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## Infant Formula Shortage Highlights WIC's Critical Role in Feeding Babies

By Zoë Neuberger, Katie Bergh, and Lauren Hall

Infant formula shortages triggered by a safety recall have brought attention to the role that the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), which serves more than 40 percent of U.S. infants and accounts for more than half of formula consumption, plays in the infant formula market.<sup>1</sup> This paper aims to correct some misconceptions about WIC and the current shortage by explaining how WIC obtains infant formula and how policymakers have responded to the shortage thus far. It also raises key questions that policymakers will need to address as they develop policies to prevent an infant formula supply disruption like this from happening again.

WIC provides nutritious foods (including infant formula), nutrition education, breastfeeding support, and referrals to health care and social services for millions of low-income families, improving lifetime health for women, their infants, and young children.<sup>2</sup> For decades, WIC has supported breastfeeding — including by providing additional WIC foods that breastfeeding parents and breastfed infants need — while also allowing low-income families to get formula they might not otherwise be able to afford.

WIC uses a competitive bidding process under which infant formula manufacturers offer substantial discounts to state WIC programs in order to be selected as the sole formula provider to WIC participants in the state, except when families need specialized formula for medical reasons. (A state or, in some cases, an alliance of states conducts a competitive bidding process and selects a WIC provider.) This process, adopted through bipartisan legislation in 1989, saves the federal government \$1 billion to \$2 billion per year; in fiscal year 2021 the savings totaled \$1.6 billion. These savings reduce program costs and have played an important role in allowing WIC to serve all eligible applicants with the limited funding the program receives through the annual appropriations process.

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<sup>1</sup> In 2018, WIC accounted for an estimated 56 percent of infant formula consumption. U.S. Department of Agriculture, Economic Research Service, “Infants in USDA’s WIC Program consumed an estimated 56 percent of U.S. infant formula in 2018,” May 23, 2022, <https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=103970>.

<sup>2</sup> Steven Carlson and Zoë Neuberger, “WIC Works: Addressing the Nutrition and Health Needs of Low-Income Families for More Than Four Decades,” CBPP, updated January 27, 2021, [www.cbpp.org/wicworks](http://www.cbpp.org/wicworks).

For more than 20 years WIC has not turned away eligible applicants or put them on a waiting list due to lack of funds.

To help families cope with the current formula shortage, the U.S. Department of Agriculture (USDA) has, among other steps, expanded state flexibility over formula purchases by WIC participants. In particular, in many states WIC participants can now use their WIC benefits to select formula from more than one manufacturer. This is a temporary measure to cope with shortages; the basic structure of the competitive bidding process remains in place.

Policymakers will need to explore longer-term responses to prevent future shortages, and it will be important to engage in thoughtful analysis instead of rushing to solutions that could have unintended consequences. While WIC's purchasing power could allow it to play an important role, changes must be considered carefully. A key goal must be to maintain WIC's ability to serve all eligible applicants so that low-income families can obtain infant formula and the other nutritious food WIC provides.

## **WIC Uses Competitive Bidding to Obtain Infant Formula**

Although WIC recognizes and promotes breastfeeding as the optimal source of nutrition for infants, it provides iron-fortified infant formula for babies who are not exclusively breastfed. More than 47,000 grocery stores nationwide have been approved to accept WIC benefits based on their prices and the variety of foods they offer.<sup>3</sup> Participants select their WIC-approved foods, including infant formula, from grocery store shelves and use a WIC electronic benefits card to pay at the register. (See Figure 1.)

State WIC programs — individually or in alliances of several state agencies — solicit bids for discounts on formula.<sup>4</sup> The process is competitive; generally two or three companies bid for each contract. The bidder offering the lowest net price becomes the sole provider of regular infant formula through WIC in the state, provided it can meet the other contract requirements.<sup>5</sup> (Babies or young children who need a specific kind of formula can get it through the WIC program even if the company that won the bid doesn't manufacture that type.) Federal laws and regulations provide detailed instructions on the bidding and selection processes, which are conducted in a transparent way.<sup>6</sup>

Although one manufacturer is selected for the contract, it is misleading to call this a “sole source” contract, since that term typically describes a *non-competitive* process where one company is awarded a contract without a bidding process, usually because no other company can meet the contract requirements. The Small Business Administration defines a sole source contract for federal business

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<sup>3</sup> U.S. Department of Agriculture, Food and Nutrition Service, “About the WIC Program,” May 12, 2022, <https://www.fns.usda.gov/wic/state-agency>.

