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Formula for a Crisis

Protectionism and Supply Chain Resiliency—the Infant Formula Case Study

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It has become accepted wisdom in Washington that the COVID-19 pandemic revealed how openness to international trade and investment increases U.S. vulnerability to economic shocks and contributes to widespread shortages of food, medicine, and other essential goods. This official narrative, however, ignores ample economic research showing that, while disruptions are inevitable in a modern economy, the alternative to free trade—a protectionism-driven onshoring of global supply chains—carries its own risks and can even heighten vulnerability by inhibiting natural market adjustments to economic shocks. The infant formula crisis, which lasted for most of 2022 and was unique to the United States, provided an unfortunate real-world lesson in this regard.

Widespread shortages and media attention pushed policymakers to implement a series of temporary ad hoc actions to address the infant formula crisis. But these actions did not fix the fundamental policy problems that allowed the situation to metastasize, and several of them have expired or will do so in early 2023. Congress should therefore consider new reforms to ensure real, long-term resiliency in the U.S. baby formula market.

This brief provides an overview of the problematic trade, regulatory, and welfare policies underpinning the crisis and proposes reforms that would leave the U.S. infant formula supply chain, and the millions of parents that depend on it, not only better prepared in the event of any future shocks but better off overall.

BACKGROUND

Between September 2021 and February 2022, the U.S. Food and Drug Administration (FDA) investigated four reports of ill children—two of whom died—after consuming formula produced by Abbott Nutrition at its plant in Sturgis, Michigan.[1] In October 2021, a whistleblower complained to the FDA,



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alleging unsanitary conditions at the same facility.[2] Investigations by the FDA and the Centers for Disease Control (CDC) found that the *Cronobacter sakazakii* bacteria may have contributed to the deaths of the two children. The FDA also found traces of this pathogen in Abbott's Sturgis facility.[3] While Abbott disputed that the infant deaths were connected with consumption of its products, the company voluntarily issued recalls of some of its Sturgis-made formula and shut down the facility altogether in February 2022.[4] Even before the Abbott plant closed, national average weekly out-of-stock rates climbed, reaching 24 percent by the end of January.[5] After the closure, the shortages became much more widespread. Abbott produces around 40 percent of the infant formula consumed in the United States, most of which is made in Sturgis. National weekly out-of-stock rates thus skyrocketed from 28 percent at the end of February to more than 74 percent at the end of May. By early June, a fifth of the United States saw out-of-stock rates above 90 percent.[6]

This troubling situation, and widespread media coverage during an election year, pushed policymakers to implement a series of "emergency" responses:

- In May:
  - the Biden administration initiated "Operation Fly Formula" to use military planes to deliver formula from Europe, and it required the FDA to expedite the approval process for new formula brands;
  - President Biden delegated specific Defense Production Act (DPA) authorities to the Health and Human Services (HHS) Secretary to direct domestic production of infant formula in the hopes of increasing domestic production and supply; and
  - the Federal Trade Commission initiated an investigation to identify the factors contributing to the crisis, including those that hampered policymakers' response.
- In July, Congress passed legislation to suspend tariffs on imports of finished formula until December 31, 2022.
- In August, the United States Department of Agriculture (USDA) waived the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) requirement that benefits can only be used to buy state-contracted formula.[7]
- Finally, in September, Congress passed legislation to suspend tariffs on imports of infant formula base powder until December 31, 2022.

Figure 1 provides a timeline for some of the most important events in the crisis.

While infant formula inventories improved somewhat in the following months, they remained depressed into November, and U.S. consumers continued to report difficulty finding formula through the end of 2022.[8]

THE INGREDIENTS FOR A FRAGILE MARKET

Given the pandemic's intense, unpredictable, and heterogenous effects on supply and demand patterns in the U.S. and abroad, supply chain problems (delays, shortages, gluts, etc.) inevitably arose for numerous products. However, baby formula was unique in both its magnitude and duration, as well as its being isolated to the United States and avoided in the rest of the developed world and neighboring countries (save a brief period in Canada when Americans traveled there for emergency supplies).[9] Although some of this special situation resulted from the uniqueness of the product itself—formula is essential and babies stir passions—much of it was owed to U.S. policy.

Trade Barriers

As shown in Figure 2, U.S. manufacturers accounted for more than 98 percent of American baby formula consumption in 2021—among the highest domestic market shares of any product sold.[10]

Two types of trade barriers contributed to this situation by effectively blocking imports into the U.S. market, *despite* certain foreign infant formula brands being in high demand in the United States.[11]

Tariff barriers. The United States maintains a base tariff rate of 14.9 to 17.5 percent on imported formula (depending on the tariff classification). These products are also subject to a complex system of tariff-rate quotas—imports are permitted in limited quantities at the base rates, and higher rates apply above the quantity threshold. (Some imports also receive duty-free treatment within a quota, but are

Figure 1

Infant formula shortages became a national emergency in early 2022, and the federal government responded by enacting temporary tariff, regulatory, and welfare program flexibilities

09/20/2021: The Food and Drug Administration (FDA) learns of an infant who contracts a *Cronobacter sakazakii* infection after consuming formula produced in Abbott's Sturgis, Michigan, facility.

10/21/2021: The FDA receives a complaint from a whistleblower alleging unsanitary practices at Abbott's Sturgis facility.

12/1/2021: The FDA learns of a second infant who contracts a *Cronobacter* infection. The infant died. (The FDA learns of a third infant who contracts a Cronobacter infection, and also dies, on **1/11/2022**.)

1/31–3/18/2022: The FDA conducts an on-site inspection of Abbott's plant in Sturgis.

2/15/2022: After finding numerous samples of *Cronobacter* in Abbott's Sturgis plant, the FDA recommends the company to voluntarily cease production of infant formula. Abbott proceeds to do so.

2/17/2022: The FDA learns of a fourth infant who contracts a *Cronobacter* infection. The FDA issues a consumer advisory warning consumers to avoid certain Abbott-made infant formula. Abbott voluntarily issues a recall of these products. Additional products are recalled on **2/28**.

2/23/2022: Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) programs across the nation begin offering flexibilities to certain administrative requirements in light of the voluntary recall of Abbott's infant formula.

5/18/2022: After infant formula shortages become a national crisis, the FDA issues guidance on discretionary enforcement of certain industry regulations to facilitate the entry of new formulas to the U.S. market.

5/19/2022: President Biden approves first Operation Fly Formula flights, whereby foreign-made formula is flown into the United States via military aircraft. Twenty-six such flights had taken place by **10/05**.

