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June 24, 2022

The Honorable Lina M. Khan  
Chair  
U.S. Federal Trade Commission  
600 Pennsylvania Ave. N.W.  
Washington, DC 20580

Submitted Electronically via Regulations.gov

**Re: Comments by the Attorneys General of the States of West Virginia, Arizona, Arkansas, Idaho, Indiana, Kansas, Kentucky, Mississippi, Missouri, Montana, New Hampshire, Oklahoma, South Carolina, Texas, and Utah In Response to the Request for Information Entitled, “Solicitation for Public Comments on Factors that May Have Contributed to the Infant Formula Shortage and Its Impact on Families and Retailers”**

Dear Chair Khan:

The undersigned Attorneys General submit this comment in response to 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” (“RFI”) (May 24, 2022), *available at* <https://bit.ly/3O2RcG5>.

The RFI asks for feedback on several topics related to the infant-formula shortage. Among other things, the Commission seeks information on the experiences of families, the difficulties of small retailers, and the effect of mergers and acquisitions on supplier availability. RFI at 1. In this comment, though, we respond specifically to the Commission’s requests for information concerning “the impact of FDA regulations” on the shortage, as well as the “impact of state WIC [Special Supplemental Nutrition Program for Women, Infants, and Children] competitive bidding.” *Id.*

As we explain below, overregulation and WIC-related market distortions exacerbated a formula shortage already worsened by the Biden administration’s flat-footed response to problems at a critical manufacturing facility. Besides taking a more proactive approach when problems arise in the supply of a critical product like infant formula, the administration should lift needless regulations and revise the competitive-bidding process. We conclude that the sort of regulatory

reform and reduction to barriers to entry that we propose can be achieved without sacrificing quality or creating any increased risk of adulteration.

This painful supply-chain ordeal has once again shown that federal government control is no answer to the problems facing everyday Americans. Regulatory changes would better allow free-market solutions to remedy formula-supply bottlenecks in the future.

## BACKGROUND

Across the country, parents have recently struggled to find formula in stores. The situation is dire, as the national out-of-stock rate recently reached 74 percent. Martine Paris, *One in Five US States Is 90% Out of Baby Formula*, BLOOMBERG (June 2, 2022, 1:03 PM), <https://bloom.bg/3MCGBAu>. Desperate parents have searched far and wide to feed their children, often scouring a dozen or more stores and websites to find only barren shelves and out-of-stock messages. Madeline Holcombe, *Homemade infant formula can be dangerous. Experts share how to feed your baby through the shortage*, CNN (May 11, 2022, 7:15 PM), <https://cnn.it/3zrmzWF>. And parents requiring specialty formulas for their children's specific medical needs face even more substantial challenges with even greater consequences. See, e.g., Brenda Goodman, *2 Children Hospitalized in Memphis Because Their Specialty Formula Is Out of Stock*, CNN (May 18, 2022, 11:24 AM), <https://cnn.it/3xvmVsZ>.

Meanwhile, the shortage has struck some of America's most vulnerable populations hardest. In West Virginia, for instance, rural mothers living far from grocery stores and operating under government-assistance restrictions have found it even harder to find the food their children need. See Amelia Ferrell Knisely, *WV Low-Income Mothers, and Their Babies, Are Among the Hardest-Hit By the Baby Formula Shortage*, MOUNTAIN STATE SPOTLIGHT (May 20, 2022), <https://bit.ly/3MPUonx>. And across the board, "[i]nfants in low-income families, infants of color, and infants living in rural communities are more likely to use formula and therefore may be hardest hit by the formula shortage." Elizabeth Williams & Samantha Artiga, *Key Characteristics of Infants and Implications of the Recent Formula Shortage*, KAISER FAMILY FOUNDATION (June 9, 2022), <https://bit.ly/3mJdFwj>.

In other words, this shortage is not a mere inconvenience. It is a crisis.

This issue is not a partisan one. Any reasonable observer can see that this crisis is severe. In a statement released along with this RFI, you acknowledged the shortage "is causing enormous anxiety, fear, and financial burden for American Families." Statement of Chair Lina M. Khan Regarding Solicitation for Public Comments on the Infant Formula Shortage (May 24, 2022), available at <https://bit.ly/3NPBZZr>. Some locales have even been forced to declare a state of emergency. See, e.g., Press Release, City of New York, Mayor Adams Declares NYC State of Emergency Amid Nationwide Infant Formula Shortage (May 22, 2022), <https://on.nyc.gov/3tvIIEY>.

