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The Contradictory Nature Of U.S. Laws And Nutrition Programs And Their Effects On Infant Feeding

Lily Patel

I. Introduction

The contradictory nature of U.S. laws, including the laws concerning infant feeding, though supposedly aligned with policies to promote wellness in Americans, can exacerbate gender and race inequality and work against the National Strategy. The overarching goal of U.S. laws concerning infant feeding is to ensure that infants are fed, nourished, and receive proper nutrition. However, the laws often appear to be directly contradictory to one another in the priorities they are promoting. The United States Department of Agriculture's (USDA) "mission is to increase food security and reduce hunger in partnership with cooperating organizations by providing children and people with low income access to food, a healthy diet, and nutrition education in a manner that supports American agriculture and inspires public confidence."¹ As such, the USDA supports many different programs,² and sometimes in its efforts to broadly maintain and promote all of agriculture, the ultimate result appears to be contradicting priorities at odds with one another leading to inequity. The conflicting nature of the universal USDA agriculture programs represents the overall conflicting nature of U.S. laws and causes confusion. U.S. laws are meant to improve Americans' overall well-being, but can sometimes lead to inequitable results.

The USDA - Food and Nutrition Service (FNS) supports and promotes breastfeeding and publishes guidance regarding breastfeeding.³ "WIC promotes and supports breastfeeding as an

¹ *FNS Nutrition Programs*, U.S. DEP'T OF AGRIC. FOOD AND NUTRITION SERV., <https://www.fns.usda.gov/programs#:~:text=Our%20mission%20is%20to%20increase,agriculture%20and%20inspires%20public%20confidence> (last visited Sept. 19, 2023).

² *See About USDA*, U.S. DEP'T OF AGRIC., <https://www.usda.gov/our-agency/about-usda> (last visited Sep. 11, 2023).

³ *See About WIC Breastfeeding Support and Formative Research Findings*, U.S. DEP'T OF AGRIC. WIC BREASTFEEDING SUPPORT, <https://wicbreastfeeding.fns.usda.gov/about-wic-breastfeeding-support-and-formative-research-findings> (last visited Sep. 11, 2023) (The goal of the campaign is to equip WIC moms with the information, resources, and support they need to successfully breastfeed.).

important part of the nutrition service benefits to meet its mission of safeguarding the health of low-income women, infants and

children.”⁴ However, the USDA’s Supplemental Nutrition Assistance Program (SNAP) and Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) programs allow for SNAP and WIC benefits to be used to purchase infant formula.⁵ “WIC is the major purchaser of infant formula in the United States.”⁶ While the USDA supports breastfeeding, it also supports the infant formula industry in its overarching goal to support infant feeding and to ensure that infants do not go hungry.⁷ However, USDA’s priorities can seem directly contradictory to one another, causing confusion that affects infant feeding.

II. History of Infant Feeding and Formula Use

In 1865, Justus von Liebig, a chemist, developed an infant food, first in a liquid form and then in a powdered form for better preservation.⁸ Liebig’s formula was made from cow’s milk, wheat and malt flour, and potassium bicarbonate, and was considered the “perfect infant food.”⁹

⁴ *FNS Nutrition Programs*, *supra* note 1; see INST. OF MED. OF THE NAT’L ACADS., INFANT FORMULA: EVALUATING THE SAFETY OF NEW INGREDIENTS 46 (2004) <https://www.ncbi.nlm.nih.gov/books/NBK215837/> (“Manufacturers desire to produce products that mimic the advantages of breastfeeding. This motivation implies that formula...is inferior when compared with human milk.”).

⁵ See *WIC Frequently Ask Questions*, U.S. DEP’T OF AGRIC. FOOD AND NUTRITION SERV., <https://www.fns.usda.gov/wic/frequently-asked-questions> (last updated Apr. 4, 2023); *Is baby food and infant formula eligible for purchase with SNAP program benefits?*, U.S. DEP’T OF AGRIC. ASKUSDA, [https://ask.usda.gov/s/article/Is-baby-food-and-infant-formula-eligible-for-purchase-with-Supplemental-Nutrition-Assistance-](https://ask.usda.gov/s/article/Is-baby-food-and-infant-formula-eligible-for-purchase-with-Supplemental-Nutrition-Assistance-Program#:~:text=Yes%2C%20you%20can%20use%20your,any%20other%20eligible%20food%20item.)

[Program#:~:text=Yes%2C%20you%20can%20use%20your,any%20other%20eligible%20food%20item.](https://ask.usda.gov/s/article/Is-baby-food-and-infant-formula-eligible-for-purchase-with-Supplemental-Nutrition-Assistance-Program#:~:text=Yes%2C%20you%20can%20use%20your,any%20other%20eligible%20food%20item.) (Last visited Apr. 20, 2023).

⁶ *The WIC brand of infant formula varies by State*, U.S. DEP’T OF AGRIC. ECON. RSCH. SERV., <https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=78481#:~:text=USDA's%20Special%20Supplemental%20Nutrition%20Program,is%20purchased%20with%20WIC%20benefits> (last visited Sept. 19, 2023).

⁷ See *FNS Nutrition Programs*, *supra* note 1.

⁸ See Emily E. Stevens, ET AL., *A History of Infant Feeding*, J. OF PERINATAL EDUC., 32, 36 (2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2684040/pdf/jpe-18-032.pdf>.

⁹ *Id.*

By the early 1900s, most doctors were male¹⁰ and advocated for scheduled feedings of babies as opposed to feeding on demand, which severely and adversely affected breastmilk production in women, facilitating the way for formula companies to make formula-feeding a more attractive option for feeding infants.¹¹ “By 1910, the United States had an estimated 9,015 female physicians, representing 6.0% of the profession.”¹² This means that 94% of the physicians were male. At the same time, formula companies (likely headed by male CEOs) promoted relentlessly to new parents who, as a result, believed that formula was “a more modern and scientific choice than breastfeeding.”¹³ It seems that males were impacting and directing mothers on their infant feeding methods.

A pretty high percentage, “84% of American newborns, start out breastfeeding, but only 25.8% exclusively breastfeed until 6 months of age per CDC recommendations.”¹⁴ Some federal laws have been designed to protect lactating workers, such as workplace lactation rooms and insurance coverage of breast pumps¹⁵; however, these protections are inadequate because pumping is not the same as directly breastfeeding a baby.¹⁶ These federal laws assume that breastfeeding and pumping are the same when they are not.¹⁷ Moreover, breastfeeding is not the same as pumping because an infant is better at extracting breastmilk than the pump is.¹⁸ Also, “close [physical] contact between the mother

¹⁰ See Anna Walling ET AL., *The Only Woman in The Room: Oral Histories of Senior Women Physicians in a Midwestern City*, WOMEN'S HEALTH REPORT, 279, 279 (Apr. 29, 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7784804/#:~:text=By%201910%2C%20the%20United%20States,representing%206.0%25%20of%20the%20profession.> (“By 1910, the United States had an estimated 9015 female physician, representing 6.0% of the profession.”).

¹¹ See Carla Cevasco *What We Get Wrong About Life Before Modern Baby Formula*, TIME (May 17, 2022 3:39 PM), <https://time.com/6177644/baby-formula-breastfeeding-history/>.

¹² Walling ET AL., *supra* note 10.

¹³ Cevasco, *supra* note 11.

¹⁴ *Id.*

¹⁵ See *id.*

¹⁶ See Catherine Crider, *What's Best for You? Exclusively Breastfeeding or Pumping?*, HEALTHLINE (Jan. 21, 2023), <https://www.healthline.com/health/breastfeeding/breastfeeding-vs-pumping> (“Pump suction is also not always as effective as a baby’s mouth at getting milk out of the breast. As a result, depending on the person, exclusively pumping can result in less milk production than breastfeeding.”).

¹⁷ See *id.*

¹⁸ See *id.*

and child stimulates the mother to make antibodies against bacteria colonized in the infant and to secrete these antibodies in her milk.”¹⁹ This special property about breastmilk can be lost if a mother’s physical proximity to her baby is impeded and if the baby is only getting expressed breastmilk. The lack of distinction made between pumping versus directly breastfeeding indicates that there may be confusion, misinformation, or an inadequate definition on what being a lactating mother means, and, therefore, inadequate protections for lactating mothers. It is often much harder to keep breastmilk supply up when exclusively pumping versus directly breastfeeding.²⁰ The lack of universal paid family leave also prevents many working parents from breastfeeding.²¹

Research found that formula feeding is more common in wealthy households across the world while breastfeeding is significantly higher in children living in the poorest households across the world.²² Infant formula use is more common in families with wealth.²³ Therefore, it will likely become more common as countries continue to develop and to increase in wealth.²⁴ However, in the U.S., it seems the opposite, that formula feeding is more common in low-income households as opposed to in upper middle class homes where the choice to breastfeed is more available.²⁵ Black women, who disproportionately are the workers of low-wage jobs and often the primary wage earner in the household, do not have the time to breastfeed and end up formula-feeding because they need to return to work sooner and their work hours tend to be inflexible.²⁶ Also, because infant formula is subsidized by the

¹⁹ INFANT FORMULA: EVALUATING THE SAFETY OF NEW INGREDIENTS, *supra* note 4, at 46.

²⁰ See Crider, *supra* note 16.

²¹ Cevasco, *supra* note 11.

²² See Paulo A R Neves et al., *Infant Formula Consumption is Positively Correlated with Wealth, Within and Between Countries: A Multi-Country Study*, 150 J. NUTRITION 910, 910-916 (2020).

²³ See Neves et al., *supra* note 22, at 910.

²⁴ See *id.*

²⁵ See Christina Szalinski, *For low-income families, getting formula has always been a strain*, TAMPA BAY TIMES (June 21, 2022), <https://www.tampabay.com/news/health/2022/06/21/for-low-income-families-getting-formula-has-always-been-a-strain/>; see also Amani Echols, *The Challenges of Breastfeeding as a Black Person*, ACLU (Aug. 15, 2019), <https://www.aclu.org/news/womens-rights/challenges-breastfeeding-black-person>.

²⁶ See Laura Santhanam, *Racial disparities persist for breastfeeding moms. Here’s*

federal government through WIC and SNAP, which are programs that have eligibility requirements based on income,²⁷ government programs, in combination with low-wage jobs that often have inflexible hours, may have an impact on infant feeding in the U.S., leading to more formula-feeding in low-income and WIC-eligible families. “Mothers’ own milk is the best source of nutrition for nearly all infants.”²⁸ Efforts need to be made to protect, promote, and to support breastfeeding to reduce infant formula use, which has hazards associated with its use.²⁹ Recent events such as the *Cronobacter* bacteria contamination in infant formula produced by Abbott at the Sturgis, Michigan location that sickened infants show just how hazardous infant formula use can be.³⁰ Another potential risk of formula feeding can result from its “preparation . . . with water contaminated with infectious agents.”³¹

“The word *formula* stems from the 1890s and it literally was taken from mathematical formulas—physicians were absolutely desperate to find a way to save babies’ lives. They thought that they could “humanize” cow’s milk if they could make it mimic the substances they could recognize, like the percentage of fat, the percentage of protein, the percentage of

why., PBS NEWS (Aug. 29, 2019, 8:08 PM, EDT),

<https://www.pbs.org/newshour/health/racial-disparities-persist-for-breastfeeding-moms-heres-why>; see also Echols, *supra* note 25.

²⁷ See *WIC Frequently Ask Questions*, U.S. DEP’T OF AGRIC. FOOD AND NUTRITION SERV., <https://www.fns.usda.gov/wic/frequently-asked-questions> (last updated Apr. 4, 2023).

²⁸ See Crider, *supra* note 16 (“Breast milk nutrients match your baby’s needs especially well when your body is interacting with your baby in the close way that breastfeeding requires. Your breast responds to the baby’s saliva content, producing antibodies for viruses or bacteria to which the baby has been exposed.”); *Breastfeeding Benefits*, U.S. DEP’T OF AGRIC. WIC BREASTFEEDING SUPPORT, <https://wicbreastfeeding.fns.usda.gov/breastfeeding-benefits> (last visited Sep. 16, 2023) (stating “Breast milk... changes to meet your baby’s need as he or she gets older.”); Federica Guaraldi & Guglielmo Salvatori, *Effect of Breast and Formula Feeding on Gut Microbiota Shaping in Newborns*, FRONTIERS (Oct. 16, 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3472256/pdf/fcimb-02-00094.pdf> (“Breast milk, whose beneficial health-effects are undoubtedly unique, has to be considered the food of choice for infants in the first 6 months of life.”).