5/19–5/21/2022: Congress passes, and President Biden signs into law, the Access to Formula Act, which expands the secretary of agriculture's authority to approve temporary flexibilities to the WIC program during certain emergencies, disasters, and supply chain disruptions.

6/4/2022: Abbott's Sturgis plant reopens but is forced to shut down again nine days later due to flooding.

7/1/2022: Abbott's Sturgis factory reopens.

7/21/2022: Congress passes, and President Biden signs into law, the Formula Act, which provides for the temporary elimination of tariffs on certain imported formula and components through **12/31**.

7/31/2022: National infant formula out-of-stock rate hits a peak of 30.04 percent, according to market research firm IRI.

8/19/2022: Under the expanded authority granted by the Access to Formula Act, the secretary of agriculture waives certain WIC regulations to allow "state" WIC agencies to authorize and issue certain infant formulas imported under the FDA's Infant Formula Enforcement Discretion Policy. These flexibilities will completely expire after **06/30/2023**, at the latest.

9/29/2022: The FDA issues new guidance providing for a pathway for certain foreign-made infant formulas to permanently enter the U.S. market.

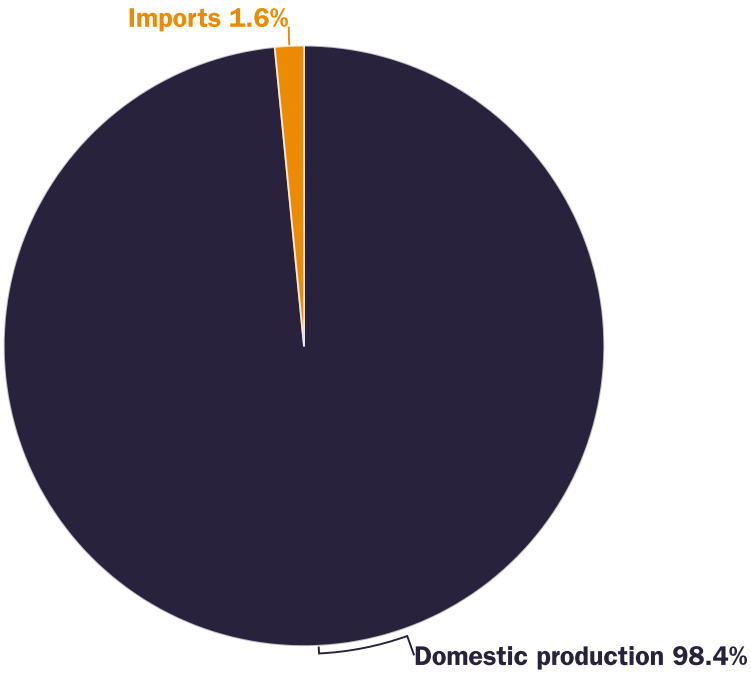
9/29–10/10/2022: Congress passes, and President Biden signs into law, the Bulk Infant Formula to Retail Shelves Act, which provides for the elimination of tariffs on imported infant formula base powder through **12/31**.

1/1/2023: Tariffs on certain infant formula and base powder, eliminated by the Formula Act and the Bulk Infant Formula to Retail Shelves Act, respectively, are reinstated.

Sources: Daniella Diaz, Betsy Klein, and Brenda Goodman, "Breaking Down the Biden Administration's Response to the Baby Formula Shortage," *CNN*, June 3, 2022; "Timeline of Infant Formula Related Activities," U.S. Food and Drug Administration; Shauneen Miranda, "Abbott Reopens Michigan Baby Formula Plant after Flooding," NPR, July 10, 2022; "Infant Formula Guidance Documents and Regulatory Information," U.S. Food and Drug Administration, September 30, 2022; "Biden Administration Approves First Operation Fly Formula Mission," press release, White House, October 5, 2022; Jesse Newman and Kristina Peterson, "Families Still Struggle to Find Baby Formula Nearly One Year after Shortages Began," *Wall Street Journal*, October 17, 2022; Formula Act, H.R. 8351, 117th Cong. (2022); Bulk Infant Formula to Retail Shelves Act, H.R. 8982, 117th Cong. (2022); "Additional WIC Flexibilities—Imported Infant Formula under FDA's Infant Formula Enforcement Discretion," U.S. Department of Agriculture, August 19, 2022; Diane M. Kriviski to Regional and WIC State Agency Directors, memorandum, December 19, 2022; and Access to Baby Formula Act of 2022, H.R. 7791, 117th Cong. (2022).

Figure 2

In 2021, more than 98 percent of U.S. formula consumption was serviced by domestic production



Source: Christopher A. Casey, "Tariffs and the Infant Formula Shortage," Congressional Research Service, IN11932.

banned once the threshold is hit.) The United States also grants duty-free treatment to Mexican imports of infant formula, but certain formula from Mexico is subject to hard quotas of 100 metric tons in a calendar year. Imports from most other free trade agreement partners, including major dairy producers such as Canada and Australia, are subject to some form of tariff restriction.[12] In Canada's case, the United States-Mexico-Canada Agreement restricts Canada's exports of infant formula worldwide and imposes an export tax on any Canadian formula exports exceeding the threshold set out in the agreement.

The Congressional Research Service estimates that less than 20 percent of infant formula imports between 2012 and 2021 entered the United States duty-free, while the remainder faced an average effective calculated duty rate of 25.1 percent.

Nontariff barriers. Even more restrictive than tariff barriers are the nontariff barriers that foreign-made formula faces. Most notably, the FDA imposes strict nutritional, labeling, and other standards and requires retailers to notify the agency at least 90 days in advance of selling a new formula product—and that is after manufacturers of new brands have submitted detailed explanations of the development of the formula, the results of clinical trials and studies on the nutrients in the formula, and details on quality controls in the production facilities, as well as having undergone FDA sampling and inspections of their facilities. As the *Financial Times* reported in July 2022, these regulations are a key contributor to the American market's lack of foreign competition:

> The US market has always been structurally quite concentrated, and one of the reasons for that concentration is that there are very high barriers to entry," said Will McMahon, [UK formula producer] Kendal's commercial director.
>
> New entrants are required to prove "from scratch" that their products are safe, including through an animal study and clinical study on humans to the regulator's specific requirements, even if they are already approved for sale elsewhere, he said.
>
> "With any new ingredients you are using, you have to show that they are generally recognised as safe," he added. "It's hard to believe but because we use

> natural milk fats instead of palm oil, the FDA needed us to prove to them that whole milk is 'generally accepted as safe'.[13]

