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Should Human Milk Be Regulated?

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Should Human Milk Be Regulated?

Mathilde Cohen*

Markets in human milk are booming. They take two main forms: informal markets—women giving or selling their milk peer-to-peer—, and formal markets—for-profit or non-profit organizations collecting, processing, and distributing donor milk to neonatal intensive care units and a few outpatients for a fee. The legal regime applicable to these human milk transactions is fragmented and unstable. The federal government does not define human milk as anything. The Food and Drug Administration has declined to regulate milk banks even though it oversees blood, cord, oocytes, semen, and stool banks. Only a handful of states have laws on the books pertaining to human milk.

In light of the growing demand for human milk and public health professionals' calls for government oversight due to fears of pathogen contamination, this Article asks whether human milk should be regulated more tightly and, if so, what types of legal reforms would be most desirable. It concludes that human milk should not be treated as a disembodied product under a food, drug, and tissue law paradigm, but rather as the product of a relationship between breastfeeders and breastfed babies. It is this relationship that is in urgent need of legal protections so that more parents can breastfeed their children and make extra milk available for others. Though the risks of contamination are real, they can be, and are, mitigated by milk banks, as well as by peer-to-peer donors and recipients. But many children who need donor milk do not obtain it either because it is unavailable or too expensive. Legal reforms should therefore focus on increasing the supply via robust breastfeeding and donor milk support, which in turn will make human

* Professor of Law, University of Connecticut. For helpful conversations and comments on earlier drafts, I am grateful to Naomi Bar-Yam, Bridget Crawford, Amy DiBona, Jennifer Carter-Johnson, Amy Cohen, Michael Dorf, Elizabeth Emens, Andrea Freeman, Iselin Gambert, Megan Grant, Peter Barton Hutt, Kimberly Krawiec, Brendan Maher, Ralf Michaels, Sean Pager, Sachin Pandya, Julie Smith, Julie Suk, and Hannah Ryan as well as participants in the First Annual Conference on Food Law and Policy at Harvard Law School, the Cornell Law School Faculty Workshop, the Michigan State University College of Law Faculty Workshop, and the Duke University School of Law Faculty Workshop. For research assistance, I thank Emilie Dajer-Pascal and Ciarra Minacci-Morey. For library assistance, I thank the University of Connecticut law library staff, in particular Tanya Johnson, Adam Mackie, and Anne Rajotte. My thanks also go to the editorial board of the *UC Irvine Law Review* for the care they brought to the editorial process.

milk accessible to all those who need it regardless of their socioeconomic status. This approach entails shifting from a single-minded focus on health and safety to considering the conditions of people who produce and donate milk and the health insurance market that often fails to cover it.

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INTRODUCTION

Imagine that you need to buy formula to feed your baby. Easy. It's available in any supermarket, drug store, or convenience store. It can be ordered with a few taps on your keyboard and delivered right to your doorstep in a few hours. Several

varieties are offered. You can choose between cow's milk-based formula, by far the most common, or plant-based formula, typically made with soy. You can also find lactose-free, organic, or goat's milk-based formulas. Formula is convenient, easily transportable, does not need to be refrigerated, and is relatively cheap—the average price per ounce is about \$0.11.¹ Formula is even provided for free or at a discount by the government to low-income families who qualify for it.² You are also assured some level of quality—formula is closely regulated by the Food and Drug Administration (FDA) and must meet federal nutrient requirements.³

Now imagine that you need to buy human milk for your baby. Why would you ever be in that situation? Suppose that your baby was born prematurely or has a medical condition calling for human milk and you cannot produce milk, or enough of it, be it because you are a man; because you are an adoptive or intended parent; because a medical condition prevents you from lactating; because the drugs you need to take could be harmful to a baby; or because social circumstances, such as your job, make it impossible for you to breastfeed. How will you obtain human milk? If your baby is hospitalized in a neonatal intensive care unit (NICU) that uses donor human milk, it will be provided by the hospital.⁴ But if your baby is at home or at a hospital that does not use donor human milk, you will need to procure it yourself. You will certainly not find it at your local Walmart or CVS, or on ordinary baby supplies websites. You could, however, purchase or obtain free milk directly from donors who advertise online via sites such as “Human Milk 4 Human Babies,” “Eats on Feets,” or “Only The Breast.”⁵ But if you are looking for medically-sanctioned milk from screened donors, your only option is to approach one of the couple dozen human milk banks and companies that exist in the United States.⁶

Formula is available over the counter, but a doctor's prescription is required to procure human milk from a bank.⁷ Another complication lies in locating a bank near you that has human milk available. The twenty-three non-profit milk banks currently operating in the United States prioritize hospitalized infants and critically ill babies,⁸ leaving parents of babies requiring milk for other indications, such as formula intolerance, with no alternatives other than for-profit milk companies and

1. Breastfeeding Center of Ann Arbor, *Cost of Formula Feeding*, BFCAA.COM, <https://bfcaa.com/resources/cost-of-formula-feeding/> [https://perma.cc/E2P3-UR9P] (last visited Feb. 3, 2019).

2. See Elizabeth Jensen & Miriam Labbok, *Unintended Consequences of the WIC Formula Rebate Program on Infant Feeding Outcomes: Will the New Food Packages Be Enough?*, 6 BREASTFEEDING MED. 145 (2011) (discussing the Special Supplemental Nutrition Program for Woman, Infants, and Children (WIC), the largest purchaser of infant formula in the country).

3. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 et seq. (2010).

4. See *infra* Section III.B.

5. See *infra* Section II.C.

6. See *infra* Section II.B.

7. See Nancy E. Wight, *Donor Human Milk for Preterm Infants*, 21 J. PERINATOLOGY 249, 251 (2001).

8. See Kimberly Martino & Diane Spatz, *Informal Milk Sharing: What Nurses Need to Know*, 39 AM. J. MATERNAL/CHILD NURSING 369, 370 (2014).

peer-to-peer markets. A growing number of commercial human milk companies, such as Ambrosia, the International Milk Bank, Medolac, Ni-Q, and Prolacta Bioscience, has opened its doors in recent years.⁹ These companies sell their human milk products to NICUs, and, some of them, to private customers willing to pay a hefty price tag. It is challenging to quote an exact price range for their products given that pricing is rarely disclosed on their websites. According to a 2015 trade article, Prolacta’s “standardized milk starts at \$10 an ounce.”¹⁰ Medolac currently lists its shelf-stable milk at \$5.75 an ounce on its website.¹¹ Milk obtained from non-profit banks is expensive too at an average processing fee of \$4.50 per ounce—approximately forty times more than formula.¹² Babies between one and six months consume on average thirty ounces per day,¹³ which could cost families about \$135 per day for non-profit milk and \$172–\$300 for commercial milk. Private health insurance rarely reimburses the costs of donor human milk for outpatients and coverage is typically authorized only on a case-by-case basis.¹⁴ Families relying on public insurance in one of the few states that permit Medicaid to cover human milk are in luck—but milk is seldom covered unless one’s baby is hospitalized.¹⁵

In sum, access to human milk—humans’ primary food, which in theory should be plentiful—is often fraught with difficulties.¹⁶ In the past couple of decades, several public health authorities have taken a stance in favor of encouraging the use of donor human milk.¹⁷ Despite these pronouncements, many infants fail to receive

9. See Anna Petherick, *The Breast Milk Products of the Future*, SPLASH! MILK SCIENCE UPDATE (Jul. 2015), <http://milkgenomics.org/article/the-breast-milk-products-of-the-future/> [<https://perma.cc/S3Z6-N52Y>] (describing the rise of commercial human milk companies and their products). Note that Ambrosia has closed in 2017. See *infra* notes 220–30 and accompanying text.

10. Marni Usheroff, *Babies Nurse Milk Firm’s Growth*, 37 L.A. BUS. J. 1, 59 (2015).

11. *The True Cost of Donor Milk*, MEDOLAC, <https://medolac.com/collection/#cost> [<https://perma.cc/TKD4-TM8T>] (last visited Feb. 3, 2019).

12. See Linda C. Fentiman, *Marketing Mothers’ Milk: The Commodification of Breastfeeding and the New Markets for Breast Milk and Infant Formula*, 10 NEV. L.J. 29, 67 (2009).

13. See *id.*

14. See Kimberly Horton Updegrave, *Donor Human Milk Banking: Growth, Challenges, and the Role of HMBANA*, 8 BREASTFEEDING MED. 435, 436 (2013).

15. See *infra* Section IV.D.1 & 2 (discussing donor milk insurance coverage).

16. See generally Mathilde Cohen, *Regulating Milk. Women and Cows in France and the United States*, 65 Am. J. Comp. L. 469 (2017) (identifying the paradox of our culture’s attitude toward milk: while animal milk, in particular in the form of cow’s milk and formula, is ubiquitous, human milk, the only type of milk produced for humans is hard to come by).

17. See, e.g., OFFICE OF THE SURGEON GEN., CTRS. FOR DISEASE CONTROL AND PREVENTION, & OFFICE ON WOMEN’S HEALTH, THE SURGEON GENERAL’S CALL TO ACTION TO SUPPORT BREASTFEEDING, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICE 49 (2011); see also American Academy of Pediatrics, *Breastfeeding and the Use of Human Milk*, 129 PEDIATRICS e827 (2012) (discussing a policy statement recommending that all preterm infants to receive their mother’s milk, or pasteurized donor milk if their mother’s milk is unavailable or contraindicated. It also recommended the use of donor milk as an alternative to breastfeeding or expressed mother’s milk for healthy term infants); NAT’L WIC ASS’N, THE USE OF BANKED DONOR MILK IN WIC (2014) (“As the premier public health nutrition program, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) should authorize donor human milk to ensure medically fragile infants who

human milk, whether because it is unavailable, too costly, or because families are wary of turning to unscreened milk obtained peer-to-peer.¹⁸ Much of the public health and legal scholarship about human milk in the past years has concentrated on health and safety issues.¹⁹

Some commentators deplore the lack of federal oversight over milk banks, haphazard state regulation, and the expanding peer-to-peer milk markets, which have captivated public health officials and the general public by raising the specter of contaminated milk administered to fragile infants.²⁰ The proposed solutions found in the existing literature have generally consisted of calling for greater federal intervention in the form of food, drug, and tissue law.²¹ The underlying argument is that since the Food and Drug Administration already regulates infant nutrition products such as formula and fortifiers, as well as bodily fluids or “biologics” such as blood, cord, oocytes, semen, and stool, it would only be natural for it to regulate human milk.

Informed by feminist theory and a commitment to social justice, this Article takes a different direction. It builds upon, on the one hand, the work of scholars such as Donna Dickenson,²² Kimberly Krawiec,²³ and Catherine Waldby,²⁴ who have uncovered the gender implications of the commercialization of the human body, and, on the other hand, those who have written on human milk

continue to need it after discharge from the hospital are not denied access to safe, effective, optimal nutrition.”).

18. See generally Cohen, *supra* note 13, at 31.

19. See Martino & Spatz, *supra* note 8; David Stephanie Dawson, *Legal Commentary on the Internet Sale of Human Milk*, 126 PUB. HEALTH REP. 165 (2011); Karleen D. Gribble & Bernice L. Hausman, *Milk Sharing and Formula Feeding: Infant Feeding Risks in Comparative Perspective?* 5 AUSTRALASIAN MED. J. 275 (2012); Roxanne Nelson, *Breast Milk Sharing Is Making a Comeback, but Should It?*, 112 AM. J. NURSING 19 (2012); Nancy Brent, *The Risks and Benefits of Human Donor Breast Milk*, 42 PEDIATRIC ANN. 84 (2013); Frances Jones, *Milk Sharing: How It Undermines Breastfeeding*, 21 BREASTFEEDING REV. 21 (2013); Sarah Steele et al., *Risks of the Unregulated Market in Human Breast Milk. Urgent Need for Regulation*, 350 BRITISH MED. J. h1485 (2015); Sarah Steele et al., *More Than A Lucrative Liquid: The Risks for Adult Consumers of Human Breast Milk Bought from The Online Market*, 108 J. ROYAL SOC'Y MED. 208 (2015); Jenine Kenna, *Got Milk? A Call for Federal Regulation and Support of Human Donor Milk*, 36 WOMEN'S RTS. L. REP. 435 (2015); Eisenhauer, *A Call for FDA Regulation of Human Milk Sharing*, 32 J. HUM. LACTATION 389 (2016); Crystal Oparaake, *White Milk, Black Market: A Call for the Regulation of Human Breast Milk over the Internet*, 60 HOW. L.J. 561, 592 (2017).

20. See sources cited *supra* note 19.

21. See, e.g., Kenna, *supra* note 19, at 462–67.

22. See DONNA DICKENSON, *BODY SHOPPING: CONVERTING BODY PARTS TO PROFIT* 163–68 (2009). Though I do not share the author's anti-commodification premises, I am persuaded by her thesis that current biotechnological practices, especially the collection of human cells and tissues on a mass scale, have resulted in the feminization of the human body.

23. See, e.g., Kimberly D. Krawiec, *A Woman's Worth*, 88 N.C. L. REV. 102 (2010) (pointing out that the commodification of “taboo trades” involving female embodied goods such as sex, eggs, and wombs is incomplete in a way that disadvantages women by constraining their agency, earning status, and status).

24. See, e.g., MELINDA COOPER & CATHERINE WALDBY, *CLINICAL LABOUR: TISSUE DONORS AND RESEARCH SUBJECTS IN THE GLOBAL BIOECONOMY* (2014) (offering a gendered analysis of the bioeconomy).

markets specifically—Linda Fentiman, Narin Hassan, Kara Swanson, Pamela Laufer-Ukeles, Arianne Renan Barzilay, and Sarah Waldeck.²⁵ Identifying and valorizing unrecognized and often uncompensated (or undercompensated) feminized forms of labor, in particular lactation, has been a central task of these two groups of scholars.

There is no denying that human milk raises legal questions about food, drug, and tissue. But unlike other foods and drugs, human milk is produced by persons whose interests should be taken into account and protected.²⁶ Cisgender women comprise the majority of those who lactate, but bio-males and people identifying as male or as any gender falling outside of the gender binary may lactate and breastfeed too.²⁷ Human milk's human origin justifies moving away from a model in which it is considered a disembodied product that could be regulated in isolation from its producers.²⁸ Milk is a relational substance secreted by women in response to the stimuli of a baby in a way that is responsive to the cultural and social values of the society. There can be no human milk without lactation, and for people to lactate, they typically need to breastfeed their own children. To obtain ample donor milk, we must ensure that women can breastfeed successfully and create surplus milk available for donation. Donor milk should be made affordable to all children who need it, through subsidization or health insurance reform. Ensuring surplus requires changing work, public health, and insurance laws. Work laws can affect women's ability to work outside the home while breastfeeding and expressing milk. Public health laws can support lactation through a diversity of milk collection and

25. Sarah E. Waldeck, *Encouraging a Market in Human Milk*, 11 COLUM. J. GENDER & L. 361, 369 (2002); Fentiman, *supra* note 12; *see also* Narin Hassan, *Milk Markets: Technology, the Lactating Body and New Forms of Consumption*, 30 WOMEN'S STUD. Q. 209 (2010); KARA W. SWANSON, *BANKING ON THE BODY. THE MARKET IN BLOOD, MILK, AND SPERM IN MODERN AMERICA* (2014); Pamela Laufer-Ukeles & Arianne Renan Barzilay, *The Health/Care Divide: Breastfeeding in the New Millennium*, 35 COLUM. J. GENDER & L. 264 (2018). As I argue below, however, I would not classify milk expression and human milk markets as separation strategies as Pamela Laufer-Ukeles and Arianne Renan Barzilay have proposed. Some amount of milk expression is necessary for most breastfeeders to maintain a full milk supply and for some to feed their babies given that not all babies can suckle at the breast and not all women can nurse directly from the breast. Human milk markets have the potential to create and maintain new forms of communication between donors and recipients and as such, they may be connection-enhancing rather than undermining. *See infra* Section III.D.2.