²⁹ See Neves et al., *supra* note 22, at 916.

³⁰ See Press Release, Rosa DeLauro, United States Rep., DeLauro Shares Whistleblower Report, Contaminated Infant Formula Led to Hospitalizations and Deaths (Apr. 28, 2022), <https://delauro.house.gov/media-center/press-releases/icymi-delauro-shares-whistleblower-report-contaminated-infant-formula>.

³¹ INFANT FORMULA: EVALUATING THE SAFETY OF NEW INGREDIENTS, *supra* note 4, at 51.

milk sugar.”³²

During the Civil War, troops received canned milk, which led to food companies introducing infant foods.³³ They did not claim to be better than breastmilk, but compared themselves to other infant foods.³⁴ Nestle then came out with a powdered infant milk that did not need to be mixed with cow milk, which often spoiled in cities because there were not farms nearby.³⁵ Because cow milk spoiled, the infant milk alternatives using cow milk could be deadly.³⁶

In the 1880s and 1890s the U.S. industrialized, and there was less time to breastfeed, and, as a result, babies were subjected to schedules.³⁷ Regarding breastfeeding, the more a baby suckles, the more breastmilk will be produced.³⁸ In contrast, if a baby is placed on a strict schedule, the mother’s breastmilk supply will decrease.³⁹

However, doctors believed that the decreased lactation was due to a medical problem in mothers.⁴⁰ Doctors did not connect this to the change in feeding habits forced upon infants and their mothers.⁴¹ “There was a large group of doctors who feared that girls in school during the time they were going through puberty were causing their reproductive systems to compete with their brains for energy, and their brains were winning.”⁴² These doctors believed that girls were over-educated and that getting an education interfered with the female reproductive system. These false beliefs discriminated against women, and provided evidence of ongoing gender inequality in history; the history of breastfeeding is a part of women’s history. Because of existing laws and an American society that does not support breastfeeding, a

³²Lily Rothman, *Desperate Women, Desperate Doctors and the Surprising History Behind the Breastfeeding Debate*, TIME (Jul. 31, 2018, 4:00 PM), <https://time.com/5353068/breastfeeding-debate-history/>.

³³ See *id.*

³⁴ See *id.*

³⁵ See *id.*

³⁶ See *id.*

³⁷ See *id.*

³⁸ See *id.*

³⁹ See *id.*

⁴⁰ See *id.*

⁴¹ See *id.*

⁴² *Id.*

woman's career impacts that woman's time and ability to breastfeed and sometimes to pump.

Breastfeeding takes time; time taken away from a woman's career. Working mothers struggle with balancing their careers and being a mother,⁴³ struggles that fathers do not face.

"There are all kinds of reasons why women choose to feed their babies however they decide to feed their babies."⁴⁴ Things are different in the U.S. in that employers do not accommodate breastfeeding mothers like similarly wealthy countries do by allowing for a lengthy paid maternity leave.⁴⁵ Breastfeeding in the U.S. is very hard as a mother because the social supports are not in place.⁴⁶

In the 1890s, you could find breast pumps for purchase, but it was for pumping breastmilk for premature babies that were too weak to suckle at the breast.⁴⁷ Pumping is quite common now, especially because so many women work, and it is mainly privileged women with personal work offices that can take time during the workday to close the door for privacy to pump.⁴⁸

Recent events chronicle a struggle with the formula shortage and trying to find formula.⁴⁹ This infant formula shortage could have been a good opportunity for the federal government to reinforce its guidance supporting breastfeeding.⁵⁰ Focusing on having adequate infant formula supply may deflect from supporting breastfeeding and ultimately impact infant feeding.

⁴³ See Lauren Smith Brody, *How to Be Mostly O.K. (and Occasionally Fantastic) at the Whole Working Mom Thing*, N.Y. TIMES, <https://www.nytimes.com/guides/working-womans-handbook/how-to-be-a-working-mom> (last visited Sept. 16, 2023) ("‘We expect women to work like they don’t have children, and raise children as if they don’t work.’ That’s a recipe for mommy guilt...") (quoting AMY WESTERVELT, *FORGET HAVING IT ALL: HOW AMERICA MESSED UP MOTHERHOOD – AND HOW TO FIX IT*, (Seal Press 2018)).

⁴⁴ Rothman, *supra* note 32.

⁴⁵ See *id.*

⁴⁶ See *id.*

⁴⁷ See *id.*

⁴⁸ See *id.*

⁴⁹ See Ximena Bustillo, *It's Getting Easier to Find Baby Formula. But You Might Still Run into Bare Shelves*, NAT'L PUB. RADIO (Oct. 27, 2022, 5:00 AM), <https://www.npr.org/2022/10/27/1131561457/its-getting-easier-to-find-baby-formula-but-you-might-still-run-into->.

⁵⁰ See generally *Breastfeeding Benefits*, *supra* note 28.

III. Laws and Nutrition Programs Implicated

A. FDA Regulates Infant Formula Under the Federal Food, Drug, and Cosmetics Act

The agencies and laws that regulate the American food system are fractionated and often confusing to reconcile. The USDA regulates food products such as meat and poultry.⁵¹ The Food and Drug Administration (FDA) regulates most of the other foods, including infant formula.⁵² However, there are overlaps between foods that contain a certain amount of meat, depending on the amount, and eggs, depending on if they are shelled or not.⁵³ Under the authority of the Infant Formula Act (21 U.S.C. § 350(a))⁵⁴ in 1982, the FDA issued regulations for infant formula quality control procedures (21 C.F.R. § 106).⁵⁵ The FDA regulates foods and drugs, including foods that are processed,⁵⁶ such as infant formula, which does not come from an animal. Instead, it is a substance made from many different ingredients.⁵⁷

While the USDA does not regulate infant formula, its feeding programs such as SNAP and WIC support the infant formula industry, and SNAP and WIC benefits can be used to purchase infant

⁵¹ See *What Foods Does the Food and Drug Administration Regulate?*, U.S. DEP'T OF AGRIC. ASKUSDA (Jan. 12, 2023), <https://ask.usda.gov/s/article/What-foods-does-the-FDA-regulate#:~:text=Foods%20regulated%20by%20the%20Food,juices%2C%20vegetarian%20entrees%2C%20etc.>

⁵² See *id.*

⁵³ See *Markets, Regulation, and Policy*, U.S. DEP'T OF AGRIC. ECON. RSCH. SERV. (Mar. 10, 2023), <https://www.ers.usda.gov/topics/food-safety/markets-regulation-and-policy/#:~:text=USDA%20is%20responsible%20for%20regulating,and%20almost%20all%20other%20foods.> (“USDA is responsible for regulating meat and poultry, processed egg products, and catfish, whereas the U.S. Food and Drug Administration (FDA) oversees food safety for fresh eggs and almost all other foods.”).

⁵⁴ See 21 U.S.C. § 350(a).

⁵⁵ See FDA ENFORCEMENT MAN. § 1653 OTHER FOOD PROCESSING CGMP REGULATIONS (2023).

⁵⁶ See 21 U.S.C. § 350(a); *How to Start a Food Business*, U.S. FOOD AND DRUG ADMIN. (May 13, 2021), [https://www.fda.gov/food/food-industry/how-start-food-business#:~:text=FDA%20regulates%20all%20foods%20and,Department%20of%20Agriculture%20\(USDA\)](https://www.fda.gov/food/food-industry/how-start-food-business#:~:text=FDA%20regulates%20all%20foods%20and,Department%20of%20Agriculture%20(USDA)) (“FDA regulates all foods and food ingredients introduced into or offered for sale in interstate commerce, with the exception of meat, poultry, and certain processed egg products regulated by the U.S. Department of Agriculture.”).

⁵⁷ See discussion *infra* Section IV.B.

formula.⁵⁸

*B. 21 U.S.C. § 342 Adulterated Food and 21 C.F.R. § 109.6
Added Poisonous or Deleterious Substances*

21 U.S.C. § 342 applies to adulterated food. A food is considered adulterated if: “(a)(1) it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health;” or “(a)(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.”⁵⁹ The contaminated formula manufactured at Abbott’s Sturgis, Michigan facility could be considered “adulterated” under 21 U.S.C. § 342 because it was “injurious to [the] health” of the infants that ingested the infant formula. The substance may not have been an added substance, but it was of the quantity that rendered it “injurious to health.”⁶⁰ It also was “prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health.”⁶¹ Therefore, the infant formula could be argued as “adulterated under this clause,”⁶² and shown to be hazardous to the health of infants. Though infant formula can be dangerous to the health of infants,⁶³ it still seems to be promoted more than breastfeeding.

21 C.F.R. § 109.6 states that: “(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive, will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409 of the act, or when the added poisonous or deleterious substance is not a food additive, a tolerance, regulatory limit, or action level may be established

⁵⁸ See *What Can Snap Buy?*, U.S. DEP’T OF AGRIC. FOOD AND NUTRITION SERV. (Apr. 14, 2021), <https://www.fns.usda.gov/snap/eligible-food-items>; See also *WIC Fact Sheet*, U.S. DEP’T OF AGRIC. FOOD AND NUTRITION SERV. (Aug. 2, 2022), <https://www.fns.usda.gov/wic/wic-fact-sheet>.

⁵⁹ 21 U.S.C. §§ 342(a)(1), (a)(4).

⁶⁰ *Id.* § 342(a)(1).

⁶¹ *Id.* § 342(a)(4).

⁶² *Id.* § 342(a)(1).

⁶³ See Neves et al., *supra* note 22, at 916.

pursuant to the criteria in paragraphs (b), (c), or (d) of this section.”⁶⁴ Although 21 C.F.R. § 109.6 regulates contaminants in food, this section does not apply to this case, because the *Cronobacter* bacteria was not “added.” Although it is naturally occurring, the bacteria was likely introduced because of the insanitary conditions found at the Sturgis, Michigan plant.⁶⁵ Because the *Cronobacter* bacteria was not “added,” 21 C.F.R. § 109.6 does not apply and does not need to be considered regarding whether a tolerance may be established in this case, and it reverts to 21 U.S.C. § 342, adulterated foods.

Many baby-food and formula companies promote their products heavily to new parents.⁶⁶ However, these companies did not ensure that their formula products were free from contaminants. In fact, there is evidence that Abbott knew that there were issues with its infant formula, but did not stop producing or marketing it despite knowledge of the issues.⁶⁷ Representative DeLauro shared a whistleblower report about contaminated infant formula, detailing falsification of records, untested formula, and information being hidden in a 2019 FDA Audit, but FDA did not take action until the infant formula recall in February 2022.⁶⁸ In September 2021, the FDA learned from a former Abbott plant employee about a possible *Cronobacter* bacteria contamination in the powdered infant formula made at Abbott’s Sturgis, Michigan facility that caused four hospitalizations and the deaths of at least two babies.⁶⁹ Perhaps this inaction by the FDA might not rise to the level of the federal government not caring about the health of infants, but it could show that the federal government supports big infant formula manufacturers so much that it allows them to continue operating even among possible food safety issues.

The whistleblower report stated an existence of falsified records including shipping packages with weights lower than what the label stated; release of untested formula; failure to properly sanitize; failure to maintain traceability of the product; hiding information during the 2019 FDA audit; failure to correct defective

⁶⁴ 21 C.F.R. § 109.6 (1990).

⁶⁵ See Christina Jewett, *F.D.A. Leader Details ‘Shocking’ Conditions At a Formula Factory*, N.Y. TIMES, May 26, 2022, at A21.

⁶⁶ Cevalco, *supra* note 11.

⁶⁷ See DeLauro, *supra* note 30.

⁶⁸ See *id.*

⁶⁹ See *id.*

and deficient testing procedures; and retaliation against any employees who raised concerns.⁷⁰ Abbott did not stop putting its formula on the market, even after months of problems with contamination, and the FDA reacted very slowly to this whistleblower report, not initiating the formula recall until February 2022, which was five months after FDA learned of the possible contamination.⁷¹ Again, this gives the impression that the federal government was less concerned with infant safety as compared with supporting formula companies, because it did not require big infant formula manufacturers to cease production until five months after FDA learned of the possible contamination, which goes against the goals of the National Strategy. This gives the appearance of conflicting actions and priorities.