The FDA also maintains a "red list" of noncompliant products that are immediately subject to detention upon entry into the United States. Formula produced in the European Union is notably affected by these barriers. Despite being in high demand by American parents and being subject to similar regulatory scrutiny in their home countries as U.S.-produced formula is in the United States, European formula cannot be imported into the United States for commercial use; it can only be imported through third-party delivery services for personal use. Yet even personal imports may be recalled by the FDA if they are found to be noncompliant with labeling or nutritional requirements, or they may be seized at the port of entry if the product is on the red list.[14]

U.S. trade restrictions not only ensure higher prices and less variety but also make it more difficult for the domestic market to adapt in the face of a domestic supply shock like the Abbott factory closure. During the infant formula crisis, for example, the tariffs and nontariff barriers prevented imports from meeting U.S. demand when formula became scarce. Parents were therefore left with few to no alternatives to the Abbott supplies that were suddenly unavailable, and some resorted to sharing online recipes for homemade formula or turning to breast milk donations.[15]

Just as importantly, temporarily lifting the trade barriers failed to quickly resolve U.S. shortages because the trade measures had long discouraged foreign multinational formula producers from investing in advance in the official sales and distribution channels that would have eased and accelerated deliveries once the Abbott supply shock hit. The trade restrictions similarly prevented foreign companies from establishing brand recognition—especially among doctors—and customer loyalty that would have truly diversified the U.S. market (and thus reduced the chance of a single dominant producer collapsing it). Indeed, as the FDA itself has recognized, making it easier for foreign producers to sell here is "creating more resiliency in the U.S. infant formula supply chain and reducing the risk of reliance on too few production facilities supporting the United States."[16] Uncertainties about the future of temporary relief measures also raise the question of whether without fundamental reform, such changes can truly inject more competition from foreign manufacturers in the American market.[17]

Domestic Policies

While trade barriers insulated the U.S. market from foreign competition, several aspects of domestic policy worked to limit competition, thus fueling concentration among American formula producers and exacerbating the infant formula crisis. As Figure 3 shows, three large corporations—Abbott, Reckitt/Mead Johnson, and Nestlé Gerber—accounted for more than 83 percent of total market share in 2021.[18] (The fourth large producer, Perrigo, does not have proprietary brands, but rather makes store-brand formula for multiple retailers.) This high degree of concentration left the United States vulnerable to supply shocks, as the 2022 crisis demonstrated when a problem at a single U.S. company crippled the entire market.

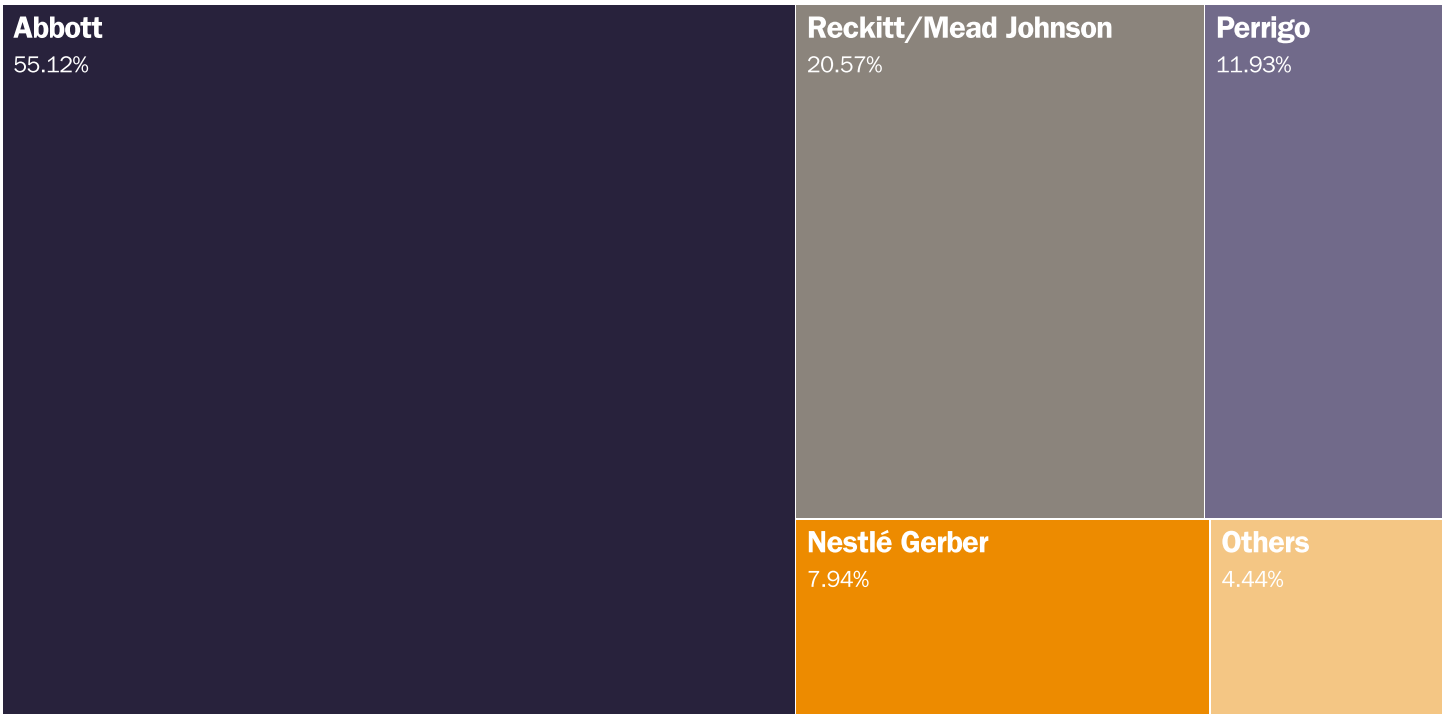
The main domestic policy drivers of this market concentration are excessive regulation of baby formula and federal welfare policy.

Excessive regulation of baby formula. The FDA regulations increase the costs of entering the U.S. formula market, thus perpetuating a lack of competition and high concentration. Since the 1980s, federal regulations have tightly restricted the content and manufacture of infant formula, and today the United States regulates formula more strictly than any other food, including formulas consumed by American toddlers.[19] Adding insult to injury, these regulations not only stifle competition in the market, but are also arguably behind the most recent nutrition science.[20]

Leaving aside the appropriate role of the federal government in ensuring food safety, empirical evidence shows that high degrees of regulation can contribute to market concentration. According to one recent study, increases in industry-specific regulation are associated with statistically significant decreases in the number of firms in a market and lower startup rates.[21] Regulatory growth also disproportionately affects smaller businesses that, unlike larger incumbents, lack the resources and experience needed to navigate a murky, onerous, or changing regulatory landscape.