26. Non-human animals are used as food or to produce food. Their interests too should be taken into consideration, as I have argued elsewhere in the context of animal milk production and regulation. *See generally* Cohen, *supra* note 16.

27. I strive to use a gender-neutral vocabulary to talk about people who lactate, but also use the terms "breastfeeding" and "women," which should not be taken to exclude those who do not identify as female, but rather as emphasizing the gender subordination of lactating persons in our cultural and legal environment. *See* Mathilde Cohen, *The Lactating Man*, in *MAKING MILK. THE PAST, PRESENT AND FUTURE OF OUR PRIMARY FOOD* 141 (Mathilde Cohen & Yoriko Otomo eds., 2017) (pointing out that cisgender women are not the only people who lactate and breastfeed).

28. Vegan feminists would argue that animal milk raises the same issues as human milk, and I agree with them, but for the purpose of this Article, I focus on human milk. *See generally* Greta Gaard, *Toward a Feminist Postcolonial Milk Studies*, 65 AM. Q. 595, 595 (2013) (critiquing the appropriation of women's and animals' milk from a postcolonial perspective).

distribution systems, including informal milk sharing. Insurance laws can make human milk more affordable by covering it as a standard of care for infants for whom it is medically indicated.

This Article's unique contribution is to frame the legal debate surrounding donor human milk in terms of production and access, rather than health and safety, in a way that values breastfeeding as a relationship as well as a means of procuring donor human milk. Rather than pitching policies that support breastfeeding against policies that support a strong market in human milk, the crux of the argument is that both are needed. In fact, the former is necessary to achieve the latter. The argument combines up-to-date legal analysis with a multi-disciplinary approach to human milk. In setting up the normative proposal, the piece not only provides a comprehensive description of existing human milk regulation at the federal and state levels, but also a reflection on the social and cultural identity of human milk that builds upon anthropology, biology, and history. This Article is premised on a relational theory of milk.²⁹ Human milk should not be pigeonholed into a single legal category such as food, drug, or tissue, but should also be approached as a relationship between a breastfeeder and a breastfed infant.

The discussion proceeds in five parts. Part I briefly describes the benefits of donor human milk and its categories of consumers. Part II turns to the current legal status of human milk under federal and state law. Part III delineates the four main ways in which human milk has been categorized historically, analyzes how these classifications still inform our thinking and practices, and argues in favor of a relational approach. Part IV evaluates the often-competing values at stake in human milk regulation: supply, cost, and safety. Finally, Part V develops a set of principles to guide legal reforms, focusing on work, public health, and insurance law.

I. WHO NEEDS HUMAN MILK?

While presenting the full case for donor human milk would be beyond the scope of this Article, this Part surveys the categories of human milk consumers, condensing the literature on donor milk's benefits. It does not enter into the "breast versus bottle" debate, which splits those in favor of breastfeeding babies and those in favor of bottle-feeding them formula.³⁰ It also does not cast breastfeeding and donor milk as opposed or conflicting. As I point out below,³¹ there is a close connection between breastfeeding and donor milk, if not only because the

29. See Mathilde Cohen & Yoriko Otomo, *Introduction to MAKING MILK: THE PAST, PRESENT AND FUTURE OF OUR PRIMARY FOOD 1* (Mathilde Cohen & Yoriko Otomo eds., 2017) (claiming that milk is a relational substance that it is produced by as well as for others).

30. See generally AMY KOERBER, *BREAST OR BOTTLE? CONTEMPORARY CONTROVERSIES IN INFANT-FEEDING POLICY AND PRACTICE* (2013) (critically examining the scientific and medical underpinning of the debate).

31. See *infra* Part IV.

availability of donor milk is dependent on the practice of breastfeeding. Milk must be produced by people who breastfeed.³²

The need for donor human milk for babies arises when their parents either cannot lactate themselves or cannot lactate sufficiently to meet their babies' needs. This can happen for social, medical, psychological, or economic reasons. Some parents cannot breastfeed because they are men,³³ adoptive or intended parents,³⁴ or because they have died or abandoned their child.³⁵ Moreover, medical issues can prevent successful breastfeeding. For example, certain babies are too sick or unable to suckle,³⁶ and parents may suffer from conditions impeding breastfeeding, such as having had a premature labor,³⁷ a C-section,³⁸ a mastectomy,³⁹ or a breast reduction surgery,⁴⁰ taking contraindicated drugs,⁴¹ having inverted nipples or other nipple malformations,⁴² having an infectious disease transmissible through milk,⁴³ experiencing breast pain or mastitis,⁴⁴ or having insufficient milk.⁴⁵ Still other parents cannot breastfeed because of trauma or lack of social or emotional support.⁴⁶ Finally, certain parents are precluded from breastfeeding because they need to work to support their families and many forms of employment are

32. Though in some instances, people have been known to trigger lactation without wanting or needing to breastfeed a baby. See generally RUTH A. LAWRENCE & ROBERT M. LAWRENCE, *BREASTFEEDING: A GUIDE FOR THE MEDICAL PROFESSION*, ch. 9 (2016) (detailing the methods and challenges of induced lactation).

33. See Cohen, *supra* note 26 (discussing the infant feeding practices of some gay and transmen).

34. Note that some adoptive or intended parents have been able to induce their lactation to breastfeed their babies. See Lawrence & Lawrence, *supra* note 31; see also Sarah L. Wittig & Diane L. Spatz, *Induced Lactation: Gaining a Better Understanding*, 33 AM. J. MATERNAL/CHILD NURSING 76 (2008).

35. See A DeMarchis et al., *Establishing an Integrated Human Milk Banking Approach to Strengthen Newborn Care*, 37 J. PERINATOLOGY 469, 469 (2017).

36. *Id.*

37. See generally GWEN GOTSCH, *BREASTFEEDING YOUR PREMATURE BABY* (1999) (describing the difficulties of breastfeeding after a premature labor).

38. See generally Heather J. Rowe-Murray & Jane R.W. Fisher, *Baby Friendly Hospital Practices: Cesarean Section is a Persistent Barrier to Early Initiation of Breastfeeding*, 29 BIRTH: ISSUES IN PERINATAL CARE 124 (2002) (considering the impact of C section on breastfeeding).

39. Hatem A. Azim Jr. et al., *Breastfeeding in Breast Cancer Survivors: Pattern, Behaviour and Effect on Breast Cancer Outcome*, 19 BREAST 527, 530 (2010).

40. See Lisa H. Amir & Verity H. Livingstone, *Management of Common Lactation and Breastfeeding Problems*, in *MANAGEMENT OF BREAST DISEASES* 81, 83 (Ismael Jatoi & Achim Rody eds., 2016).

41. See Myla E. Moretti et al., *Which Drugs Are Contraindicated During Breastfeeding? Practice Guidelines*, 46 CAN. FAM. PHYSICIAN 1753 (2000) (discussing the drugs that are incompatible with breastfeeding because of their negative effect on the baby).

42. See Amir & Livingstone, *supra* note 39, at 84.

43. See, e.g., Robert M. Lawrence & Ruth A. Lawrence, *Given the Benefits of Breastfeeding, what Contraindications Exist?*, 48 PEDIATRIC CLINICS NORTH AM. 235, 236–38 (2001) (considering various contraindications to breastfeeding, in particular HIV).

44. See Amir & Livingstone, *supra* note 39, at 89.

45. See *id.* at 89–90.

46. See Lawrence & Lawrence, *supra* note 31, at 209–12.

incompatible with successful and long-term breastfeeding.⁴⁷ The primary infant populations requiring donor human milk are severely sick infants and premature and low-weight babies whose odds of healthy survival have been shown to increase with additional human milk feeding instead of formula.⁴⁸ As pediatrics professor Mark Underwood notes, donor human milk exhibits

an impressive array of benefits . . . to this highly vulnerable population, including decreased rates of late-onset sepsis, necrotizing enterocolitis (NEC), and retinopathy of prematurity, fewer re-hospitalizations in the first year of life, and improved neurodevelopmental outcomes. In addition, premature infants that receive human milk have lower rates of metabolic syndrome, lower blood pressure and low-density lipoprotein levels, and less insulin and leptin resistance when they reach adolescence, compared to premature infants receiving formula.⁴⁹

Other infant recipients include full-term babies who experience failure to thrive on formula—that is, a state of undernutrition due to inadequate caloric intake or absorption—or intolerance to formula,⁵⁰ and otherwise healthy babies whose families believe that they are better off consuming human milk than formula.⁵¹ While the science on the benefits of donor milk is overwhelming as applied to premature, low-weight, sick, and formula-intolerant babies, it is less definite for this last group: studies comparing otherwise healthy babies who were breastfed to babies who were not question its impact on long-term health and behavior outcomes.⁵²

Though this Article primarily focuses on infant consumers of human milk, it occasionally references adult consumers. For these consumers, the resort to donor milk is more self-explanatory in that they presumably neither produce milk themselves nor have access to it through a lactating partner⁵³ and must therefore obtain it from someone else. Adult human milk consumers include sick adults, such as cancer patients, who believe that human milk can hasten recovery and minimize

47. See *infra* Part IV.

48. See American Academy of Pediatrics, *supra* note 17 (recommending that all preterm infants receive human milk, with pasteurized donor milk rather than premature infant formula the preferred alternative if a mother is unable to provide an adequate volume).

49. Mark A. Underwood, *Human Milk for the Premature Infant*, 60 PEDIATRIC CLINIC NORTH AM. 189, 192 (2013).

50. See LOIS ARNOLD, HUMAN MILK IN THE NICU: POLICY INTO PRACTICE 329–31 (2010) (discussing cases of failure to thrive on formula and intolerance to formula).

51. See Cohen, *supra* note 16, at 35–36 (discussing some of the reasons motivating these families).

52. See, e.g., Cynthia G. Colen & David M. Ramey, *Is Breast Truly Best? Estimating the Effects of Breastfeeding on Long-Term Child Health and Wellbeing in the United States Using Sibling Comparisons*, 109 SOC. SCI. & MED. 55 (2014) (suggesting that much of the beneficial long-term effects typically attributed to breastfeeding may primarily be due to selection pressures into infant feeding practices along key demographic characteristics such as race and socioeconomic status).

53. See FIONA GILES, FRESH MILK: THE SECRET LIFE OF BREASTS 97, 134 (2010) (examining breastfeeding behaviors that sit outside mainstream practices such as adult nursing and women consuming their own milk.).

side effects from drugs;⁵⁴ athletes using human milk as a performance enhancer⁵⁵ or as a recovery and muscle-building aid;⁵⁶ people who find erotic pleasure in handling or consuming human milk;⁵⁷ and “recreational” users, such as artists who integrate human milk in their creations⁵⁸ or cooks who prepare comestibles like ice cream with human milk.⁵⁹

Be it for infants or adults, donor human milk is sought for one or several of the following benefits: nutritional, immunological, hormonal, long-term health effects, and symbolic or affective properties. Human milk is a complex, changing fluid, for which more than 200 components have been identified.⁶⁰ This complexity and variability explains why some of the benefits overlap, but for expository purposes, I will address them separately.

1—Nutritional Properties. Though its composition changes from person to person and as time goes by,⁶¹ human milk is often touted as having the perfect combination of proteins, fats, vitamins, minerals, and carbohydrates for infants.⁶² As noted by UNICEF, “formula, at its best, only replaces most of the nutritional components of breast milk: it is just a food, whereas breast milk is a complex living nutritional fluid containing anti-bodies, enzymes, long chain fatty acids and hormones, many of which simply cannot be included in formula.”⁶³

54. See, e.g., Michelle Major & Lee Ferran, *Fighting Cancer With Daughter's Breast Milk?*, ABC NEWS (May 27, 2009), <http://abcnews.go.com/GMA/OnCall/story?id=7682702> [<https://perma.cc/8HH6-PLUG>] (reporting the case of a man with colon cancer using his daughter's milk).

55. See Chantalle Forgues, Jason Mazanov, & Julie Smith, *The Paradox of Human Milk Doping for Anti-Doping*, 5 PERFORMANCE ENHANCEMENT & HEALTH 158 (2017) (discussing the consumption of human milk by athletes to enhance performance).

56. See Michael Easter, *Bodybuilders Are Drinking Human Breast Milk. Are They Insane, or Super Insane?*, Men's Health (Feb. 19, 2015), <https://www.menshealth.com/fitness/human-breast-milk-and-bodybuilding> [<https://perma.cc/HGL5-6SBE>] (presenting the case for and against using human milk as a fitness drink).

57. See Giles, *supra* note 52, at 121–32 (discussing the erotic potential of breastfeeding and human milk).

58. See, e.g., Miriam Simun, *Recipe II: Human Cheese*, in THE MULTISPECIES SALON 135 (Eben Kirksey ed., 2014) (describing how she made human cheese at a traveling art exhibit).

59. See, e.g., Bill Chappell, *Breast Milk Ice Cream. A Hit at London Store*, NPR (Feb. 25, 2011), <http://www.npr.org/sections/thetwo-way/2011/02/25/134056923/breast-milk-ice-cream-a-hit-at-london-store> [<https://perma.cc/68EX-6PU5>] (reporting on a London-based restaurateur who briefly sold a human milk-based flavor at his store before being summoned to cease and desist by the local health department).

60. See Lawrence & Lawrence, *supra* note 31, at 98.

61. *Id.*

62. See, e.g., Rachele Lessen & Katherine Kavanagh, *Position of the Academy of Nutrition and Dietetics: Promoting and Supporting Breastfeeding*, 115 J. ACADEMY NUTRITION & DIETETICS 444 (2015) (“[E]xclusive breastfeeding provides optimal nutrition and health protection for the first 6 months of life, and that breastfeeding with complementary foods from 6 months until at least 12 months of age is the ideal feeding pattern for infants.”).

63. *Breastfeeding*, UNICEF, https://www.unicef.org/nutrition/index_24824.html [<https://perma.cc/B5SQ-TTKD>] (last updated Jul. 29, 2015).

2—Immunological Properties. Human milk safeguards infants, and perhaps adults, against infections.⁶⁴ Human milk is rich in immune factors that “protect the infant from infections and assist in the development of the infant’s intestinal mucosa, gut microflora and own defences.”⁶⁵ Infants who are breastfed or fed donor human milk are at a lower risk than formula-fed babies of contracting gastrointestinal, respiratory, necrotizing enterocolitis, and other infections.⁶⁶

3—Hormonal Properties. The hormonal composition of human milk seems to have a range of effects on baby recipients, which we are barely beginning to understand, from hormones enabling the infant to know when to eat, sleep, or wake, to those acting as natural painkillers or encouraging the development of various body organs.⁶⁷ Moreover, unlike formulas that are based on cow or soy milk, and therefore contain hormones adapted to calves or plants, the hormonal composition of donor milk is specifically adapted to humans.⁶⁸

4—Long-Term Health Effects. Infant feeding is an important part of long-term health outcomes. Human milk is increasingly thought to prevent the “expression of immune-mediated diseases (asthma, inflammatory bowel disease, type 1 diabetes) later in life through a balanced initial immune response”⁶⁹ as well as childhood cancers.⁷⁰ Human milk consumption by infants has also been linked to lower rates of obesity.⁷¹ There are still large gaps in our knowledge of the mechanisms underlying this protective effect, but some researchers point to growth factors, cytokines, and hormones present in human milk, which are involved in food intake regulation and energy balance.⁷²

5—Symbolic or Affective Properties. For consumers, particularly adults, part of the appeal lies in milk’s symbolic or affective properties. When someone seeks donor milk for erotic pleasure, artistic uses, or culinary provocation, milk’s

64. Foteini Hassiotou, *Maternal and Infant Infections Stimulate A Rapid Leukocyte Response in Breastmilk*, 2 CLINICAL & TRANSLATIONAL IMMUNOLOGY e3 (2013) (examining some of the immunological benefits of human milk).