The FDA regulates and monitors infant formula under section 412 of the Federal Food, Drug, and Cosmetics Act (FFDCA) (21 U.S.C. § 350(a)) and FDA's implementing regulations in 21 C.F.R. § 106 and 107, which require formula manufacturers to test their product and to verify that the product is safely manufactured using quality control procedures.⁷² The FDA's slow reaction in response to its apparent knowledge of manufacturing issues, and failure to verify the safety of infant formula is troubling, calling into question whether the FDA truly verifies the safety of domestic formula, let alone imported formula, when it failed to verify the safety of its domestic formula for several months.⁷³ These tragic events call into question the federal government's conflicting priorities of infant safety and health in alignment with the National Strategy,⁷⁴ and big corporations' ability to continue operating and profiting.

C. USDA, SNAP, and WIC

SNAP is a federally funded health and nutrition program that

⁷⁰ *See id.*

⁷¹ *See id.*

⁷² *See* 21 U.S.C. § 350(a); *see also* 21 C.F.R. §§ 106.1, 107.1.

⁷³ *See* DeLauro, *supra* note 30.

⁷⁴ *See* THE WHITE HOUSE, BIDEN-HARRIS ADMINISTRATION NATIONAL STRATEGY ON HUNGER, NUTRITION, AND HEALTH, 26 (2022), <https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf>. [hereinafter NATIONAL STRATEGY ON HUNGER, NUTRITION, AND HEALTH].

assists low-income families and children.⁷⁵ SNAP gives a monthly amount, based on household income, preloaded onto an EBT (Electronic Benefits Transfer) card to buy food for the recipient and his/her family.⁷⁶ SNAP can buy any food for the household,⁷⁷ including infant formula.⁷⁸

WIC does not give the recipient a dollar amount to buy food.⁷⁹ WIC provides nutrition education, breastfeeding support and referrals, and nutritious foods to pregnant women, breastfeeding women, postpartum women, infants, and children.⁸⁰ WIC foods are chosen based on nutritional value and USDA standards.⁸¹ WIC recipients receive a WIC card, to be used like a debit or credit card.⁸²

“The federal government not only regulates formula makers. It's also their biggest customer. About half of all formula sold in the U.S. is paid for by the Department of Agriculture, through its Special Supplemental Nutrition Program for Women, Infants and Children (WIC).”⁸³ States have to enter an exclusive contract with one of the formula manufacturers to supply subsidized infant formula to WIC-eligible families.⁸⁴ The government receives a huge discount from the formula company.⁸⁵ In exchange, the formula company gets a guaranteed market.⁸⁶ USDA research confirmed that whichever company gets the WIC contract in a state gets a market hold in that state, in effect getting a monopoly over WIC sales and also capturing a “spillover” market of non-WIC customers.⁸⁷ This is because the WIC-contracted formula company gets prime shelf space at the

⁷⁵ See *Learn the Difference Between SNAP and WIC Programs*, BENEFITS (Dec. 8, 2021), <https://www.benefits.gov/news/article/439>.

⁷⁶ See *id.*

⁷⁷ See *What Can SNAP Buy?*, *supra* note 58.

⁷⁸ See *Is Baby Food and Infant Formula Eligible for Purchase with Supplemental Nutrition Assistance Program Benefits?*, *supra* note 5 (“You can use your Supplemental Nutrition Assistance Program (SNAP) benefits to buy baby food. This includes infant formula, cereals, juices, baby food and any other eligible food item.”).

⁷⁹ See *Learn the Difference Between SNAP and WIC Programs*, *supra* note 75.

⁸⁰ See *id.*

⁸¹ See *id.*

⁸² See *id.*

⁸³ Scott Horsley, *How the U.S. got into this baby formula mess*, NAT’L PUB. RADIO (May 19, 2022, 5:00AM, ET), <https://www.npr.org/2022/05/19/1099748064/baby-infant-formula-shortages>.

⁸⁴ See *id.*

⁸⁵ See *id.*

⁸⁶ See *id.*

⁸⁷ See *id.*

grocery store, which attracts infant formula purchasers alike, WIC-eligible or not, to purchase that particular brand.⁸⁸ So, when a formula company wins the WIC contract with a state, in addition to capturing all of the WIC-eligible purchasers in that state, it results in the formula company capturing the rest of the formula purchasers in that state.

WIC exclusively contracts with Abbott in two-thirds of all the states in the U.S.⁸⁹ WIC benefits can only be used to purchase the brand that WIC has contracted with, which means that in two-thirds of U.S. states, Abbott holds the market. When Abbott temporarily shut down its Sturgis, Michigan plant, the formula market in two-thirds of U.S. states was affected. Because of the way WIC is structured, the program ended up adversely affecting formula-fed infants as an unintended consequence. Infant formula prices increased because of the ongoing infant formula supply issues and severely impacted infant feeding.⁹⁰

IV. National Strategy: White House National Strategy on Hunger, Nutrition, and Health

A. Formula Feeding and the National Strategy

The promotion of breastfeeding is supported by the National Strategy.⁹¹ 10.6% more mothers started breastfeeding during the formula shortage as compared to before the formula shortage.⁹² Breastfeeding was also more appealing due to reports of babies sickened by formula.⁹³ The National Strategy supports breastfeeding and also aims to expand breastfeeding.⁹⁴

The National Strategy states that “the Administration also

⁸⁸ See *id.*

⁸⁹ See *id.*

⁹⁰ See Conor Murray, *Enfamil Infant Formula Price Spikes: Frustrated Consumers Cry, ‘Robbery!’ As Shortages Persist*, FORBES (Mar. 22, 2022), <https://www.forbes.com/sites/conormurray/2023/03/21/enfamil-infant-formula-price-spikes-frustrated-consumers-cry-robbery-as-shortages-persist/?sh=67f0c2dd61a2>.

⁹¹ See NATIONAL STRATEGY ON HUNGER, NUTRITION, AND HEALTH, *supra* note 74, at 26.

⁹² See Annie Imboden et al., *Impact of the Infant Formula Shortage on Breastfeeding Rates*, 37 J. PEDIATRIC HEALTH CARE 279, 279 (2023).

⁹³ See *id.*

⁹⁴ See NATIONAL STRATEGY ON HUNGER, NUTRITION, AND HEALTH, *supra* note 74, at 26.

recognizes that for children and adults with digestive and inherited metabolic disorders, ensuring access to the right types of nutritional supports, such as infant formula, can prevent hospitalizations and be lifesaving. Still, there are often systematic barriers making access to these specialized nutritional supports challenging.”⁹⁵ Beyond this statement regarding infant formula, however, there are no other references to infant formula in the National Strategy. On the contrary, there is a section on page 26 about how the Administration supports breastfeeding.⁹⁶

Despite these statements, there are many barriers to breastfeeding in the U.S.⁹⁷ Many people, including health professionals, are not aware of the healthful benefits of breastfeeding for infants, and believe that infant formula is equivalent to breastmilk with respect to its health benefits.⁹⁸ This belief indicates a lack of education concerning the healthful benefits of breastfeeding. “In the United States, bottle feeding is viewed by many as the ‘normal’ way to feed infants.”⁹⁹ While formula regulations aim to protect infants and prioritize their safety, they also protect domestic formula companies from overseas competition.¹⁰⁰

While the National Strategy promotes increased access to nutritious foods, such as fruits and vegetables,¹⁰¹ and has as a goal to lower the amount of sodium in processed foods,¹⁰² it is silent regarding the consumption of ultra-processed foods,¹⁰³ and does not

⁹⁵ *Id.* at 18-19.

⁹⁶ *See id.* at 26.

⁹⁷ U.S. DEP’T OF HEALTH AND HUMAN SERVS., OFF. OF THE SURGEON GEN., NBK52688, *The Surgeon General’s Call to Action to Support Breastfeeding*, 1, 10 (2011), <https://www.ncbi.nlm.nih.gov/books/NBK52688/>.

⁹⁸ *See id.*

⁹⁹ *Id.* at 2.

¹⁰⁰ *See* Horsley, *supra* note 83.

¹⁰¹ *See* NATIONAL STRATEGY ON HUNGER, NUTRITION, AND HEALTH, *supra* note 74, at 25. This almost tracks with FAO’s *Guiding Principles for Sustainable Healthy Diets*, which states under Principle 2 that “sustainable healthy diets are based on a great variety of unprocessed or minimally processed foods, balanced across food groups, while restricting highly processed food and drink products.” *Sustainable Healthy Diets Guiding Principles*, FOOD AND AGRIC. ORG. OF THE UNITED NATIONS 12 (2019), <https://www.fao.org/3/ca6640en/CA6640EN.pdf>. The difference is that the National Strategy calls for a reduction of sodium content in processed foods rather than specifically calling for a reduction in the consumption of processed foods.

¹⁰² *See* NATIONAL STRATEGY ON HUNGER, NUTRITION, AND HEALTH, *supra* note 74, at 23.

¹⁰³ *See id.*

specifically state as a goal to lower consumption of processed foods in general.

B. How is Formula Not a Processed Food?

Formula is created in a laboratory using many ingredients.¹⁰⁴ Here in the U.S., the three main laboratories that manufacture infant formula are Abbott Laboratories, Mead Johnson, and Nestle/Gerber.¹⁰⁵ Abbott creates “life-changing technologies that . . . bring you information, medicines and breakthroughs to manage your health.”¹⁰⁶

The USDA defines processed foods under 7 C.F.R. § 65.220 as “a retail item derived from a covered commodity that has undergone specific processing resulting in a change in the character of the covered commodity . . . Specific processing that results in a change in the character of the covered commodity includes cooking (e.g., frying, broiling, grilling, boiling, steaming, baking, roasting), curing (e.g., salt curing, sugar curing, drying), smoking (hot or cold), and restructuring (e.g., emulsifying and extruding).”¹⁰⁷ Similac Advance lists its ingredients as follows: “Nonfat Milk, Lactose, High Oleic Safflower Oil, Whey Protein Concentrate, Soy Oil, Coconut Oil, Galactooligosaccharides*. Less than 2% of: Schizochytrium Sp. Oil†, M. Alpina Oil‡, Beta-Carotene, Lutein, Potassium Citrate, Calcium Carbonate, Ascorbic Acid, Soy Lecithin, Potassium Chloride, Magnesium Chloride, Ferrous Sulfate, Choline Bitartrate, Choline Chloride, Ascorbyl Palmitate, Salt, Taurine, Inositol, Zinc Sulfate, Mixed Tocopherols, d-Alpha-Tocopheryl Acetate, Niacinamide, Calcium Pantothenate, L-Carnitine, Vitamin A

¹⁰⁴ See e.g., *Product-Baby formula-Advance Powder*, SIMILAC, <https://www.similac.com/products/baby-formula/advance-powder/12-4oz-can-6ct.html> (last visited Oct. 3, 2023).

¹⁰⁵ See ABBOTT, <https://www.abbott.com> (last visited Sep. 11, 2023) (stating that they “create breakthrough products – in diagnostics, medical devices, nutrition and . . . pharmaceuticals . . .”); see also MEAD JOHNSON, <https://www.meadjohnson.com> (last visited Sep. 11, 2023) (Mead Johnson was acquired by Reckitt in June 2017); see also RECKITT, <https://reckitt.com> (last visited Sep. 11, 2023) (Stating Reckitt is “[h]ome to the world’s most loved and trusted hygiene, health and nutrition brands.”); see also NESTLE, <https://www.nestle.com> (last visited Sep. 11, 2023) (stating Nestle is “constantly pushing the boundaries of what’s possible with food, drink and nutritional health solutions.”).

¹⁰⁶ ABBOTT, *supra* note 105.

¹⁰⁷ 7 C.F.R. § 65.220 (2016).

Palmitate, Copper Sulfate, Thiamine Hydrochloride, Riboflavin, Pyridoxine Hydrochloride, Folic Acid, Manganese Sulfate, Phylloquinone, Biotin, Sodium Selenate, Vitamin D3, Vitamin B12, Calcium Phosphate, Potassium Phosphate, Potassium Iodide, Potassium Hydroxide, and Nucleotides (Adenosine 5'-Monophosphate, Cytidine 5'-Monophosphate, Disodium Guanosine 5'-Monophosphate, Disodium Uridine 5'-Monophosphate).^{*}
 Prebiotic[†] Source of DHA.[‡] Source of ARA.^{»108}

It is hard to understand what the majority of these ingredients are. These ingredients do not naturally come together, and are structured like this in a laboratory to create an infant milk alternative. This “formula” has been constructed and has “undergone changes to its natural state,”^{»109} arguably making it a processed food.