Figure 3

Four producers dominate the U.S. infant formula market, with Abbott having the highest market share



Source: Jack Curran, "Infant Formula Manufacturing," IBISWorld, Industry Report OD4287, June 7, 2022, p. 25.
Note: Perrigo makes store-brand formula for Walmart, Target, and Amazon, among others.

This problem is evident in the U.S. infant formula market, which welcomed in 2022 its first new manufacturer since 2007. That new player, ByHeart, waited more than five years and paid $190 million "to get its manufacturing facility opened, supply chain in place, clinical trial completed and regulatory approval secured."[22] The company's CEO told the *Wall Street Journal* that ByHeart spent years studying and understanding the FDA's regulations on infant formula. The CEO of another formula startup similarly assessed that the market "remains largely impenetrable to newcomers," thanks in large part to regulations.[23]

Compounding the regulatory burden are simple administrative delays, as the FDA struggled in recent years with a backlog of submissions for new formulas (infant formula manufacturers must notify the FDA before marketing a new formula).[24] In 2021, for example, the agency reviewed only 15 out of 42 applications, and the final outcome in each case was unclear. The agency's most recent budget request estimates the review time for new formula submissions will increase from 90 to 150 days.[25] How many small companies can afford to wait five months before even beginning to try to market and sell their product here?

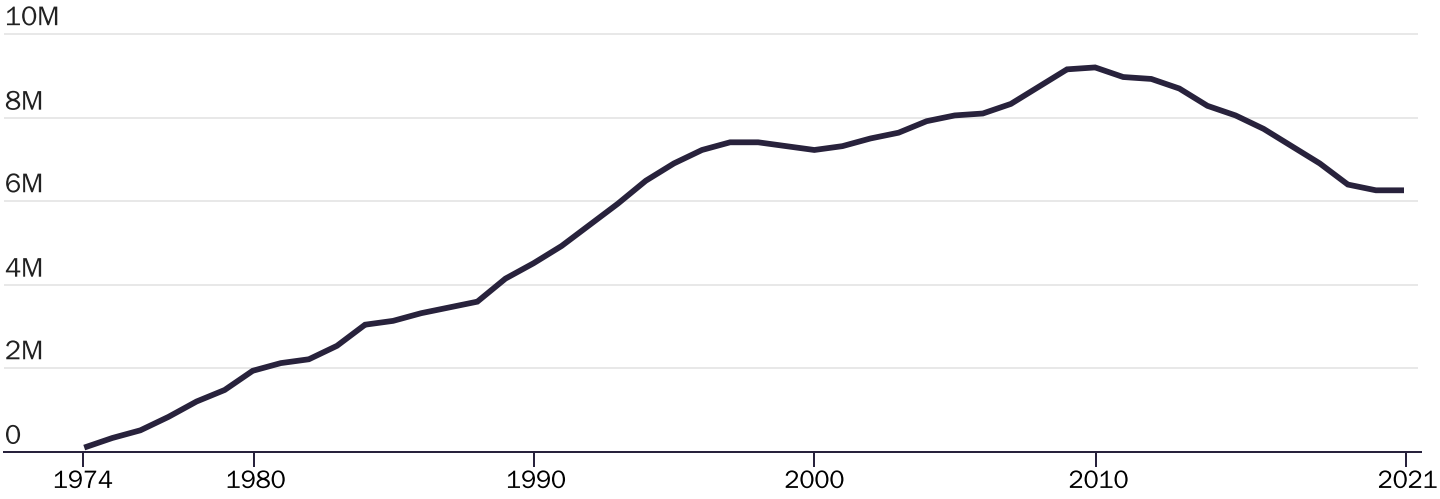
Federal welfare policy. The size and structure of the WIC also played a significant role in creating the oligopolistic U.S. infant formula market. This program provides vouchers for low-income Americans to buy a predetermined brand of formula at approved retailers. The program is administered by the USDA through 89 "state" agencies covering the 50 states, 33 tribes, the District of Columbia, and 5 territories. As Figure 4 shows, since its inception in 1974, the program has grown significantly, from fewer than 100,000 enrollees to more than 6.2 million in 2021 and is estimated to account for more than half of all U.S. infant formula sales each year.[26]

The WIC's size and design effectively ensure market concentration in the United States. Companies bid against themselves to offer the government the lowest price for formula—on average, 92 percent below wholesale value—in exchange for being a state's sole provider of formula for WIC recipients and receiving other benefits such as prime shelf space and credibility that comes from being the government's choice.[27]

This system likely saves taxpayer dollars but creates serious distortions. First, American formula producers try to

Figure 4

The number of Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) program participants has grown significantly since 1975



Source: "WIC Program Participation and Costs," U.S. Department of Agriculture, November 10, 2022.
Note: Data for 2021 are preliminary.

offset losses from discounts by marking up prices on formula for non-WIC recipients and for complementary products, such as diapers.[28]

Second, the system breeds market concentration: sole-source contracts not only give a winning bidder exclusive access to a large pool of WIC consumers but also increase the company's sales of formula in the state's non-WIC market. Research shows that a formula manufacturer's market share increases by an average of 84 percent after securing a WIC contract due to increased sales of both WIC-eligible and non-WIC-eligible formula.[29] Furthermore, only large established corporations have the production capacity, capital, and regulatory expertise needed to participate in WIC (e.g., to navigate the contracting process across numerous states and to afford steep, up-front discounts on large volumes of formula). And, to the extent that WIC's steep discounts, rigid contracts, and market power artificially depress market prices or prevent prices from increasing in times of short supply, the system further discourages new players from entering the U.S. market.[30]

Indeed, only three producers—Abbott, Nestlé Gerber, and Reckitt/Mead Johnson—hold all state, territory, and tribe WIC contracts, and the largest of them, Abbott, was awarded 43 of these contracts (including 32 out of 50 state WIC contracts), as Figure 5 shows.

A LACKLUSTER RESPONSE TO THE CRISIS

The measures adopted by the administration and Congress in mid-2022 to alleviate the crisis targeted the issues and policies discussed here but are temporary, superficial, and incomplete. As a result, these policies had a limited measurable effect on domestic infant formula supplies and, more importantly, they do nothing to improve the U.S. market's long-term stability.

