Responses to Questions for the Record

submitted by

Scott Lincicome
Director, General Economics and the Herbert A. Stiefel Center for Trade Policy Studies
Cato Institute

to accompany the Wednesday, June 15, 2022 hearing on

"Baby Formula and Beyond: The Impact of Consolidation on Families and Consumers"
Subcommittee on Competition Policy, Antitrust, and Consumer Rights
Senate Committee on the Judiciary
United States Senate

Submitted July 1, 2022

Questions from Senator Thom Tillis

1. **Data analysts recognized potential infant formula supply chain problems almost a year ago, what role did our regulatory scheme play in hampering our ability to adapt to foreseen shortages?**

   Response: The regulatory system hampered U.S. adaptation in two ways. First, high tariffs and onerous FDA regulatory barriers prevented foreign infant formula producers from quickly responding to the U.S. supply shock caused by the Abbott factory closure and recall. These trade barriers not only created a high and costly hurdle to accessing the U.S. market when the crisis hit but also discouraged foreign producers from creating in the preceding years the official U.S. sales and distribution channels that would have eased and accelerated deliveries today.

   Second, strict FDA regulation of the domestic production and sale of infant formula, promulgated pursuant to the Infant Formula Act of 1980 and subsequent amendments, discouraged new entrants into the U.S. market before and during the current crisis. Until a few weeks ago, in fact, there had not been a new formula manufacturer in the United States since 2007, and it took the new player, ByHeart, more than $190 million and five years "to get its manufacturing facility opened, supply chain in place, clinical trial completed and regulatory approval secured." The company's CEO told the *Wall Street Journal* recently that "he understands why more new brands haven't tried to break into the industry"—in particular, "We spent years trying to study and understand FDA regulations." The CEO of Bobbie—another startup that relies on an existing U.S. manufacturer—said much the same, noting that "the market remains largely impenetrable to newcomers."

2. **What kinds of improvements need to be made in coordinating information and data sharing between agencies and the administration so as to avoid future critical failures in other crucial industries?**

Response: In my opinion, avoiding future failures in crucial U.S. industries is less about interagency communication and far more about systematically reviewing and reducing trade and regulatory barriers to marketing, sales, distribution, and investment in these industries. The free market – whether through price signals, internal corporate monitoring systems, or third-party logistics and supply chain support – is wholly capable of monitoring and communicating potential supply chain failures and then quickly responding thereto. Problems inevitably will arise, but the most serious and persistent ones have occurred in those sectors featuring abnormally high levels of government regulation and barriers to entry.

3. **What sort of changes to tariff policy could we make that would allow the baby formula industry greater flexibility to pivot on production methods in times of shortages?**

   Response: Ideally, the federal government would permanently eliminate all tariffs and tariff rate quotas on imported infant formula, and revise all U.S. trade agreements (e.g., the USMCA) to allow for the free movement of infant formula between signatory countries. Permanent changes are needed to ensure that foreign multinational producers (1) invest *in advance* in the official sales and distribution channels that would have eased and accelerated deliveries today; and (2) establish brand recognition (especially among doctors) and loyalty to truly diversify the U.S. market and thus reduce the chance of a single, dominant producer collapsing the whole market. If permanent changes are impossible, however, the law should be revised to authorize the president to waive tariff and non-tariff (FDA) barriers in times of emergency (e.g., when a certain national inventory threshold is breached).

4. **How could the WIC (Women, Infants, and Children) program procurement policy be changed so that there is more incentive for new producers to break into the U.S. infant formula market?**

   Response: As WIC currently accounts for more than half of all U.S. infant formula sales, it should be scaled back to reduce the market distortions caused by this monopsony power. Also, WIC should move from a state-based, sole source contracting system to a national voucher system in which remaining eligible participants may purchase any infant formula lawfully sold in the U.S. market.