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The Baby-Formula Crisis as a Lesson in Federalism

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Shortages of infant formula first happened in April 2020. Shortages persist. Why? A careful analysis of the crisis casts light on the complex federal structures that affect the production, distribution, and consumption of baby formula. What does this crisis tell us about our federal system, and how can this case be used by students and teachers?

Background

In our federal division of power, the U.S. Food and Drug Administration (FDA)--created to enforce the 1906 Pure Food and Drug Act--seeks to ensure food, drug, and cosmetics safety nationwide. Before 1906, most states and many local governments regulated food and drugs. With the rise of interstate food and drug commerce during the 1800s, public and industry interests pressed for federal rules that would be uniform and better able to capture the new interstate commerce (Art. I, Sec. 8, Para. 3 of U.S. Constitution) that eluded state and local regulation.

The Pure Food and Drug Act and later amendments preempted (i.e., suspended), via the U.S. Constitution's supremacy clause (Art. VI), many state and local food and drug laws but didn't eliminate state and local regulation. States regulate *intrastate* (i.e., contained within a state) food and drug matters, including marijuana in states that legalize it. Local governments inspect restaurants and retail food establishments.

The Shortage Crisis

Baby-formula shortages first emerged in April 2020 when Covid-19 lockdowns by local and state governments (and governments abroad) interrupted supply chains. Later, starting in September 2021, four infants in Minnesota, Ohio, and Texas fell ill from *Cronobactor sakazakii* bacteria. Two died. Although a whistle-blower informed the FDA on October 21, 2021, that formula-maker Abbott Nutrition did not destroy a batch of allegedly tainted formula, the FDA was slow to investigate. By October, the FDA had also failed to counteract the Covid-induced shortage. Democratic and Republican members of Congress later criticized the FDA's snail pace.

Zeroing in on Abbott's Sturgis, Michigan, plant, the FDA found unsanitary conditions and urged Abbott in February 2022 to recall Similac and other formulas, although no bacteria strains associated with the infant deaths were linked to the plant. The Sturgis plant produced about 40% of the country's formula. Abbott's recall and five-month production shut-down triggered a critical shortage of formula nationwide, panicking parents. By late May, the out-of-stock rate for formula reached a high of 86 percent. Other producers, such as Enfamil-maker Reckitt Benckiser Group plc/Mead Johnson (Reckitt) and Nestlé Gerber, could not replenish the supplies.

Responses Across the Federal System

On May 18, 2022, President Joe Biden invoked the Defense Production Act (1950) to increase formula production. The next day, Biden approved the first military airlift, called Operation Fly Formula, of about 1.5 million 8-ounce-equivalent bottles of formulas from Ramstein Air Base in Germany to Indianapolis on May 22. By September 5, 2022, Operation Fly Formula had transported more than 85 million 8-ounce bottle equivalents into the United States.

On June 1, President Biden acknowledged that he had not been aware of the shortage until April—two months after Abbott and Reckitt warned the FDA and big-box retailers of a looming crisis. On May 12, Biden asked the Federal Trade Commission and state attorneys general to investigate price gouging in the formula market. On July 21, he signed the Formula Act, which suspended tariffs on imported baby formula. On October 11, Biden signed

the Bulk Infant Formula to Retail Shelves Act, temporarily lifting tariffs on imported 'base powder,' a key component filled with proteins, fats, and carbohydrates that is mixed with nutrients and other ingredients to make baby formulas.

State and local governments tried to help parents get formula. Many states launched an online clearinghouse to update parents and tell them where formula was available. States also helped distribute formula products delivered from abroad. In June, Pennsylvania aimed to boost production by pouring another $8.25 million into ByHeart, the nation's newest FDA-approved formula manufacturer, based in the Keystone State.

Abbott reopened its Sturgis plant on July 1, 2022, to produce Elecare. It restarted Similac production on August 26. On February 15, 2023, however, the U.S. Department of Justice announced a criminal investigation of Abbott for its role in the shortage.

Although formula supplies reached higher levels by the end of 2022, recalls, supply-chain delays, and other problems caused continued regional and nationwide shortages in 2023, especially in rural communities. Many big stores, such as CVS and Target, still limit how much formula a family can buy at one time. Also, the baby-formula tariffs, suspended for five months, snapped back in January 2023 due to dairy-industry objections to the FDA's plan to continue tariff suspensions through 2025.

Reckitt predicts the formula shortage will last until spring 2023. Others believe it will last longer.

Why Do Barriers to Formula Availability Persist?

Baby formula is one of our most stringently regulated products. The predominant buyer of baby formula is the federal-state Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) established by Congress in 1972.

Birth-Rate and Behavioral Barriers

Two non-governmental barriers to more production and competition are the 16-year decline of the U.S. birth rate, plus an increased rate of breast feeding, both of which discourage investment in new formula firms. Breast feeding, however, is more common among upper income parents than lower income parents. The latter rely more on baby formula.

Trade Rules

Baby-formula production and sales are dominated by domestic companies that accounted for 98% of the market in 2021, partly because imported formulas face effective tariff rates as high as 25 percent, except for duty-free imports from some countries. The less than 2% amount of imported formula came mostly from Ireland followed by Chile and the Netherlands in 2021. Further, the 2020 United States-Mexico-Canada Agreement (USMCA) limits Canadian firms from exporting formula globally and to the United States by setting quotas which, if exceeded, generate export charges. However, a 2022 Congressional Research Service report concluded: "It is difficult to assess the impact U.S. tariffs have had on the current shortage."