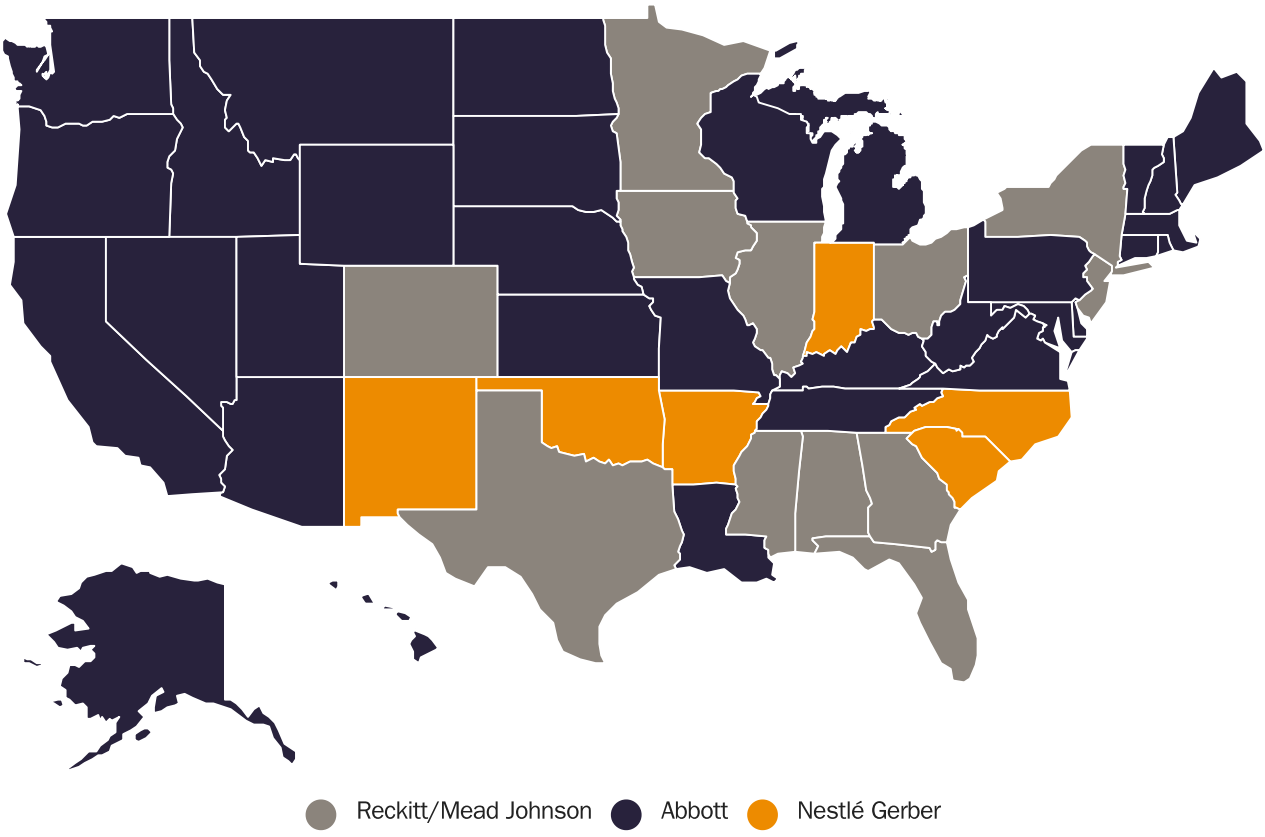
The White House and Broader Executive Response

In May, the White House undertook multiple actions to increase foreign supplies of infant formula into the U.S. market. Biden initiated "Operation Fly Formula" to import formula using military aircraft. By the end of September, 97.9 million eight-ounce bottle equivalents of foreign-made infant formula had been airlifted into the United States. The president also invoked the DPA to authorize the Health and Human Services secretary to direct production to increase supply of formula.

Neither of these actions, however, were sufficient to fix the problems plaguing the U.S. market, which by the end of September was still short 13 percent of demand (the equivalent of 73 million eight-ounce bottles of infant formula,

Figure 5

Only three U.S. companies hold all Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) contracts



Source: "WIC State Agency Infant Formula Rebate Contracts," U.S. Department of Agriculture, Food Nutrition Service, September 30, 2022.
Note: Abbott also holds four of five WIC contracts for U.S. territories and 6 of 14 WIC contracts for tribal organizations.

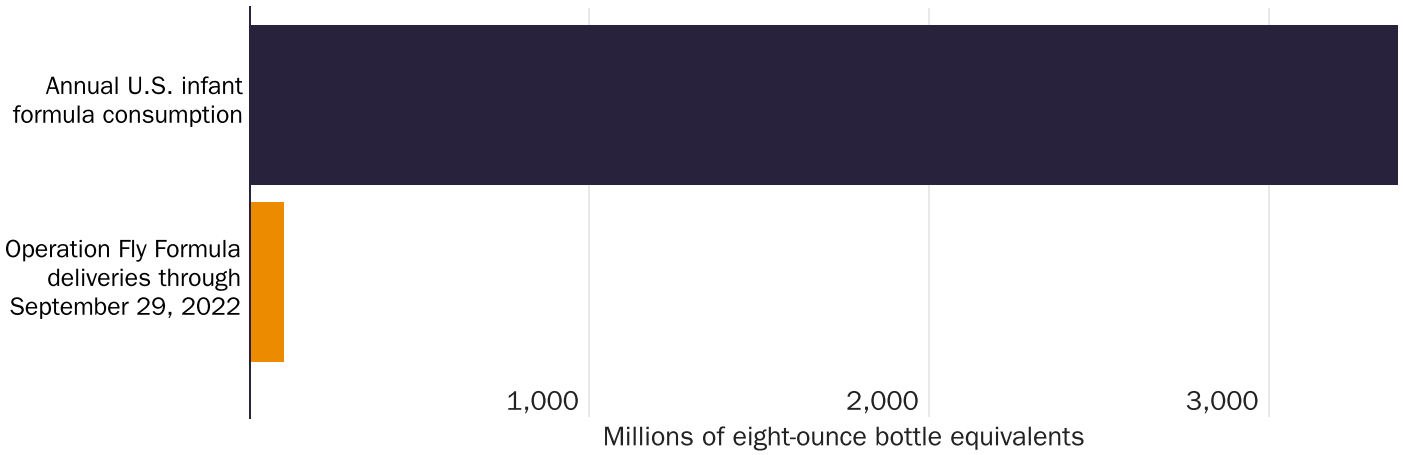
based on author's calculations for a six-month-old infant's one-day supply).[31] The Operation Fly Formula flights, for example, represented a small share of domestic formula demand, which totaled almost 3.4 billion eight-ounce bottle equivalents in 2021 (Figure 6).