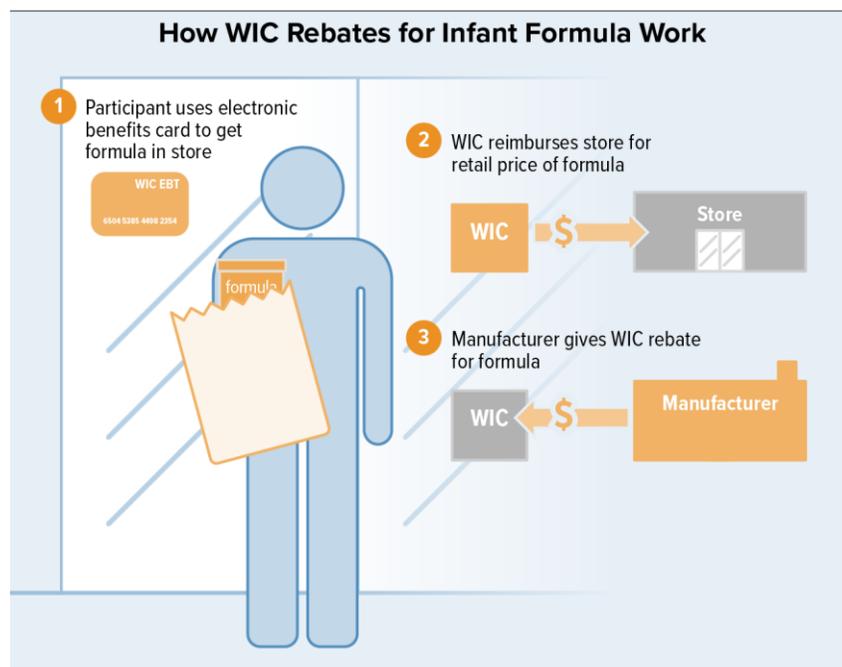
<sup>4</sup> *Ibid.* While geographic state agencies serve the vast majority (97 percent in fiscal year 2021) of WIC participants, territories or tribal organizations can serve as state agencies operating the WIC program.

<sup>5</sup> Larger states or alliances are required to conduct separate competitive bids for milk-based and soy-based formula.

<sup>6</sup> 7 C.F.R. § 246.16a.

as “a kind of contract that can be issued without a competitive bidding process.”<sup>7</sup> In contrast, WIC’s bidding process is so competitive that WIC receives large discounts off the wholesale price of infant formula.

FIGURE 1



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## Competitive Bidding Significantly Reduces WIC’s Infant Formula Costs

For infant formula manufacturers, winning a WIC contract results in purchases increasing among *non*-WIC participants as well as WIC participants. This could reflect wide availability of their product, favorable shelf space in stores, samples or recommendations provided by health care providers, and/or word of mouth. The increase in WIC brand purchases arises even for formulas, like toddler formulas, that are not typically available through WIC. Estimates suggest that sales to non-WIC participants in a state might double or triple when a manufacturer wins a WIC contract in that state.<sup>8</sup>

<sup>7</sup> U.S. Small Business Administration, “Types of contracts,” <https://www.sba.gov/federal-contracting/contracting-guide/types-contracts>.

<sup>8</sup> U.S. Department of Agriculture, Economic Research Service, “The Infant Formula Market: Consequences of a Change in the WIC Contract Brand,” August 2011, [https://www.ers.usda.gov/webdocs/publications/44900/6918\\_err124.pdf](https://www.ers.usda.gov/webdocs/publications/44900/6918_err124.pdf); Mike Abito *et al.*, “Demand Spillover and Inequality in the WIC Program,” presentation at 20<sup>th</sup> annual International Industrial Organization Conference, May 2022, <https://drive.google.com/file/d/1fzBl3LYuqo6nw9QJlVboNFXQ6y56h6K/view>; Christian A. Rojas and Hongli Wei, “Spillover Mechanisms in the WIC Infant Formula Rebate Program,” *Journal of Agricultural & Food Industrial Organization*, Vol. 17, No. 2, December 14, 2018, <https://doi.org/10.1515/jafio-2018-0019>; Yoon Y. Choi, Alexis Ludwig, and Tatiana Andreyeva, “Effects of United States WIC infant formula contracts on brand sales of infant formula and toddler milks,” *Journal of Public Health Policy*, Vol. 41, September 2020, <https://doi.org/10.1057/s41271-020-00228-z>.