During this trying time, many parents have resorted to unsafe means to feed their hungry children. Holcombe, *supra*. Some have turned to an illegal formula black market. Christina

Szalinski, *A Very Expensive, Technically Illegal Workaround to the Formula Shortage*, THE ATLANTIC (May 19, 2022), <https://bit.ly/397mwok>. Others are using cow or other animal milk, while still others are trying to prepare formula at home. Holcombe, *supra*. Another desperate group are struggling to stretch what little formula they have across a longer period, hoping to outlast the shortage. *Id.* These “options” are not just risky—they are potentially deadly.

The crisis could have been avoided. According to Congressional testimony and other sources, Biden administration officials were aware of potential problems with formula production at a Michigan Abbott facility by September 2021 (and perhaps as early as 2019). See Daniella Diaz et al., *Breaking Down the Biden Administration’s Response to the Baby Formula Shortage*, CNN (June 3, 2022, 10:31 AM), <https://cnn.it/3Hisbo9>. Even so, officials moved at a snail’s pace—supposedly because of problems such as “mailroom issues” at the FDA. Ximena Bustillo, *The FDA Is Facing An Investigation Into Its Handling of the Baby Formula Shortage*, NPR (June 3, 2022, 6:21 PM), <https://n.pr/3aWTb09>; see also Jessica Winter, *The Baby-Formula Blame Game*, THE NEW YORKER (May 28, 2022), <https://bit.ly/3zvqC4q> (“Somehow, widespread stories of desperate parents unable to feed their infants did not inspire immediate federal action.”).

The federal government’s sluggishness produced, among other things, a weeks’ long shutdown period for the critical plant, which produced one-fifth of the nation’s formula. *Id.* That shutdown, of course, fed a formula shortage that spiraled out of control while the White House did very little. See Nikki Carvajal, *Biden Concedes He Didn’t Understand How Big an Effect Abbott Plant Shutdown Would Have on Baby Formula*, CNN (June 1, 2022, 7:38 PM), <https://cnn.it/3NOTyc1>. After eventually invoking the Defense Production Act, the administration could not even explain how that action would meaningfully alleviate the formula supply problems. See Michael D. Shear et al., *Big Questions Remain About White House Plan to Speed Formula to Shelves*, N.Y. TIMES (May 19, 2022), <https://nyti.ms/3zz7DWA>. At the same time, the administration waited months before it took basic steps like suspending certain FDA requirements and temporarily waiving formula-related WIC restrictions. And it was not until mid-May 2022 that the Department of Justice entered a consent decree with Abbott to fix the problems that shuttered its facility. See Consent Order, *United States v. Abbott Labs.*, No. 1:22-cv-00441-HYJ-SJB (W.D. Mich. May 16, 2022), ECF No. 8.

In short, as one former Obama administration advisor observed, this crisis resulted from “bureaucratic bungling, slowness and not dealing with the implications of an oversupply economy.” Sara Ballou, *Biden Admin’s ‘Bureaucratic Bungling’ Made Baby Formula Shortage Worse, CEO Who Rescued GM Says*, YAHOO! NEWS (May 17, 2022), <https://yhoo.it/3zzokRE>. And the mistakes have seemed to continue. For instance, the White House announced that the Department of Justice would be “engaging with state attorneys general to encourage them to use their powers to monitor and address price gouging in the infant formula market.” Press Release, White House, Fact Sheet: President Biden Announces Additional Steps to Address Infant Formula Shortage (May 12, 2022), <https://bit.ly/3HmI0dl>. But in truth, other than a single cursory letter, we have received no meaningful outreach, support, or “engagement” from the Department of Justice or otherwise on any of these issues.

Yet even before the Biden administration's repeated missteps in responding to this acute issue, overregulation of the infant formula primed the industry for disaster. Because of the time, capital, and resources required to manufacture infant formula, the market is inaccessible to all but the largest companies. Even these companies lack genuine incentive to innovate in the face of costly compliance requirements. Thus, the market is stagnant.