According to the NOVA food classification system, ultra-processed foods are “not foods, but are formulations of ingredients.”^{»110} Applying Monteiro’s definition of ultra-processed foods to infant formula, infant formula is an ultra-processed food because it is a “formulation of ingredients,” and a milk alternative that is designed to replace breastmilk.^{»111} Because infant formula is an “industrial formulation,” under the NOVA classification system, infant formula is an ultra-processed food.^{»112}

According to the National Strategy, obesity is on the rise, and poor eating patterns via an excess calorie intake are a cause of diet-related diseases.^{»113} According to the CDC, about one in five women aged fifteen to forty-nine are not able to get pregnant after one year of trying.^{»114} Obesity is increasing and has negative effects on

¹⁰⁸ *Product-Baby formula-Advance Powder*, *supra* note 104.

¹⁰⁹ See *Processed Foods and Health*, HARV. SCH. PUB. HEALTH, <https://www.hsph.harvard.edu/nutritionsource/processed-foods/> (last reviewed Aug. 2023).

¹¹⁰ Monteiro, *The NOVA food classification system*, YOUTUBE (Jan. 6, 2021), https://www.youtube.com/watch?v=wucc_Ra4wuo.

¹¹¹ See *id.*

¹¹² See *Food, Nutrition & Fitness I: The Digestion Journey Begins with Food Choices*, EDUCHANGE (2018), <https://ecuphysicians.ecu.edu/wp-content/uploads/sites/78/2021/07/NOVA-Classification-Reference-Sheet.pdf>.

¹¹³ See NATIONAL STRATEGY ON HUNGER, NUTRITION, AND HEALTH, *supra* note 74, at 7.

¹¹⁴ See *Infertility FAQs*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/reproductivehealth/infertility/index.htm#%3A~%3Atext%3D>

fertility.¹¹⁵ There is a mistaken belief for babies that “big is healthy,” which can lead to formula-feeding as “mothers . . . may be encouraged to supplement breastfeeding with formula.”¹¹⁶ Thus, consumption of processed foods, excess calories, and infant feeding methods have a direct correlation with obesity and diet-related diseases.

Substituting formula for breastfeeding, along with the lack of support for breastfeeding and the effects of not breastfeeding on the gut microbiome of infants, has a lasting effect, can change the nature of mothering, and can affect human health outcomes.¹¹⁷ An increased use of formula can lead to a decreased need for breastfeeding. The less the baby is near the mother, the less breastmilk supply a mother’s body will have, similar to how milking cows have to be pregnant to have milk supply.¹¹⁸ With continued use of formula-feeding and the lack of support for breastfeeding, perhaps the need and ability to breastfeed is being bred out, which affects only the female gender because males cannot lactate, and also does not support the National Strategy.

C. Is Infant Formula a food or a drug under FFDCA?

The laws make it confusing to determine whether infant formula is a food or a drug. It does not occur naturally and is made in a laboratory. However, it is the only source of food and nutrition for some infants under the age of 6 months. Under the FFDCA, “‘food’ means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”¹¹⁹ Under the FFDCA, a “drug” is an “(B) article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.” Some infant formulas are used for medical

Is%20infertility%20a%20common%20problem%2Cyear%20of%20trying%20(infertility) (last visited Oct. 14, 2023).

¹¹⁵ See Özcan Dağ & Dilbaz, *Impact of obesity on infertility in women*, NAT’L LIBR. MED. 111, 114 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4456969/>.

¹¹⁶ See *The Surgeon General’s Call to Action to Support Breastfeeding*, *supra* note 97, at 11.

¹¹⁷ See discussion *infra* Sections VIII(A), IX.

¹¹⁸ See *About Dairy Cows*, COMPASSION IN WORLD FARMING, <https://www.ciwf.com/farmed-animals/cows/dairy-cows/> (last visited Sept. 15, 2023) (“Like humans, cows only produce milk as a result of being pregnant. Dairy cows must give birth to one calf per year in order to continue producing milk. Typically they are artificially inseminated within three months of giving birth.”).

¹¹⁹ 21 U.S.C. § 321(f).

purposes, such as “hypoallergenic formulas for children with cow’s milk protein allergy” that serves a critical medical purpose,¹²⁰ making it seem more like a drug than food. Though formula may be less beneficial neurologically or immunologically, it is not unsafe¹²¹ as a food for infants. In fact, compared to animal milk substitutes which are insufficient nutritionally and sometimes unsafe, infant formula is a better substitute for breastmilk¹²² as a food source for infants.

V. Other Federal Laws that Impact Infant Feeding

A. Fair Labor Standards Act

“Workplace barriers contribute to low rates of breastfeeding. Research shows that supportive state laws correlate with higher rates, yet by 2009, only 23 states had adopted any laws to encourage breastfeeding in the workplace.”¹²³ The “reasonable break time” provision of the Patient Protection and Affordable Care Act is time given to pump for [and *not* to directly feed] children younger than one year, and exempts small employers that demonstrate hardship from having to provide this “reasonable break time.”¹²⁴

The National Strategy “support[s] extending workplace protections to breastfeeding mothers,” because it recognizes that “parents who choose to breastfeed continue to face substantial barriers in sustaining this choice.”¹²⁵ It is apparent that there is a need for laws to be put in place to protect breastfeeding, because of the barriers that discourage breastfeeding. Even though there are laws to protect breastfeeding, it is not clear how effectively these laws are enforced, as barriers to breastfeeding still exist and impede continued

¹²⁰ See Press Release, The White House, President Biden Announces First Two Infant Formula Defense Production Act Authorizations (May 22, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/22/president-biden-announces-first-two-infant-formula-defense-production-act-authorizations/>.

¹²¹ See INFANT FORMULA: EVALUATING THE SAFETY OF NEW INGREDIENTS, *supra* note 4, at 41.

¹²² See *id.* at 43.

¹²³ Lindsey Murtagh & Anthony D. Moulton, *Working Mothers, Breastfeeding, and the Law*, AM J. PUB. HEALTH. 217, 217 (2011).

¹²⁴ See *id.* (emphasis added).

¹²⁵ See NATIONAL STRATEGY ON HUNGER, NUTRITION, AND HEALTH, *supra* note 74, at 26.

breastfeeding.¹²⁶

B. 42 U.S.C. § 1790 Breastfeeding Promotion Program

Under 42 U.S.C. § 1790, “The Secretary, from amounts received under subsection (d), shall establish a breastfeeding promotion program to promote breastfeeding as the best method of infant nutrition, foster wider public acceptance of breastfeeding in the United States, and assist in the distribution of breastfeeding equipment to breastfeeding women.”¹²⁷ Even though this law promotes breastfeeding for infants and assists breastfeeding women, the stigma surrounding breastfeeding, especially in public places,¹²⁸ acts as a deterrent to breastfeeding. A 2001 study found that only 43% of U.S. adults believed that women have the right to breastfeed in public places.¹²⁹ Many mothers have been asked to stop breastfeeding in public places.¹³⁰ This correlates to an embarrassment connected to the disapproval of public breastfeeding.¹³¹ These feelings caused some women to choose supplementing with formula or to give up breastfeeding in its entirety.¹³²

Another barrier to breastfeeding is a father’s general opposition to it as a feeding method, due to concerns around their role in feeding and whether they would be able to bond with their infant if they were personally unable to feed the infant.¹³³ A lack of education about the benefits of breastfeeding and the right to breastfeed¹³⁴ are also barriers to breastfeeding. Breastfeeding does not require equipment. Breastfeeding equipment, as referenced in the above statute, refers to pumping, and pumping is not the same as breastfeeding.

¹²⁶ See *The Surgeon General’s Call to Action to Support Breastfeeding*, *supra* note 97, at 5, 10.

¹²⁷ 42 U.S.C. § 1790.

¹²⁸ See *The Surgeon General’s Call to Action to Support Breastfeeding*, *supra* note 97, at 13.

¹²⁹ See *id.*

¹³⁰ See *id.*

¹³¹ See *id.*

¹³² See *id.*

¹³³ *Id.* at 12. Some fathers being opposed to breastfeeding, along with the CEOs of the big infant formula companies being male, indicates lack of male support for breastfeeding, and gender inequality issues surrounding infant feeding. See *id.*

¹³⁴ See *The Surgeon General’s Call to Action to Support Breastfeeding*, *supra* note 97, at 10-11, 13.

Working mothers find that returning to work is a barrier to breastfeeding due to inflexible work hours, lack of privacy for breastfeeding or expressing milk, and limited maternity leave benefits.¹³⁵ Workplaces generally do not allow infants.¹³⁶ Many working mothers are pressured not to take breaks to pump or breaks are not long enough to allow for enough time for pumping.¹³⁷ Some working mothers have to pump in the restroom, which is insanitary and leads to premature weaning.¹³⁸

Unfortunately, the USDA's goals to prevent hunger in children under the age of five, federal programs supporting infant formula, social stigma, lack of knowledge, and work barriers to breastfeeding, all end up as factors that contribute to formula feeding of infants. Male employees do not face the same challenges around infant feeding that female employees do. While laws allow for pumping, pumping is not the same as breastfeeding. Laws that allot time to pump are not equivalent to laws that allot time to breastfeed an infant. Similar to a pregnant dairy cow with a calf nearby to continue milk production,¹³⁹ it can be challenging for a mother to be able to pump breastmilk when her body does not detect the infant nearby to detect the infant's need for breastmilk. Pumping breastmilk does not ensure that the mother will be able to keep up her breastmilk supply.¹⁴⁰ The mother's body will readjust to the apparent decreased need to produce breastmilk, because the baby is not directly breastfeeding, and if she misses a pumping session because of work, her breastmilk supply can decrease.¹⁴¹ Increasing her breastmilk supply after this decrease is not easy.¹⁴²

¹³⁵ See *id.* at 14.

¹³⁶ See *id.*

¹³⁷ See *id.*

¹³⁸ See *id.*

¹³⁹ See *About Dairy Cows*, *supra* note 118.

¹⁴⁰ See Rothman, *supra* note 32 ("The more a baby sucks, that's what stimulates milk production. If you put a baby on a strict schedule, mothers' milk supplies go down.").

¹⁴¹ See *Low Milk Supply*, WIC BREASTFEEDING SUPPORT, <https://wicbreastfeeding.fns.usda.gov/low-milk-supply> (last visited Sep. 17, 2023) (listing the following as possible "[c]auses of Low Milk Supply: limiting your baby's breastfeeding sessions, or giving your baby infant formula instead of breastfeeding.").

¹⁴² See *id.* (recommending women "breastfeed every time your baby is hungry" as a main way to increase milk supply... [because] [y]our body will make milk to meet your baby's demand.").

VI. Infant Formula Shortage

A. Federal Nutrition Programs—Such as Entitlement to WIC for Formula Feeding—and Their Effects on the Formula Market and Infant Feeding

WIC-qualified brands get prominent shelf placing, which induces non-WIC parents to buy more of the WIC-qualified brands, because that brand is more visible on the grocery store shelves.¹⁴³ Because there are so few infant formula manufacturers in the U.S., and formula is not a competitive market (tariffs are 17.5% on foreign formula¹⁴⁴), there is no incentive for formula to evolve, or for other formula companies to enter the market. This caused a formula shortage in the U.S. when Abbott, one of the four companies that control 90% of the formula market, temporarily paused operations at its Sturgis, Michigan plant.¹⁴⁵ Abbott holds a WIC contract with two-thirds of the states in the country.¹⁴⁶ Because Abbott held a two-thirds majority, WIC participants in those states were most impacted because they could not purchase or even find WIC-approved formula.¹⁴⁷

In recent history, the WIC program ended up leading to monopolies and exacerbating the problems with shortages, highlighting a need to overhaul the U.S. food system.¹⁴⁸ WIC is for “Women, Infants, and Children” because, historically, “Congress

¹⁴³ See Horsley, *supra* note 83.

¹⁴⁴ See Julie Creswell & Madeleine Ngo, *Baby Formula Shortage Has an Aggravating Factor: Few Prods.*, N.Y. TIMES, May 20, 2022 (§ A), at 1.