As a result, even though bidding is entirely voluntary, manufacturers routinely compete aggressively on WIC contracts and offer substantial rebates. Nationwide, the competitive bidding process yields \$1 billion to \$2 billion a year in rebates. (See Figure 2.) The 2021 savings of \$1.6 billion were enough to provide WIC benefits to more than 2 million low-income women, infants, and young children. Even with the savings, the WIC program spent more than half a billion dollars on infant formula in fiscal year 2018 (the most recent year available), much of which likely went to retailers to cover their markup.<sup>9</sup>

FIGURE 2

### Infant Formula Rebates Save WIC \$1-2 Billion Annually

In billions of dollars



Source: U.S. Department of Agriculture administrative data

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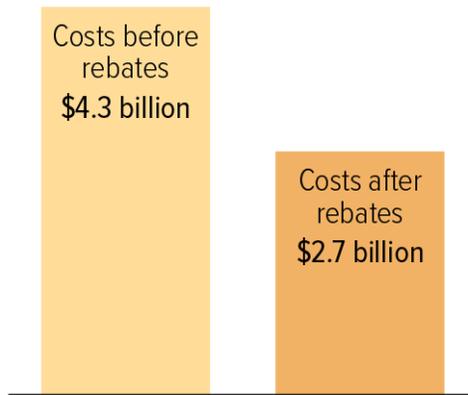
Due to the savings on infant formula, WIC’s total spending on the foods it provides — including discounted formula plus other WIC foods, which are generally not discounted — is well below their full retail value.<sup>10</sup> (See Figure 3.)

<sup>9</sup> Nicole Kline, Kevin Meyers Mathieu, and Jeff Marr, “WIC Participant and Program Characteristics 2018 Food Packages and Costs,” Table ES.1, Insight Policy Research, Inc., November 2020, <https://fns-prod.azureedge.us/sites/default/files/resource-files/WICPC2018FoodPackage-1.pdf>.

<sup>10</sup> The average monthly federal cost of WIC foods was \$35.34 per participant in fiscal year 2021, but the average retail value of WIC foods was \$56.68 per participant (excluding the increase to fruit and vegetable benefits funded through the American Rescue Plan). CBPP analysis of Department of Agriculture WIC administrative data available at <https://www.fns.usda.gov/pd/wic-program>.

FIGURE 3

## Infant Formula Rebates Reduce Federal WIC Food Costs Considerably



Source: U.S. Department of Agriculture administrative data. Data are for fiscal year 2021.

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### Savings Allow WIC to Serve All Eligible Applicants

WIC receives “discretionary” funding through the annual congressional appropriations process, competing with a broad range of other programs for the limited funding available. Congress authorizes a specific amount of funding each year and USDA gives each state a grant to operate the program.

Most other federal nutrition programs, such as the Supplemental Nutrition Assistance Program (SNAP, formerly known as food stamps) and the National School Lunch Program, operate as “entitlements,” meaning their budgets automatically expand to ensure that all eligible applicants can receive benefits. With WIC, by contrast, the number of families that can receive benefits depends upon the size of the annual appropriation, any carryover funding from the prior year, the formula discounts WIC receives, and the cost of providing WIC foods and formula and operating the program. The competitive bidding process, by substantially lowering WIC’s infant formula costs, has slowed the overall growth of WIC food costs, allowing the program to serve more eligible families within each year’s funding level. (See Figure 4.)

For many years after WIC’s creation in 1974, Congress did not provide enough funding to serve all eligible low-income women and children who sought benefits. State agencies provided benefits to those with the most serious health conditions and created waiting lists for other eligible individuals.<sup>11</sup> Over time, with bipartisan support, Congress gradually raised the annual WIC appropriation with the goal of eventually providing enough funding each year to serve all eligible

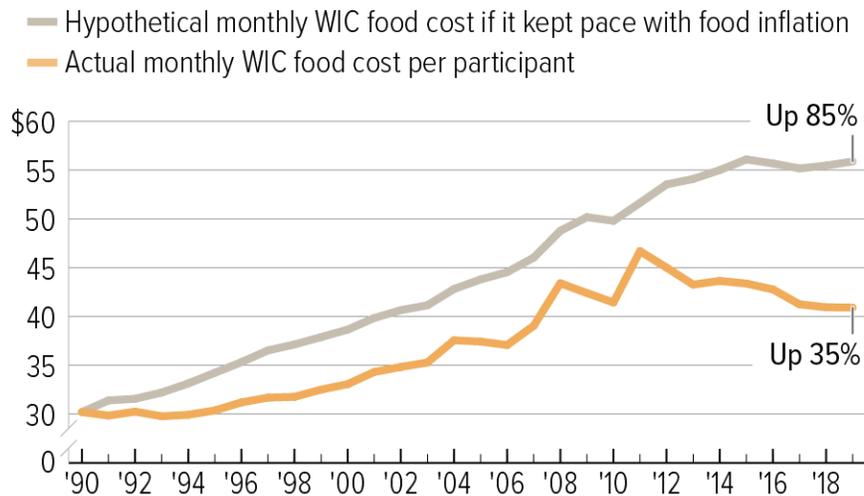
<sup>11</sup> WIC rules establish seven priority categories. In general, priority goes to persons with medically based nutrition risks over dietary-based nutrition risks, to pregnant and breastfeeding women and infants over children, and to children over postpartum women. See 7 C.F.R. § 246.7(e)(4).