65. *Id.* at 1.

66. *Id.*

67. See, e.g., Katie Hinde, *Lactational Programming of Infant Behavioral Phenotype*, in BUILDING BABIES. PRIMATE DEVELOPMENT IN PROXIMATE AND ULTIMATE PERSPECTIVE 187, 194–96 (Kathryn B.H. Clancy et al. eds., 2013) (describing some of the connections thought to exist between hormones in female primates’ milk and infant behavior).

68. Francesco Savino & Stefania A. Liguori, *Update on Breast Milk Hormones: Leptin, Ghrelin and Adiponectin*, 27 CLINICAL NUTRITION 42 (2008) (reviewing studies on hormones present in human milk and summarizing their function).

69. W. Allan Walker & Rajashri Shuba Iyengar, *Breast Milk, Microbiota, and Intestinal Immune Homeostasis*, 77 PEDIATRIC RESEARCH 220, 220 (2015).

70. See Margaret K. Davis, *Review of the Evidence for an Association Between Infant Feeding and Childhood Cancer*, 11 INT’L J. CANCER SUPPLEMENT 29, 29 (1998) (“[H]uman milk may make the breast-fed infant better able to negotiate future carcinogenic insults by modulating the interaction between infectious agents and the developing infant immune system or by directly affecting the long-term development of the infant immune system.”).

71. See generally Francesco Savino, *Breast Milk Hormones and Their Protective Effect on Obesity*, 2009 INT’L J. PEDIATRIC ENDOCRINOLOGY 1 (reviewing the data on hormones in human milk).

72. *Id.* at 1.

nutritional, anti-infectious, hormonal, and long-term health benefits are not at stake, or at least not primarily.⁷³ Rather, users are attracted by human milk's ambivalent place in our culture as a fluid simultaneously revered as a perfect food and symbol of maternal devotion, and reviled as a vile and dangerous bodily fluid.⁷⁴ Parents of infant recipients may also be motivated by human milk's symbolic and affective qualities, as Susan Falls has shown in her ethnography of milk sharing.⁷⁵ Some families may resort to donor human milk out of the desire to connect with like-minded people on parenting matters.⁷⁶ Others may see it as a form of resistance against the formula industry and what it represents to them—a male-dominated trade relying on large-scale, inhumane dairy farming, which has an enormous environmental footprint.⁷⁷

In sum, there is a wide range of reasons why people seek donor human milk, from saving a baby's life to simply having fun or making a political statement. Note that lactation is also beneficial for those who lactate, from short-term benefits such as easier recovery from childbirth thanks to the release of the hormone oxytocin and an improved metabolism⁷⁸ to long-term benefits such as decreased risk of various cancers and detoxification.⁷⁹ Part II turns to the ways in which American law regulates human milk.

II. THE LEGAL STATUS OF HUMAN MILK

A. No National Definition

While the cow's milk that most American children and adults drink daily, and the formula that infants consume are hyper-regulated food products,⁸⁰ human milk tends to be either legally undefined, or defined as something other than food.⁸¹

73. See, e.g., Simun, *supra* note 58. The artist, Miriam Simun, was primarily motivated by animal-human comparisons in her human milk cheese project.

74. See Cohen, *supra* note 16 (describing our culture's ambivalent relationship with human milk).

75. SUSAN FALLS, *WHITE GOLD. STORIES OF BREAST MILK SHARING* (2017).

76. *Id.*

77. See, e.g., Tehila Sasson, *Milking the Third World? Humanitarianism, Capitalism, and the Moral Economy of the Nestlé Boycott*, 121 AM. HIST. REV. 1196 (2016) (tracing the history of one of the most famous anti-formula industry movements, Nestlé boycott in the 1970s).

78. See Ruth Feldman et al., *Maternal and Paternal Plasma, Salivary, and Urinary Oxytocin and Parent-Infant Synchrony: Considering Stress and Affiliation Components of Human Bonding*, 14 DEVELOPMENTAL SCI. 752 (2011).

79. See Fiona Giles, *The Well-Tempered Breast: Fostering Fluidity in Breastly Meaning and Function*, 34 WOMEN'S STUD. 301, 310–11 (2005) (pointing out that lactation is the most efficient way for women to rid their bodies of accumulated toxins).

80. See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 *et seq.* (2018), and FDA regulations implementing the Act.

81. *But see* EMILY C. TAYLOR & MIRIAM H. LABBOK, CAROLINA GLOB. BREASTFEEDING INST., *DONOR HUMAN MILK ACCESS IN THE UNITED STATES: FINDINGS AND RECOMMENDATIONS* 23, 24 (2015) (noting that banked donor milk is classified “as a nutraceutical, which means a medically indicated food,” that is “regulated and inspected as food,” and must “be recalled in a similar manner as any other commercially available food”).

Federal law defines milk as “the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows.”⁸² This definition is the so-called “standard of identity” for milk—that is, the mandatory requirements set by the FDA to determine what milk must contain to be marketed as “milk.” “Milk” is thus legally defined as *cow’s* milk. Federal law also defines infant formula, be it composed of cow’s milk or other base ingredients, as “a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.”⁸³ Formulas marketed in the United States must meet federal nutrient requirements and manufacturers must notify the FDA prior to marketing a new formula.⁸⁴ Both cow’s milk and infant formula are considered foods, therefore the laws and regulations governing foods apply to them.⁸⁵

By contrast, human milk remains undefined under federal law, or rather, defined only in the negative. The only time human milk is mentioned in the Code of Law of the United States, it is to be excluded from the definition of human tissue: “Human tissue . . . means any tissue derived from a human body . . . which . . . [e]xcludes semen or other reproductive tissue, *human milk*, and bone marrow.”⁸⁶ This negative definition tells us what human milk is *not* according to the federal government: it is not human tissue. Neither the American Association of Tissue Banks nor the FDA classifies human milk as anything.⁸⁷ The FDA does not regulate human milk.⁸⁸ The only human milk-based product the FDA oversees⁸⁹ is the 100% human milk fortifier marketed by Prolacta used to increase the nutrient content of human milk for premature infants.⁹⁰ According to Prolacta, it is classified as “exempt infant formula.”⁹¹ Exempt infant formulas are formulas created for

82. 21 C.F.R. § 133.3 (2018).

83. Federal Food, Drug, and Cosmetic Act (FFDCA) § 201(z), 21 U.S.C. § 321 (2018). FDA regulations define infants as persons not more than twelve months old. 21 C.F.R. 105.3(e) (2018).

84. See 21 C.F.R. § 106 (2018) (specifying infant formula nutrient quality control procedures); 21 C.F.R. § 107 (2018) (stating the labeling and nutrient specifications of infant formula). In 2014 the agency revised its infant formula regulations (21 C.F.R. Parts 106 and 107) to establish quality factors, current good manufacturing practices, and revised quality control procedures. See 79 Fed. Reg. 111 (June 10, 2014).

85. The FDA defines both cow’s milk and infant formula under Title 21: “Food and Drugs” and specifically the subchapter for Food for Human Consumption. See 21 C.F.R. § 133.3 (2018); 21 C.F.R. § 107.3 (2018).

86. 21 C.F.R. § 1270.3(j)(5) (2018) (emphasis added).

87. See Cohen, *supra* note 16, at 495.

88. See generally 21 C.F.R. § 107 (2018).

89. 21 C.F.R. § 107.3 (2018). See generally U.S. Food & Drug Admin., *Exempt Infant Formulas Marketed in the United States By Manufacturer and Category* (Apr. 18, 2017), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/ucm106456.htm> [<https://perma.cc/3P8A-GEAH>].

90. See Sertac Arslanoglu et al., *Adjustable Fortification of Human Milk Fed to Preterm Infants: Does It Make a Difference?*, 26 J. PERINATOLOGY 614 (2006) (describing the uses of fortification of human milk for premature babies).

91. Prolacta, *Regulatory Information*, PROLACTA BIOSCIENCE, <http://www.prolacta.com/regulatory-information> [<https://perma.cc/A5ZL-W9TZ>] (last visited Feb. 10, 2019) (“Prolacta’s

specific uses, such as low birth weight and other medical and dietary issues that may differ in their nutritional content from the formulas manufactured for healthy, term infants.⁹²

Given the lack of federal definition, states, which retain the traditional authority to regulate foods,⁹³ could have chosen to categorize human milk as a food, but no state has done so. Only seven states appear to define human milk at all.⁹⁴ Six states—California, Idaho, Indiana, Maryland, New York, and Virginia—start from a premise opposite from that of the federal government, considering human milk to be a tissue or bodily fluid.⁹⁵ The seventh state, Utah, implicitly defines human milk as a drug.⁹⁶ A few jurisdictions have enacted regulations related to milk banks, focusing mainly on health and safety issues. These states are California, the District of Columbia, Idaho, Maryland, New Jersey, New York, Ohio, and Texas.⁹⁷ Of them, four (California, Idaho, Maryland, and New York) regulate milk banks on the premise that human milk *is* a tissue and therefore require tissue-banking licenses to collect, process, use, and distribute donor milk on the model of other biobanks.⁹⁸ Some jurisdictions have enacted rules going beyond health and safety. New York, for instance, includes an educational component in its statutes, which claims to

added-mineral products are to be regulated as infant formulas. As such, Prolacta Bioscience is required to be in compliance with Federal regulations governing the production and labeling of such items as covered by statute in 21 C.F.R. 100–0169, and, in particular, parts 105–107 dealing with infant foods.”).

92. See U.S. Food & Drug Admin., *supra* at note 88.

93. 35A AM. JUR. 2D *Food* § 3 (2018) (“It is inherent in the plenary power of the state, which enables it to prohibit all things hurtful to the comfort, safety, and welfare of society, to regulate the food and drink industry. The power to regulate the manufacture and sale of food is found in and limited by the police power of the state.”).

94. These are California, Idaho, Indiana, Maryland, New York, Ohio, Utah, and Virginia.

95. See CAL. HEALTH & SAFETY CODE § 1635 (West 2018) (defining human milk as a “tissue”); IDAHO ADMIN. CODE r. 16.02.07.003 (2017) (defining human milk as a “body tissue . . . and fluid”); IND. CODE § 35-45-16-2(a) (2018) (defining human milk as “tissue” for the purpose of criminal law); MD. CODE REGS. 10.50.01.03 (2018) (defining human milk as “tissue”); N.Y. COMP. CODES R. & REGS. tit. 10, § 52-1.1 (2017) (defining human milk as a “tissue” when it is not “the mother’s own”); *Commonwealth of Virginia, Department of Taxation*, PD 15-219, 2015 WL 9459879, at *1 (Va. Dept. Tax, Dec. 8, 2015) (defining human milk as a “body fluid” for the purpose of tax law).

96. UTAH ADMIN. CODE r. 414-60-5 (2018) (“[State] Medicaid [pharmacy program] does not cover the following drugs . . . (j) Breast milk, breast milk substitutes, baby food, or medical foods, except for prescription metabolic products for congenital errors of metabolism . . .”).

97. These are California, District of Columbia, Idaho, Maryland, New York (enacted and proposed bill), Ohio, and Texas. See S. 47, 2017 Leg., 239th Sess. (N.Y. 2017); CAL. HEALTH & SAFETY CODE § 1647-78 (West 2017); D.C. CODE § 7-881 (2017); IDAHO ADMIN. CODE r. 16.02.07.008 (2017); MD. CODE REGS. 10.50.01.03 (2017); N.J. Stat. Ann § 26:2A-17-22 (West 2018); N.Y. PUB. HEALTH LAW § 2505 (McKinney 2017), N.Y. COMP. CODES R. & REGS. tit. 10, § 52-9.1 (2017); OHIO ADMIN. CODE 3701-7-14 (2017); and 25 TEX. ADMIN. CODE § 227.1 (2017) (note that Texas regulates milk banks by “adopt[ing] by reference the publication entitled ‘Guidelines for the Establishment and Operation of a Donor Human Milk Bank’, Ninth Edition, 2000, as amended, written by the Human Milk Banking Association of North America, Inc.” 25 TEX. ADMIN. CODE §227.1 (2010), 28 Tex. Reg. 3337 (Apr. 18, 2003)).

98. CAL. HEALTH & SAFETY CODE § 1635 (West 2018); IDAHO ADMIN. CODE r. 16.02.07.003 (2018); MD. CODE REGS. 10.50.01.03 (2018) (defining human milk as “tissue”); N.Y. COMP. CODES R. & REGS. tit. 10, § 52-1.1 (2017).

educate the public, healthcare providers, and families about “the availability of human breast milk for infants,”⁹⁹ and “to inform potential donors of the opportunities for proper donation.”¹⁰⁰ California stands out as the only state specifying the nature of human milk transactions—according to the California Health and Safety Code, the use of donor human milk is a “service,” not a “sale.”¹⁰¹ This anti-commodification stance could be construed as prohibiting commercial human milk manufacturers and peer-to-peer milk transactions in which money changes hands from operating in the state.

In sum, the absence of federal definition and regulation of human milk, conjoined with states’ rare and discordant interventions, leaves human milk providers and consumers on uncertain legal footing. In theory, in the majority of the states, anyone could set up shop and begin to donate or sell human milk undisturbed by the law. Against this backdrop, milk banks have adopted a self-regulatory model which is the subject of the next section.

B. *Self-Regulating Milk Banks*

Federal law governs the operations of blood banks, cord banks, plasma banks, oocyte and semen banks, organ banks, and, since 2015, stool banks, but milk banks remain outside of its purview.¹⁰² This may come as a surprise, considering that milk was the first bodily product to be banked in the United States, with collection and distribution efforts beginning as early as 1910.¹⁰³ That year, a Boston-based doctor set out to create a directory of potential milk donors to fill a pressing need at a time when wet nursing disappeared as a profession and infant formula was not yet as developed and reliable as it is today.¹⁰⁴ Present-day milk banks are organizations established to collect human milk from donors, and to process and distribute it to sick or premature babies whose parents cannot breastfeed—or not fully. For most of their history, milk banks have been non-profit, charitable institutions with goals to provide affordable donor milk to families in need. Early milk banks, often called “milk bureaus,” offered their milk on a sliding scale fee, giving a portion away for free to indigent families.¹⁰⁵

In the past decades, two new forms of human milk collection and distribution have developed. First, for-profit or commercial milk banks and companies have emerged to service hospitals and researchers, with some also selling their milk

99. N.Y. PUB. HEALTH LAW § 2505 (McKinney 2017).

100. *Id.*

101. CAL. HEALTH & SAFETY CODE § 1647 (West 2017).

102. *See* Swanson, *supra* note 26, at 21–23.