¹⁴⁵ These events that impact the U.S. food supply so drastically should prompt the U.S. to reconsider allowing concentration in the different industries, and for these monopolies to form, and to consider an overhaul of the U.S. food system to protect against crises such as the ones facing infants’ food source, which is limited to breastmilk or infant formula when they are under six months of age. See Horsley, *supra* note 83 (“Other parts of the food chain have similar vulnerabilities. When the giant meatpacking company JBS was hit by a ransomware attack last year, 20% of the nation’s beef and pork slaughtering capacity was temporarily idled.”).

¹⁴⁶ See *The WIC brand of infant formula varies by state*, U.S. DEP’T OF AGRIC. ECON. RSCH. SERVS. (Sept. 22, 2015), <https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=78481>.

¹⁴⁷ See *id.*; see also *Information for Health Care Providers*, MICH. HEALTH & HUM. SERVS., <https://www.michigan.gov/mdhhs/assistance-programs/wic/medicalproviders#:~:text=The%20current%20Michigan%20WIC%20infant,2021%20through%20October%2031%2C%202026>. (last visited Oct. 15, 2023) (“The current Michigan WIC infant formula manufacturer contract with Abbott Nutrition is effective November 1, 2021 through October 31, 2026.”)

¹⁴⁸ See *id.*

[found] that substantial numbers of pregnant women, infants and young children are at special risk in respect to their physical and mental health by reason of poor or inadequate nutrition or health care, or both.”¹⁴⁹

An overall lack of education on the benefits of breastfeeding led many people, even some health professionals, to believe that infant formula is just as beneficial as breastmilk.¹⁵⁰ Together with the federal nutrition programs, this barrier to breastfeeding can have an impact on infant feeding and can lead to increased infant formula feeding.¹⁵¹ Because more women of color rely on formula-feeding, this shortage disproportionately affected women of color.¹⁵²

B. Three Main Infant Formula Companies Monopolize the Formula Market

Infant formula is regulated by the FDA. The U.S. produces 98% of the formula it consumes,¹⁵³ which contributes to a monopoly for the three main companies in the domestic infant formula market, and deters foreign infant formula manufacturers from being able to export formula to the U.S.¹⁵⁴ FDA regulates domestic and foreign formula equally.¹⁵⁵ Foreign infant formula manufacturers are unlikely to export infant formula to the U.S. because of higher manufacturing costs to meet FDA’s requirements, in addition to 25% duties on imports into the U.S. of foreign formula.¹⁵⁶

¹⁴⁹ Victor Oliveira, et al., *The WIC Program: Background, Trends, and Issues*, 27 FOOD ASSISTANCE AND NUTRITION RSCH. REP., iii, 1, 8, 10 (2002).

¹⁵⁰ See *The Surgeon General’s Call to Action to Support Breastfeeding*, supra note 97, at 10.

¹⁵¹ See *id.*

¹⁵² See Jason Breslow, *As the baby formula crisis worsens, it’s also magnifying disparities in the U.S.*, NAT’L PUB. RADIO (June 19, 2022), <https://www.npr.org/2022/06/02/1102479185/baby-formula-shortage-disparities>; see also Mariel Padilla, *The 19th Explains: Why baby formula is still hard to find months after the shortage*, 19TH NEWS (Dec. 1, 2022), <https://19thnews.org/2022/12/19th-explains-infant-formula-shortage/#%3A~%3Atext%3DLow%2Dincome%20parents%2C%20particularly%20women%2Cfor%20Disease%20Control%20and%20Prevention>. (“Low-income parents, particularly women of color, rely on formula to feed their babies at higher rates and continue to be most impacted by the shortage, according to data from the Centers of Disease Control and Prevention.”).

¹⁵³ See Hassan Z. Sheikh, ET AL., CONG. RSCH. SERV., IF12123, *Infant Formula Shortage: FDA Regul. and Fed. Response* (2022).

¹⁵⁴ See Creswell & Ngo, supra note 144.

¹⁵⁵ See Sheikh, ET AL., supra note 153.

¹⁵⁶ See *id.*

During the ongoing formula shortage, FDA guidance dissuaded new parents from making their own formula.¹⁵⁷ Low-income families, especially new mothers of color, suffered more at the mercy of the big three formula companies during this shortage.¹⁵⁸ Further, new mothers unable to breastfeed are shamed for not breastfeeding,¹⁵⁹ which shows the lack of understanding for the mechanism of breastfeeding. Women of color who are single mothers needed to go back to work,¹⁶⁰ and not all workplaces provide a lactation space for breastfeeding mothers to express milk.¹⁶¹ Due to decreased breastfeeding capability, decreased breastmilk supply from not expressing milk, or other reasons that cause a mother's breastmilk supply to drop,¹⁶² many mothers eventually turn to formula to supplement. This infant formula shortage combined with the stigma of not being able to exclusively breastfeed to sustain the baby's life,¹⁶³ something a father does not experience, caused extreme stress, especially on mothers of color.¹⁶⁴

The infant formula market is highly lucrative.¹⁶⁵ Providing free hospital packs of infant formula led mothers to not exclusively breastfeed past ten weeks as compared to mothers who did not receive free packs while in the hospital.¹⁶⁶ This result provides an advantage

¹⁵⁷ See *FDA Advises Parents and Caregivers to Not Make or Feed Homemade Infant Formula to Infants*, FOOD & DRUG ADMIN. (Feb. 24, 2021), <https://www.fda.gov/food/alerts-advisories-safety-information/fda-advises-parents-and-caregivers-not-make-or-feed-homemade-infant-formula-infants>.

¹⁵⁸ See Breslow, *supra* note 152; See also Padilla, *supra* note 152.

¹⁵⁹ See Rebekah Diamond, *Why breastfeeding isn't a solution to the formula shortage*, NBC NEWS (May 12, 2022, 4:18 PM ET), <https://www.nbcnews.com/think/opinion/baby-formula-shortage-mothers-breastfeeding-blamed-rcna28595>.

¹⁶⁰ See Breslow, *supra* note 152; Padilla, *supra* note 152.

¹⁶¹ See *The Surgeon General's Call to Action to Support Breastfeeding*, *supra* note 97, at 14.

¹⁶² See *Low Milk Supply*, *supra* note 141.

¹⁶³ See Cevalco, *supra* note 11 ("Breastfeeding has never been possible for everyone and people have always needed substitutes for breastmilk."); Diamond, *supra* note 159.

¹⁶⁴ See Breslow, *supra* note 152; Padilla, *supra* note 152.

¹⁶⁵ See *U.S. Baby Infant Formula Market Is Expected to Reach \$6.78 Billion by 2030*, GLOBE NEWSWIRE (Jun. 15, 2022), <https://www.globenewswire.com/en/news-release/2022/06/15/2463074/0/en/U-S-Baby-Infant-Formula-Market-Is-Expected-to-Reach-6-78-Billion-by-2030-Says-AMR.html>.

¹⁶⁶ See Kenneth D. Rosenberg et al., *Marketing Infant Formula Through Hospitals: the Impact of Commercial Hospital Discharge Packs on Breastfeeding*, 98 AM. J.

to the three main formula companies and encourages these companies to begin marketing in the hospital to new delivering mothers.¹⁶⁷ Companies that provide hospitals with formula samples that can be given to new moms for free incentivize new moms to formula-feed. On the one hand, the availability of formula for new mothers can relieve stresses that new mothers experience with breastfeeding.¹⁶⁸ However, the lack of support for breastfeeding from employers¹⁶⁹ and society is also to the advantage of the formula industry. It should not be a surprise that the CEOs of the big three U.S. formula companies are all male.¹⁷⁰ In addition to supermarkets giving prime shelf space to the WIC-contracted formula company, pediatricians also recommend certain brands more readily to new parents,¹⁷¹ and physicians hold significant credibility when it comes to infant feeding recommendations.¹⁷² This makes it difficult for parents that formula-feed their infants to find infant formula, especially when a brand facing a shortage (Abbott) is the WIC-contracted formula brand in that particular state.¹⁷³ Marketing practices and medical advice contribute to the disproportionate effects of U.S. laws and nutrition programs on new mothers, impact infant feeding, and exacerbate gender and race inequality.

PUB. HEALTH, 290, 290 (2008) (“Commercial hospital discharge packs are one of several factors that influence breastfeeding duration and exclusivity. The distribution of these packs to new mothers at hospitals is part of a longstanding marketing campaign by infant formula manufacturers and implies hospital and staff endorsement of infant formula.”).

¹⁶⁷ See *id.*

¹⁶⁸ See generally *The Surgeon General’s Call to Action to Support Breastfeeding*, *supra* note 97, at 11.

¹⁶⁹ See *id.* at 14.

¹⁷⁰ See *id.* at 12 (“Paternal influences on maternal feeding practices are critically important in early decision making about breastfeeding.”); See also *Executive Team*, ABBOTT, <https://www.abbott.com/corpnewsroom/utilities/executive-team.html> (last visited Sept. 30, 2023); Julia Musto, *US Formula Shortage to Improve by October, Gerber CEO Projects*, FOX BUS. (Sept. 13, 2022), <https://www.foxbusiness.com/markets/us-formula-shortage-improve-october-gerber-ceo-projects#>; *Mead Johnson Nutrition CEO and Executive Team*, CRAFT, <https://craft.co/mead-johnson-nutrition/executives> (last visited Sept. 30, 2023).

¹⁷¹ See Horsley, *supra* note 83.

¹⁷² It is troubling to know that “a recent survey of pediatricians showed that many believe the benefits of breastfeeding do not outweigh the challenges that may be associated with it, and they reported various reasons to recommend against breastfeeding.” Such a recommendation against breastfeeding because of its challenges is directly contrary to the National Strategy’s recommendation to promote breastfeeding and nutrition science’s evidence that breastfeeding is best for an infant. See *The Surgeon General’s Call to Action to Support Breastfeeding*, *supra* note 97, at 15.

¹⁷³ See Horsley, *supra* note 83.

VII. Effects of Laws on New Mothers' Behaviors

A. Infant Formula Offered to New Mothers Post-Birth Impacts Infant Feeding

The First Amendment Right to Free Speech, applied to commercial speech, allows companies to use speech as long as it is not false or misleading.¹⁷⁴ Some hospitals allow infant formula companies to market their infant formulas at the hospital to new mothers (at their most vulnerable) after delivering their babies, by offering formula instead of assisting in initiation of breastfeeding,¹⁷⁵ as long as the information is not false or misleading.¹⁷⁶ As a result of this marketing, infant formula companies receive positive views for promoting their infant formulas for free. The infant formula samples may be free, but formula-feeding affects the mother's breastmilk supply and interferes with breastfeeding.¹⁷⁷ The shortage of infant formula in the past year,¹⁷⁸ together with the government's high tariffs on imported formula,¹⁷⁹ placed parents, in particular mothers of color,¹⁸⁰ in a debilitating position where the possibility of not being able to feed their infant was a real concern.

Infant formula companies incentivized formula use by distributing samples to hospitals and encouraging hospital workers to

¹⁷⁴ See *Turtle Island Foods SPC v. Soman*, 424 F. Supp. 3d 552, 561 (E.D. Ark. 2019) (finding First Amendment commercial speech protects against "a restriction on commercial speech that prevents companies from sharing truthful and non-misleading information about their products.").

¹⁷⁵ See Szalinski, *supra* note 22 ("Previous research shows hospital maternity wards that serve larger black populations are less likely to help black women initiate breastfeeding after giving birth or offer lactation support following delivery, according to the CDC study. Often, staff in these facilities instead offer black babies formula."); see also Echols, *supra* note 22 ("Hospitals in communities with an above-average Black population are significantly less likely to promote nursing than hospitals located in other neighborhoods. Black women are also more likely to experience in-hospital formula introduction, which is associated with lowered breastfeeding rates.").

¹⁷⁶ See Cevalco, *supra* note 11.

¹⁷⁷ See *Low Milk Supply*, *supra* note 141.

¹⁷⁸ See Horsley, *supra* note 83.