low-income women, infants, and young children who applied. With the help of savings from infant formula competitive bidding as well as larger appropriations, the program finally reached this “full funding” level by 1997, and administrations and Congresses of both parties have continued to fully fund WIC since then to meet projected needs. One reason for this bipartisan support is that studies have shown that investments in prenatal WIC lead to substantial health care savings.<sup>12</sup>

As a result of these funding increases, combined with the significant savings each year from infant formula discounts, for more than 20 years WIC has not turned away eligible applicants or put them on a waiting list due to lack of funds. Maintaining that access is critical as policymakers add much-needed resiliency to the infant formula supply, so low-income families with young children or pregnant adults can afford the nutritious food, including formula, they need for healthy development.

FIGURE 4

### WIC Food Costs Have Grown More Slowly Than Inflation



Source: CBPP analysis of U.S. Department of Agriculture administrative data

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<sup>12</sup> For example, a 1990 study found that every \$1 spent on the prenatal WIC program resulted in Medicaid savings of \$1.77 to \$3.13 for newborns and mothers in the first 60 days after birth. See “The Savings in Medicaid Costs for Newborns and Their Mothers from Prenatal Participation in the WIC Program, Volume 1,” Mathematica, October 1, 1990, <https://fns-prod.azureedge.us/sites/default/files/SavVol1-Pt1.pdf>. A more recent study found that spending an additional \$1 on prenatal WIC in California would result in savings of \$1.24 to \$6.83 by reducing the risk of adverse birth outcomes. See Roch A. Nianogo, “Economic evaluation of California prenatal participation in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) to prevent preterm birth,” *Preventive Medicine*, Vol. 124, July 2019, <https://www.sciencedirect.com/science/article/abs/pii/S0091743519301355?via%3Dihub>.

## Bidding Process Revised Over Time to Improve Competition

Despite objections from infant formula manufacturers, in 1989 Congress and President George H.W. Bush enacted legislation on a bipartisan basis requiring all state WIC programs to use competitive bidding for the purchase of infant formula, unless the state could institute an alternative mechanism that would provide comparable savings.<sup>13</sup> (No state has yet used an alternative.)

While there has been some speculation that WIC's competitive bidding process contributed to consolidation among infant formula manufacturers, the market was already highly concentrated when competitive bidding was adopted, and the number of major players in this sector has remained largely unchanged since then. Only three formula manufacturers bid on states' early WIC contracts: two large companies, Mead Johnson and Ross Laboratories, and a smaller company, Wyeth. A fourth competitor, Nestlé, entered the U.S. market when it acquired Carnation in 1989 and participated in a limited number of bids starting in 1990. But Wyeth exited the WIC program in 1996 and switched to producing generic-branded formula, bringing the number of competitors back to three.<sup>14</sup>

More than three decades later, there are still three companies receiving state WIC contracts: Abbott, Mead Johnson, and Nestlé (Gerber).<sup>15</sup> (See Figure 5.) The players are ultimately the same as well. Ross Laboratories was acquired by Abbott in the sixties and changed its name to Abbott Nutrition in 2007.<sup>16</sup> In addition, Nestlé and Wyeth are now the same company: Wyeth was acquired by Pfizer in 2009, and then subsequently acquired by Nestlé in 2012.<sup>17</sup>

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<sup>13</sup> The enactment of the competitive bidding requirement and its aftermath is described in Steven Carlson, Robert Greenstein, and Zoë Neuberger, "WIC's Competitive Bidding Process for Infant Formula Is Highly Cost-Effective," CBPP, updated February 17, 2017, <https://www.cbpp.org/research/food-assistance/wics-competitive-bidding-process-for-infant-formula-is-highly-cost>.

<sup>14</sup> U.S. Department of Agriculture, Economic Research Service, "Impact of the WIC Program on the Infant Formula Market," January 2009, <https://naldc.nal.usda.gov/catalog/32816>.