103. *Id.*

104. *Id.*

105. *See, e.g.,* Mary D. Blankenhorn, *A Breast Milk Dairy*, 11 *Hygeia* 411, 412 (1933) (noting that at the New York milk bureau, it “is sold at 30 cents an ounce except in those cases in which the presence of destitution forbids its purchase. Last year, 360 quarts [about 10% of the bureau’s stock] were given away, and about as much was sold at a greatly reduced price to those able to pay only a few cents an ounce for the precious fluid.”).

products directly to the public.¹⁰⁶ Prolacta was the pioneer, opening in California in 1999,¹⁰⁷ soon followed by Ambrosia (now closed),¹⁰⁸ the International Milk Bank, Ni-Q, and Medolac. Second, peer-to-peer milk sharing has emerged as a growing practice.¹⁰⁹ The expression “milk sharing” refers to the practice in which a donor gives or sells milk directly to another individual. In what follows, I present the ways in which each of these three markets—non-profit banks, for-profit banks, and milk sharing—operate.

1. *Non-Profit Banks*

Milk banking has long been a self-regulating activity. The first national standards for the operation for milk “bureaus” were laid out by the Committee on Mothers’ Milk of the American Academy of Pediatrics in 1943.¹¹⁰ Among other things, these standards stipulated that milk bureaus should comprise a medical advisory committee made up of pediatricians, comply with local health department regulations, and employ both professional and non-professional staff.¹¹¹ In 1985, the Human Milk Banking Association of North America (HMBANA) was created to develop new guidelines and coordinate the various non-profit organizations involved in milk banking.¹¹² The new association adopted “Guidelines for the Establishment and Operation of a Donor Human Milk Bank,” which are updated annually and represent a “mandatory minimum” standard for all HMBANA banks.¹¹³ These guidelines have become the gold standard in the profession. Tellingly, some jurisdictions incorporated the HMBANA standards by reference when they resolved to regulate milk banking.¹¹⁴ HMBANA membership requires sites to “conduct annual self-assessments using a specific tool created by HMBANA,” and a peer-reviewed evaluation is conducted periodically by members from an alternate HMBANA bank.¹¹⁵ The HMBANA Executive Board reviews

106. For instance, individuals can purchase donor milk from Medolac via the Mother’s Milk Coop. See *Donor Milk*, MOTHER’S MILK COOP, http://www.mothersmilk.coop/order_donor_milk (noting that “recipients of donor milk [must] provide a doctor’s note; prescription is not required.”).

107. See Fentiman, *supra* note 12, at 67.

108. See *infra* notes 220–221 and accompanying text.

109. See Aunchalee E.L. Palmquist & Kirsten K. Doehler, *Contextualizing Online Human Milk Sharing: Structural Factors and Lactation Disparity Among Middle Income Women in the U.S.*, 122 SOC. SCI. & MED. 140 (2014) (empirical study of human milk sharing).

110. See American Academy of Pediatrics, *Recommended Standards for the Operation of Mothers’ Milk Bureaus*, 23 J. Pediatrics 112 (1943).

111. *Id.*

112. HUMAN MILK BANKING ASS’N OF N. AM., GUIDELINES FOR THE ESTABLISHMENT AND OPERATION OF DONOR HUMAN MILK BANKS (2018).

113. *Id.*

114. CAL. HEALTH & SAFETY CODE § 1648 (West 2017); OHIO ADMIN. CODE 3701-7-01 (2017); D.C. Mun. Regs. tit. 29, § 10003 (2017); 25 TEX. ADMIN. CODE § 227.1 (2017). According to HMBANA, Maryland and New York also “formally recognized” their Guidelines. See HUMAN MILK BANKING ASS’N OF N. AM., *supra* note 111 at 3.

115. See Elizabeth A. Brownell et al., *Donor Human Milk Bank Data Collection in North America*, 30 J. Hum. Lactation 47, 48 (2014).

these annual assessments.¹¹⁶ Noncompliance may result in suspension from HMBANA if deficiencies are not corrected in a timely manner.¹¹⁷

HMBANA's standards rely on multiple levels of screening similar to the standards promulgated by AABB (formerly known as the American Association of Blood Banks), the professional association for institutions engaged in the collection and transfusion of blood and blood products.¹¹⁸ First, potential milk donors are verbally screened for physical status, social behavior, and prior medical history. Disqualifications include behaviors that may cause milk contamination, such as smoking; using certain medications, drugs, alcohol, or herbs; having received a blood transfusion or an organ or tissue transplant in the last twelve months; engaging in at-risk sexual behavior; or having lived abroad.¹¹⁹ The prospective donor must also fill out a medical questionnaire expounding on the verbal screening.¹²⁰ Second, banks contact the donor's OB-GYN and her baby's pediatrician to obtain a release form.¹²¹ Third, banks order a blood test panel similar to that used by other tissue banks for serology, including tests for HIV, HTLV, Hepatitis B, Hepatitis C, and Syphilis.¹²²

In addition to these three steps, milk banks incorporate collection and testing protocols. Donors are instructed on how to express, handle, and store their milk to avoid bacterial contamination.¹²³ The first few batches of milk supplied by a new donor are sent separately for bacteriologic screening and a donor may be dismissed if her milk fails the test repeatedly.¹²⁴ Once a donor is vetted, her milk is pooled with other donors' milk and pasteurized using the Holder pasteurization method (62.5 degrees Celsius for thirty minutes).¹²⁵ A sample from each batch is sent for microbiological testing before it can be bottled and distributed.¹²⁶ Finally, HMBANA has a tracking and recall system in place: every bottle of milk can be traced back to specific donors who contributed to any given batch.¹²⁷

Throughout the years, HMBANA and member banks have been in conversation with the FDA as well as with other federal agencies, such as the Center

116. *Id.*

117. *Id.*

118. *See* Taylor & Lobbok, *supra* note 80, at 28.

119. To reduce the risk of transmission of Creutzfeldt-Jakob Disease, women who lived in Europe for more than five years or visited the UK, France, or Saudi Arabia for more than three months are excluded from donating.

120. Human Milk Banking Ass'n of N. Am., *supra* note 111.

121. *Id.*

122. *Id.*

123. *Id.*

124. *Id.*

125. *See* Jean-Charles Picaud & Rachel Buffin, *Human Milk—Treatment and Quality of Banked Human Milk*, 44 CLINICS IN PERINATOLOGY 95, 100 (2017) (noting that Holder pasteurization is recommended by the Human Milk Banking Association of North America and is the standard method used worldwide by milk banks).

126. HUMAN MILK BANKING ASS'N OF N. AM. GUIDELINES FOR THE ESTABLISHMENT AND OPERATION OF DONOR HUMAN MILK BANKS (10th ed. 2018).

127. *Id.*

for Disease Control (CDC) and, more rarely, the U.S. Department of Agriculture (USDA). Mary Rose Tully, a founding member and former chair of HMBANA, asserted in 2000 that the “FDA staff have regularly given input into the development and updating of the *Guidelines* since 1987.”¹²⁸ The FDA website recommends the use of human donor milk obtained through a milk bank and offers a link to HMBANA’s website.¹²⁹ It even points out that milk obtained this way should be safe because of the voluntary guidelines imposed by HMBANA and, in certain states, because of the state’s own safety standards.¹³⁰ However, the FDA also asserts that it “has not been involved in establishing these voluntary guidelines or state standards.”¹³¹ Thus far, the FDA has never reversed its position that it will not directly regulate milk banks. In 2010, its Pediatric Advisory Committee convened to discuss available information about the practices, benefits, and risks associated with milk donation and banking.¹³² During this meeting, the FDA representatives made it clear that the agency had no plans to “enhance its role” in the regulation of milk banking.¹³³ To the contrary, the agency concluded that increasing federal oversight and requiring a more controlled collection process than what was already in place would run the risk of decreasing milk donations.¹³⁴ In light of the development of for-profit human milk companies however, the agency may still decide to step in.

2. For-Profit Banks and Companies

For-profit human milk manufacturers are not members of HMBANA and do not share among themselves a set of common guidelines or a trade organization.¹³⁵ Because they market a greater variety of products than non-profit banks, their regulatory environment is also more complex. Non-profit banks have so far focused exclusively on dispensing minimally-processed, bottled human milk.¹³⁶ This is partly

128. Mary Rose Tully, Human Milk Banking Association of North America, *A Proposal for Collaboration Between the FDA and the Human Milk Banking Association of North America to Assure Quality and Safety of Donor Human Milk*, HUMAN MILK BANKING ASS’N OF N. AM. (Apr. 14, 2000), <http://www.fda.gov/ohrms/dockets/dockets/00n0001/ts00019.pdf> [<https://web.archive.org/web/20170706003524/http://www.fda.gov/ohrms/dockets/dockets/00n0001/ts00019.pdf>].

129. U.S. FOOD AND DRUG ADMIN., *Use of Donor Human Milk*, <http://www.fda.gov/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/ucm235203.htm> [<https://perma.cc/BS7R-J7W2>] (last updated Mar. 22, 2018).

130. *Id.*

131. *Id.*

132. U.S. FOOD AND DRUG ADMIN., MEETING OF THE PEDIATRIC ADVISORY COMMITTEE (2010), <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/UCM251799.pdf> [<https://wayback.archive-it.org/7993/20170404142953/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/UCM251799.pdf>].

133. *Id.* at 15.

134. *Id.* at 304 (Doctor Brahm Goldstein, one of the pediatricians heard at the meeting, noted, “additional regulation may not be a great idea if it’s going to inhibit use”).

135. Human Milk Banking Ass’n of N. Am., *supra* note 112.

136. Human Milk Banking Ass’n of N. Am., *supra* note 112.

a choice and partly a necessity due to their limited financial resources and ability to conduct expensive research and development. Meanwhile, for-profit banks have raised millions to develop new products such as human milk-based fortifiers, enriched human milk, human milk-based formula, and shelf-stable human milk.¹³⁷ As mentioned above,¹³⁸ fortifiers, be they based on cow milk or human milk, are considered “exempt formula” by the FDA, which means that their manufacturers must follow specific federal regulations.¹³⁹ A company such as Prolacta, which produces a standardized human milk formulation and is the first and only to market a 100% human milk-based fortifier, uses this regulatory complexity to its advantage, priding itself on following multiple layers of regulation and creating a safer product than non-profit banks.¹⁴⁰ Prolacta thus claims that it follows not only food regulations such as federal Food Good Manufacturing Practices,¹⁴¹ but also the FDA’s Pasteurized Milk Ordinance used by the dairy industry,¹⁴² infant formula regulations, and state tissue banking regulations.¹⁴³

In terms of donor screening, milk testing, and processing, for-profit companies maintain that they go further than HMBANA banks in quality assurance, but their exact methodologies are not released to the public, unlike HMBANA’s, thus making “it difficult to investigate the efficacy and provide external validation of nutritional composition for the resulting products.”¹⁴⁴ Prolacta is illustrative of for-profit companies in this respect. The initial screening process its prospective donors go through—an online health and lifestyle interview, after which they must supply confirmation of their and their baby’s health status from a licensed physician—is similar to that of HMBANA’s.¹⁴⁵ One of Prolacta’s distinctive features, however, is the use of DNA testing to ensure that the milk supplies match

137. See, e.g., Dana Bartholomew, *Prolacta Bioscience Raises \$9 Million*, L.A. BUS. J. (May 15, 2018), <http://labusinessjournal.com/news/2018/may/15/prolacta-bioscience-raises-9-million/> [<https://perma.cc/XB5C-3NYT>] (reporting that Prolacta raised nearly \$9 million during a recent funding round); see also Petherick, *supra* note 9 (discussing some of these new products).

138. See *supra* notes 89–92 and accompanying text.

139. See *supra* notes 91–92 and accompanying text.

140. See generally PROLACTA BIOSCIENCE, STATE-OF-THE-ART TESTING, SCREENING, AND STANDARDIZED PRODUCTION PROCESS (2017), <https://www.prolacta.com/Data/Sites/14/media/PDF/mkt-0173-prolacta-process-flow.pdf> [<https://perma.cc/XS6V-9JC3>].

141. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human, 21 C.F.R. § 110 (2011) (describing the methods, equipment, facilities, and controls for producing processed food).

142. *Fact Sheet: Donor Milk Safety: Prolacta’s Screening, Testing & Manufacturing Process*, PROLACTA BIOSCIENCE, <https://www.prolacta.com/Data/Sites/14/media/PDF/mcc-140041-donor-milk-safety-and-screening-processes-fact-sheet.pdf> [<https://perma.cc/PBM3-NDRR>] (last visited Jan. 15, 2019) [hereinafter *Donor Milk Safety Fact Sheet*].

143. See *Regulatory Information*, PROLACTA BIOSCIENCE, <http://www.prolacta.com/regulatory-information> [<https://perma.cc/8U4W-APV3>] (last visited Feb. 10, 2019).

144. Hope Katherine Lima, *Optimizing Medical Nutrition for Exclusively Human Milk Fed Infants 10* (2018) (Ph.D dissertation, North Carolina State University), <https://repository.lib.ncsu.edu/handle/1840.20/35162> [<https://perma.cc/8T8C-LFH5>].

145. See U.S. FOOD AND DRUG ADMIN. *supra* note 131, at 157–64; *Donor Milk Safety Fact Sheet*, *supra* note 142 (describing Prolacta’s screening and processing protocols).

the donor's genetic identity.¹⁴⁶ The company sends donors a cheek swab to create a personal DNA ID and phlebotomists to collect blood samples directly from donors' homes.¹⁴⁷ It also provides donors materials to ship milk, including gel bricks and bar codes.¹⁴⁸ Prolacta tests all the milk it collects for *Bacillus cereus*, a bacterium that survives pasteurization and can be harmful to babies,¹⁴⁹ prior to pooling and processing.¹⁵⁰ By contrast, HMBANA banks endorse a post pooling and processing approach. They send a sample of each already-pooled, pasteurized tray to a lab for bacterial cultures and discard the entire batch if *Bacillus cereus* growth is detected. Prolacta conducts a nutritional analysis of its final product for micronutrients and minerals, generating specific nutrient labels,¹⁵¹ which neonatologists are fond of as it makes formulation within the hospital setting easier and more consistent.¹⁵² HMBANA does not require its member banks to include nutritional analysis, be it for internal information or for labeling the milk bottles.¹⁵³

Medolac—another commercial human milk company created in 2014 by Elena Medo, Prolacta's original founder—also positions itself as offering a superior product to HMBANA's from a quality assurance perspective. The primary Medolac “difference,” according to the company, is that it markets “precision nutrition for preterm babies,” achieving “the highest level of safety with commercial sterilization” (instead of using standard Holder pasteurization).¹⁵⁴ Non-profit

146. *Donor Milk Safety Fact Sheet*, *supra* note 142 (describing Prolacta's screening and processing protocols); *see also* Taylor and Labbok, *supra* note 80, at 73 (noting that Prolacta also tests for illegal drugs, nicotine, caffeine, dilution, and adulteration).

147. *Donor Milk Safety Fact Sheet*, *supra* note 142 (describing Prolacta's screening and processing protocols).

148. *Id.* at 159. Some HMBANA banks furnish boxes and prepaid shipping labels to donors to send in their milk but most require women to travel to milk depots to drop it off. *See, e.g., Frequently Asked Questions*, NY MILK BANK, <https://www.nymilkbank.org/faq> [<https://perma.cc/7EH9-SH4T>] (last visited Feb. 10, 2019) (“The milk is packed tightly into a cooler, insulated with bubble wrap and shipped overnight through Federal Express using a prepaid shipping label provided by the processing center.”).