Just four companies manufacture about 90 percent of all formula in the United States: Abbott Nutrition and Mead Johnson Nutrition (the two traditional giants), Nestle USA (a more recent entrant), and Perrigo Company (a generic and house-brand manufacturer). Sarah Beckman, *Yes, 4 companies control a majority of the infant formula industry in the US*, WCNC CHARLOTTE (May 18, 2022, 12:54 AM), <https://bit.ly/3xicRDf>. Of these, Abbott alone controls 48 percent of the market. Julie Creswell and Madeleine Ngo, *Baby Formula Shortage Has an Aggravating Factor: Few Producers*, N.Y. TIMES (May 20, 2022), <https://nyti.ms/3NPBRZX>.

Overwhelming entry barriers and regulations produce this massive market concentration. Only the largest companies can afford to get into the industry. Once in, a "lack of meaningful competition" caused by "rules and regulations [is] designed to protect the incumbents." Creswell and Ngo, *supra*. The market's regulatory entry barriers are so daunting that, until a few weeks ago, no new manufacturer of infant formula had registered with the FDA since 2007. Scott Lincicome, *Baby Formula and Beyond: The Impact of Consolidation on Families and Consumers*, CATO INSTITUTE (June 15, 2022), available at <https://bit.ly/3mOBAu2>. That manufacturer, ByHeart, spent more than \$190 million and worked for five years to "get its manufacturing facility opened, supply chain in place, clinical trial completed and regulatory approval secured." Lauren Debter, *A Startup Wanted To Make A Better Baby Formula. It Took Five Long Years*, FORBES (May 17, 2022, 3:10 PM), <https://bit.ly/39vSfj9>. The current shortage shows that this industry cannot be so reliant on such few players. If something goes wrong—like it did with Abbott's recall—a dramatic ripple effect follows.

In your recent statement, you called out the "fragile" and "highly regulated" infant formula market as a leading cause of the shortage. Khan, *supra*. You noted that these regulations have led to the market having "substantial barriers to entry." *Id.* We agree with that the regulatory backdrop gave rise, at least in part, to the formula shortage. But your statement does not go far enough to bring attention to the actual extent of the FDA's overregulation and WIC's market distortion in this area. And oddly, neither FDA nor the U.S. Department of Agriculture (which oversees WIC) have announced plans to make any *permanent* changes to either formula food regulations or WIC purchasing requirements (save some recent changes allowing emergency waivers).

## DISCUSSION

We recognize that infant formula is an important industry pertaining to a sensitive and cherished population. Infants must receive substantial protection. But FDA regulations should protect consumers by ensuring the product's safety. Current regulations do not achieve safety but instead operate as constraints on innovation and diversity in the market. In the end, these regulations have created a dangerous shortage of an essential resource.

Additionally, the WIC competitive bidding process should be reevaluated. The federal government should not use its market influence to grant a handful of corporations control over something upon which so many children's lives depend. Because of its role in promoting the de facto monopolization of the infant formula market, the administration should reexamine the process and its potential to cause anticompetitive results.

### **I. Excessive Regulatory Requirements For Infant Formula Manufacturing Have Blocked Others From Entering The Market.**

The FDA has often been accused of putting up barriers to market entry; one expert, for instance, has called it a “bureaucratic monopolist” that “represents a major systematic threat to drug innovation and public health.” Richard Epstein, *A Taste of Government-Run Healthcare*, DEFINING IDEAS (June 26, 2012), <https://hvr.co/3MShhqe>. The infant-formula market has proven no different. For formula, FDA regulatory requirements are high at every stage of the process. Indeed, one expert has declared that “[i]nfant formula is the most regulated food that exists, by far.” Abby Vesoulis, *Washington Politicians Helped Create the Baby Formula Shortage. Can They Solve It?*, TIME (May 17, 2022, 9:00 AM), <https://bit.ly/3NWv9Bq> (quoting Dr. Steven A. Abrams, a professor at the Dell Medical School at the University of Texas at Austin and the chair of the American Academy of Pediatrics’ Committee on Nutrition).

If a company wants to manufacture a new infant formula, they must start by showing that the formula meets two separate “quality factors.” 21 C.F.R. § 106.96. The first concerns “normal physical growth,” *Id.* § 106.96(a), while the second is “sufficient biological quality of protein,” *Id.* § 106.96(e). Meeting these quality factors is a difficult process requiring significant front-end investment.

