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# The Infant Formula Crisis in the United States: A Cautionary Tale of Regulatory Capture

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In October of 2021, an infant formula plant in the state of Michigan in the United States was shut down by Abbott Nutrition after allegations that contamination in its products had caused the deaths of two children. As a result, Abbott also voluntarily recalled several of its infant formula products from the market. At the time, the company was producing approximately 40% of all infant formula in the country. This occurred as the nation was experiencing skyrocketing national out-of-stock rates in many sectors of the economy due to the COVID-19 pandemic. By June of the following year, about a fifth of the U.S. was witnessing out-of-stock rates of baby formula that exceeded 90%. Acute shortages would remain for all of 2022 and into early 2023. Panic buying and hoarding, with parents driving from supermarket to pharmacy, caused large-chain retail operations like Walmart, CVS, Target, and Walgreens to establish draconian purchase limits for customers.

The baby formula industry in the U.S. operates under a cumbersome matrix of governmental agencies that maintain tight regulations beyond the norm in the general food industry. The federal government's Food and Drug Administration (FDA) establishes rules and regulatory review on how formula is produced, stored, packaged, and labelled. This is complicated by the fact that baby formula is not generic but, rather, is especially produced to consider for food allergies, respiratory reactions, and other health considerations. The federal government's U.S. Department of Agriculture (USDA) oversees the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) which operates through single-supplier rebate contracts for infant formula. In essence, this federal program is administered by state-level agencies throughout the fifty states to provide vouchers for low-income individuals to purchase a predetermined brand of infant formula. Beginning

with only 100,000 enrollees in 1974, like most federal government programs, it grew to over six million enrollees by 2024, accounting for more than half of all the infant formula sold in the country on an annual basis.

The USDA provides federal money to the fifty states who then individually contract with one manufacturer each with the exclusive right to provide formula to WIC participants in that state. This created a blatant nexus of corporatism whereby the largest and most powerful of the formula makers, with powerful lobbyists and political action committees with campaign contributions, were able to obtain exclusivity arrangements that granted them monopoly status on a state basis. As a result, just three companies – Abbott, Nestlé/Gerber, and Reckitt/Mead Johnson, all with a total of only seven formula producing factories- came to hold all WIC contracts within the fifty states and to dominate the formula market. Abbott alone received exclusivity contracts for thirty-two of the fifty states.

This created a market concentration with serious vulnerabilities to economic shock and which resulted in adverse pricing at the retail level. With only seven factories among the three companies, the disruption of only one, as was the case with the closure of Abbott's plant in Michigan, could and did create an adverse wide-spread effect on production and consequential accessibility of the product to WIC and non-WIC consumers alike. The federal government granted monopoly status on a state-to-state basis to the three companies regarding WIC consumers (half of the market) who were only allowed use the government vouchers to make purchases from the designed company even if the sole company's brand was out of stock. In addition, WIC recipients could not make on-line purchases.

Ample and prime shelf space in retail outlets, coupled with the prestige and credibility of having their brand chosen by the government, allowed the monopoly-status companies to boost their sales to non-WIC consumers with marked-up pricing, thereby compensating for lower

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revenue from WIC voucher purchases. However, retailers came to experience that WIC reacted to increases in the general retail price of formula by increasing the face value of the vouchers. Over time, this also allowed wholesale prices to creep upward. Top administrators at the USDA accommodated price increases beyond inflation due to pressure from politicians rewarded by lobbyists. Others collaborated to seek eventual transition of employment in the companies they were regulating.

The dysfunctional regulatory structure of the WIC program extended to tariff barriers regarding the importation of foreign infant formula. The federal government imposed a base tariff of about 15% to 17.5% on imported formula which was also subjected to tariff-base quotas operationalized within a complex system based on quantity thresholds. As a result of this protectionism, approximately 98% of all infant formula consumed in the United States has been domestically produced. During the COVID-19 pandemic, the federal government was slow to distinguish the infant formula shortage from shortages of other products as a result of disrupted supply chains. However, media outlets widely reported that parents in the United States were crossing the U.S-Mexico border to purchase formula in municipalities on the Mexican side, such as Tijuana, Ciudad Juárez, and Matamoros, where inventories of infant formula were in ample supply due to more liberal policies on importation, particularly from Europe.