149. *See* Elizabeth B. Froh, Jill Vanderpool, & Diane L. Spatz, *Best Practices to Limit Contamination of Donor Milk in a Milk Bank*, 47 J. OBSTETRIC GYNECOLOGIC & NEONATAL NURS. 547, 547–48 (2018) (discussing the dangers of banked milk's contamination of the *Bacillus* genus and noting that the bacteria can survive the pasteurization process).

150. *See* PROLACTA, STATE-OF-THE-ART TESTING, SCREENING, AND STANDARDIZED PRODUCTION PROCESS (2017), <https://www.prolacta.com/Data/Sites/14/media/PDF/mkt-0173-prolacta-process-flow.pdf> [<https://perma.cc/4ZZY-6SZ3>].

151. Human milk-based fortifiers are regulated as exempt infant formula, which means that labels must include directions for preparation and use, expiration date, vitamin range, macronutrient, and mineral content. *See* Food and Drug Administration, *See* U.S. FOOD AND DRUG ADMIN., *supra* note 132, at 165 (statement by Scott Eaker, Vice President of Quality and Regulatory Affairs at Prolacta) (“Our Neo20 is labeled in compliance with the Nutrition Labeling Act because it is, being human milk, a food.”) (statement by Scott Eaker, vice president of Quality and regulatory affairs at Prolacta).

152. *See* Taylor & Labbok, *supra* note 80, at 40 (noting that “providers have said they will not prescribe ‘term’ human milk or human milk with unknown calorie counts”).

153. HUMAN MILK BANKING ASS'N OF N. AM., GUIDELINES FOR THE ESTABLISHMENT AND OPERATION OF A DONOR HUMAN MILK BANK 38 (2018).

154. *Our Products: A Powerful Difference*, MEDOLAC, <https://medolac.com/collection/> [<https://perma.cc/8DTJ-Y9BB>] (last visited Feb. 10, 2019).

banked milk, which is typically delivered frozen or thawed, must be used within twenty-four hours once defrosted.¹⁵⁵ It varies in terms of nutritional and other contents as HMBANA banks only pool milk from a few donors, which makes it harder to regiment. Medolac's product, in contrast, relies on high-temperature pasteurization rendering the milk sterile.¹⁵⁶ It can be stored at room temperature and has a shelf life of up to two years.¹⁵⁷ It is a standardized product providing identical nutrition from batch to batch. Like Prolacta, Medolac emphasizes its approach to *Bacillus cereus*, suggesting that it tests raw milk for the bacteria and that its sterilization process destroys it.¹⁵⁸ There is still no peer-reviewed literature on the health outcomes of premature infants who are fed sterile human milk processed according to Medolac's specifications.¹⁵⁹ However, a 2018 study cautions against the widespread adoption of sterilization after finding that sterilized milk had significantly less immune protective proteins and human milk oligosaccharides.¹⁶⁰

After having surveyed the regulatory landscape of non-profit and for-profit milk banks, the next section turns to peer-to-peer markets.

C. Unregulated Peer-to-Peer Milk Markets

Human milk is exchanged peer-to-peer, outside of the hospital and milk banking contexts. Donors and recipients use online and offline networks to facilitate the circulation of milk either gratuitously or against payment.¹⁶¹ According to social scientists Aunchalee Palmquist and Kirsten Doehler, who conducted field work on these markets, far from being marginal, "milk sharing appears to be commonplace in the U.S., notably among middle-income, college educated women who self-identify as Caucasian/white."¹⁶² In 2015, Sarah Keim and her colleagues estimated

155. Human Milk Banking Ass'n of N. Am., *supra* note 112.

156. *Donor Milk Safety Fact Sheet*, *supra* note 142.

157. See PROLACTA, HOSPITAL DONOR HUMAN MILK PROGRAM (2016), <https://www.prolacta.com/Data/Sites/14/media/PDF/mkt-0300-hospital-donor-milk-program.pdf> [<https://perma.cc/SJU8-9LCS>].

158. *Id.*

159. See Hope K. Lima et al., *Bacteria and Bioactivity in Holder Pasteurized and Shelf-Stable Human Milk Products*, 2017 CURRENT DEVELOPMENTS IN NUTRITION 1, 6.

160. See Laura Meredith-Dennis et al., *Composition and Variation of Macronutrients, Immune Proteins, and Human Milk Oligosaccharides in Human Milk From Nonprofit and Commercial Milk Banks*, 34 J. HUM. LACTATION 120 (2018).

161. For example, see the milk sharing websites EATS ON FEETS, www.eatsonfeets.com [<http://web.archive.org/web/20190109051601/http://www.eatsonfeets.org/>] (last visited Jan. 9, 2019); ONLY THE BREAST, <http://www.onlythebreast.com> [<https://web.archive.org/web/20190110205532/https://www.onlythebreast.com/>] (last visited Jan. 10, 2019); MILK SHARE, <http://milkshare.birthingforlife.com> [<https://web.archive.org/web/20180611081415/http://milkshare.birthingforlife.com/>] (last visited June 11, 2018); see also HUMAN MILK 4 HUMAN BABIES, www.hm4hb.com [<https://perma.cc/5EQX-D9DK>] (last visited Feb. 10, 2019) (Facebook group).

162. Aunchalee E.L. Palmquist & Kirsten K. Doehler, *Human Milk Sharing Practices in the U.S.*, 12 MATERNAL CHILD & NUTRITION 278, 279 (2016). Note that in reality lower income parents and/or parents of color may be practicing milk sharing in larger numbers than those reported in the literature. Several factors could explain this discrepancy. White and middle-class researchers may seek

that there were “13 000 postings or advertisements annually on popular US Web sites” offering human milk for sale or donation.¹⁶³ Why do certain families turn to informal markets rather than procuring milk from banks?

First, the demand for banked milk exceeds what non-profit banks are currently able to provide.¹⁶⁴ There is a mismatch between how banks see donor human milk—a medical food reserved to a narrow group of infants—and how some consumers see it—the ideal nutrition for all babies who cannot be fully breastfed by their parents, and for some adults. HMBANA banks prioritize hospitalized, premature, and critically ill infants, leaving parents of otherwise healthy, full-term infants who do not meet their eligibility criteria with the choice between formula, informal markets, or commercial human milk, when they can obtain and afford it.¹⁶⁵ Examples of families who may be in this situation include those with babies who do not have any severe condition, but whose parents cannot breastfeed them, or not fully, such as adopted babies; babies born through surrogacy; babies whose mothers are cancer survivors, suffer from other medical conditions interfering with breastfeeding, or experience supply issues; and babies who fail to thrive on formula. In addition, adults seeking human milk for their own consumption must resort to milk sharing as milk banks will only serve them in rare circumstances.¹⁶⁶

Second, costs may motivate people to turn to informal markets. Non-profit banks charge an average processing fee of \$4.50 per ounce.¹⁶⁷ Commercial milk companies command even higher prices.¹⁶⁸ Because insurance plans rarely cover human milk for non-hospitalized babies and only for a short period of time, most families cannot afford the \$68–\$135 daily expense required to feed a baby during its first year on non-profit banked milk or the much higher expense for commercial milk. Peer-to-peer markets offer free or lower-cost milk. The average price of milk

and gain access more readily to study participants in their own communities. Also, as noted to me by Jennifer Peregoy in a personal communication, lower income communities and communities of color may practice milk sharing differently, relying more on personal network sharing as opposed to online exchanges. Besides, they may be more reluctant to discuss it given the history of government—and other third parties’—intrusion in their reproductive and child rearing choices, as brilliantly articulated by Khiara Bridges’ scholarship. *See, e.g.*, KHIARA BRIDGES, *THE POVERTY OF PRIVACY RIGHT* (2017) (arguing that poor mothers have been disenfranchised of their rights to privacy).

163. Sarah A. Keim, *Cow’s Milk Contamination of Human Milk Purchased via the Internet*, 135 *PEDIATRICS* 1, 2 (2015).

164. *See* Updegrove, *supra* note 14, at 435.

165. *See* HUMAN MILK BANKING ASS’N OF N. AM., *GUIDELINES FOR THE ESTABLISHMENT AND OPERATION OF A DONOR HUMAN MILK BANK* 72–73 (2018) (spelling out suggested priorities for dispensing donor human milk).

166. *See* Major & Ferran, *supra* note 53 (mentioning that as of 2009 only six milk banks provided milk to adults); *see also* Maria Teresa Asquith et al., *Clinical Uses, Collection, and Banking of Human Milk*, 14 *CLINICS PERINATOLOGY* 173, 177 (1987) (“Milk has been refused for such frivolous requests as to make human yogurt by health food enthusiasts, for consumption by body builders, and for the mere convenience of mothers of well babies.”).

167. *See supra* note 9 and accompanying text.

168. *See supra* note 9 and accompanying text.

purchased peer-to-peer ranges between \$1.50–\$2.50 per ounce, nearly half that of non-profit banked milk.¹⁶⁹

Third, some consumers believe in the superiority of unprocessed, raw human milk over the processed, pasteurized milk dispensed by banks.¹⁷⁰ The effects of pooling milk from different donors, freeze-thaw cycles, container changes, and pasteurization on the nutritional, bacteriostatic, and immunological properties of human milk are the subject of continuing debates.¹⁷¹ Certain researchers argue that processing degrades some of the nutritional and immunological properties of milk. One study found that container transfers are particularly problematic as milk fat sticks to the side and does not get transferred into the final product.¹⁷² Pasteurization inactivates viruses present in human milk and reduces microbial contamination, but it also destroys certain bioactive components of milk, in particular, cytokine and lactoferrin,¹⁷³ which are known for protecting against a host of morbidities.¹⁷⁴ Alternative processing methods that eliminate pathogens but preserve immune factors are under investigation, such as high-temperature short-time pasteurization, irradiation, and high-pressure processing.¹⁷⁵ Based on a risk-benefit calculus, some parents of full-term babies, who are less fragile than premature infants, as well as some adult consumers may prefer to acquire raw milk.

Fourth, there may be cultural or religious impediments to using milk banks. In some Muslim communities, human milk creates kinship between infants receiving milk from the same woman leading to marriage prohibitions.¹⁷⁶ While there has long been a wet nursing tradition in majority-Muslim countries, milk kinship contributes to the rarity of milk banking.¹⁷⁷ Banked milk is typically pooled from multiple anonymous donors, making it practically impossible to abide by the matrimonial

169. See Cohen, *supra* note 16, at 503.

170. See Cohen, *supra* note 16, at 535.

171. See Chiara Peila et al., *The Effect of Holder Pasteurization on Nutrients and Biologically-Active Components in Donor Human Milk: A Review*, 8 NUTRIENTS 377, 378 (2016) (finding that the existing literature indicates that pasteurization degrades several milk components despite variability in test protocols).

172. See Nadia Raquel Garcia-Lara et al., *Effect of Holder Pasteurization and Frozen Storage on Macronutrients and Energy Content of Breast Milk*, 57 J. PEDIATRIC GASTROENTEROLOGY NUTRITION 377 (2013).

173. See A.A. Reeves et al., *TGF-beta2, A Protective Intestinal Cytokine, Is Abundant in Maternal Human Milk and Human-Derived Fortifiers but Not in Donor Human Milk*, 8 BREASTFEEDING MED. 496 (2013) (concluding that pasteurization decreases concentrations of most cytokines and lactoferrin in donor milk).

174. See J.B. Ewaschuk et al., *Effect of Pasteurization on Immune Components of Milk: Implications for Feeding Preterm Infants*, 36 APPLIED PHYSIOLOGY NUTRITION & METABOLISM 175 (2011).

175. See generally Picaud & Buffin, *supra* note 124 (reviewing the various experimental technologies being developed to sanitize milk all the while retaining its properties).

176. See Mohammed Ghaly, *Milk Banks Through the Lens of Muslim Scholars: One Text in Two Contexts*, 26 BIOETHICS 117, 119–20 (2010).

177. See Afif EL-Khuffash & Sharon Unger, *The Concept of Milk Kinship in Islam. Issues Raised When Offering Preterm Infants of Muslim Families Donor Human Milk*, 28 J. HUM. LACTATION 125 (2012).

prohibition.¹⁷⁸ By contrast, peer-to-peer markets, much like wet nursing, allow families to connect directly and even meet in person, avoiding the risk of violating the taboo.

Because federal and state laws are silent on the issue of milk sharing, it can be construed as lawful in the United States.¹⁷⁹ That being said, the practice has been the object of a chorus of condemnation by the public health community,¹⁸⁰ popular media,¹⁸¹ and regulators.¹⁸² Prominent among those voices, the FDA has recommended against milk sharing due to the risk of contamination by viruses, bacteria, or drugs.¹⁸³ In 2015, HMBANA issued a joint statement with the European Milk Bank Association warning of the “health risks to infants receiving” informally shared milk which claimed that peer-to-peer milk markets “reduce[] the supply available for milk banks to dispense to very low birth weight and preterm infants.”¹⁸⁴ A 2017 policy statement from the American Academy of Pediatrics advises against Internet-based or informal human milk sharing systems “considering . . . the risks

178. See Noraida Ramli et al., *Human Milk Banks—The Benefits and Issues in an Islamic Setting*, 15 EASTERN J. MED. 163, 165–66 (2010). *But see* Aliaa Khalil et al., *Milk Kinship Is Not an Obstacle to Using Donor Human Milk to Feed Preterm Infants in Muslim Countries*, 105 ACTA PAEDIATRICA 462, 465 (2016) (“The Hanafi School states that marriage prohibitions are not established if the milk is collected from several women whose exact number and identities are not known and whose milk has been pooled together.”).

179. It is illegal in other countries such as France. See Cohen, *supra* note 16, at 6.

180. See, e.g., S.R. Geraghty et al., *Got Milk? Sharing Human Milk Via the Internet*, 126 PUB. HEALTH REPORTS 161, 163 (2011); Steele et al., *supra* note 19; Eisenhauer, *supra* note 19. La Leche League (LLL) was initially negative but has relaxed its views. See La Leche League, *La Leche League International Offers Guidelines on Human Milk Sharing*, LA LECHE LEAGUE (Apr. 20, 2015), <http://www.llli.org/release/milksharing.html> [<https://web.archive.org/web/20180108010818/http://www.llli.org/release/milksharing.html>] (describing the new policy of the organization according to which Leche League Leaders’ “role” includes providing “information and support” on “formal, commercial or informal (peer-to-peer) forms of milk sharing” but should never use their “position as an LLL Leader to set up any type of milk-sharing network.”).

181. See Shannon K. Carter et al., *Liquid Gold or Russian Roulette? Risk and Human Milk Sharing in the US News Media*, 17 HEALTH RISK & SOC. 30 (2015) (discussing the popular media reporting on milk sharing).

182. A few states have attempted to ban informal milk sharing, most recently Michigan. See H.B. 4691, 2015 Leg., Reg. Sess. (Mich. 2015) (proposed legislation stating that “a person shall not, for valuable consideration, knowingly sell human breast milk over the internet.”). A New Jersey bill, introduced on January 17, 2013, sought to establish a “public awareness campaign to advise pregnant women, new parents, and women who are breast feeding their children about the dangers of casual milk sharing.” A.B. 3702, 215th Leg. § 2 (N.J. 2013). In 2010 a Tennessee bill that would have made it a misdemeanor to sell human milk informally, failed to make it past committee review. H.B. 3704, 106th Leg., Gen. Assemb. (Tenn. 2010).

183. FOOD AND DRUG ADMIN., USE OF DONOR HUMAN MILK, <https://www.fda.gov/scienceresearch/specialtopics/pediatrictherapeuticsresearch/ucm235203.htm> [<https://perma.cc/AF8A-J4EQ>] (last updated Mar. 22, 2018).

