

Factors Contributing to the Infant Formula Shortage

In brief...

The United States is experiencing a prolonged shortage of infant formula. For a long-term solution to this issue, the government should eliminate unnecessary regulations and barriers to entry.

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Introduction

The U.S. is experiencing a prolonged shortage of infant formula that began with supply-chain problems caused by the Covid-19 pandemic and was exacerbated by a recall of infant formula in February 2022 and two subsequent shutdowns of an Abbott infant formula production plant in Sturgis, Michigan. Prior to these shutdowns, the Sturgis plant produced about [one-fifth](#) of the infant formula supply in the U.S.

Government Attempts to Augment Supply

The government has, belatedly, some would argue, taken several steps to bring more infant formula to the market, including [airlifting](#) infant formula from Europe and easing regulatory requirements for both foreign and domestic brands, as outlined in a [White House fact sheet](#), and [FDA's temporary guidance](#). On May 26, [FDA Commissioner Robert Califf](#) announced that “[w]ithin two, months we should be beyond normal and with a plethora.”

Unfortunately, these measures [have not succeeded](#) in eliminating the shortage. In early July, about 30 percent of infant formula products were out of stock, and retailers sold on average 11 varieties of formula versus an average of 24 varieties between 2018 and 2021.

On July 6, 2022, the FDA announced a plan to adopt some of its temporary measures on a [long-term basis](#). This plan is a good first step to resolving the shortage, although the new measures alone cannot eliminate the risks to the infant formula supply. There are other factors under the government's control that discourage entry and prevent entrants from achieving more than a small presence in the market.

The best way to reduce the risk of shortages in the future is for the government to eliminate all the barriers to entry under its control. These barriers include, most significantly, tariffs on imported formula and anti-

competitive provisions built into the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). The FDA should also continue to search for additional ways to ease costly regulation without jeopardizing the safety of the infant formula supply.

Tariffs

The most obvious step would be to eliminate tariffs. The tariff rate paid by World Trade Organization members is between 14.9 percent to 17.5 percent on imports of infant formula, and this rate increases when imports reach a certain level. Only a small amount of infant formula is imported duty-free, for example, from Mexico. Of the infant formula imports into the United States between 2012 and 2021, 19.4 percent entered duty-free, and the average effective calculated duty rate on the remaining 80.6 percent of imports was 25.1 percent, as described by the [Congressional Research Service](#). Not surprisingly, imports are currently very small. If tariffs were eliminated, foreign manufacturers would have the incentive to enter the U.S. market and expand.

Anti-competitive Rebate System

Another barrier to entry is posed by the rebate system used in the WIC program. The WIC program is designed to help meet the nutritional needs of low-income pregnant women, infants, and pre-school children by allowing participants to obtain infant formula and other nutritious foods free of charge. The [program](#) is funded through annual appropriations and is administered by state and local WIC agencies and clinics. It is estimated that [at least 50 percent](#) of infant formula in the United States goes through the WIC program, and the rest is sold to consumers at the retail price.

Since 1989, state WIC agencies have been required by federal law to use [competitive bidding](#) for infant formula or another method that results in comparable savings. Under the competitive bidding system, the WIC agency invites manufacturers authorized by the federal government to bid to be the exclusive provider of WIC infant formula in the state's authorized WIC retailer stores. The manufacturer that offers the lowest net price (wholesale price minus rebates) enters a contract with the WIC agency to become the sole provider of infant formula to WIC participants in that state.

According to the National WIC Association, the rebates transfer between [\\$1.5 billion and \\$2 billion](#) from the WIC providers to the government each year. In 2017, the WIC rebates for infant formula paid for [30 percent of the government's total costs](#) of WIC foods, including foods other than infant formula.

The infant formula manufacturers [compete aggressively](#) for WIC exclusive contracts. Although they earn low or even no profits from WIC sales, their status as the WIC provider increases their market share in the non-WIC part of the market. The increase in share is due to "spillovers" to the exclusive WIC provider. These spillovers include increased shelf space, increased credibility from being the WIC brand, the possibility that doctors will recommend the WIC brand to non-WIC parents, and brand loyalty from parents whose children are no longer eligible for formula through WIC but are still using formula.

These spillovers artificially increase demand for the WIC provider's brand in the non-WIC part of the market, reducing competitors' sales, and creating a barrier to entry for new brands.

In addition to increasing the market share of the WIC provider in the non-WIC part of the market, the rebate program increases retail prices. Research shows that the average retail infant formula price is [increasing in the relative size of WIC participation](#) in the state. That is, the larger the share of infant formula that goes to WIC participants, the higher the average price of infant formula in the market.

At this time, the federal government has approved [only the top three U.S. manufacturers](#) to be WIC providers. They have long-term contracts, typically lasting for four years. The top three manufacturers have contracts in each of the 50 states and the District of Columbia, and [all but two of the states](#) use competitively bid rebate contracts. The sole-source rebate program significantly increases concentration at the state and local level, with [the winner receiving on average 84 percent of the market](#) in the contract area.

Given that the sole-source WIC rebate program is used by most state WIC agencies, and the WIC provider obtains such a large share of the market, it may be necessary to allow entrants to compete in state WIC sole-source competitions. Unless an entrant could become a WIC provider in one or more states, it would be relegated to a very small share of the market. As an alternative, the WIC agencies could use [“open-market” WIC contracts](#), in which the agency gives a WIC contract to any approved manufacturer that offers a rebate, although rebates are smaller with open-market contracts.

Another solution would be to eliminate the WIC rebate program. While this would reduce funding for the WIC program, it would create more competitive conditions in the infant formula market.

Unnecessary Regulation

Finally, the FDA should continue to search for ways to ease [regulatory requirements](#). In addition to regulating infant formula nutrient content and product labeling, the regulatory process involves waiting periods and regular plant inspections. As mentioned above, the FDA [eased regulations](#) during the current crisis to bring infant formula to the market more quickly, including “expediting the necessary certificates,” “offering a streamlined import entry review process,” and “exercising enforcement discretion on minor labeling issues for both domestic and imported products to help increase volume of product available as quickly as possible.”

These measures alone are insufficient to resolve the industry’s supply problems. The current high tariffs and the anti-competitive barrier created by the WIC rebate program reduce the likelihood that a new entrant could succeed in the market.

Conclusion

In conclusion, the government’s current policies make it unlikely that the market for infant formula will change in the future in ways that benefit consumers and help prevent future supply shortages. To help prevent shortages of infant formula in the future, the government should eliminate the barriers to entry under its control.