For normal physical growth, the manufacturer must “demonstrate that a formula supports normal physical growth in infants when fed as a sole source of nutrition.” 21 C.F.R. § 106.96(b). Manufacturers must conduct “an adequate and well-controlled growth monitoring study,” *id.*, of “no less than 15 weeks” long, *id.* § 106.96(b)(1), and “enrolling infants no more than 2 weeks old at time of entry,” *id.* It must then “include[] the collection and maintenance of data” on “anthropometric measures of physical growth, including body weight, recumbent length, head circumference, average daily weigh increment, and average daily recumbent length increment.” *Id.* § 106.96(b)(2). These measurements must be made “at the beginning and end of the study,” as well as “at least four additional” times “with three of the six total measurements made within the first 4 weeks” and three made “at approximately 4-week intervals over the remaining 11 weeks.” *Id.* § 106.96(b)(3). The process is exhaustive and hands-on throughout, requiring that participants be monitored near constantly. And just gathering the measurements is only the first part of the trial. Next, the company must “[c]ompare[] the anthropometric data for the test group to a concurrent control group.” 21 C.F.R. § 106.96(b)(4). Manufacturers must perform this comparison “at each time point” and must compare the data for each infant. *Id.* Then, the test group and the control group must be compared to the 2009 CDC growth charts for normal physical growth. *Id.*

On the face of the regulation, the physical growth quality may look like step one, but a manufacturer must perform a separate preclinical study. First, the new formula must be shown to have a “sufficient biological quality of protein.” 21 C.F.R. § 106.96(e). To do so, the manufacturer must “establish[] the biological quality of the protein in the infant formula when fed as the sole source of nutrition using an appropriate modification of the Protein Efficiency Ratio.” *Id.* § 106.96(f). This ratio is described in the “Official Methods of Analysis of AOAC International,” and manufacturers must follow its specific experiment in determining the protein efficiency “rat bioassay.” *Id.* In simple terms, then, the manufacturer must separately (and redundantly) prove that formula will be effective in producing the outcomes that clinical growth studies would establish anyway.

The regulations do allow for exemptions to the testing requirements for the quality factors, but they are limited and complicated. To exempt from physical-growth testing, a manufacturer must modify an existing formula or show an “alternative method or study design.” 21 C.F.R. §§ 106.96(c)(1)-(2). The manufacturer must then show that “the formula supports normal physical growth in infants when the formula is fed as the sole source of nutrition.” *Id.* Likewise, an exemption for modification is limited to “changing the type of packaging” or some other “change made ... [that] does not affect the ability of the formula to support normal physical growth.” *Id.* In short, a prospective manufacturer can rarely avoid performing extremely difficult and expensive studies to satisfy the physical growth requirement.<sup>1</sup>

After performing the multiple required studies and meeting both of these quality factors, manufacturers are expected to include extremely detailed nutrient specifications in infant formulas. They must adhere to specific ranges for 30 nutrients. 21 C.F.R. § 107.100(a). Each of these nutrients has minimum (and many times maximum) levels that must be met. *Id.* Manufacturers must undertake substantial testing and apply extensive labeling to ensure the formula includes each nutrient in the amounts required. Beyond these standards, many other ingredient requirements apply. *Id.* § 107.10. Again, considering these requirements, only a company with access to extensive resources and testing ability could even label their product consistently with the regulations, let alone perform the tests required.

Still other labeling requirements apply, such as painstakingly detailed directions for use. 21 C.F.R. § 107.20. For starters, the label must include a heading titled “Directions for Preparation and Use.” *Id.* § 107.20(a). This heading must then be followed by: (1) directions for storage after the container has been opened; (2) a statement to shake the container before opening; (3) a statement that “[s]terilization” of “water, bottles, and nipples” is necessary; and (4) dilution instructions. *Id.* §§ 107.20(a)(1)-(4). And near these directions, the FDA mandates a “pictogram depicting the major steps for preparation.” *Id.* § 107.20(b). The FDA’s example pictogram shows

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<sup>1</sup> The exemption process for sufficient biological quality of protein is largely the same. It allows for exemptions for modifications to packaging, 21 C.F.R. § 106.96(g)(1), and when the manufacturer can “demonstrate that the change made to an existing formula does not affect the bioavailability of the protein,” *Id.* § 106.96(g)(2). Finally, manufacturers can show biological quality of protein by “demonstrat[ing] that an alternative method” to the one prescribed “is based on sound scientific principles” and can “demonstrate that the formula supports the quality factor for the biological quality of the protein.” *Id.* § 106.96(g)(3). Any of these “exemptions” seem to require further trials, so the exemption process is hardly an effective alternative.