The federal government also has strict rules that lead to border seizures of foreign products that fail to meet such U.S. standards as formula recipes, labels not written in English, non-compliant scoop sizes, and insufficient nutrient listings. The FDA has a "red list" of unacceptable foreign formulas. Federal rules also require retailers to wait at least 90 days before marketing a new baby formula. Hence, major international formula brands occupied little shelf space in U.S. stores until the federal government authorized their emergency entry in 2022.

Domestic Regulation

ByHeart, which began production in 2022, is the first new formula manufacturer to enter the market since 2007. ByHeart spent five years and about $190 million seeking to comply with federal rules.

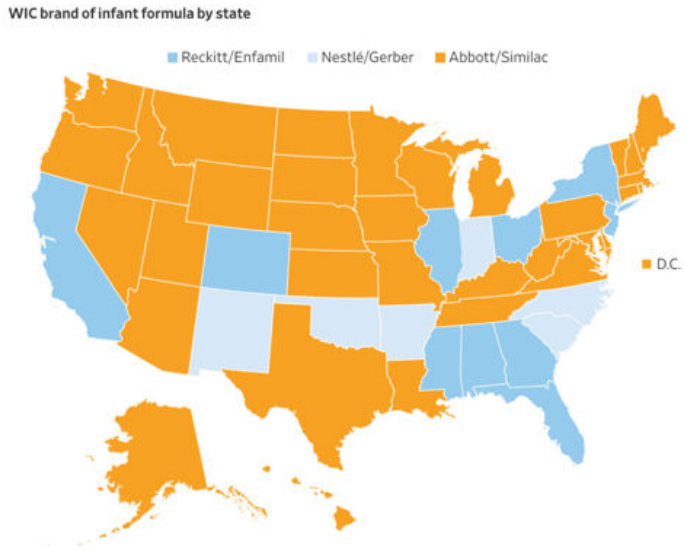
"The Infant Formula Act of 1980 is one of the most specific and detailed acts ever passed by Congress," says the National Library of Medicine. The act's regulatory hurdles are much higher than most FDA food rules. New market entrants and veteran producers wanting to make a new formula must meet numerous requirements, including extensive research on the formula's nutrients, thorough explanations of how the company developed the formula, and complete details about the manufacturing facility's quality-control procedures. The FDA also inspects the plant, observes production, and analyzes nutrient and microbiological samples.

WIC

A major barrier to founding new formula companies is the 51-year-old Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Funded at about $6 billion annually by the federal government, WIC provides categorical grants to states for supplemental foods, healthcare referrals, and nutrition education for low-income pregnant, breastfeeding, and non-breastfeeding postpartum women, and to infants and children up to age 5 who are at nutritional risk.

States administer WIC, determine eligibility, and deliver the services. With about 1.2 million infants receiving formula through WIC, state WIC agencies buy more than half of all the country's baby formula. To do so, however, each state must obtain competitive bids from formula manufacturers and then select one firm to be the sole provider of baby formula for all the state's WIC recipients. Manufacturers bid aggressively for these contracts. In return, the winning manufacturer must provide the state with a significant price discount on its formula. Owing to this arrangement, WIC recipients must use WIC vouchers to purchase formula at in-state brick-and-mortar stores, not online. Many hospitals also contract with one brand so as to obtain a discount.

Only three firms have had recent contracts to provide WIC formulas. Abbott supplied formula to about 47% of WIC infants, Reckitt to 40%, and Gerber to 12% at the start of 2022. Abbott and Reckitt account for more than 80% of all domestic formula production. Hence, risk of a major shortage is high if Abbott or Reckitt cannot meet demand.



Source: Jesse Newman and Annie Gasparro, "Why the Baby-Formula Market Is a Mess: Low Competition, High Regulation," Wall Street Journal, May 20, 2022,

This market arrangement saves the federal government about $1.7 billion per year, and the price discount enables states to serve more infants and children than if they had to pay full prices. However, the 34 states served exclusively by Abbott experienced deeper and longer shortages. Further, WIC recipients cannot buy another formula brand if the exclusive state-contracted brand is sold out.

David E. Davis of South Dakota State University found that physicians tend to recommend their state's exclusive brand to non-WIC mothers and that stores give more shelf prominence to their state's exclusive brand. In fact, WIC requires retailers to stock more of WIC-approved formulas, which increases purchases by non-WIC parents. Consequently, small stores often carry only the WIC-approved brand. These market dynamics, plus the discount that must be provided by the exclusively contracted formula producer, make it difficult for small and would-be formula makers to enter the market.

Beginning with the Families First Coronavirus Response Act of 2021, the U.S. Department of Agriculture (USDA), which administers WIC, was authorized to offer states waivers of federal law to give state WIC agencies more flexibility, including, in February 2022, allowing recipients to buy alternate formula brands and sizes. However, not all states adopted all waivers.

The USDA now has permanent authority from Congress to offer waivers to states for WIC recipients to buy alternate formulas during shortages. Also, formula manufacturers must now provide a contingency plan in their WIC contract for managing supply disruptions.

Reforms?

Two commonly mentioned reforms are to (1) overhaul the FDA's management structure and mission and (2) split the FDA into two agencies, with one devoted solely to food safety. There seems to be little political support for lowering tariffs or altering the exclusive contract arrangements in order to induce more competition in the formula market.

Classroom Questions

- Should the federal government reduce tariffs to allow more foreign firms to sell formulas here?
- Should WIC recipients be allowed to purchase any FDA-approved formula rather than being limited to one brand?
- Should WIC encourage recipients to increase breastfeeding and reduce formula use?
- Should states have authority to respond to formula shortages, such as securing alternate supplies, if federal action lags?
- How might the private companies and the federal and state governments work together more effectively to prevent and respond to shortages?

About the Author

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