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Public Interest Comment[1] on

The Federal Trade Commission's

Solicitation for Public Comments on Factors that May Have Contributed to the Infant Formula Shortage and Its Impact on Families and Retailers

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Mary Sullivan, Ph.D., Visiting Scholar[2]

The George Washington University Regulatory Studies Center

The George Washington University Regulatory Studies Center improves regulatory policy through research, education, and outreach. As part of its mission, the Center conducts careful and independent analyses to assess rulemaking proposals from the perspective of the public interest. This response to the Federal Trade Commission's request for comment on factors that may have contributed to the recent infant formula shortage does not represent the views of any particular affected party or special interest, but is designed to consider the FTC's questions from a consumer welfare perspective.

Introduction

The staff at the Federal Trade Commission has solicited comments on the factors that may have contributed to the recent infant formula shortage. The topics proposed in the solicitation include regulatory barriers to entry, barriers to entering the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC program), and the impact of Federal Drug Administration

1 This comment reflects the views of the author, and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center's policy on research integrity is available at http://regulatorystudies.columbian.gwu.edu/policy-research-integrity.

2 The author is a Professorial Lecturer of Public Policy & Public Administration at George Washington University, formerly taught at the University of Chicago Booth School of Business and the George Washington School of Business, and was an economist at the Antitrust Division of the U.S. Department of Justice and the Federal Trade Commission.

(FDA) regulations on the number of infant formula suppliers, as well as any other topics considered relevant.

Causes of Infant Formula Shortage

The factors that led to the infant formula shortage are easy to understand. The shortage, which began with supply-chain problems caused by the Covid-19 pandemic, was exacerbated by a recall of infant formula and the shut-down of a major production facility due to contamination. The government has, belatedly, some would argue, taken several steps to bring more infant formula to the market, including easing regulatory requirements for both foreign and domestic brands (White House fact sheet, FDA news release) and airlifting infant formula from Europe (airlift).

These temporary measures will partially make up for the deficiency in supply in the short run, but after the shuttered plant resumes normal production, the same future risks to infant formula supply will remain unless steps are taken to resolve underlying problems on a permanent basis.

Many are taking this crisis as evidence that the market is too concentrated: if one large firm has a production shortfall, there will not be enough capacity in the industry to make up for the deficiency. It is important to note if there are economies of scale at the plant level, demanding redundancy in US plants (whether run by a few firms or by many) would be costly.

The best way to reduce the risk of shortages in the future is for the government to ease or eliminate the barriers to entry under its control. These barriers include, most significantly, tariffs on imported formula, costly regulation, and anticompetitive provisions built into the WIC program.

Tariffs

The most obvious step would be to eliminate tariffs. The tariff rate paid by World Trade Organization members is between 14.9% to 17.5% 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% entered duty free, and the average effective calculated duty rate on the remaining 80.6% of imports was 25.1% (US infant formula tariffs). Not surprisingly, imports are currently very small. If tariffs were eliminated, the foreign manufacturers would have the incentive to enter the U.S. market and expand.

Unnecessary Regulation

Next, the FDA should consider ways to ease regulatory requirements to make entry less costly. In addition to regulating infant formula nutrient content and product labeling, the regulatory process involves waiting periods and regular plant inspections (infant formula regulations). During the current crisis, the FDA eased regulations 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" (FDA news release). The FDA should permanently adopt these measures and consider other ways to safely reduce the regulatory burden on both domestic and foreign manufacturers.

Anticompetitive 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 (USDA 2009). It is estimated that at least 50% of infant formula in the US goes through the WIC program (Senate letter), and the rest is sold to consumers at the retail price.

Since 1989, WIC agencies have been required by federal law to use competitive bidding for infant formula or another method that results in comparable savings (WIC and Retail Prices). Under the competitive bidding system, the WIC agency invites authorized manufacturers 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.

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 (WIC advocacy group). In 2017, the WIC rebates for infant formula paid for 30% of the government's total costs of WIC foods, including foods other than infant formula (WIC funding).

The infant formula manufacturers compete aggressively for WIC exclusive contracts (competitive bidding). 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 (USDA 2011).

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 (WIC and retail prices).

At this time, only the top three U.S. manufacturers are approved by the government to be WIC providers (PBS). 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 (USDA 2015). The sole-source rebate program significantly increases concentration at the state and local level, with the winner receiving on average 84% of the market in the contract area (USDA 2011).

Given the prevalence of the sole-source WIC rebate program, and the advantages that it confers on the WIC provider, it may be necessary to allow entrants to compete to be the WIC provider. 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 (GAO 1990).

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.

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 reduce or eliminate the barriers to entry under its control.