a teakettle, water poured from the teakettle, and two containers being poured simultaneously into a third. *Id.*

But that’s still not the end of the labeling—or even of pictures, for that matter. For instance, manufacturers also need to include a “Use by” date based on their testing. 21 C.F.R. § 107.20(c). Then, they must also include “Add Water,” or “Do Not Add Water,” as “appropriate.” *Id.* § 107.20(d). If that statement is not explanatory enough, the FDA requires another picture here which shows the reader how to mix the formula and water together, which according to the picture should be done by pouring them out simultaneously and in midair. *Id.* Next up, the FDA says that a long warning such as “THE HEALTH OF YOUR INFANT DEPENDS ON CAREFULLY FOLLOWING THE DIRECTIONS FOR PREPARATION AND USE” must be included. *Id.* § 107.20(e). Finally, a statement to “USE AS DIRECTED BY A PHYSICIAN” is needed. *Id.* § 107.20(f). In all, the FDA requires dozens of words, 30 nutrients, and multiple pictures be on the label.

Even once all the testing is done, studies performed, labeling accomplished, and the contents of the formula have met the strict requirements of the FDA’s regulations, a manufacturer still cannot start selling its product. Instead, “[a]t least 90 days before” the formula is “introduced or delivered for introduction into interstate commerce,” the manufacturer has to “submit notice of its intent to do so to” the FDA. 21 C.F.R. § 106.120(a). And this submission is substantial. It must include: “[t]he name and description of the [formula’s] physical form,” *id.* § 106.120(b)(1), “[a]n explanation of why the formula is a new infant formula,” *id.* § 106.120(b)(2), “[t]he quantitative formulation of each form of the infant formula ... and the weight of powder to be reconstituted with a specified volume of water,” *id.* § 106.120(b)(3), and a description of any changes in processing the formula, which includes a “side-by-side, detailed schematic diagram[] comparing the new processing to the previous processing,” *id.* § 106.120(b)(4).

This submission also requires multiple lengthy assurances for quality factors, nutrient contents, and compliance with the Federal Food, Drug, and Cosmetic Act. *Id.* §§ 106.120(b)(5)-(6). If the manufacturer is seeking an exemption, the manufacturer must further present the “scientific evidence that the manufacturer is relying on to demonstrate that the stability of the new infant formula will not differ from the stability of” similar formulas “for which there are extensive stability data.” *Id.* § 106.120(b)(7).

At this point, a potential manufacturer has gone through *at least* 15 weeks of studies, multiple testing points, prepared and submitted a long report, and waited 90 days for the FDA’s response. Yet the FDA still might not approve the submission; it may request more information. 21 C.F.R. §§ 106.120(d)-(e). In this case, if the new information is considered a “substantive amendment,” the FDA may restart the 90 days all over. *Id.* § 106.120(f).

But even if the FDA finds the information sufficient and “readily understandable,” 21 C.F.R. § 106.120(d), the manufacturer is still not done. In other words, *at least* 195 days into the process, manufacturers have not sold a single unit. Instead, they have been forced to incur over half-a-year of only expenses and difficult procedures just to get a chance to sell infant formula. And unfortunately for them, they still can’t.

Instead, the FDA requires yet another submission. This time, the manufacturer must make a “verification submission” “after the first production and before the introduction into interstate commerce of a new infant formula.” 21 C.F.R. § 106.130(a). Now, the FDA wants “the name of the infant formula,” the “filing date” for the new infant formula submission described above, and the identification number assigned to it by the agency following the first submission. *Id.* § 106.130(b)(1). And also three other things: “[a] statement that the infant formula to be introduced into interstate commerce is the same as the infant formulas that was the subject of the new infant formula notification,” *id.* § 106.130(b)(2); “[a] summary of test results of the level of each nutrient required ... and any nutrient added by the manufacturer,” *id.* § 106.130(b)(3); and “[a] certification that the manufacturer has established current good manufacturing practices,” *id.* § 106.130(b)(4).

At this point, the manufacturer would *finally* be able to bring its product to market—but the requirements would not relent. Meticulous anti-adulteration regulations must be met. 21 C.F.R. § 106.5. Controls on finished formula must be met. 21 C.F.R. § 106.70. Extensive records must be kept on all of the above stages of the process. 21 C.F.R. § 106.100. Audits must be done. 21 C.F.R. § 106.94. And on and on.