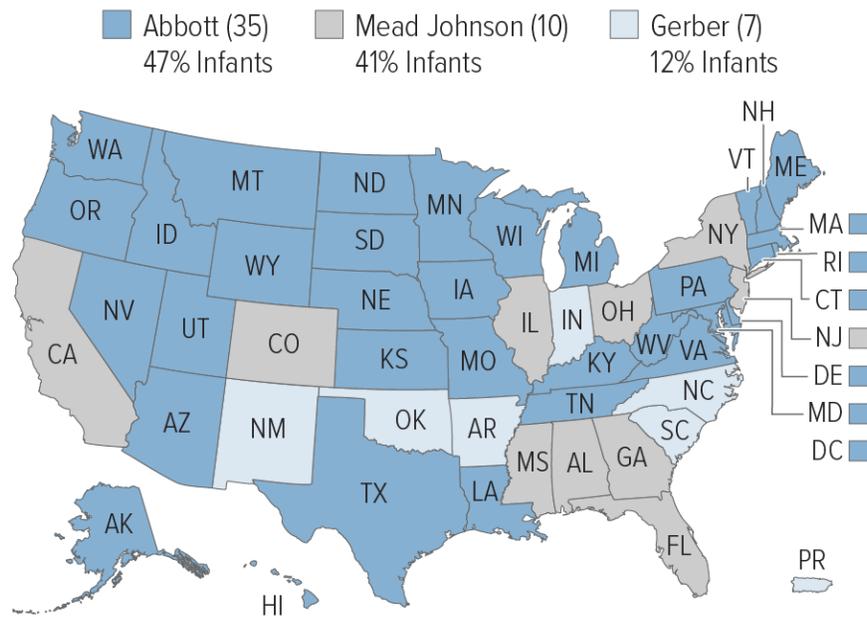
<sup>15</sup> *Ibid.* Gerber is currently owned by Nestlé, but Mead Johnson also had an agreement to market Gerber-brand formula from 1989 to 1997.

<sup>16</sup> "Abbott retires Ross name, keeps proud tradition," *Columbus Dispatch*, November 7, 2007, <https://www.dispatch.com/story/business/2007/11/08/abbott-retires-ross-name-keeps/23419834007/>.

<sup>17</sup> Pfizer, "Pfizer Completes Acquisition Of Wyeth," Business Wire, October 14, 2009; Nestlé, "Wyeth nutrition acquisition," <https://www.nestle.com/investors/overview/mergers-and-acquisitions/wyeth-nutrition-acquisition>.

FIGURE 5

### Three Manufacturers Supply WIC Infant Formula



Note: Contract status as of May 2022. Share of infants by manufacturer in legend refers to the infants participating in WIC in the 50 states, D.C., U.S. Territories, and Indian tribal organizations that have contracts with that manufacturer.

Source: U.S. Department of Agriculture administrative data

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Without the competitive bidding process, infant formula manufacturers would receive full price on formula provided through WIC. Congress has rejected industry efforts to eliminate or weaken the basic structure of the competitive bidding process, instead implementing modest changes over time to make the process fairer and to make it easier for smaller companies to bid. These changes include:<sup>18</sup>

- **Addressing partial redemptions.** Initially, infant formula manufacturers’ rebates were based on the number of cans of formula listed on WIC participants’ vouchers, which may have substantially exceeded the number of cans that participants actually redeemed at stores. In 2004, Congress required state agencies to establish a system to ensure that rebate invoices provided a reasonable estimate or an actual count of the number of cans sold to participants.
- **Limiting the size of state alliances.** In 2004, Congress also added new limits on the size of state alliances (groups of states that procure infant formula together through the same bid solicitation) so that companies with less production capacity would have more contracts to bid on. In general, due to the limit, state alliances may only serve up to 100,000 infants,

<sup>18</sup> These and other provisions related to competitive bidding for infant formula are contained in 42 U.S.C. § 1786(h)(8)(A).

though alliances that existed prior to this change were permitted to continue and serve additional infants as long as they did not add new states.

- **Requiring separate bids for milk- and soy-based formula.** Congress in 2004 also required large state agencies and alliances serving a monthly average of 100,000 infants or more to solicit separate bids for milk-based and soy-based formula. This can allow two different manufacturers to provide formula to WIC participants in a state, one for each category. In addition, because less soy-based formula is provided, separate bid solicitations might make it easier for companies with less production capacity to bid on these contracts.