Despite its trade restriction policy, in May 2022, under pressure to act, the Biden Administration invoked the Defense Production Act (a relic of the Cold War period) to be able to utilize military aircraft and to commandeer civilian aircraft to conduct *Operation Fly Formula* which imported over 100 million bottles of foreign-made infant formula (about the same amount that is typically sold over two days in the U.S.), mostly from Europe and Australia. In addition, in July of 2022, the U.S. Congress, under heavy public pressure and with much fanfare, suspended tariffs on imports of certain foreign formula and, later, on formula base powder. However, the tariff liberalization legislation was short-lived, quietly expiring on December 31 of 2022 with WIC reverting back to the status quo of maintaining an oligopolistic market structure.

The lack of competition within the infant formula industry, due to government-sanctioned monopolies at the state level, was exacerbated by highly restrictive

non-tariff barriers with a protectionist orientation. The federal government's Food and Drug Administration (FDA) imposed strict regulations pertaining to the manufacture (including nutrient content), labelling, and distribution of formula, as well as standards for quality control in production facilities. This significantly discouraged new entries into the U.S. formula market from potential domestic and foreign competitors due to the high costs caused by excessive regulations. Under FDA dictates, infant formula from the European Union (EU) cannot be imported into the U.S. for commercial use and is only allowed to be imported through third-party delivery services for the intent of personal use, not sale. This is despite the fact that scrutiny on the production and distribution of infant formula in the EU is equal to standards in the U.S. and that the EU's infant mortality rate has consistently recorded tendencies of being lower than that of the U.S.

### **What Should be Learned From the Infant Formula Crisis?**

In March of 2024, the federal government's Federal Trade Commission (FTC) issued a report on the infant formula industry, suggesting liberalization in certain aspects of existing government regulation but did not recommend any liberalization as to existing tariff policies. In addition, the FTC report also discussed the possibility of creating a new office within the FDA exclusively for specific oversight of the infant formula industry. However, any of these reforms can only take place through legislative action by both chambers of the U.S. congress and, before that, such reforms would have to survive a long gauntlet of congressional hearings being conducted by lawmakers under the heavy influence of corporate lobbyists and their ties to political campaign contributions.

Lost in the limited public scrutiny of the infant formula crisis was any revelation of the actual culprit: regulatory capture through corporatism. Regulatory capture was best articulated by Nobel laureate economist George Stigler who noted that, though their collective wealth, large corporations are able to control the regulatory agencies created to oversee their industries by influencing legislators who pass laws that create and fund the regulatory review frameworks. The process of capturing is conducted through well-financed lobbyists and political

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campaign contributions given to these politicians. Influence is also exerted over the agencies themselves by way of offering top administrators, with the specialized and insider knowledge they acquire, to accept lucrative employment in the government affairs office or other employment within the incumbent corporations. As a result, the captured agencies then focus on benefitting those they are supposed to regulate.

Corporatism, as a macroeconomic phenomenon, is a form of statism and is not capitalism or even a variant of capitalism. It is an amalgam of elite corporations and government where political means within regulatory cartelization are utilized to benefit those corporations with taxpayer bailouts, infrastructure subsidies, state-enforced restrictions on competitive entry, and the socialization of an array of corporate costs (e.g., state subsidization of research and development, international marketing, physical protection of assets abroad, and the externalizing of other operating expenses).

In its limited coverage of the infant formula crisis, the fourth estate in the U.S. failed to focus an urgently needed spotlight on corporatism and its consequences. Instead, the legacy media characterized the infant formula industry as yet another sector of the market victimized by disrupted supply chains and crippled distribution channels brought on by the COVID-19 pandemic. It was mostly the independent (non-corporate) media that pointed out that the trade-restricted infant formula crisis seemed deeper and more prolonged than the distortions in other market sectors dealing with more freely traded products. The legacy media's focus was driven by two main factors: Firstly, it is largely populated by egalitarians who could not risk drawing criticism or scrutiny of a government program supposedly catering to vulnerable low-income families with infants – the ideal recipients for those advocating a robust welfare state. Secondly, with a dwindling viewership as more news seekers turn to a splintering nexus of often ideologically tribalized outlets in social media, the legacy media has become increasingly hesitate to confront any large corporation (but especially in Big Pharma) for fear of losing already declining advertising revenue.

The infant formula industry remains today as fragile as before the COVID-19 crisis. A single disruption can again have an industry-wide effect. The state-facilitated cartelization of the industry has concentrated decision-

making to an elite few where price fixing has replaced price determination by the spontaneous order of the market. The continued interventionist measures applied through corporatism will preserve an inability to enact rapid response to future economic shocks and to guarantee open, fair, and robust competition in the infant formula industry.