The FDA need not put such massive burdens and costs on infant formula. Excepting certain specialty formulas, FDA considers infant formula a food, not a drug. It should thus be treated that way. We see many potential reforms:

- The FDA could ease regulations and revert to a standards-based approach, rather than dictate processes at an excruciatingly granular level.
- Timeframes should be shortened to limit steep front-end capital outlays, and needless delay (like the 90-day waiting period for market entry) should be eliminated entirely.
- Redundant regulations should be stricken.
- Labelling requirements should be eased—indeed, the FDA has already done so temporarily. See Elizabeth Nolan Brown, *FDA Will Ease Enforcement of Baby Formula Regulations To Address Shortage*, REASON (June 13, 2022 9:30 a.m.), <https://bit.ly/39jauYW>.

We take solace in the simple fact that the FDA does not apply this kind of regulation to baby food—producing a safe but diverse market for nutrition for our nation’s smallest *without* gross market distortions. In other words, we believe a streamlined approach could guarantee the formula’s safety while still allowing for meaningful opportunity for new manufacturers to emerge.



## II. The WIC Bidding Process Has Created Market Distortions.

In the unlikely event a potential formula manufacturer did manage to navigate its way through all these regulations, it would emerge only to be met by the anticompetitive wall that is WIC's bidding process.

Regulations describe WIC's bidding process as a "cost containment system." 7 C.F.R. § 246.16a(a). Under this system, manufacturers provide substantial refunds to WIC programs in return for the exclusive right to provide their products to the state's WIC participants. Though it might keep unit costs low for WIC itself, this discounting program appears to have distorted the market as a whole. Currently, "only large, established producers have the capacity, capital and regulatory expertise to navigate the WIC contracting process across numerous states and to offer steep, up-front discounts on large volume government contracts." Lincicome, *supra*. As a result, four companies now control 90 percent of the market; at other times, market concentration has been even higher. Eric Berger, *Why is there a baby formula shortage in the US, and what can parents do?*, THE GUARDIAN (May 19, 2022, 5:08 PM), <https://bit.ly/3aDFrY6>; see also, e.g., George Kent, *WIC's Promotion of Infant Formula in the United States*, 1(8) INT'L BREASTFEEDING J. 1, 1 (2006) (describing the infant formula "triopoly").

Worse still, just three of those companies control every WIC contract. Matthew Perrone, *Safety rules keep competition out of infant formula market, set stage for shortages*, PBS (May 24, 2022, 7:25 PM), <https://to.pbs.org/3MCHjh8>. And some industry experts believe the situation will only worsen, lamenting that "[i]f the government doesn't change [the WIC] system, things will go back to the way they were—a forced duopoly." Sharon Terlep & Annie Gasparo, *Baby-Formula Shortage Has Spurred Competition, but Tough Road Remains to Unseat Similac, Enfamil*, THE WALL ST. J. (June 12, 2022, 5:30 AM), <https://on.wsj.com/3MW6YBs>. At the same time, federal officials have long understood that the WIC single-source contract "increase[s] the supermarket price for infant formula for non-WIC consumers." VICTOR OLIVEIRA ET AL., ECON. RSCH. SERV., USDA, USDA-ERS FANRP 39-1, WIC AND THE PRICE OF INFANT FORMULA v (2004).

WIC contracts are extremely valuable for these three companies. In the past, state WIC contracts have given the winning manufacturer an average 74 percent increase in market share for that State. Meredith Lee and Helena Bottemiller Evich, *How the baby formula shortage links back to a federal nutrition program*, POLITICO (May 19, 2022, 4:30 AM), <https://politi.co/3xdQrTP>. And a WIC contract does not just produce a ready customer base; it also brings shelf space, visibility, and a greater likelihood that a physician will recommend the product to all patients. See Jennifer Pomeranz & Jennifer L. Harris, *Federal Regulation of Infant and Toddler Food and Drink Marketing and Labeling*, 45 AM. J. L. & MED. 32, 48 (2019). What's more, by engendering widespread customer loyalty, "[i]nfant formula manufacturers who win state WIC contracts receive substantial benefits, beyond sales of products included in WIC packages, through increased sales of higher-priced infant specialty formulas and toddler milks." Yoon Y. Choi et al., *Effects of United States WIC Infant Formula Contracts on Brand Sales of Infant Formula and Toddler Milks*, 2020 J. PUB. HEALTH POL. 1, 17 (2020).

