WIC Administrative Policy

The current administrative procedures for the WIC program are likely the largest contributor to the levels of concentration seen within the infant formula market. Since this program relies on collaboration between different levels of government, this scholarship makes a

series of recommendations for what different groups of lawmakers could do to remedy the problem at hand.

The first and most significant action step is to modify the structure of the WIC program at the federal level to incorporate a flexible contracting system that expands available options for program recipients. This could be done by directly modifying the language outlined in existing public law from the Child Nutrition Act of 1966 to remove the "primary contract infant formula" distinction defined in § 17 (b)(22) and described in § 17 (g)(8)(B)(v).[50] Removal of this distinction from the program's authorizing policy would mark a step in allowing USDA regulators and state administrative agencies to deviate from the existing sole-source contract system and explore more options providing a greater diversity of eligible products.

Similarly, greater details on new procedures for contracting and procurement could be written into the Code of Federal Regulations by the USDA. First, the agency should remove the "contract brand infant formula" and "non-contract brand infant formula" distinctions defined in 7 CFR 246.2. Next, the USDA should modify 7 CFR 246.16 to remove existing contracting procedures and instead outline the requirements for a brand to obtain individual product eligibility for consumer purchase using WIC funds. In making these changes, the infant formula element of the WIC program will function similarly to other voucher-based elements such as that which is in place for fresh fruit. This allows brands within supermarkets and general vendors to meet a set of eligibility requirements to become a WIC voucher-eligible brand.

These changes must finally trickle down from Public Law and federal regulations to be encoded in state-level procedures for administering benefits through the WIC program. Under 7 CFR 246.4, each state agency must submit an annual State Plan to USDA's Food and Nutrition Service ("FNS") outlining yearly goals, a budget plan, statewide participation estimates, an

affirmative action plan, vendor application plans, and a cost-containing plan for awarding contracts.[51] With the modification of federal regulations surrounding cost containment mechanisms in contracting, state agencies will individually be enabled to extend existing voucher mechanisms for consumer products to also cover infant formula products from federally-compliant brands.

Federal Regulatory Standards

The essential nature of product safety is amplified in the context of infant formula. These recommendations seek to enable the FDA to establish more efficient regulatory standards for formula products while simultaneously encouraging the entry of new manufacturers into the market. Two areas identified as requiring policy reconsideration include import review procedures and cosmetic versus compositional quality standards.

Concerning standards for imported infant formula products, the FDA should permanently implement some of the standards adopted in response to the supply shock that rattled the infant formula market in 2022.[52] Specifically, the FDA should formalize a process through which foreign infant formula products with favorable inspection records could undergo an expedited review. The agency could take this a step further and take into consideration prior inspection records produced by international counterparts with similar regulatory standards such as the European Food Safety Authority ("EFSA").[53] Ultimately, the agency should seek to permanently integrate policies that reduce processing redundancies and prioritize approving historically-compliant brands, all while maintaining high standards of product safety and quality assurance.

The second recommendation addresses the regulatory barriers to entry that are inherent in the infant formula market while also considering the tradeoffs necessitated by agency resource

limitations. Faced with widespread shortages in 2022, the FDA announced its intent to exercise a certain amount of discretion in handling minor discrepancies with product labeling. Although the accuracy of labeling information plays an important role in ensuring consumer safety, the exceptions made tended to concern nonmaterial and cosmetic elements. The continued adoption of these standards for review would place primary emphasis on a product's physical makeup and essential consumer information. Especially for an agency that suffers from backlogs due to a lack of resources, this policy approach would ensure that inspection efforts focus less on considerations like the intricacies of a package's label illustrations, and focus more on batch testing, facility inspections, and auditing safety logbooks. Ultimately, continued flexibility in terms of product cosmetic standards will have a dual effect of encouraging market entrants while also enabling the FDA to focus its efforts on the enforcement of more substantive standards for physical product quality.

Feasibility

Stakeholder Perspective

The study of stakeholder perspectives will consider the broader practicality of recommended policies in the context of the net direction of groups' political capital and the overall drive to operationalize change.