¹⁷⁹ See *id.*

¹⁸⁰ See Breslow, *supra* note 152; see also Padilla, *supra* note 152 ("Low-income parents, particularly women of color, rely on formula to feed their babies at higher rates and continue to be most impacted by the shortage, according to data from the Centers for Disease Control and Prevention.").

pass out those samples to new mothers.¹⁸¹ However, a mother's breastmilk is also free. After a baby is born, breastfeeding can be difficult, and its success often depends on early access to an in-hospital lactation consultant.¹⁸² A new mother's milk is commonly not immediately available after the baby is born.¹⁸³ In these critical early days, new mothers can become extremely discouraged due to a belief of inadequacy from a lack of milk supply, and therefore succumb to pressures to formula feed.¹⁸⁴ Women are particularly vulnerable in these moments after childbirth,¹⁸⁵ and formula companies that give samples of formula in the hospital may cause a new mother to formula-feed instead of breastfeed.¹⁸⁶ Even for the first several weeks of the new infant's life, it is difficult to establish breastfeeding, especially if there is not support from the workplace or from society in general.¹⁸⁷ It may even lead a new mother to use the free formula samples from the hospital to feed the infant.¹⁸⁸ This affects the mother's milk supply¹⁸⁹ and ultimately impacts infant feeding.

¹⁸¹ Nathaniel Meyersohn, *Companies aggressively marketed baby formula. Then there was a shortage.*, CNN (July 1, 2022, 1:50 PM), <https://www.cnn.com/2022/07/01/business/baby-formula-marketing-tactics/index.html>; see also Rosenberg et al., *supra* note 166; see also *The Surgeon General's Call to Action to Support Breastfeeding*, *supra* note 97, at 15.

¹⁸² See *The Surgeon General's Call to Action to Support Breastfeeding*, *supra* note 97, at 13 ("Successful initiation depends on experiences in the hospital as well as access to instruction on lactation from breastfeeding experts, particularly in the early postpartum period.").

¹⁸³ See *Breastfeeding and Delayed Milk Production*, JOHN HOPKINS MED., <https://www.hopkinsmedicine.org/health/conditions-and-diseases/breastfeeding-and-delayed-milk-production#:~:text=Sometimes%20a%20mother%20has%20a,%2C%20don't%20feel%20discouraged> (last visited Sep. 25, 2023).

¹⁸⁴ See *The Surgeon General's Call to Action to Support Breastfeeding*, *supra* note 97, at 13 ("Lack of confidence in breastfeeding or not understanding the normal physiology of lactation can lead to the perception of an insufficient milk supply when in fact the quantity is enough to nurture the baby.").

¹⁸⁵ See *id.*

¹⁸⁶ See *id.*; see also Meyersohn, *supra* note 181.

¹⁸⁷ See *The Surgeon General's Call to Action to Support Breastfeeding*, *supra* note 97, at 12-13.

¹⁸⁸ See Meyersohn, *supra* note 181. ("The linchpin of their marketing strategy is to get free samples into the hands of breastfeeding mothers. What they hope will happen is if a breastfeeding mother runs into any trouble at all she will have formula already in a bottle and ready to put in her baby's mouth.").

¹⁸⁹ See *Low Milk Supply*, *supra* note 141.

B. WIC promotes Breastfeeding in Alignment with the National Strategy

WIC benefits for formula makes sense for fathers because they have no other way of feeding a child as males cannot breastfeed.¹⁹⁰ Thus, WIC benefits may not impact fathers in the same way as they do mothers when it comes to infant feeding decisions. However, WIC benefits and breastfeeding guidance are contradictory. Conflicting advice about solutions to breastfeeding problems, a lack of confidence in breastfeeding, and a lack of understanding of the physiology of lactation leading to the misperception of inadequate milk supply,¹⁹¹ are contradictory concepts that can impact infant feeding decisions.

WIC benefits can be used for infant formula.¹⁹² However, WIC's website promotes breastfeeding and is in alignment with the National Strategy.¹⁹³ WIC encourages breastfeeding on demand,¹⁹⁴ but does not take into account that many working mothers face inflexible work schedules.¹⁹⁵

The USDA's Food and Nutrition Service (FNS) recommends breastfeeding as "one of the best things you can do for your baby," and to "breastfeed your baby as much as you can, and for as long as you can."¹⁹⁶ However, the U.S. government's position concerning breastfeeding appears inconsistent. While the Fair Labor Standards Act (FLSA) allows for lactation rooms, this is for pumping and not for direct breastfeeding.¹⁹⁷ Pumping and breastfeeding are not the

¹⁹⁰ See generally *Welcoming Dads to WIC Family*, U.S. DEP'T OF AGRIC. FOOD AND NUTRITION SERV. (Jun. 9, 2022), <https://www.fns.usda.gov/wic/welcoming-dads-to-wic-family>.

¹⁹¹ See *The Surgeon General's Call to Action to Support Breastfeeding*, *supra* note 97, at 11.

¹⁹² See *WIC Frequently Ask Questions*, *supra* note 5 ("WIC recognizes and promotes breastfeeding as the optimal source of nutrition for infants. For women who do not fully breastfeed, WIC provides iron-fortified infant formula.").

¹⁹³ See generally *Breastfeeding Benefits*, *supra* note 28 (stating "Breast milk is one of the best things that your baby needs to grow and develop.").

¹⁹⁴ See *Low Milk Supply*, *supra* note 141.

¹⁹⁵ See *The Surgeon General's Call to Action to Support Breastfeeding*, *supra* note 97, at 14.

¹⁹⁶ *About WIC Breastfeeding Support and Formative Research Findings*, *supra* note 3.

¹⁹⁷ See *FLSA Protections to Pump at Work*, U.S. DEP'T OF LAB., <https://www.dol.gov/agencies/whd/pump-at-work/> (last visited Oct. 15, 2023) ("The

same.¹⁹⁸ When a new mother knows that she is able to pump during work, she may choose to go back to work sooner, which will affect her breastmilk supply, because pumping is not as effective at keeping milk supply up as direct breastfeeding.¹⁹⁹ Exclusively breastfeeding requires mothers to not be away from their babies for long stretches of time, which the FLSA does not address.²⁰⁰ It simply gives a mother the ability to pump during work. Pumping can be more difficult than direct breastfeeding,²⁰¹ which impacts infant feeding and can lead to a mother's use of formula. "The lack of universal paid family leave still prevents some working parents from breastfeeding,"²⁰² which impacts infant feeding and can also lead to formula use.

Though the USDA, FNS supports breastfeeding as preferred over formula-feeding, many factors such as the lack of paid leave for working parents and financial support to new parents through WIC, impact infant feeding decisions and lead to formula-feeding. Plus, hospitals are allowed to give formula samples provided by infant formula companies during the first few days after the baby is born when the mother is most vulnerable,²⁰³ which can impact infant feeding and lead to formula-feeding. This misleads new mothers into believing that the hospital is endorsing those formula companies.²⁰⁴ The government's position concerning breastfeeding appears conflicting, because while it provides WIC for formula purchases, it does not provide paid leave to new parents to facilitate, support, and

Fair Labor Standards Act (FLSA) requires employers to provide reasonable break time for an employee to express breast milk for their nursing child for one year after the child's birth each time such employee has need to express the milk. Employees are entitled to a place to pump at work, other than a bathroom, that is shielded from view and free from intrusion from coworkers and the public.").

¹⁹⁸ See generally Crider, *supra* note 16.

¹⁹⁹ See Leisa Bailey, *Breastfeeding: Returning to Work*, FAMILYDOCTOR.ORG (July 2022), <https://familydoctor.org/breastfeeding-returning-to-work/>.

²⁰⁰ See Crider, *supra* note 16.

²⁰¹ See *id.*

²⁰² Cevalco, *supra* note 11.

²⁰³ See Rosenberg et al., *supra* note 166 ("Among women who had initiated breastfeeding, 66.8% reported having received commercial hospital discharge packs. Women who received these packs exclusively breastfed for fewer than 10 weeks as compared to the women who had not received the packs. Commercial hospital discharge packs are one of several factors that influence breastfeeding duration and exclusivity. The distribution of these packs to new mothers at hospitals is part of a longstanding marketing campaign by infant formula manufacturers and implies hospital and staff endorsement of infant formula. Commercial hospital discharge pack distribution should be reconsidered in light of its negative impact on exclusive breastfeeding.").

²⁰⁴ See *id.*

promote breastfeeding.²⁰⁵

Breastfeeding mothers can participate in WIC longer than non-breastfeeding mothers,²⁰⁶ which could be an incentive for mothers to breastfeed. However, the lack of paid family leave, difficulty in continued lactation the longer a mother is away from her infant,²⁰⁷ and adversity stacked against breastfeeding,²⁰⁸ mothers wanting to breastfeed long-term may find it infeasible.

Allowing breastfeeding mothers to participate in WIC longer than non-breastfeeding mothers²⁰⁹ may have an unintended inequitable effect against women who are physically unable to breastfeed due to physiological reasons, but might have done so if they were physically able.²¹⁰ These mothers might have wanted to breastfeed if they were physiologically able to in order to avail themselves of WIC's benefit of extended coverage for breastfeeding mothers.²¹¹ The nutrition benefits programs thus have an unequal effect on mothers depending on their physical ability to breastfeed. Once again, these concerns do not affect males at all.

WIC takes active steps to ensure fathers feel included in childhood development.²¹² However, granting a father access to WIC feels counter-intuitive because the program was designed to help support low-income and nutritionally disadvantaged women, infants, and children; even further, women, rather than men, are incredibly vulnerable post-birth.²¹³ WIC was specifically created to address

²⁰⁵ See Cevalco, *supra* note 11.

²⁰⁶ See *WIC Fact Sheet*, *supra* note 58.

²⁰⁷ See Mary Sauer, *How to handle a sudden decrease in milk supply*, BABYCENTER (Aug. 15, 2022), https://www.babycenter.com/baby/breastfeeding/i-think-my-milk-supply-is-dwindling-what-could-be-the-proble_8872.

²⁰⁸ See generally *The Surgeon General's Call to Action to Support Breastfeeding*, *supra* note 97.

²⁰⁹ See *WIC Fact Sheet*, *supra* note 58.

²¹⁰ See Amy McKeever, *Many women struggle to breastfeed. Scientists are starting to ask why.*, NAT'L GEOGRAPHIC (AUG. 9 2023), <https://www.nationalgeographic.com/premium/article/many-women-struggle-to-breastfeed-scientists-are-starting-to-ask-why> ("Only about five to 10 percent of women are physiologically unable to breastfeed.").

²¹¹ See *WIC Fact Sheet*, *supra* note 58.

²¹² See *Welcoming Dads to WIC Family*, *supra* note 190.

²¹³ See Victor Oliveira et al., *The WIC Program: Background, Trends, and Issues*, U.S. DEP'T OF AGRIC. ECON. RSCH. SERV. (Sept. 2002), https://www.ers.usda.gov/webdocs/publications/46648/15841_fanrr27_1_.pdf?v=0

public concern of malnutrition among low-income mothers and children,²¹⁴ and only women, not men, can be pregnant.²¹⁵

The FNS states, “We don't encourage dads to step up and then we wonder why they don't show up.”²¹⁶ This appears to place blame on those who do not encourage dads to step up as fathers, excuses dads for not stepping up, and places the responsibility on external forces that should have encouraged these dads to step up. While it could be true that dads are not encouraged to be fathers, the WIC program was created to address public concern of malnutrition specifically found in low-income mothers²¹⁷ and not fathers. Moreover, the USDA historically reflects an American farmer demographic of white males.²¹⁸ Statements like these on the USDA's website continue to highlight the underlying gender discrimination that exists and exacerbates gender inequality issues that have been allowed to fester and continue in our country, perhaps not overtly, but insidiously. Allowing fathers to participate in WIC is not in alignment with the purpose of WIC, which was to address the special needs of pregnant women arising from their pregnancy condition,

(“The origin of WIC dates back to the 1960s when the Nation began to recognize that many low-income Americans were suffering from malnutrition.....special attention be given to the nutritional needs of low-income pregnant women and preschool children...in response to the growing public concern about malnutrition among low-income mothers and children.”).

²¹⁴ See *id.*

²¹⁵ See *Geduldig v. Aiello*, 417 U.S. 484, 496-97, n.20 (1974).

²¹⁶ See *Welcoming Dads to WIC Family*, *supra* note 190.

²¹⁷ See Oliveira, et al., *supra* note 213.