More recently, some members of Congress have proposed further changes. For example, child nutrition reauthorization bills in both the House and Senate in 2016 included proposals requiring state agencies to: ensure that infant formula rebate invoices provide an actual count of the number of units sold to participants; allow manufacturers holding infant formula contracts to conduct annual audits of rebate invoices; limit the duration of contracts and require mutual consent for extensions; and make a reasonable effort to notify all approved infant formula manufacturers when the state published a bid solicitation.<sup>19</sup> In the current Congress, bipartisan bills have been introduced in both chambers that would require USDA to establish a public database of all state bid solicitations for infant formula to make it simpler for potential bidders to access information about contract opportunities.<sup>20</sup>

Even though Gerber has been a consistent bidder, states contracting with Gerber serve a far smaller share of infants participating in WIC nationally than states contracting with Abbott or Mead Johnson. Gerber's share increased following the 2004 legislative changes, reaching 28 percent in 2012, but has since decreased again.<sup>21</sup> While these changes may have helped the smallest bidder gain ground at least temporarily, they did not attract new entrants; the same three manufacturers have continued to hold all state WIC contracts.

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<sup>19</sup> The Improving Child Nutrition Integrity and Access Act (S. 3136) and Improving Child Nutrition and Education Act (H.R. 5003) were both reported out of committee in the 114<sup>th</sup> Congress but neither was considered on the floor. Both bills also included provisions requested by infant formula manufacturers regarding adjunctive eligibility for WIC. Medicaid, SNAP, and TANF monthly cash assistance payment recipients are "adjunctively eligible" for WIC, which means they are considered income-eligible and do not need to separately document their income to enroll in WIC. (See 7 C.F.R. § 246.7 (d)(2)(vi).) As the Affordable Care Act's Medicaid expansion allowed states to extend eligibility to higher-income households, some infant formula manufacturers feared that families who would otherwise have paid full price for formula would instead receive it through WIC at the heavily discounted rate. Both bills included provisions allowing infant formula manufacturers to unilaterally terminate their WIC contract if a state increased its income eligibility limit in Medicaid in a manner that would substantially increase the number of infants served by WIC. See also Tennille Tracy, "Makers of Baby Formula Press Their Case on WIC Program," *Wall Street Journal*, April 27, 2015, <https://www.wsj.com/articles/makers-of-baby-formula-press-their-case-on-wic-program-1430177799>.

<sup>20</sup> The WIC Healthy Beginnings Act (S.3216/H.R. 7603).

<sup>21</sup> In fiscal year 2012, Nestlé had contracts with 13 states with 28 percent of infants participating in WIC; Abbott had contracts with 22 states and the District of Columbia with 34 percent of infants participating in WIC; and Mead Johnson had contracts with 15 states with 38 percent of infants participating in WIC. As of May 2022, Nestlé (Gerber) had contracts with six states and Puerto Rico with 12 percent of infants participating in WIC; Abbott had contracts with 34 states and the District of Columbia with 47 percent of infants participating in WIC; and Mead Johnson had contracts with ten states with 41 percent of infants participating in WIC. (See Figure 5.) CBPP analysis of U.S. Department of Agriculture and state administrative data.

## WIC Responding to Current Shortage by Expanding State Flexibility

In February 2022, Abbott recalled formula manufactured at a Michigan factory that produced a large share of its formula — and roughly one-quarter of *all* domestic formula — and halted production at that factory due to safety concerns.<sup>22</sup> As a result of the recall, WIC participants in states that provide Abbott formula needed an alternative. USDA, other federal policymakers, and formula manufacturers have taken several steps to address the shortage in states that have contracts with Abbott and other states with shortages arising from the ripple effects of the recall.<sup>23</sup>

- USDA promptly gave states the opportunity to request waivers so they could allow WIC participants to use WIC benefits to buy other brands and types of formula without the medical documentation they would ordinarily need.<sup>24</sup> All states with Abbott contracts and nearly all other states have been approved for these waivers.<sup>25</sup> USDA is continuing to approve waivers and has urged states to use all available flexibilities to help families obtain formula.<sup>26</sup> While this doesn't put more formula on store shelves, it helps low-income families get the formula that is available.
- USDA is providing information on an ongoing basis to state WIC agencies and WIC participants about the recall. In addition, the Food and Drug Administration, Centers for Disease Control and Prevention, and American Academy of Pediatrics have posted information for families about the recall and safe infant feeding practices.<sup>27</sup>
- Other companies have been sending some of their formula to the states with Abbott contracts to alleviate the shortages there. These companies are still obligated to provide formula in the states where they have contracts, but there are reports of shortages in non-Abbott states, perhaps due to supply reductions and panic buying.<sup>28</sup>

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<sup>22</sup> Food and Drug Administration, “FDA Investigation of Cronobacter Infections: Powdered Infant Formula,” February 2022, <https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022>; Michael Barbaro *et al.*, “What Really Caused the Baby Formula Shortage,” *New York Times*, May 27, 2022, <https://www.nytimes.com/2022/05/27/podcasts/the-daily/baby-formula-shortage-bacteria.html>.