Trade policy recommendations including gradually decreasing duties while raising caps for infant formula imports are mixed in terms of their feasibility. Regardless of its adverse effects on consumers and overall market performance, protectionism is notoriously difficult to reverse because of the political dynamics within which it places itself. Simply put, existing trade policies create a system of concentrated benefits and diffused costs.[54] This is to say that domestic

producers of infant formula enjoy significant gains from current tariff rates and import caps, as these constrain the supply of more expensive foreign formula. Whereas a handful of producers benefit from this, costs are widely dispersed among millions of consumers who notice only small additional costs that are not perceived as being worth protesting. Of course, with more consumer knowledge of the wider long-term costs and volatility brought about by trade policies, electoral voice would likely influence lawmakers to scale back protectionism to a more moderate level. One source of advocacy for policy change could come from within the government itself. Voices within federal and state WIC administrations along with the White House are becoming attuned to the impacts of trade barriers on domestic consumers. Recent statements from the Biden Administration praised the FDA's willingness to cut "red tape" to increase imports and aid consumers.[55] While the elimination of trade barriers is likely an unreasonable expectation, there is some promise that modest reductions in tariffs and increases in import caps could gain political momentum and contribute to better outcomes for markets and consumers.

Recommendations regarding modifications to the WIC program are the most likely to see implementation. Those receiving WIC benefits comprise a large voting group with much at stake in an electoral sense. The continued long-term expansion of benefits and coverage speaks both to the program's popularity as an outlet for providing constituent benefits, as well as the trend toward its classification as being a politically untouchable, "must-fund" annual expenditure. Framed in terms of providing choice to WIC recipients, discourses around substituting a voucher program for sole-source contracting would garner wide support from the growing category of program beneficiaries. Likely the strongest opposition would be voiced by infant formula manufacturers that are dominant in the market today. Although this shift would enable non-

contract brands to increase sales in formerly-captured markets, this would mark a small gain compared to the loss attributed to phasing out sole-source contracts. Thus, is expected that legacy infant formula brands would leverage political capital against policy changes, and would likely gain transition-softening provisions in the form of subsidies, tax advantages, or new WIC-preferred brand status. Ultimately, political tensions are likely to mount over the issue of expanded choice in WIC programs. The political risk associated with denying program expansion makes it likely that recipients would win out and existing brands would receive some sort of economic relief as consolation.

Changes in the regulatory standards upheld by the FDA are likely to arouse a host of concerns, clarifications, and eventual support. Likely the biggest advocates of these changes will be non-dominant domestic and international firms seeking to gain a portion of the domestic market share. Although these firms possess relatively little political capital, they are likely to gain the sympathies of economically conservative lawmakers with a chief emphasis on slashing red tape. There would likely be an amount of nuance in the positions taken by dominant firms, as simplified and more efficient regulations would generate windfall profits while also opening the market to additional competition. Depending on messaging, consumers will likely be a swing group on this topic. If framed as a regulatory restructuring designed to place more emphasis on the physical attributes and safety compliance of infant formula, this recommendation will likely gain more traction among consumers than if framed as a scaling back of safety standards. While this recommendation primarily affects the FDA, its contents would likely garner agency support on the grounds that it assigns additional discretionary power to individual regulators and positions the agency to refocus on physical product safety rather than cosmetic compliance. The

fate of this recommendation will in large part be determined by the verbiage adopted by the individuals, firms, and lawmakers who ultimately operationalize the policy change.

Conclusion

The increasing trend toward industry concentration disrupts the stability of the infant formula market and disproportionately harms society's most vulnerable. With the benefit of hindsight, it is appropriate to reflect on the widespread product shortages in 2022 and develop an understanding of the role that existing policies played— and continue to play— in suppressing competition and priming the next crisis. This scholarship adopted a broad stakeholder view in discerning the roles that diverse stakeholder groups play in infant formula policy. From this, individual policies were presented, critiqued, and subsequently tied into a series of policy recommendations. It is recommended that policymakers prioritize the long-term health and stability of the infant formula market immediately working to induce organic competition through measures like tapered tariff reductions and gradual import cap increases. Furthermore, policymakers should amend the WIC program's authorization on the federal level to grant state authorities the power to distribute recipient vouchers rather than awarding sole-source contracts to producers. Lastly, the FDA should pursue measures to permanently direct a greater focus on enforcing essential material/chemical safety requirements while exercising greater discretion for cosmetic labeling considerations without clear ties to consumer safety. Through this policy mix, policymakers can empower the infant formula market to achieve a safer, more reliable future with real competition among a greater variety of firms.

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