And, leaving aside the obvious problem of deeming baby formula to be a national defense issue, there is little public evidence that the administration's invocation of the DPA actually boosted domestic formula production, especially since little action was taken to significantly reduce costs for these businesses.[32] Indeed, domestic inventory levels only began to improve after imports increased and the Abbott facility came back online.

Regarding said imports, the White House also instructed the FDA to exercise "enforcement discretion" and thus permit certain foreign producers to sell a predetermined amount of their output to American consumers without having to comply with every infant formula regulation on the books. To be eligible for such treatment, producers had to submit an application certifying the health and safety of their infant formula to the FDA; if they were approved, the agency waived enforcement of rules on relatively minor issues, such as labeling.[33] Despite dozens of applications, the agency inexplicably authorized only eight manufacturers in nine foreign countries (including Ireland, Germany, Mexico, Australia, and New Zealand) under this policy.[34] In September, perhaps recognizing its shortcomings, the FDA announced it would continue to relax enforcement of infant formula regulations for the eight preapproved foreign manufacturers until January 6, 2023, "with further extensions possible for firms that express interest in and take steps toward remaining on the U.S. market."[35] These producers must comply with all FDA regulations covering infant formula by October 2025 and may continue to sell their products in the United States in the meantime. However, the FDA made no clear, long-term changes to its

Figure 6

Through the end of September 2022, Operation Fly Formula delivered only a fraction of the total annual U.S. consumption of formula



Sources: "11 Operation Fly Formula Flights Completed by September 29," press release, Department of Health and Human Services, October 6, 2022; Jesse Newman and Jaewon Kang, "Baby-Formula Shortage Deepens, Defying Replenishment Efforts," *Wall Street Journal*, July 14, 2022; and author's calculations.

onerous system nor did it consider more ambitious plans for permanently opening the U.S. market, such as by entering into formula-specific mutual recognition agreements with the health and safety authorities of high-standard countries in Europe, Australia, and New Zealand. The FDA efforts remain limited to providing foreign manufacturers with technical assistance to comply with existing regulations, and its relaxed enforcement remains wholly discretionary (and thus subject to change).[36]

Indeed, long after the crisis hit and the Biden administration pinpointed imports as a key source of relief, the FDA continued to seize and destroy non–Operation Fly Formula imports of infant formula upon arrival, including those from countries with high health and safety standards.[37] Such actions both contradict the Biden administration's views regarding imports' vital role in alleviating shortages and discourage market actors from buying or selling those products.

Lastly, the USDA implemented two reforms to WIC. First, the agency temporarily relaxed federal food assistance program requirements that limit beneficiaries' choice to specific types of formula. Under WIC, beneficiaries must purchase the formula produced by the company with the sole-source contract. Since Abbott is responsible for 32 states and could not supply many of its WIC recipients, the USDA permitted state agencies to allow WIC recipients to buy any formula available in stores.[38] The USDA also launched a webpage to centralize WIC formula contract solicitations.[39] Supporters claim this dedicated page will reduce costs for new entrants, but new competitors' chief problem with WIC is not transparency but that the program effectively requires the bidding power, financial resources, and production capacity that only large incumbents have. Thus, much like the FDA's actions, the USDA's moves are insufficient: not only are the relaxed requirements temporary (expiring after June 30, 2023, at the latest), but the agency did nothing to change the underlying system—deep discounts, sole source contracts, de facto import restrictions, et cetera—that breeds market concentration and thus vulnerability to future supply shocks.[40]

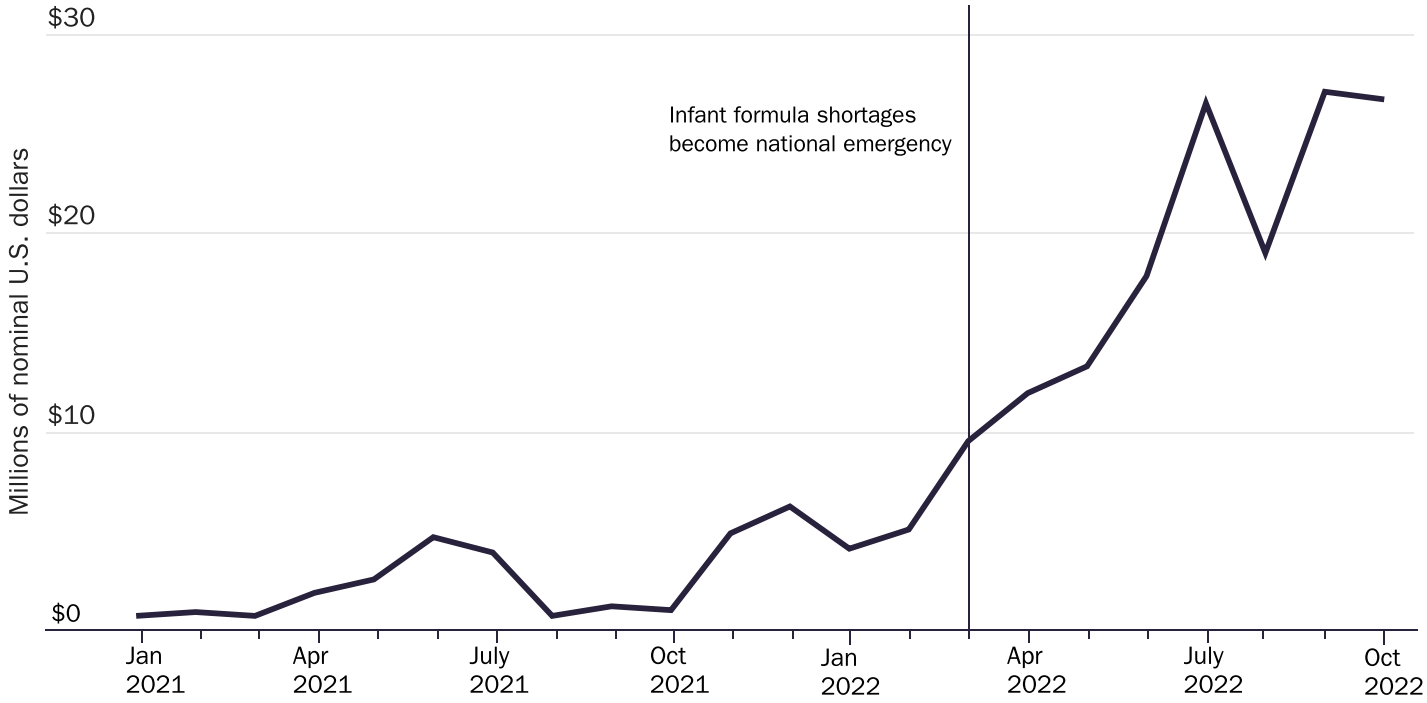
Legislative Reforms

Congress enacted two reforms in response to the infant formula crisis:

- **WIC reform.** Congress passed a bill in May 2022 to give state WIC agencies and the USDA more mechanisms for anticipating and taking action during periods of scarcity by mandating that future WIC contracts specify remedies in case of recalls and giving the USDA the ability to waive contractual restrictions during shortages and give participants access to a greater variety of formula options.[41]
- **Tariff suspension.** While formula imports rose shortly after the shortage became a national crisis in

Figure 7

When domestic baby formula supplies collapsed in 2022, imports helped fill the gap



Source: U.S. International Trade Commission.
Note: Infant formula only (HTSUS codes 1901.10.05–1901.10.49).