184. Joint EMBA and HMBANA statement on milk sharing has been released, EUROPEAN MILK BANK ASS’N (Jan. 2015), <https://europeanmilkbanking.com/joint-emba-and-hmbana-statement-on-milk-sharing-has-been-released/> [<https://perma.cc/MD5Z-9KJ5>].

of bacterial or viral contamination of nonpasteurized human milk and . . . the possibilities of exposure to medications, drugs, or herbs in human milk.”¹⁸⁵

Critics of informal markets often cite two studies purporting to show that milk obtained online is frequently contaminated with bacteria and pathogens by indicating that about 10% of the samples obtained were adulterated with cow’s milk.¹⁸⁶ Defenders of milk sharing point out that the studies relied on samples purchased on the internet and shipped by mail, failing to reflect the majority of informal milk transactions, which are non-commercial and involve face-to-face or telephone interactions.¹⁸⁷ Of particular relevance, the researchers who conducted the studies terminated the transaction “if sellers inquired about a recipient infant or insisted on telephone or in-person communication.”¹⁸⁸ This strategy may have resulted in excluding sellers who care about the well-being of their infant clients and hope to create a relationship with the recipient family. In other words, the research design could have been biased towards selecting those donors least likely to be motivated by the desire to help an infant in need—people selling their milk rather than offering it for free and lacking interest in establishing a personal rapport with recipients. Finally, proponents of milk sharing emphasize that detractors typically fail to note that the common alternative to human milk—bovine or plant-based infant formula—is not itself risk-free.¹⁸⁹

Whether or not peer-to-peer milk sharing is ultimately seen as a safe practice, some measure of self-regulation is undeniably taking place among participants.¹⁹⁰ A study conducted in 2013–2014 concluded that

the risks associated with the anonymous sale of human milk, including microbial contamination and tampering with bovine milk, may not be broadly applicable to commerce-free milk sharing practices in which social relationships are familiar, localized, and donors and recipients make decisions to give or receive milk using lay screening practices.¹⁹¹

The same study suggested that even if remunerative milk transactions are less safe, the risks can be mitigated—all of the eighteen recipients surveyed who

185. American Academy of Pediatrics, *Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States*, 139 PEDIATRICS 1, 1 (2017).

186. Sarah A. Keim et al., *Microbial Contamination of Human Milk Purchased Via the Internet*, 132 PEDIATRICS e1227 (2013); Keim, *supra* note 163.

187. Alison M. Stuebe et al., *Differences Between Online Milk Sales and Peer-to-Peer Milk Sharing*, PEDIATRICS (Jan. 3, 2014) (E-letter reply to Sarah A. Keim et al., *Microbial Contamination of Human Milk Purchased via the Internet*).

188. See Keim et al., *supra* note 186, at e1228.

189. See Gribble & Hausman, *supra* note 19, at 277; see also James E. Akre et al., *Milk Sharing: From Private Practice to Public Pursuit*, 6 INT’L BREASTFEEDING J. 1 (2011); Melinda E. McNiel et al., *What Are the Risks Associated with Formula Feeding? A Re-Analysis and Review*, 37 BIRTH 50 (2010) (analyzing the risks of formula feeding).

190. See generally Karleen D. Gribble, *Perception and Management of Risk in Internet-Based Peer-to-Peer Milk-Sharing*, 184 EARLY CHILD DEV. & CARE 84 (2014) (exploring the perception and management of the risks of peer-to-peer milk sharing via a written questionnaire administered to 97 peer milk donors and 41 peer milk recipients recruited via Facebook).

191. Palmquist & Doehler, *supra* note 162, at 285.

reported buying milk had screened their donors.¹⁹² Similarly, a 2014 study conducted via a written questionnaire administered to ninety-seven peer milk donors and forty-one peer milk recipients found that “[a]ll recipient respondents employed strategies to mitigate the risks of peer-to-peer milk sharing.”¹⁹³ Milk sharing websites post guidance on how to minimize health and safety risks so as to educate donors and recipients.¹⁹⁴ Certain participants follow quality assurance protocols inspired by milk banks: they interview prospective donors about their lifestyle and medical history, ask for copies of blood test results, request new lab tests, meet with the donors and children in person to ascertain that they are breastfeeding healthy babies, and they may opt to pasteurize the milk.¹⁹⁵

* * *

A striking similarity unites the three human milk collection and distribution arrangements described in this Part: none is subject to federal regulation and very few states regulate them. However, all three systems self-regulate to some extent. The strongest form of self-regulation is found in HMBANA banks, whose guidelines have become so authoritative that they are employed as templates for state lawmaking.¹⁹⁶ Peer-to-peer markets exhibit the weakest form of self-regulation, as donors and recipients operate independently from any organization and differ greatly in their knowledge and perception of the risks. Commercial milk companies present an intermediary case. As innovative firms in competition with one another, they are uncoordinated so far, but are highly aware of the health, safety, regulatory, and compliance risks associated with their business. Before addressing the question of whether and how to regulate donor milk in these different contexts, the next Part focuses on definitional issues.

III. THE MULTIPLE IDENTITIES OF HUMAN MILK

What is human milk and how should it be defined, if at all? Relying on history, anthropology, and the scientific study of milk, this Part presents four ways in which

192. Palmquist & Doehler, *supra* note 162, at 285.

193. See Gribble, *supra* note 190.

194. For example, the website Only The Breast lists the precautions that recipient families can take to minimize risks as well as recommendations for donors on how to collect and package their milk in sanitary conditions. See *Breast Milk and Donor Screening*, ONLY THE BREAST <http://www.onlythebreast.com/buy-sell-donate-breast-milk/breast-milk-screening/> [<https://web.archive.org/web/20180730173219/http://www.onlythebreast.com/buy-sell-donate-breast-milk/breast-milk-screening/>] (last visited July 30, 2018); see also *Collecting Handling and Storing Breast Milk*, ONLY THE BREAST, <http://www.onlythebreast.com/breast-milk-tips/collecting-handling-and-storing-breast-milk/> [<https://perma.cc/APB2-E2XF>] (last visited Feb. 12, 2019). The website Human Milk 4 Human Babies addresses pasteurization and contamination questions. See *Frequently Asked Questions*, HUMAN MILK 4 HUMAN BABIES, <http://hm4hb.net/faq/> [<https://perma.cc/FY34-6JT4>] (last visited Feb. 10, 2019).

195. See ONLY THE BREAST, *supra* note 194. Note that these methods do not eliminate all risks, in particular adulteration with a fluid other than human milk such as cow’s milk, and toxic contaminants such as chemical residues from the environment, the presence of which the donor herself may be unaware of.

196. See *supra* note 113 and accompanying text.

human milk has been categorized cross-culturally, as a food, a medicine, a body fluid, and a form of relationship or communication.

A. Food

Human milk is most obviously a food. It is the paradigmatic food for humans, their primary food.¹⁹⁷ Milk is one of the few foods produced specifically to be eaten, and the only food humans produce with their own bodies.¹⁹⁸ The other foods humans consume come from predation or agriculture. Milk is distinctive as it can be described as a “complete” food blurring the food-drink dichotomy. It is a substance on which infants can entirely subsist for six months or more without ingesting any other solids or even water.¹⁹⁹ In some cultures, linguistic practice underscores this wholeness. For instance, for the Fula people from West Africa, the verb for eating, rather than for drinking, is used to describe the consumption of milk.²⁰⁰

Historically, human milk has not been confined to an infant food. At various times and places, it has been consumed by older children and adults. In seventeenth- and eighteenth-century England and America, it was commonly used as nourishment for the weak and medicine for the sick.²⁰¹ According to a report from the turn of the twentieth century, in some Szechuan cities of China, “human milk [was] sold for the diet of aged persons, great faith being placed in its nutritive qualities.”²⁰² In Myanmar, men were expected to drink a pint of milk when they reached the age of forty in the belief that the value of their mothers’ milk, consumed as infants, could be revived by ingesting additional small amounts.²⁰³

Adult human milk consumption is not only a practice of the past. In her 2003 book, Fiona Giles relays stories of adult nursing, women putting their milk in tea, or using human milk in cooking and on breakfast cereals.²⁰⁴ She provides cooking recipes calling for human milk such as sourdough bread, “Pump-kin Pie,” and ice

197. See generally MAKING MILK. THE PAST, PRESENT, AND FUTURE OF OUR PRIMARY FOOD (Mathilde Cohen & Yoriko Otomo eds., 2017) (a collection of essays analyzing the various ways in which milk, including animal, human, and plant milk, has been constructed as humans’ primary food).

198. Except if one considers other self-consumption practices such as placentophagy, autologous blood donations, or urotherapy. See generally Mathilde Cohen, *The Law of Self-Eating* (working paper) (on file with author) (describing various self-eating practices and the legal questions they raise).

199. See Christopher Duggan et al., Nutrition in Pediatrics: Basic Science, Clinical Applications 369 (Patricia Bindner ed., 4th ed. 2008).

200. See Sada Mamadou BA, *Dis-moi ce que tu manges et je te dirai qui tu es. Le lait des Peuls, Kosam Foulbé*, 39 ANTHROPOZOOLOGICA 27, 32–33 n. 33 (2004).

201. See Marylynn Salmon, *The Cultural Significance of Breastfeeding and Infant Care in Early Modern England and America*, 28 J. SOC. HIST. 247 (1994).

202. Isabella L. Bird Bishop, 2 THE YANGTZE VALLEY AND BEYOND 26 (1900).

203. See Frederick J. Simoons, *The Traditional Limits of Milking and Milk Use in Southern Asia*, 65 ANTHROPOS 547, 554 (1970).

204. See Giles, *supra* note 2, at 134, 143.

cream.²⁰⁵ In the United States, human milk is said to be ingested as a fitness drink²⁰⁶ and has occasionally popped up as the main ingredient of artisanal cheeses.²⁰⁷ In 2011,²⁰⁸ and then again in 2015,²⁰⁹ human milk ice cream was marketed in London under the flavor name “Baby Gaga.” While marginal, these practices signal a renewed interest in utilizing human milk as a food item for those well beyond the age of weaning.

Could human milk be legally categorized as food under existing legal frameworks? Under federal law, the word “food” is a very general term which applies to all that is eaten to nourish the body.²¹⁰ The FDA understands foods to consist in “articles used primarily for taste, aroma, or nutritive value.”²¹¹ This definition is broad enough to encompass human milk, especially considering that the government does not label it as something other than a food.²¹² Federal regulations surrounding blood and other tissues explicitly exclude human milk, which could suggest, *a contrario*, that if it is not a tissue, then it must be a food.²¹³ Federal law invites characterization in positive ways as well. Since the passage of the 2001 Bioterrorism Act,²¹⁴ which directs the FDA to take steps to protect the public from a threatened or actual terrorist attack on the food supply and other food-related emergencies, milk banks have registered as food facilities with the FDA.²¹⁵ As a result, they are subject to random, unscheduled visits from FDA Consumer Safety Officers, as well as from their state Department of Health Services, to ensure

205. Giles, *supra* note 2, at 250–55.

206. See, e.g., Chavie Lieber, *Meet the Men Who Drink Breast Milk*, N.Y. MAG. (May 28, 2014), <http://nymag.com/thecut/2014/05/meet-the-men-who-drink-breast-milk.html> [<https://perma.cc/VJ9V-45EM>].

207. See Robert Sietsema, *Five Reasons Why Manufacturing Human Breast Milk Cheese is Disgusting*, VILLAGE VOICE (Feb. 27, 2011), <https://www.villagevoice.com/2011/02/27/five-reasons-why-manufacturing-human-breast-milk-cheese-is-disgusting/> [<https://perma.cc/9RT3-7DYQ>].

208. See Chappell, *supra* note 59.

209. See Khushbu Sha, *Oh Great, Breast Milk Ice Cream Is Back*, EATER (Apr. 24, 2015), <https://www.eater.com/2015/4/24/8491303/breast-milk-ice-cream-london-the-lickators-royal-baby> [<https://perma.cc/6MCC-D38K>].

210. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 (f) (defining “food” as “articles used for food or drink”).

211. Federal Food, Drug and Cosmetic Act, 52 Stat. 111 (1938); 21 U.S.C. § 9210 et seq. (2012); see also *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983).

212. This seems to be the view shared by non-profit milk banks themselves. See Taylor & Labbok *supra*, note 80.

213. See, e.g., 21 C.F.R. § 1270.3(j)(5) (2009) (excluding human milk from the definition of human tissue in regulations addressing human tissue intended for transplantation). In addition, the National Organ Transplant Act of 1984, Pub. L. No. 98–507, prohibits the buying and selling of many nonrenewable body products, which can only be given, but it does not cover human milk.

214. See the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. §§ 201–202. (2002).

215. Nat’l WIC Ass’n, *supra* note 17, at 2.

that regulations for food manufacturers are followed.²¹⁶ A quick tour of a milk bank would in fact strike anyone who has ever visited a dairy farm with a feeling of *déjà vu*. Similar equipment is employed to process, store, and package human milk as cow milk: vats, flasks, pasteurizers, homogenizers, bottles, refrigerators, and freezers. Similar processes can be observed with pooling, pasteurizing, cooling, homogenizing, testing for pathogens, content analysis, bottling, packaging, labeling, refrigerating, and shipping.²¹⁷

Commercial milk companies are keen to present themselves as food manufacturers when it comes to their regulatory environment, perhaps because food regulations are more lenient than tissue or drug regulations.²¹⁸ For instance, the Nevada based International Milk Bank touts on its website, “[a]s required by law, a company operating as a food manufacturer within U.S. Food and Drug Administration (FDA) and the Department of Homeland Security guidelines must be registered as such.”²¹⁹ Utah-based company Ambrosia, which collected milk in foreign countries to sell in the United States before being stopped by public outcry,²²⁰ used to declare on its website, which no longer exists, “[b]reast milk is regulated by the Food and Drug Administration (FDA) as a food item. We adhere to all FDA guidelines, Good Manufacturing Practices, and industry best practices.”²²¹ Medolac notes that its “state of the art facility . . . [f]ollows FDA Current Food Good Manufacturing Practices.”²²² As for Prolacta, it maintains that it follows the FDA’s Pasteurized Milk Ordinance (PMO), that is, the set of minimum standards and requirements for cow’s milk production and processing in place since 1924.²²³

Despite the longstanding and seemingly natural classification of human milk as a food, it is unlike any other food product due to the ethical and safety issues it

216. See Kim Updegrave, *From the President*, 3 HMBANA MATTERS (June 2014), <http://archive.constantcontact.com/fs193/1113583621652/archive/1117766821765.html> [<https://perma.cc/D4VA-CWZE>].

217. See generally Cohen, *Regulating Milk*, *supra* note 16, at 29–31 (discussing parallels between human and cow milk processing in the United States and France).

218. Ni-Q cryptically declares that it uses “FDA-approved handling protocols” and that its product “HDM Plus™ is overseen by FDA,” without specifying under which category of regulation. *About The Company: FAQs, NI-Q | HDM PLUS*, <https://www.ni-q.com/about-us/> [<https://perma.cc/4UHT-C36P>] (last visited Feb. 10, 2019).

219. *Regulatory Information*, THE INT’L MILK BANK, <http://www.internationalmilkbank.com/regulatory-information/> [<https://perma.cc/4Y82-Z33T>] (last visited Feb. 10, 2019).