<sup>23</sup> A regularly updated summary of the federal response to the infant formula shortage is available at <https://www.whitehouse.gov/formula/>.

<sup>24</sup> U.S. Department of Agriculture, “USDA Grants Additional WIC Flexibilities Amid Abbott Recall of Certain Powder Infant Formula,” February 23, 2022, <https://www.usda.gov/media/press-releases/2022/02/23/usda-grants-additional-wic-flexibilities-amid-abbott-recall-certain>.

<sup>25</sup> U.S. Department of Agriculture, Food and Nutrition Service, “Infant Formula Safety: Infant Formula Recall & Supply,” 2022, <https://www.fns.usda.gov/ofs/infant-formula-safety>.

<sup>26</sup> U.S. Department of Agriculture, Food and Nutrition Service, “Letter to State Directors Regarding Infant Formula,” May 13, 2022, <https://www.fns.usda.gov/wic/state-director-letter-infant-formula>.

<sup>27</sup> Links to all of these resources are available at <https://www.fns.usda.gov/ofs/infant-formula-safety>. The federal government's main consumer-oriented website is <https://www.hhs.gov/formula/index.html>. Information for families that need specialty formula for medical reasons is available at <https://naspghan.org/recent-news/naspghan-tools-for-heaps-affected-by-formula-recall/>.

<sup>28</sup> See, for example, Stephanie Stamm, “Baby Formula Shortage Stuns States Including Tennessee, Kansas and Delaware,” *Wall Street Journal*, May 14, 2022, <https://www.wsj.com/articles/baby-formula-shortage-stuns-states-including-tennessee-kansas-and-delaware-11652526002>.

- In states that contract with Abbott, the company has been providing the rebates on purchases of other brands that it normally provides on its own products, so WIC costs haven't surged, and it has committed to continuing to do so through August.<sup>29</sup>
- The federal government is working to obtain specialty formula for babies (and other children and adults) with medical conditions who cannot tolerate regular formula and for whom formula may be their sole source of nutrition. In normal circumstances, low-income families whose infants have special nutritional needs can receive specialty formula through WIC with medical documentation, even if their state does not have a contract with that product's manufacturer.<sup>30</sup> Unfortunately, the Abbott facility affected by the recall was a leading producer of several of these specialty products. In late April, the Food and Drug Administration (FDA) updated its infant formula advisory to recognize that families' need for these products may outweigh the risks in some cases;<sup>31</sup> the FDA has worked with Abbott to release limited stock of certain metabolic, amino acid-based, and other specialty formulas produced at the affected facility on a case-by-case basis.<sup>32</sup> The Administration has also prioritized specialty infant formulas in its efforts to bring in formula from other countries.<sup>33</sup> Most of these specialty formulas are being distributed to families, including WIC participants, by health care providers.
- USDA recently began allowing states that hold contracts with Mead Johnson or Gerber, which are not providing rebates on other brands, to use WIC funds to cover the full cost of other brands of regular formula if the contracted company cannot provide enough and agrees to this flexibility.<sup>34</sup> While this would increase WIC food costs, the funding provided for the current fiscal year is sufficient to absorb the increase on a temporary basis. It will be important to make sure that the WIC appropriation for fiscal year 2023 is again sufficient to serve all eligible applicants.

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<sup>29</sup> Abbott, "Abbott Restarts Production of Specialty Formulas at its Michigan Plant," June 4, 2022, <https://www.abbott.com/corpnewsroom/nutrition-health-and-wellness/abbott-update-on-powder-formula-recall.html>.

<sup>30</sup> WIC can provide specialty formula for infants with special medical needs, sometimes referred to as "exempt" formula, but states do not receive rebates on these products from the manufacturers. State WIC agencies are also required to coordinate with the state's Medicaid program and other potential medical payors regarding these specialty infant formulas and can only cover the cost of these formulas in situations where reimbursement is not provided by another entity. See 7 CFR § 246.10(e)(3)(vi).

<sup>31</sup> Food and Drug Administration, "FDA Investigation of Cronobacter Infections: Powdered Infant Formula (February 2022)," February 2022, <https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022>.

<sup>32</sup> Abbott, "Abbott to Release Metabolic Nutrition Formula," April 29, 2022; Abbott, "Abbott to Release Elecare® Amino Acid-Based Formulas to Help Meet Critical Patient Need," May 24, 2022.