²¹⁸ See Laura Reiley & Andrew Van Dam, *Advocates hoped census would find diversity in agriculture. It found old white people.*, THE WASH. POST (Apr. 13, 2019, 6:30 AM), <https://www.washingtonpost.com/business/2019/04/13/advocates-hoped-new-report-would-find-diversity-ag-it-found-old-white-people/>; see also *2012 Census of Agriculture Highlights: Women Farmers*, U.S. DEP'T OF AGRIC. NATION'L AGRIC. STAT. SERV. (Sept. 2014), https://www.nass.usda.gov/Publications/Highlights/2014/Highlights_Women_Farmers.pdf

(Outlining statistical findings of women farmers in the US); see also Seth L. Ellis, *Disestablishing "The Last Plantation": The Need for Accountability in the United States Department of Agriculture*, 4 J. FOOD L. & POL'Y 93, 94 (2008) (“Many American citizens do not share Abraham Lincoln's view of the USDA as being the ‘people's Department’; rather, they identify it as being ‘the last plantation’ due to its long history of open discrimination against African- American farmers...In 1865, Congress established the Bureau of Refugees, Freedmen, and Abandoned Lands (Freedmen's Bureau) to oversee the allocation of Southern land to former slaves. The Act which founded the Freedmen's Bureau ‘promised every *male* citizen, whether refugee or freedman, forty acres of land at rental for three years with an option to buy.”) (emphasis added).

which is a condition that men can never be in.

VIII. Breastfeeding vs. Formula Feeding

A. Benefits of Breastfeeding

Research shows that breastfeeding has lifelong benefits for both mother and child.²¹⁹ Breastfed children are more likely protected against infections and childhood death.²²⁰ Breastfeeding can also protect babies against asthma and sudden infant death syndrome (SIDS).²²¹ Breastfed babies also have less ear infections and stomach bugs.²²² Research also shows an increase in intelligence and reduced rates of obesity and diabetes in childhood, lasting into adulthood.²²³ Mothers that breastfeed are more likely protected against ovarian and breast cancer.²²⁴ Type 2 diabetes and high blood pressure are less common in women who breastfeed.²²⁵ Breastfeeding is also linked to lower risks of obesity, Type 1 diabetes, and asthma in children.²²⁶ Breastmilk changes as the baby grows to specifically meet that baby's nutritional needs,²²⁷ whereas infant formula does not.²²⁸

The potential public health consequences of not supporting women to breastfeed²²⁹ are increased obesity in mothers and undeveloped microbiome in infants. These public health consequences must be examined in tandem with formula companies that “have real clout”²³⁰ and influence on women's decisions to breastfeed or to formula-feed.

²¹⁹ See Neves, et al., *supra* note 22, at 910.

²²⁰ See *id.*

²²¹ See *Breastfeeding Benefits Both Baby and Mom*, CTDS. FOR DISEASE CONTROL AND PREVENTION: DIVISION OF NUTRITION, PHYSICAL ACTIVITY, AND OBESITY (Sept. 7, 2023), <https://www.cdc.gov/nccdphp/dnpao/features/breastfeeding-benefits/index.html#%3A~%3Atext%3DBreastfeeding%20can%20help%20protect%20babies%20Cear%20infections%20and%20stomach%20bug>.

²²² See *id.*

²²³ See Neves, et al., *supra* note 22, at 910.

²²⁴ See *id.*

²²⁵ See *Breastfeeding Benefits Both Baby and Mom*, *supra* note 221.

²²⁶ See Roni Caryn Rabin, *U.S. Guidelines Sidestep Scientific Advice to Cut Sugar and Alcohol*, N.Y. TIMES, Dec. 30, 2020, at A17.

²²⁷ See *Breastfeeding Benefits Both Baby and Mom*, *supra* note 221.

²²⁸ See INFANT FORMULA: EVALUATING THE SAFETY OF NEW INGREDIENTS, *supra* note 4, at 44-46.

²²⁹ Rothman, *supra* note 32.

²³⁰ *Id.*

Breastmilk is a living substance²³¹ which affects not only the neonatal gut and immune system, but also lifelong health.²³² A new study also “showed that what really helped prevent obesity was getting breast milk directly from the breast,” as opposed to from a bottle.²³³

B. Is Breastfeeding a Right?

According to the USDA, breastfeeding mothers have certain rights, and there are laws about breastfeeding in public and pumping at work.²³⁴ However, working moms who are hourly workers, as opposed to salaried workers, do not have as much control over their schedules, which makes it difficult for them to take the time to pump during work hours.²³⁵

Mothers choose not to breastfeed for many reasons including misinformation about the adequate nutrition of breastmilk²³⁶ and a lack of support for lactating women,²³⁷ especially in the workplace.²³⁸ Even WIC benefits themselves may sway working mothers that need to earn money to support their families to decide to formula-feed rather than to breastfeed. Working mothers are pressured to not take breaks to pump and babies are not allowed

²³¹ See INFANT FORMULA: EVALUATING THE SAFETY OF NEW INGREDIENTS, *supra* note 4, at 46.

²³² See Rothman, *supra* note 32.

²³³ Claire McCarthy, *The Real Link Between Breastfeeding and Preventing Obesity*, HARVARD MED. SCH. (Oct. 16, 2019), <https://www.health.harvard.edu/blog/the-real-link-between-breastfeeding-and-preventing-obesity-2018101614998>.

²³⁴ See *Your Breastfeeding Rights*, U.S. DEP’T OF AGRIC. WIC BREASTFEEDING SUPPORT, <https://wicbreastfeeding.fns.usda.gov/your-breastfeeding-rights#:~:text=There%20is%20no%20national%20law,any%20public%20or%20private%20place> (last visited Oct. 14, 2023). There are laws about breastfeeding in public and pumping at work, but not breastfeeding while at work, because for the most part, babies are not allowed at the workplace. See *The Surgeon General’s Call to Action to Support Breastfeeding*, *supra* note 97, at 14.

²³⁵ See *The Surgeon General’s Call to Action to Support Breastfeeding*, *supra* note 97, at 14–15.

²³⁶ See *id.* at 10.

²³⁷ See McKeever, *supra* note 210 (stating there is “minimal institutional support for women who are trying to breastfeed. In contrast to the dairy industry, which has funded extensive studies of lactation in cattle, researchers have barely scratched the surface with human milk.”).

²³⁸ Cevalco, *supra* note 11.

in the workplace²³⁹ because both take the working mother away from her job duties.

Infant formula companies promote their product, infant formula, but the big three infant formula companies all have male CEOs.²⁴⁰ Women should have the choice to decide how they use their bodies and whether they want to breastfeed or formula-feed. However, laws, nutrition programs, breastfeeding barriers, and other societal factors, impact a woman's choice around infant-feeding methods. Women are sometimes discouraged to breastfeed and end up formula-feeding.

During the infant formula shortage in 2022,²⁴¹ a mother might have experienced less anxiety knowing that she had breastmilk,²⁴² one of two possible sources of acceptable and safe foods if, at the time, she had an infant less than six months of age. However, the barriers to breastfeeding, which might have led a mother to formula-feed instead of breastfeed, together with the formula shortage, take away her feelings of assurance that her infant will be fed. Although the "American Academy of Pediatrics (AAP) recommends *exclusive* breastfeeding for approximately 6 months after birth,"²⁴³ mothers receive conflicting information from their doctors,²⁴⁴ and the laws and nutrition programs also appear contradictory concerning infant feeding and impact infant feeding decisions.

²³⁹ See *The Surgeon General's Call to Action to Support Breastfeeding*, *supra* note 97, at 14.

²⁴⁰ See also *Executive Team*, *supra* note 170; see also Musto, *supra* note 170; see also *Mead Johnson Nutrition CEO and Executive Team*, *supra* note 170.

²⁴¹ See *Horsley*, *supra* note 83.

²⁴² See Imboden et al., *supra* note 92, at 1.

²⁴³ Joan Meek & Lawrence Noble, *Policy Statement: Breastfeeding and the Use of Human Milk*, 150 AM. ACAD. OF PEDIATRICS 1, 1, (June 27, 2022) (emphasis added).

²⁴⁴ See *The Surgeon General's Call to Action to Support Breastfeeding*, *supra* note 97, at 5 ("Women report receiving conflicting advice from clinicians about how to solve problems with breastfeeding." And "a recent survey of pediatricians showed that many believe the benefits of breastfeeding do not outweigh the challenges that may be associated with it, and they reported various reasons to recommend against breastfeeding.").

C. Overall Lack of Support for Breastfeeding and its Impact on Infant Feeding

While National Strategy written materials²⁴⁵ and the FNS's website indicate that the federal government recommends breastfeeding, written materials and actual actions are inconsistent with respect to what the government really recommends. "WIC is the major purchaser of infant formula in the United States."²⁴⁶ The federal government appears to support time for lactating workers to pump breastmilk, but this is not the same as breastfeeding.²⁴⁷ This also assumes employers follow all required laws.²⁴⁸ While one method of feeding recommendation does not mean an exclusion of other feeding methods, a recommendation for formula-feeding ultimately discourages breastfeeding.²⁴⁹ The same is not true in reverse because the success of formula-feeding does not rely on a mother's milk supply; breastfeeding success requires milk production and is adversely impacted by a decrease in milk supply due to increased formula feeding.²⁵⁰ Breastfeeding is more cost-effective than formula-feeding for a mother.²⁵¹ If breastfeeding is not supported or encouraged, the end result is that mothers pay to formula-feed their infant when they already had a more cost-effective method in their own breastmilk.

Mothers who breastfeed their infants require less sick leave absences to care for sick children as compared to mothers who formula-feed their infants because of reduced occurrences of health problems in breastfed babies and their mothers.²⁵² Many mothers that chose formula out of necessity are women of color.²⁵³ Increased health problems could occur in formula-fed babies and their mothers, and these health problems may not occur if exclusive breastfeeding

²⁴⁵ See generally NATIONAL STRATEGY ON HUNGER, NUTRITION, AND HEALTH, *supra* note 74, at 26.

²⁴⁶ See *The WIC brand of infant formula varies by State*, *supra* note 6.

²⁴⁷ See Crider, *supra* note 16, at 4.

²⁴⁸ Many working mothers are pressured not to take breaks to pump, or breaks are not long enough to allow enough time for pumping. See *The Surgeon General's Call to Action to Support Breastfeeding*, *supra* note 97, at 4.

²⁴⁹ See *Low Milk Supply*, *supra* note 141, at 3.

²⁵⁰ See *id.*

²⁵¹ See *Breastfeeding Benefits*, *supra* note 28.

²⁵² See Nicole Kennedy Orozco, *Pumping at Work: Protection from Lactation Discrimination in the Workplace*, 71 OHIO ST. L.J. 1281, 1289 (2010).

²⁵³ See Breslow *supra* note 152, at 5; See Padilla *supra* note 152, at 7.

was promoted.²⁵⁴ These babies of color that were not exclusively breastfed, because it was not supported or encouraged, may start out their lives at a disadvantage being formula-fed rather than breastfed.

“Successful breastfeeding promotion policies can have nontrivial impacts on the U.S. labor market.”²⁵⁵ Marketing infant formula-feeding or breastfeeding also impacted the duration and initiation of breastfeeding.²⁵⁶ For the most part, exposure of mothers to infant formula marketing shortened the duration and initiation of exclusive breastfeeding, and instead resulted in formula-feeding.²⁵⁷ Exposure to breastfeeding, for the most part, caused higher rates of initiation and duration of breastfeeding.²⁵⁸ Because of the infant formula shortage, the rate of mothers initiating breastfeeding increased by 10.6% compared to before the shortage.²⁵⁹ The reports of sick babies due to consumption of formula caused a preference for breastfeeding.²⁶⁰

The lack of universal paid family leave exacerbates the problem faced by American women when it comes to paid leave to care for a baby.²⁶¹ When a mother is at work and not in the presence of her baby, her body senses that there is not a need to make

²⁵⁴ See *Breastfeeding Benefits Both Baby and Mom*, *supra* note 221; see also Neves et al., *supra* note 22, at 916 (“There is ample evidence on the hazards associated with formula feeding and suboptimal breastfeeding practices. These include not only increased child morbidity and mortality, but also reduced human capital in adulthood associated with lower intelligence, and possible effects on diabetes and obesity. . . . Urgent action is needed in order to promote and support exclusive breastfeeding in all social groups.”).

²⁵⁵ Bidisha Mandal et al., *Work and breastfeeding decisions are jointly determined for higher socioeconomic status US mothers*, REV. OF ECON. OF THE HOUSEHOLD 237, 237 (2014), <https://doi.org/10.1007/s11150-012-9152-y>.