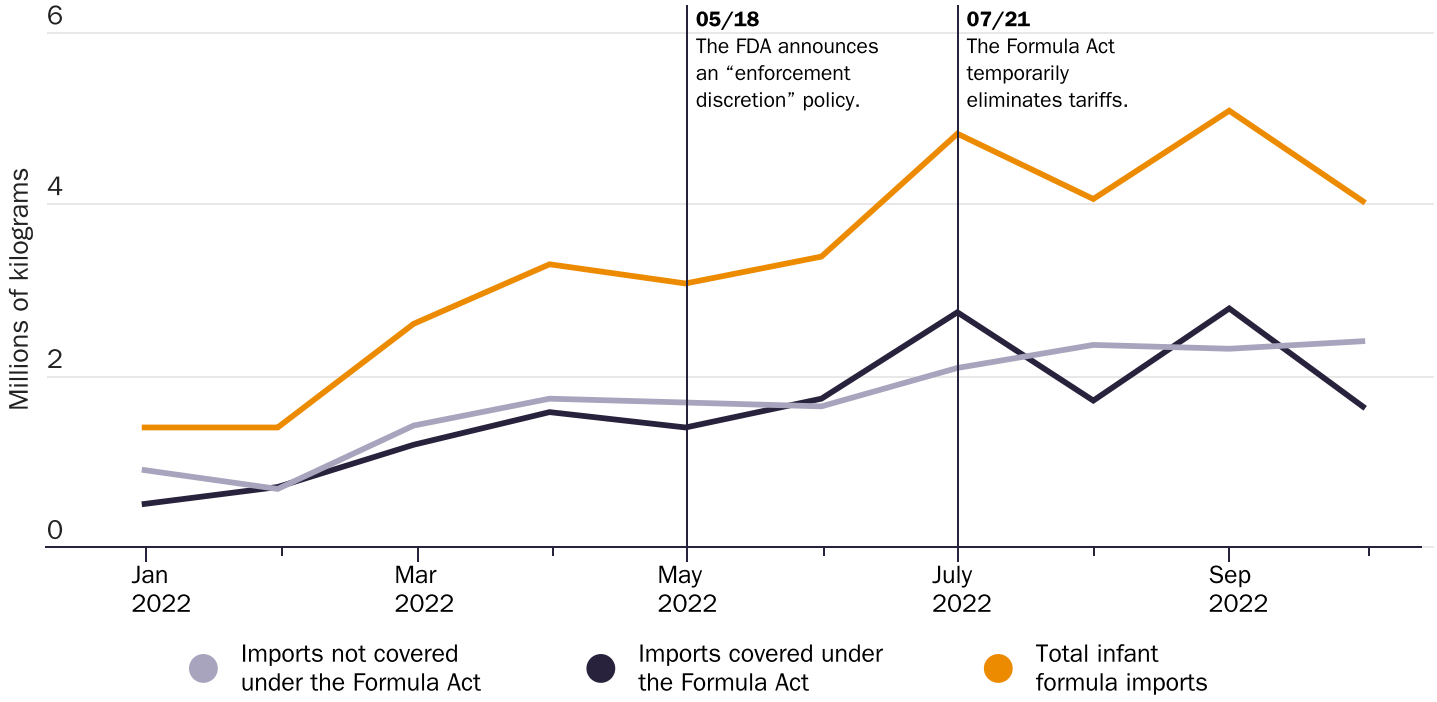
July 2022 (Figure 7), Congress almost unanimously passed legislation to suspend tariffs on certain imports of formula; in September Congress suspended tariffs on formula base powder. These tariff reductions, along with the previously described FDA "enforcement discretion" policy, helped imports of infant formula increase, as Figure 8 shows. By the end of October 2022, the United States imported more than 70 million eight-ounce bottle equivalents of infant formula from 16 different trading partners, compared to about 26 million eight-ounce bottle equivalents from 9 trading partners in 2018.[42]

Like the White House's actions, these legislative measures will not engender long-term structural improvements in the U.S. formula market. The WIC reforms did not go far enough in addressing the issue that the program's size and structure foments an oligopolistic market structure. The USDA effectively proceeded to issue waivers that allow state and other WIC agencies to offer participants the opportunity to purchase formula from brands, or of sizes and forms, other than those covered by their current contracts. Yet these waivers are set to expire on June 30, 2023, at the latest.[43] Should this be the last action to be taken with respect to WIC, the country will exit the crisis without any real solutions to the most glaring domestic policy issue that contributed to causing it in the first place. Further, the problem remains that WIC recipients can only use their benefits in store. Some states are enrolled in pilot programs to allow WIC benefits to be used online but there are technological hurdles, thus delaying the uptake of even the pilot programs.

Finally, tariff liberalization expired on December 31, 2022, even though the FDA's "enforcement discretion" was extended through most of 2025. An effective tariff of 25 percent on FDA-authorized formula imports will inevitably reduce consumption of those products because foreign formula producers will be forced to absorb some or all of the tariff cost and/or raise prices, as executives with the UK's Kendamil recently suggested.[44] The tariffs might also discourage new market entrants from considering the U.S. market, especially given that the FDA seems intent to maintain existing regulatory and enforcement hurdles in the long term.[45] Indeed, even the threat of a tariff snapback may have discouraged shipments in the waning weeks of 2022,

Figure 8

The elimination of tariff and non-tariff barriers accelerated infant formula imports in 2022



Source: U.S. International Trade Commission.
Note: Formula Act covers HTSUS codes 1901.10.16, 1901.10.26, 1901.10.29, 1901.10.36, 1901.10.44, and 1901.10.49. The act also includes 2106.90.97 and 2106.90.99, but these are broader categories and are not included in the data above.

given the length of time needed for imports to travel from their origin countries to the United States. Finally, foreign producers will remain at a competitive disadvantage if WIC contracts are not reformed.