<sup>33</sup> The White House, "Biden Administration Approves First Operation Fly Formula Mission," May 19, 2022, <https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/19/biden-administration-approves-first-operation-fly-formula-mission/>.

<sup>34</sup> See U.S. Department of Agriculture, "USDA Offers Funding Flexibility to Help States, WIC Families Amid Infant Formula Shortages," May 25, 2022, <https://www.usda.gov/media/press-releases/2022/05/25/usda-offers-funding-flexibility-help-states-wic-families-amid>. For example, California allowed WIC participants to obtain brands, types, and container sizes of formula that they are not usually covered by WIC benefits. See California Department of Health, "100+ New Formula Options Added to the California WIC Authorized Product List," June 2, 2022.

- Federal legislation enacted in May will put the WIC program in a better position to respond to supply disruptions going forward.<sup>35</sup> It allows USDA, in the event of an emergency, disaster, or supply chain disruption, to adopt program flexibilities similar to those it is now employing under temporary COVID-19 rules. The legislation also requires each new or renewed infant formula contract to explain how the manufacturer will protect WIC participants from disruptions in the event of a recall. In light of the recall and shortages, the next round of bid solicitations might be more contentious than in the past; USDA can facilitate the process by providing states with examples of contract provisions that would help prevent and respond to supply disruptions.
- Using authority from the May legislation, USDA began offering nationwide waivers to allow states to authorize and issue infant formula that the federal government is importing to address the shortage even though it may not meet all WIC requirements. For example, WIC requires states to only issue formula obtained from manufacturers that are registered with the FDA, which may not be applicable for this imported formula.<sup>36</sup> These waivers ensure that formula that is now available to non-WIC participants is also accessible to WIC participants.

## Where Do We Go From Here?

The current shortage has highlighted this nation’s lack of a backup plan for a major disruption in infant formula supply. While efforts are still underway to address the current shortage, we need to determine how to avoid future shortages for all babies in the United States while ensuring that low-income families continue to have access to breastfeeding support and infant formula through WIC. Key policy questions include:

- **How can we build resiliency into the infant formula market for both regular and specialty formulas?** This would include measures like increasing production and storage capacity so extra formula is on hand in the event of a disruption; increasing infant formula manufacturers’ capacity to surge production; identifying other manufacturers that could produce infant formula if necessary; increasing factory diversification; identifying and addressing possible risks to the supply of infant formula ingredients or packaging materials; and/or increasing imports of infant formula to reduce reliance on current manufacturers.
- **How can WIC play a role in building resiliency?** As the purchaser of more than half the infant formula sold in the U.S., WIC’s competitive bidding process could offer a mechanism to establish resiliency-related requirements. But the changes needed to accomplish this must be designed carefully so as not to create unintended negative consequences for the WIC program. In addition, building resiliency through WIC will require added funding. While it may be appropriate for the federal government to cover some or all of the extra costs, as it does with some other vital medical supplies, funding would need to be provided in a way that ensures WIC can continue serving all eligible low-income families that apply.
- **Are there other changes to WIC’s competitive bidding process that would improve the infant formula market without undermining access to WIC?** While it is unclear

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<sup>35</sup> Access to Baby Formula Act of 2022, 7791 H.R. § Text. (Pub. L. 117–129).

<sup>36</sup> U.S. Department of Agriculture, Food and Nutrition Service, “Additional WIC Flexibilities — Imported Infant Formula under FDA’s Infant Formula Enforcement Discretion,” June 2, 2022, <https://www.fns.usda.gov/wic/flexibilities-formula-enforcement-discretion>.

whether WIC's competitive bidding process has contributed to consolidation of the infant formula market, it is worth considering whether process changes could make it easier for additional companies to bid on WIC contracts and whether there are changes that could make the process less burdensome for state WIC programs.

Over the years, infant formula manufacturers have urged policymakers to consider a multi-source contracting process, and a number of state and federal policymakers, including members of Congress, have expressed interest in that approach in light of the current shortages. But without the market share advantage that being the sole provider in a state confers, manufacturers are not likely to offer the substantial discounts that reduce the federal cost of WIC by \$1 billion to \$2 billion annually. Unless a multi-source approach could be designed to limit the reduction in discounts, it could well result in low-income families missing out on WIC, since it's far from clear that policymakers would provide the substantial, ongoing increase in WIC funding needed to enable the program to continue serving all eligible applicants.

These questions are complicated and warrant a deliberative approach. Congress and the Administration have the opportunity — once the current crisis abates — to develop a thoughtful policy response to prevent an infant formula supply disruption like this from happening again, while protecting WIC's ability to serve all eligible applicants.