²⁵⁶ See Yuanting Zhang et al., *The Association of Prenatal Media Marketing Exposure Recall with Breastfeeding Intentions, Initiation, and Duration*, J. HUM LACT. 500 (2013), <https://pubmed.ncbi.nlm.nih.gov/23686404/> (“Exposure to infant formula information from print media was associated with shorter intended duration of exclusive breastfeeding, and formula information from websites was related to lower odds of both intended and actual initiation. Exposure to breastfeeding information from websites was related to higher odds of both intended and actual initiation and longer intended duration of any breastfeeding. Breastfeeding information from print media was associated with longer duration of any breastfeeding, but information from broadcast media was associated with shorter duration of any breastfeeding.”).

²⁵⁷ See *id.*

²⁵⁸ See *id.*

²⁵⁹ See Imboden et al., *supra* note 92, at 279.

²⁶⁰ See *id.*

²⁶¹ See generally Imboden et al., *supra* note 92.

breastmilk.²⁶² Infant formula companies can benefit from this. Once the mother's milk dries up, it can be a difficult process to get it to come back (relactation).²⁶³

IX. Effects of Formula Feeding on Health

A. Mothers and Weight Control

Babies and kids start out life with an innate biological knowledge to not overeat.²⁶⁴ They stop breastfeeding or eating when they have had enough. However, "parents can teach children to distrust their internal hunger and fullness cues by serving portions that exceed children's needs which, in turn, prompts children to overeat."²⁶⁵ This can happen with formula-feeding from a bottle. Babies are not able to control how much they eat, and because babies do not need to latch onto a bottle to make the milk come out, babies have less control in formula-feeding.²⁶⁶ Because babies do not control the amount of food given to them from a bottle, this can lead to overeating. Therefore, formula-feeding from a bottle can lead to a generation of humans that do not learn to read their own body's signals that would inform them when they are full and have had enough to eat. Each human is an individual and the right amount of food for one person may not be the same as the amount for another.

When a mother breastfeeds exclusively, it promotes greater weight loss than feeding some combination of breastmilk and formula.²⁶⁷ Exclusive breastfeeding can prevent obesity.²⁶⁸

²⁶² See Sauer, *supra* note 207.

²⁶³ See *How To Reintroduce Lactation After Stopping Breastfeeding*, CLEVELAND CLINIC (Jun. 16, 2022), <https://health.clevelandclinic.org/relactation/>.

²⁶⁴ See Eck et al., "My Tummy Tells Me" *Cognitions, Barriers and Supports for Parents and School-Age Children for Appropriate Portion Sizes*, NAT'L LIBR. MED. (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6115960/> ("Healthy children are born with an innate ability to self-regulate their dietary intake to match their needs.").

²⁶⁵ *Id.*

²⁶⁶ See, McCarthy, *supra* note 233.

²⁶⁷ See Irene E. Hatsu et al., *Effect of infant feeding on maternal body composition*, INT'L BREASTFEEDING J., 18, 18 (2008), <https://internationalbreastfeedingjournal.biomedcentral.com/articles/10.1186/1746-4358-3-18>.

²⁶⁸ See *id.* at 18, 23 ("There is a need to encourage mothers to exclusively breastfeed as a means of overweight and obesity prevention."). *But see* Breslow, *supra* note 152 (recognizing exclusive breastfeeding is difficult for women of color

Breastfeeding outcomes correlate directly with race and income; white and Asian babies are breastfed more than Black infants.²⁶⁹ Low-income women of color that have to rely on formula to feed their babies²⁷⁰ often do not experience the weight-controlling benefits of breastfeeding.²⁷¹ When a father formula feeds, he does not experience the same health consequences as a mother, especially a mother that chose one method of infant feeding over another. Infant feeding choices thus have consequences that do not equally impact women and men (based on gender), and women of color (based on race). Continued studies that examine the effects of laws on infant feeding and its impacts on inequality are crucial for this reason.

B. Babies and Failure to Develop Proper Gut Microbiome

Breastmilk helps babies to develop proper microbiomes. When babies are not breastfed for long enough, they do not learn how to develop proper microbiomes.²⁷² “Babies who drink breast milk are more likely to have certain bacteria in their digestive tracts that help prevent obesity.”²⁷³ “The higher protein content of artificial baby milk compared to the lower protein content in breastmilk is responsible for the increased growth rate and adiposity during the influential period of infancy of formula-fed infants.”²⁷⁴ Breastfed infants consume less milk than the same infant given infant formula during early months and consume less calories than formula-fed infants.”²⁷⁵

An individual is first exposed to microorganisms during delivery in the mother’s birth canal and through breastmilk, and exactly which microbiota species an infant is exposed to depends on the mother’s DNA.²⁷⁶ Formula feeding can alter the structure and

who often have to formula-feed because their work schedules are inflexible in accommodating pumping or breastfeeding); *see also* Padilla, *supra* note 152.

²⁶⁹ *See* Cevalco, *supra* note 11.

²⁷⁰ *See* Breslow, *supra* note 152; *see also* Padilla, *supra* note 152.

²⁷¹ *See* Hatsu, *supra* note 267, at 18, 23.

²⁷² *See* National Public Radio, *The Invisible Universe Of The Human Microbiome*, YOUTUBE (Nov. 5, 2013), <https://www.youtube.com/watch?v=5DTrENdWvM>.

²⁷³ McCarthy, *supra* note 233.

²⁷⁴ Wendy H. Oddy, *Infant feeding and Obesity risk in the Child*, 20 BREASTFEEDING REV. 7, 7 (2012).

²⁷⁵ *See* INFANT FORMULA: EVALUATING THE SAFETY OF NEW INGREDIENTS, *supra* note 4, at 46.

²⁷⁶ *See The Microbiome*, HARV. SCH. PB. HEALTH,

relative abundances of the bacterial communities normally found in a breastfed infant's gut.²⁷⁷ "Cesarean section[s] (C-section[s]), perinatal antibiotics, and formula feeding . . . have been linked to increased risks of metabolic and immune diseases."²⁷⁸ Breastfeeding and formula-feeding influence microbiota.²⁷⁹ "Breast-fed newborns have been demonstrated to carry a more stable and uniform population when compared to the formula-fed ones," and the type of feeding method used "has a major impact on the development of immune functions."²⁸⁰ Studies have shown that "milk formula with prebiotics, probiotics, and lactoferrin has been demonstrated to change newborns' microflora composition toward breast-feeding pattern and to stimulate immune response. [However,] no definitive results are available regarding the real health improvement, so that breast milk, whose beneficial health-effects are undoubtedly unique, has to be considered the food of choice for infants in the first 6 months of life."²⁸¹

Providing formula has an unintended potential consequence on an infant's ability to develop the necessary microbiota to fight off infections, diabetes, and obesity. To replace that necessary microbiota that infants receive from mother's breastmilk with probiotics, feeds into a multi-billion dollar industry.²⁸²

If infant formula is an ultra-processed food in alignment with the NOVA4 food classification, then it can impact human health including pro-inflammatory microbiome contribution.²⁸³ Higher consumption of ultra-processed foods also leads to obesity, depression, diabetes, hypertension, cardiovascular diseases, breast cancer, and higher mortality.²⁸⁴ Formula-feeding, with a

<https://www.hsph.harvard.edu/nutritionsource/microbiome/> (last visited Oct. 1, 2032) ("A person is first exposed to microorganisms as an infant, during delivery in the birth canal and through the mother's breast milk... [l]ater on, environmental exposures and diet can change one's microbiome to be either beneficial to health or place one at greater risk for disease.").

²⁷⁷ See Noel T. Mueller et al., *The Infant Microbiome Development: Mom Matters*, 21 NAT'L LIBR. MED. 109, 115 (2015).

²⁷⁸ *Id.* at 109.

²⁷⁹ See Guaraldi & Salvatori, *supra* note 28, at 3.

²⁸⁰ *Id.* at 3-4.

²⁸¹ *Id.* at 5.

²⁸² See *The Microbiome*, *supra* note 276 ("Probiotic supplement sales exceed \$35 billion in 2015, with a projected increase to \$65 billion by 2024.").

²⁸³ See *Food, Nutrition & Fitness I*, *supra* note 112, at 4; See also Monteiro, *supra* note 110, at 22:58.

²⁸⁴ Monteiro, *supra* note 110, at 23:53.

disproportionately higher prevalence in low-income women of color,²⁸⁵ may lead to continued poor communities as a result of reduced health outcomes that originated from lack of consumed breastmilk during infancy.

X. Recommendations

This article recommends, in alignment with the National Strategy: (1) instructing federal agencies to work together to reduce confusion around existing laws that impact infant feeding; and (2) increasing educational outreach efforts to Americans around breastfeeding benefits, including obesity reduction and disease reduction in mothers and infants.²⁸⁶ Americans should be educated regarding the benefits of breastmilk including: (1) its more appropriate protein content;²⁸⁷ (2) naturally-present nutrients in breastmilk that are added to infant formulas to mimic breastmilk;²⁸⁸ (3) its ability to help babies to develop microbiota, which protect from infections;²⁸⁹ and (4) a reduced risk of obesity risk and diet-related disease.²⁹⁰ Increased educational outreach efforts are also consistent with the goals of the National Strategy to support overall efforts of encouraging breastfeeding.²⁹¹

XI. Conclusion

Conflicting laws in the U.S. lead to confusion and significantly impact infant feeding. Marketing infant formula in the hospital post-birth impacts infant feeding by incentivizing new mothers, at a time when they are vulnerable and impressionable, to formula-feed. This impacts a new mother's ability to breastfeed,

²⁸⁵ See Breslow, *supra* note 152; see also Padilla, *supra* note 152.

²⁸⁶ See Neves, et al., *supra* note 22 at 910-16; see also *Breastfeeding Benefits Both Baby and Mom*, *supra* note 221.

²⁸⁷ See Oddy, *supra* note 274, at 9-10 ("The adverse long-term effects of early growth acceleration emerge as fundamental in later overweight and obesity. The higher protein content of artificial baby milk compared to the lower protein content in breastmilk is responsible for the increased growth rate and adiposity during the influential period of infancy of formula-fed infants.").

²⁸⁸ See INFANT FORMULA: EVALUATING THE SAFETY OF NEW INGREDIENTS, *supra* note 4, at 44-45.

²⁸⁹ See Guaraldi & Salvatori, *supra* note 28, at 1-2.

²⁹⁰ See Neves, et al., *supra* note 22, at 916.

²⁹¹ See NATIONAL STRATEGY ON HUNGER, NUTRITION, AND HEALTH, *supra* note 74, at 26.

which leads to increased purchases of infant formula over the lower-cost option of breastfeeding.

While U.S. laws support breastfeeding, these laws often seem to contradict one another and can affect how a woman decides to feed her infant. Mothers, especially low-income working mothers of color, end up being pressured into buying formula to formula-feed their infants. Moreover, workplace factors that do not contribute to breastfeeding or even pumping further exacerbate this pressure. Formula-feeding interferes with breastfeeding. Nutrition science demonstrates that feeding methods, such as formula-feeding, are not optimal, and can affect the health of both the infant and mother.

Making infant formula available to mothers, in particular working mothers, as an alternative to breastfeeding could cause unintentional impacts leading to inequality based on race and gender. The infant formula shortage led to higher prices and disproportionately impacted low-income women of color. This presents a problem when formula is food that an infant needs to survive if a mother is unable to breastfeed for whatever reason, including inflexible work hours. Because the use of infant formula affects a mother's breastmilk supply, a new mother can lose confidence in her ability to breastfeed, or feel that she has an inadequate supply of breastmilk to sustain her baby. This could therein cause her to formula-feed her baby, which also affects her breastmilk supply and ability to breastfeed.

Women, in particular low-income women of color, often must choose between work and children. The lack of paid maternity leave, inflexibility from an employer that does not allow pumping in the workplace, and a lack of breastfeeding support, all contribute to women that choose to formula-feed. This shows a troubling lack of power that women have over their own bodies and choices.

Enacted laws to support breastfeeding often seem to be contradictory. Because infant feeding choices have consequences that do not equally impact women and men (based on gender), and women (based on race), it is important to continue studying the impacts of laws on infant feeding that lead to inequality, and continue finding equity solutions to address these disparities. Paid maternity leave is one way to encourage more breastfeeding, a solution consistent with the National Strategy. Other options in support of

breastfeeding should also be researched and explored to help reach overall health and nutrition goals in the National Strategy for Americans.