220. See AFP in Phnom Penh, *Cambodia Bans Export of Human Breast Milk After US Operation Raises Concern*, GUARDIAN (Mar. 28, 2017), <https://www.theguardian.com/world/2017/mar/28/cambodia-breast-milk-us-export-ambrosia-labs> [<https://perma.cc/669D-5T6W>] (reporting that one of Ambrosia’s supplying countries, Cambodia, banned selling and exporting human milk because of the risk of exploitation of poor women).

221. *FAQ*, AMBROSIA LABS, <https://ambrosiamilk.com/faq/> [<https://web.archive.org/web/20161102175104/https://ambrosiamilk.com/faq/>] (last visited Nov. 2, 2016).

222. *Our Products*, MEDOLAC, <https://medolac.com/collection/#process> [<https://perma.cc/WE3X-VV6E>] (last visited Feb. 10, 2019).

223. INT’L MILK BANK, *supra* note 219.

raises.²²⁴ Human milk is, by definition, produced by humans, which so far has prevented it from scaling-up on an industrial scale like other popular food items. The United States and a few European countries share an infamous history of forcing female slaves to breastfeed their masters' children, and also systematically exploiting poor, peasant, minority, and foreign women as wet nurses for the benefit of richer and whiter nurslings.²²⁵ Herding women for their milk is therefore not an unknown phenomenon, but it is generally considered immoral or at least ethically problematic.²²⁶ In addition, human milk consumption poses specific safety risks that are unheard of for other food products, given that it can transmit infectious diseases such as Hepatitis B, Hepatitis C, HIV, Syphilis,²²⁷ and perhaps even Zika.²²⁸ The classification that would impart the strictest regulatory regime would be that of a drug, as the next section expounds.

B. Medicine

The distinction between food and medicine can be tenuous. In the 400s B.C.E., Hippocrates famously advocated: "Let food be thy medicine, and medicine be thy food."²²⁹ Human milk is a characteristic example of a food that is also understood as a medicine. There may be evolutionary reasons to this dual categorization. Milk is secreted by all mammals to supply not only nutrition, but also immunological protection to their young.²³⁰ It is a form of innate medicine. Some researchers even claim that the primary evolutionary function of milk was protective rather than nutritional, considering that the mammary gland evolved from the immune system.²³¹

Since antiquity at least, human milk has been used as a remedy. Ancient Egyptian, Greek, and Roman pharmacopeias called for human milk as a therapeutic substance to treat burns, ears, eyes, and genitals.²³² Traditional Chinese medicine employs human milk in a variety of preparations to cure diseases such as

224. See *supra* note 28.

225. See Cohen, *supra* note 16, at 486, 511, 515. But see Naomi Baumslag & Dia L. Michels, MILK, MONEY AND MADNESS 46 (1995) (nuancing the notion that wet nursing was exploitative by pointing out that it "provided a status job and financial security in a culture offering very few safe, lucrative jobs to uneducated women.").

226. See Cohen, *supra* note 16, at 486, 511, 515.

227. See generally Micah D.J. Peters et al., *Safe Management of Expressed Breast Milk: A Systematic Review*, 29 WOMEN & BIRTH 473 (2016) (reviewing the risks of pathogen transmission in human milk).

228. See Myrielle Dupont-Rouzeyrol et al., *Infectious Zika Viral Particles in Breastmilk*, 387 LANCET 1051 (2016) (reporting the presence of infective virus particles in human milk with substantial viral loads).

229. See Gregers Wegener, "Let Food Be Thy Medicine, and Medicine Be Thy Food": Hippocrates Revisited, 26 ACTA NEUROPSYCHIATRICA 1, 1 (2014).

230. Claudia Vorbach et al., *Evolution of the Mammary Gland from the Innate Immune System?*, 28 BIOESSAYS 606 (2006).

231. *Id.*

232. See Julie Laskaris, *Nursing Mothers in Greek and Roman Medicine*, 112 AM. J. ARCHAEOLOGY 459, 460 (2008); Danielle Gourevitch, *Les tire-lait antiques et la consommation médicale de lait humain*, 24 HISTOIRE DES SCIENCES MÉDICALES 93 (1990).

debilitation, arthritis, rheumatism, voiceless-ness, amenorrhea, eye infections, and poisoning.²³³ Human milk “is an ingredient in a prescription in a silk manuscript dating from 2000 B.C. known as *Prescriptions for Fifty-two Ailments*, which is the earliest pharmacopeia found in China.”²³⁴ In medieval and modern Europe, human milk was a key component in washes, elixirs, ointments, and pills.²³⁵

Contemporary scientific advances vindicate these medical uses. We now know that in the ancient world, “human milk was among the most potent antibiotics” available to humans.²³⁶ Its powerful immunological and antimicrobial properties are apparently greater than those of other mammalian milks.²³⁷ In particular, “[t]he past decade has seen a large extension in the list of immunological factors detected in human milk,” contributing to its renewed indication as a drug for infants as well as adults.²³⁸ The scientific study of milk has revealed that it is more complex and beneficial than previously imagined. Milk is composed of nutritive, immunological, and hormonal constituents increasingly thought to have therapeutic and prophylactic properties.²³⁹ Nowadays, human milk is clearly treated as a medicine in two contexts: when administered as a medical food to sick children and adults and when it is broken down into compounds by researchers for use in manufactured drugs.

Banked milk is treated as a medical food for infants whose parents cannot breastfeed them.²⁴⁰ It must, in principle, be prescribed by a licensed physician for a specific indication, as a parent’s inability to breastfeed is not, in and of itself, generally considered to be a sufficient reason.²⁴¹ Diseases or conditions said to be

233. See William C. Cooper & Nathan Sivin, *Man As a Medicine: Pharmacological and Ritual Aspects of Traditional Therapy Using Drugs Derived from the Human Body*, in CHINESE SCIENCE: EXPLORATIONS OF AN ANCIENT TRADITION 203, 227–34 (Shigeru Nakayama & Nathan Sivin eds., 1973).

234. H.T. Huang, *Hypolactasia and the Chinese Diet*, 43 CURRENT ANTHROPOLOGY 809, 809 n.4 (2002).

235. See WOLF D. STOR, THE UNTOLD HISTORY OF HEALING: PLANT LORE AND MEDICINAL MAGIC FROM THE STONE AGE TO PRESENT 278 (2017).

236. Laskaris, *supra* note 232, at 460.

237. See JAN RIORDAN & KATHLEEN G. AUERBACH, BREASTFEEDING AND HUMAN LACTATION 143 (1999).

238. Anna Petherick, *Mother’s Milk: A Rich Opportunity*, 468 NATURE S5, S6 (Dec. 2010).

239. See, e.g., Francesco Savino et al., *Breast Milk Hormones and Their Protective Effect on Obesity*, INT’L J. PEDIATRIC ENDOCRINOLOGY 1 (2009) (examining the data on hormones contained in human milk and their potential protective effect on subsequent obesity); Foteini Hassiotou & Donna T. Geddes, *Programming of Appetite Control During Breastfeeding as a Preventative Strategy Against the Obesity Epidemic*, 30 J. HUM. LACTATION 136 (2014) (arguing that certain hormones in human milk facilitate the development of appetite control mechanisms that confer short-term feeding regulation all the while protecting from obesity in later life).

240. See The Orphan Drug Act, 21 U.S.C. § 360ec(b)(3) (defining a medical food as one “which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”).

241. See *supra* notes 165–166 and accompanying text.

cured, alleviated, or prevented by ingesting human milk include being preterm or having a low birth weight—which are two of the leading causes of infant mortality and morbidity; necrotizing enterocolitis (NEC)—an inflammatory state that attacks the blood supply to the intestinal tract causing tissue death, and requiring surgery to repair or remove the intestines;²⁴² failure to thrive; malabsorption syndromes; formula intolerance; allergies; immunologic deficiencies; post-operative treatment; suppressed IgA levels; chronic renal failure; leukemia; intractable pneumonia; and HIV.²⁴³ Donor milk is also administered to adults for a variety of indications, such as, to reduce the risk of infectious complications in the post-operative period in IgA-deficient liver transplant recipients,²⁴⁴ to ease the symptoms of cancer patients,²⁴⁵ and for digestive and immune disorders.²⁴⁶ At the NICU, doctors treat human milk much like any other drug. Anthropologist Katherine Carroll quotes a neonatologist describing donor milk as follows:

The donor has been screened and the milk has been heat-treated and kept in sterile containers that have been analysed for safety prior to use, and then *it is recorded and treated like any other medicine. In that sense it becomes like the right medication, right dose, right patient*, assuming they do everything correctly. There is a mental transformation of the substance as a consequence of the process.²⁴⁷

Even if human milk is subject to minimal processing compared to synthetic drugs, it is reborn in medical discourse as a therapeutic substance, divorced from its bodily source and cultural status as a food or bodily fluid.²⁴⁸

242. See generally Sandra Sullivan et al., *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis Than a Diet of Human Milk and Bovine Milk-Based Products*, 156 J. PEDIATRICS 562 (2010); see also Maria Quigley & William McGuire, *Formula Versus Donor Breast Milk for Feeding Preterm or Low Birth Weight Infants (Review)*, 2014 COCHRANE DATABASE OF SYSTEMATIC REVIEWS CD002971 (2014) (comparing formula to donor human milk for feeding preterm or low birth weight infants and concluding that formula feeding is associated with a higher risk of developing NEC).

243. See, e.g., Maryanne Tigchelaar Perrin et al., *The Nutritive and Immunoprotective Quality of Human Milk Beyond 1 Year Postpartum: Are Lactation-Duration-Based Donor Exclusions Justified?*, 29 J. HUM. LACTATION 341, 342 (2013); *Breastfeeding and the Use of Human Milk*, 129 PEDIATRICS e827 (2012) (Policy Statement, American Academy of Pediatrics).

244. Hadar J. Merhav et al., *Treatment of IgA Deficiency in Liver Transplant Recipients with Human Breast Milk*, 8 TRANSPLANT INT'L 327 (1995) (concluding that human milk can be used in IgA-deficient liver transplant recipients to reduce the risk of infectious complications in the post-operative period).

245. Elizabeth McGuire, *Ruth Goes Home: An Adult's Use of Human Milk*, 20 BREASTFEEDING REV. 44 (2012); see also Virginia Thorley, *Mothers' Experiences of Sharing Breastfeeding or Breastmilk, Part 2: The Early 21st Century*, 2:e2 NURSING REPORTS 4, 9 (2012) (mentioning the use of donor human milk by a cancer patient).

246. Barbara Feder Ostrov, *Some Ill Adults Use Breast Milk to Fight Disease*, SEATTLE TIMES (Dec. 30, 2014), <https://www.seattletimes.com/nation-world/some-ill-adults-use-breast-milk-to-fight-disease/> [https://perma.cc/6RMA-7FCD].

247. Katherine Carroll, *Body Dirt or Liquid Gold? How the "Safety" of Donated Breastmilk is Constructed for Use in Neonatal Intensive Care*, 44 SOCIAL STUD. SCI. 466, 477 (2014) (emphasis added).

248. See Cohen, *supra* note 16, at 517–18.

Human milk is increasingly seen as a drug in the full sense, separately from being understood as a medical food. This development is owed to researchers' growing ability to isolate human milk's specific components for inclusion in laboratory-developed drugs. For example, microbiologist Catharina Svanborg and her team investigate a human milk protein, "HAMLET," which they have shown has the ability to kill cancerous tumor cells.²⁴⁹ In the past decade, researchers also discovered that human milk contains stem cells with multilineage potential similar to human embryonic stem cells.²⁵⁰ The function of these cells "is still somewhat of a mystery; however, they open up a whole new world of possibilities for not only the field of lactation, but also stem cell and cancer research and regenerative medicine."²⁵¹ Cell replacement therapies are the object of considerable scientific attention given their potential to provide novel treatment options for numerous diseases and impairments caused by injuries.²⁵² In particular, in patients suffering from neurodegenerative diseases such as Parkinson's or Alzheimer's, therapeutic benefits may be obtained by transplanting cells to replace the nonfunctioning neurons.²⁵³

Could human milk be treated as a medicine from a legal perspective? Human milk certainly appears to fall under the federal definition for drugs—that is, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."²⁵⁴ Utah is the only jurisdiction to (implicitly) define human milk as a drug, but more may come forward as human milk-based drugs become available.²⁵⁵ Yet, if experimental drugs that incorporate human milk compounds fit mainstream drug regulation and definition, donor milk administered as-is or with minimal processing would be harder to square within the drug paradigm. Unlike today's conventional drugs, which tend to be synthetic, laboratory-developed substances subject to intensive scientific research and

249. See Lotta Gustafsson et al., *Changes in Proteasome Structure and Function Caused by HAMLET in Tumor Cells*, 4 PLOS ONE e5229 (2009); James C.S. Ho et al., *Lipids As Tumoricidal Components of Human α -lactalbumin Made Lethal to Tumor Cells (HAMLET): Unique and Shared Effects on Signaling and Death*, 288 J. BIOL. CHEM. 17460 (2013).

250. See Foteini Hassiotou, et al., *Breastmilk Is a Novel Source of Stem Cells with Multilineage Differentiation Potential*, 30 STEM CELLS 2164 (2012).

251. Foteini Hassiotou & Peter E. Hartman, *At the Dawn of a New Discovery: The Potential of Breast Milk Stem Cells*, 5 ADV. NUTR. 770, 770 (2014).

252. See Joanna A. Korecka et al., *Cell-Replacement and Gene-Therapy Strategies for Parkinson's and Alzheimer's Disease*, 2 REGENERATIVE MEDICINE 425 (2007) (reviewing the progress made in the field of cell-replacement and gene-therapy for these diseases).

253. See *id.*

254. 21 U.S.C. § 321(g)(1)(B) (2018).

255. See UTAH ADMIN. CODE r. 414-60-5 (2017) (The "[State] Medicaid [pharmacy program] does not cover the following drugs . . . (j) Breast milk, breast milk substitutes, baby food, or medical foods, except for prescription metabolic products for congenital errors of metabolism"). Note that New York Senator Kemp Hannon who supported a bill that would have dramatically expanded human milk insurance coverage called human milk a "medicine" for high-risk infants [that] can be lifesaving" in his memo. KEMP HANNON, INTRODUCER'S MEMORANDUM IN SUPPORT, S. 6583, 2017 Leg., 239th Sess. (N.Y. 2016).

government pre-approval, human milk is produced by humans ready for use. Prototypical drugs are produced under controlled conditions with consistent, known ingredients. By contrast, human milk is a dynamic fluid that changes significantly in its composition based on a variety of factors.²⁵⁶ Each batch, obtained from a different donor at a different time in the day and lactation stage, has unique characteristics, making it difficult to devise a “generic” human milk. In other words, human milk cannot conform to the rigorous standards applied to conventional drugs. Also, unlike most drugs, human milk is available outside of the lab—it comes from lactating women rather than synthetic chemicals or controlled cell cultures in laboratories. Its human origin may, therefore, warrant its designation as a bodily fluid or tissue.