Although the contracts save States 1.7 billion dollars on average per year, that amount has not increased in recent years and has lagged inflation. Steven Carlson et al., *WIC's Competitive Bidding Process for Infant Formula Is Highly Cost-Effective*, CTR. ON BUDGET AND POL'Y PRIORITIES (Feb. 17, 2017), <https://bit.ly/3tplWJj>. In fact, the savings are down overall from 2008, when they reached 2 billion dollars. *Id.* Meanwhile, the increasing market concentration has likely driven up costs for States on the whole. “[D]windling competition means states will inevitably have to pay higher prices for formula.” Laura Epstein, *Women and Children Last: Anti-Competitive Practices in the Infant Formula Industry*, 5 AM. U. J. GENDER & L. 21, 22 (1996).

Because the WIC bidding process brings so much value to manufacturers, one would expect companies to aggressively compete for it—yet they do not. Instead, they have kept their bids at even levels for nearly two decades. This deliberate resistance smacks of anticompetitive behavior. These same companies engaged in that kind of behavior as soon as the WIC bidding process started. The FTC even investigated the three major bidders, settling price-fixing charges against all three. See Carolyn Skorneck, *FTC Files Antitrust Charges Against 3 Largest Makers of Infant Formula*, AP NEWS (June 12, 1992), <https://bit.ly/39sQ1B5>. On top of that action, 19 state attorneys general sued the formula manufacturers between 1990 and 1996 for price fixing. DAVID BETSON, UNIV. OF NOTRE DAME, USDA-ERS FANRP CONT. 43-3AEM-3-80107, IMPACT OF THE WIC PROGRAM ON THE INFANT FORMULA MARKET 2 (2009), <https://bit.ly/3xxVCiN>. Though the manufacturers did not admit any wrongdoing, they each settled with the States for millions of dollars. *Id.* at 3.

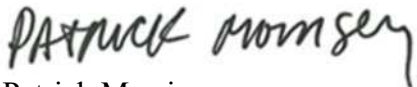
Despite these ill effects, state agencies are required to participate in this system. 7 C.F.R. § 246.16a(b). If a state agency refuses, it must “implement an alternative system.” *Id.* § 246.16a(e). But to do that, the state agency would need to show that the difference between the bidding process and its alternative “is less than 3 percent of the savings anticipated under the latter system and not more than \$100,000 per annum.” *Id.* § 246.16a(e)(1). It is not clear how States could do this. And the full costs of WIC’s bidding process are not included, only its benefits. Because of these constraints, no State has ever even tried to submit an alternative. Carlson et al., *supra*.

Given these and other issues, the entire WIC bidding process should be reevaluated. Because the winning bids of the WIC contracts have fallen so far behind inflation while the value to the companies continues to rise, this process should at least be examined to guarantee that these companies are not exploiting the system and intentionally keeping savings low once more. And it may well be that competitive bidding should no longer be required in the same universal manner that it is now. At a minimum, States should be able to opt out of participation without such a burdensome showing. Further, in times of emergency, relevant agencies should act more aggressively to provide waivers and exceptions to the exclusivity requirements that might otherwise apply. Our nation’s children deserve at least that much.

**CONCLUSION**

We appreciate the FTC looking into this important issue. We urge the Commission to seriously evaluate the effect that the FDA's regulations and WIC bidding process are having on this vital industry.

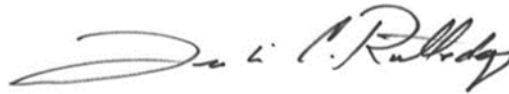
Sincerely,



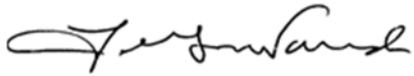
Patrick Morrisey  
West Virginia Attorney General



Mark Brnovich  
Arizona Attorney General



Leslie Rutledge  
Arkansas Attorney General



Lawrence Wasden  
Idaho Attorney General



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Eric Schmitt  
Missouri Attorney General



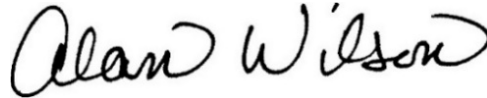
Austin Knudsen  
Montana Attorney General



John Formella  
New Hampshire Attorney General



John O'Connor  
Oklahoma Attorney General



Alan Wilson  
South Carolina Attorney General



Ken Paxton  
Texas Attorney General



Sean D. Reyes  
Utah Attorney General