LESSONS LEARNED?

The infant formula crisis hurt millions of Americans, lasted far too long, and elicited a disappointing response from federal policymakers. Yet, as is often the case with crises, the episode also provides several lessons for future policy reform efforts—for infant formula and beyond.

The Resiliency Mirage

Perhaps the most important lesson to be gleaned from the infant formula crisis is that, contrary to conventional wisdom, substantial domestic manufacturing and market share does not ensure a secure and stable supply of essential goods and can actually *increase* a nation's overall vulnerability to economic shocks and its subsequent recovery time. As numerous economic studies have demonstrated, reshoring global supply chains might insulate a nation from external supply and demand shocks but increases vulnerability to domestic shocks and inhibits adaptation when problems arise.[46] In the case of infant formula, several large American producers accounted for almost all domestic consumption, yet a single factory closure collapsed the entire U.S. market. Despite multiple emergency federal government interventions, shortages persisted for more than eight months thanks in part to an array of federal policies that effectively barred imported formula prior to the pandemic and thus prevented imports from quickly filling the void left by the Abbott factory closure.

The persistent U.S. shortages of trade-restricted infant formula stand in stark contrast to domestic markets for more freely traded products, in which imports could quickly temper domestic supply shocks. During the 2022 U.S. outbreak of avian flu, for example, private parties unencumbered by government barriers were able to respond quickly to the culling of U.S. egg-laying chickens (and thus decreased domestic supplies of fresh eggs) by increasing egg imports and raising domestic prices. Predicted egg shortages thus never materialized.[47]

The infant formula crisis is thus an unfortunate reminder that economic nationalist policies proposed to make America more resilient, such as tariffs, localization mandates, and government contracts, can actually weaken the nation by discouraging global capacity, supplier diversity, and system-wide flexibility. Each of those policies, in fact, fueled formula shortages and prevented recovery, as the federal government's emergency responses tacitly admitted.

Concentration and Market Failure

The formula crisis also provides a lesson for those seeking to use antitrust and competition policy to attack concentration in the U.S. market: to the extent that there is concentration and stagnation in an industry, it is usually caused by government action, not market failure. In the case of infant formula, trade restrictions, costly regulations, and government contracts restricted competition from abroad, bolstered the dominance of a handful of large domestic corporations, and stifled new market entrants. Policymakers looking to improve the concentrated U.S. infant formula market (and others) should first reform existing policies, not add another layer of government regulation atop the numerous existing ones.

Consumer Cost

The crisis also teaches, once again, the significant harms that intentional government restrictions on supply can inflict on American consumers, especially poorer ones. While some data show that stock rates improved by the end of 2022, consumer experience in certain areas says otherwise.[48] Survey data also indicate that low-income families have been disproportionately harmed—42 percent of families with household incomes below $75,000 (the national median) reported in November difficulty finding formula the previous week, whereas only 27 percent of families with household incomes above the same level reported such difficulties.[49]

Bare shelves are detrimental for WIC recipients because WIC benefits can only be used in physical stores and not online. While the USDA made progress by creating flexibility for WIC recipients to buy any available formula, bare shelves force WIC recipients to waste their benefits and pay out-of-pocket to purchase formula online.

Furthermore, USDA waivers that enabled WIC participants to purchase non-state-contracted formulas expire on February 28, 2023, at the latest with no indication of further extension.[50] Experts in states such as Pennsylvania do not see out-of-stock rates in their regional markets getting back to pre-recall levels in the immediate future. Local reports suggest yet another problem: some families are not even aware that the waivers exist, making them hesitant to inquire about alternatives to their usual formula in the first place.[51]

Finally, since government increased access to foreign formula, Reckitt, a British company, has become one of the most popular brands in the United States. Reckitt reportedly is feeding more than 40 percent of all low-income WIC infants.[52] Yet the expiration of the WIC waivers threatens parents on WIC who are currently using Reckitt brands because after February 28, 2023, these parents will have to switch back to the state-contracted formula. And if that formula is not available in store, parents will have to forego their benefits and pay out-of-pocket to continue buying Reckitt products, which will likely be more expensive now that the tariffs have been reinstated.[53]

Status Quo Bias and Political Resistance

Finally, the tepid and temporary government response to the infant formula crisis provides reason for skepticism of, if not outright opposition to, new proposals for government interventions in the market. Unlike private actions, the successes or failures of which are usually adjudicated (often ruthlessly) by the market, government policies often live or die based on politics rather than their actual efficacy. Most notably, interest groups (e.g., U.S. dairy farmers or state WIC offices) that disproportionately benefit from a policy routinely mobilize against reforms, while those harmed by the policy (e.g., consumers) rarely undertake similar and offsetting efforts.[54] Politicians and bureaucrats are also often hesitant to support or vote for reforms out of concern that voters will assign more blame for their actions than for their refusal to act, even where the former would produce better policy outcomes overall—an impediment commonly known as the "trolley problem." That these and other political considerations thwarted real long-lasting reforms during a legitimate national emergency is a testament to their power.

CONCLUSION AND POLICY RECOMMENDATIONS

The barriers to competition in the U.S. infant formula market, including tariff and nontariff barriers hindering foreign producers' access, the WIC program's structure, and obscure domestic policies such as FDA regulations, altogether make it harder for new entrants to compete. The crisis illustrates how these policies encourage concentration among a handful of large producers, prevent rapid adjustment to economic shocks, and require fundamental reform.

Policymakers looking to improve the U.S. infant formula market should therefore target these problematic policies, not add another layer of government regulation atop the numerous ones we already have. Reforms could include:

- eliminating all tariffs and tariff-rate quotas on imported infant formula;
- revising the United States-Mexico-Canada Agreement to allow for the free movement of infant formula between the United States, Canada, and Mexico;
- requiring the FDA to permit the importation, marketing, and domestic sale of any infant formula approved by a competent regulator abroad, such as those in Australia, Canada, the European Union, the European Economic Area, Japan, New Zealand, and Switzerland;
- reducing the size (and thus influence) of the WIC program, while also eliminating the sole source contracting model so that participants may purchase any infant formula lawfully sold in the U.S. market; and
- streamlining the FDA approval process for new market entrants and reconsidering whether Congress has struck the proper balance between public health and market competition under the Infant Formula Act of 1980 and its amendments.

Parents have already paid enough during this crisis and cannot afford for policymakers to continue sleeping on effective reforms.

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