C. Bodily Fluid

Milk is a replenishable bodily fluid analogous to blood, mucus, saliva, semen, sweat, tears, urine, or vaginal secretions—blood and semen sharing the additional trait of being commonly banked body products. Milk and blood have historically been associated in medicine and culture. At various times and places, milk was believed to be blood that had been heated and whitened—the so-called dealbation theory.²⁵⁷ The Hippocratic treatise *De glandulis* asserted that milk was produced from uterine blood.²⁵⁸ Aristotle saw milk as concocted blood.²⁵⁹ In Chinese science and medicine, milk was thought to originate in yin blood.²⁶⁰ Milk’s derivation from a woman’s blood was also widespread in Arab medicine.²⁶¹

This conception of human milk as bodily fluid is alive and well in the United States. Human milk is neither collected nor distributed by the food industry, nor is it manufactured by pharmaceutical companies to be sold in drug stores—or at least not yet. Rather, it is handled by milk banks that function on the model of other biobanks such as blood, cord, oocyte and semen, organ, plasma, and stool banks.²⁶² Like these other bodily products, it is primarily dispensed via hospitals, clinics, and doctor’s offices—though like semen and stool, and unlike blood, cord, oocytes, organs, or plasma—it also changes hands informally peer-to-peer because no

256. See L. KATHLEEN MAHAN & JANICE L. RAYMOND, *KRAUSE’S FOOD & THE NUTRITION CARE PROCESS* 286 (14th ed. 2016).

257. See, e.g., DANIELLE JACQUART & CLAUDE THOMASSET, *SEXUALITY AND MEDICINE IN THE MIDDLE AGES* 12 (1988).

258. See HIPPOCRATES, *DE GLANDULIS* 16 (8.570-72 L); see also Lesley A. Dean-Jones, *The Cultural Construct of the Female Body in Classical Greek Science*, in *WOMEN’S HISTORY AND ANCIENT HISTORY* 111 (Sarah B. Pomeroy ed., 1991).

259. See Alicia D. Myers, *Pater Nutrix: Milk Metaphors and Character Formation in Hebrews and 1 Peter*, in *MAKING SENSE OF MOTHERHOOD: BIBLICAL AND THEOLOGICAL PERSPECTIVES* 81, 85–86 (Beth M. Stovell ed., 2016).

260. See Cooper & Sivin, *supra* note 233, at 227.

261. See AVNER GILADI, *INFANTS, PARENTS AND WET NURSES: MEDIEVAL ISLAMIC VIEWS ON BREAST-FEEDING AND THEIR SOCIAL IMPLICATIONS* (1999).

262. See generally *supra* Part II.B.

medical intervention is required to retrieve and dispense it.²⁶³ Human milk's treatment in the NICUs illustrates its medico-cultural grouping with bodily fluids. There, it is necessary to obtain informed consent from an infant's parents before it can be administered on the premise that it is another person's tissue.²⁶⁴ However, no such consent is required to dispense formula based on cow's milk to a baby, even though it comes from the body of an animal.

Could human milk be treated as a tissue from a legal perspective? A few public health officials and HMBANA bank personnel have supported its classification as a tissue or biologic. According to Mary Rose Tully, the former HMBANA chair quoted above, "donor milk is a tissue with unique properties and belongs more with tissue banking, than with special formulas. The purpose is to provide a safe human tissue, which happens to also be primary nutrition for most recipients. The milk is not formulated in any way."²⁶⁵ Some state legislators seem to share this view. Four states officially classify human milk as a human tissue, requiring tissue-banking licenses for organizations to collect, process, distribute, or use it.²⁶⁶ Commercial human milk manufacturers do not seem opposed to classifying human milk as a body fluid. They may share with non-profit banks and these legislators the view that this designation will ensure quality assurance, inciting more physicians to prescribe and use donor milk in their practice. Prolacta's Vice President of Quality and Regulatory Affairs, Scott Eaker, thus declared in 2010: "[W]e approach the manufacturing of our products like the manufacturing of a biologic, and our quality systems are designed to be compliant with those GMPs [Good Manufacturing Practices]. That's what we strive for."²⁶⁷ Similarly, the International Milk Bank claims on its website:

[I]n states that define and regulate human milk as a tissue and may require specific tissue bank licenses, these regulations are specific to the proper collection, handling and distribution of human tissues, particularly human breast milk. International Milk Bank will meet or exceed all state tissue bank requirements before conducting sales or distribution to those states.²⁶⁸

In sum, three competing categorizations coexist in our culture: human milk as a food, medicine, and body fluid. However, what is often lost in debates about how to define human milk is that it is also a relationship between those who lactate and those who consume milk. The next section focuses on this quality.

263. See *infra* Part II.C.

264. See Carroll, *supra* note 247, at 478. Similarly, when foster parents wish to breastfeed their foster babies, they may be subject to county or state regulations requiring an approval process by the child's social worker when no such process is necessary to bottle feed. See Thorley, *supra* note 245, at 5.

265. Tully, *supra* note 127.

266. These are California, Idaho, Maryland and New York. See *supra* note 96 and accompanying text.

267. U.S. FOOD AND DRUG ADMIN., *supra* note 131, at 162.

268. See INT'L MILK BANK, *supra* note 219.

D. Relationship

Human milk is not just a material substance. It is primarily a relationship between a person who produces milk and one who consumes it—typically a mother and her baby.²⁶⁹ If an ontology of milk were articulated, it would be a relational one, that is, a theory premised on the idea that milk connects people to one another and the world around them.²⁷⁰ Milk is a mutual relation. It is produced *for* others and *by* others; without the suckling of an infant, lactation is hard to trigger and maintain.²⁷¹ At least three forms of communication—corporeal, affective, and symbolic—are accomplished through milk, which are analyzed in turn.

1. Corporeal Communication

Human milk literally communicates its constituent elements, which include nutrients, enzymes, immune factors, hormones, but also viruses, bacteria, and contaminants. Some of these components can be beneficial and others are harmful. The communicability of viruses through human milk in particular has long been documented.²⁷² Viral infections such as HIV, Hepatitis A, B, and C, herpes, syphilis, and CMV are transmissible through milk.²⁷³ Historically, this has led to various forms of screening strategies—from the eighteenth and nineteenth century wet nurses who were disqualified because of suspicion that they carried syphilis to contemporary donors who undergo serological testing before they can donate to banks.²⁷⁴ Since the 1950s it has also been established that environmental chemicals are present in human milk.²⁷⁵ Via their milk, breastfeeders and milk donors communicate a multitude of toxic contaminants to their nurslings, thus connecting them to the polluted world in which we live.²⁷⁶ Maia Boswell-Penc points out that

269. Note that milk is not unique in that respect as other body products are relational and co-produced, for instance placentas and embryos. *See, e.g.*, Mathilde Cohen, *The Law of Self Eating* (unpublished manuscript) (on file with author).

270. *See* Kate Boyer, *Breastmilk as Agentic Matter and the Distributed Agencies of Infant Feeding*, 10 *STUDIES IN THE MATERNAL* 1 (2018) (offering a theoretical account of milk as a relation within the framework of Karen Barad's agential realism).

271. *See* Lawrence & Lawrence, *supra* note 31, at 668 (discussing induced lactation).

272. *See, e.g.*, GEORGE D. SUSSMAN, *SELLING MOTHER'S MILK: THE WET-NURSING BUSINESS IN FRANCE 1715-1914*, at 41 (1982).

273. *See* Lawrence & Lawrence, *supra* note 32, at ch. 13 (reviewing the infectious diseases transmissible through human milk).

274. *See* Kelley L Baumgartel, Larissa Sneeringer, & Susan M. Cohen, *From Royal Wet Nurses to Facebook: The Evolution of Breastmilk Sharing*, 24 *BREASTFEED REV.* 25 (2016) (comparing the history of wet nursing to contemporary milk banks and other milk sharing practices).

275. *See* Edwin P. Laug, Frieda M., Kunze, & C.S. Prickett, *Occurrence of DDT in Human Fat and Milk*, 3 *AMA ARCH. INDUS. HYGIENE OCCUP. MED.* 245 (1951) (seminal study of DDT residues in human fat finding that DDT was present in all examined specimen except three).

276. *See* Walter J. Rogan, *Pollutants in Breast Milk*, 150 *ARCHIVES PEDIATRIC & ADOLESCENT MED.* 981, 981 (1996) (writing that “breastmilk, if regulated like infant formula, would commonly violate Food and Drug Administration action levels of poisonous or deleterious substances in food and could not be sold”). *See generally* MAIA BOSWELL-PENC, *TAINTED MILK: BREASTMILK, FEMINISMS, AND THE POLITICS OF ENVIRONMENTAL DEGRADATION* (2006) (discussing the environmental contamination of human milk from a feminist perspective).

“the human infant is at the very top of the food chain, subjected to the highest amounts of toxins of any organism”²⁷⁷ given how bioaccumulation works.²⁷⁸

There is a positive side too to milk’s corporeal communicability. As Catherine Field has proposed, “milk is the communication vehicle between the maternal immune system and the infant, a system actively directing and educating the immune, metabolic, and microflora systems within the infant, while conferring multiple means of protection from pathogens.”²⁷⁹ Milk transmits “information . . . about the environment and even the social structure around the mother.”²⁸⁰ Milk’s composition changes from day to day, hour to hour, even from the beginning until the end of a feed²⁸¹—based on geography, climate, disease conditions among a defined population, the breastfeeder’s own health and diet, and the child’s specific developmental needs, among other factors.²⁸² Human milk variation is even a medium for early flavor experiences, as it reflects the breastfeeder’s diet in its taste, texture, and sweetness.²⁸³

The relationality of milk is bidirectional: signals are not only communicated from breastfeeders to nurslings, but also from nurslings to breastfeeders. In the past decades, new studies have revealed “that milk is actively communicating between the maternal mammary epithelia and the infant’s gastrointestinal system.”²⁸⁴ All sorts of information are conveyed through milk, including the infant’s developmental, nutritional, immunological, and other needs. The mechanisms of this transmission are still under investigation, but a promising explanation is the “retrograde flow” or “salivary backwash” theory.²⁸⁵ During suckling, some of the infant’s bacteria flow back into the mammary ducts via a mix of milk and saliva.²⁸⁶ The bacteria contain timely information about the infant’s needs, prompting the

277. MAIA BOSWELL-PENC, *TAINTED MILK* 63 (paraphrasing Rachel Carson’s indictment of pesticides in her book *Silent Spring* (1962)).

278. See Krista Nickerson, *Environmental Contaminants in Breast Milk*, 51 J. MIDWIFERY & WOMEN’S HEALTH 26, 26 (2006) (explaining the phenomenon of bioaccumulation in relation to breastfeeding).

279. Catherine J. Field, *The Immunological Components of Human Milk and Their Effect on Immune Development in Infants*, 135 J. NUTRITION 1, 1 (2005).

280. Petherick, *supra* note 238, at S7.

281. See, e.g., Steven E.J. Daly et al., *Degree of Breast Emptying Explains Changes in the Fat Content, But Not Fatty Acid Composition of Human Milk*, 78 EXP. PHYSIOL. 741 (1993) (observing changes in milk fat throughout feedings).

282. See, e.g., Deborah L. O’Connor et al., *Human Milk Pasteurization: Benefits and Risks*, 18 CURRENT OPINION IN CLINICAL NUTRITION & METABOLIC CARE 269 (2015) (reviewing the risks and benefits of pasteurizing).

283. Angela Garbes, *The More I Learn About Breast Milk, the More Amazed I Am*, THE STRANGER (Aug. 26, 2015), <http://www.thestranger.com/features/feature/2015/08/26/22755273/the-more-i-learn-about-breast-milk-the-more-amazed-i-am> [<https://perma.cc/2ZH3-9SCL>].

284. J. Bruce German et al., *Bioactive Components in Milk*, 5 CURRENT OPINION IN CLINICAL NUTRITION & METABOLIC CARE 653, 653 (2002).

285. Katie Hinde & Zachery T. Lewis, *Mother’s Littlest Helpers*, 348 SCIENCE 1427, 1427 (Jun. 26, 2015).

286. *Id.*

lactating body to adapt its milk production.²⁸⁷ This process may explain why there is an “important time-dependent variation in the complement of bioactive ingredients in human milk—the molecules and cells that have biological functions beyond fueling metabolism and providing the raw materials for infant growth.”²⁸⁸ Using milk from donors who do not have any contact with their recipients breaks up the adaptive aspects of this corporeal communication, though other forms of communication may be preserved, as I argue below.

2. *Affective Communication*

Human milk represents a form of affective communication. It is usually the product of a caring relationship between a parent and a child.²⁸⁹ The very chemistry of breastfeeding appears geared toward arousing and maintaining affect. The suckling infant elevates the breastfeeder’s level of oxytocin—also known as the “love hormone”—which in turn facilitates the attachment process between the two.²⁹⁰ There is empirical evidence that parents who breastfeed experience lower levels of perceived stress and negative mood and higher levels of attachment to their babies.²⁹¹ These findings must be taken with caution, however, as separating the effects of breastfeeding from other potential confounding factors associated with breastfeeding is difficult. Specifically, the decision whether or not to breastfeed is often related to the breastfeeder’s socioeconomic status, health, personal history, and embeddedness in a community that supports, or not, breastfeeding.²⁹²

287. *Id.*

288. Petherick, *supra* note 238, at S5.

289. Exceptions include bereaved mothers donating their milk for other babies, coerced breastfeeding, breastfeeding performed exclusively for pay, or cases of emotional communication through adult breastfeeding.

290. *See, e.g.,* Ruth Feldman et al., *Maternal and Paternal Plasma, Salivary, and Urinary Oxytocin and Parent-Infant Synchrony: Considering Stress and Affiliation Components of Human Bonding*, 14 DEVELOPMENTAL SCI. 752 (2011) (assessing the role of oxytocin in human bonding); Dylan B. Jackson, *The Association Between Breastfeeding Duration and Attachment: A Genetically Informed Analysis*, 11 BREASTFEEDING MED. 297 (2016) (using twin research to conclude that longer duration of breastfeeding may help to facilitate a secure attachment among female offspring).

291. D.M. Fergusson & L.J. Woodward, *Breast Feeding and Later Psychosocial Adjustment*, 13 PAEDIATRIC & PERINATAL EPIDEMIOLOGY 144 (1999) (finding that children who were breastfed for a longer duration were more likely to report higher levels of parental attachment and tended to perceive their mothers as being more caring and less overprotective towards them compared with bottle-fed children); Nicole M. Else-Quest, *Breastfeeding, Bonding, and the Mother-Infant Relationship*, 49 MERRILL-PALMER Q. 495 (2003) (showing that breastfeeding mothers and their children have higher quality relationships but underscoring that non breastfeeding dyads do not display poor quality or precarious relationships); Elizabeth Sibolboro Mezzacappa & Edward S. Katkin, *Breast-Feeding Is Associated with Reduced Perceived Stress and Negative Mood in Mothers*, 21 HEALTH PSYCHOLOGY 187 (2002) (showing that breastfeeding is associated with a decrease in perceived stress and negative mood in mothers).

292. *See* Emilie Oster, *Everybody Calms Down About Breastfeeding*, FIVETHIRTYEIGHT (May 20, 2015) <https://fivethirtyeight.com/features/everybody-calm-down-about-breastfeeding/> [<https://perma.cc/H6AK-77MY>] (arguing that research on the benefits of breastfeeding is biased because even holding constant maternal wealth and educational level, breastfeeding is still associated with other characteristics such as maternal IQ in a way “that may drive infant and child outcomes”).

What becomes of this affective communication in milk sharing situations in which providers and recipients neither know one another nor interact in any way? Banked milk is typically pooled among multiple, anonymous donors and donated to anonymous recipients. Neither donors nor recipient families know the identity of one another, preventing the creation of an affective relationship in the usual sense. Milk donors are most often unpaid (or paid very little).²⁹³ They must therefore be motivated by non-monetary incentives to donate. Researchers have shown that these motivations may include having too much milk,²⁹⁴ wanting to help women²⁹⁵ and babies, and feeling that it is a social responsibility,²⁹⁶ hoping that someone would do the same for them,²⁹⁷ or desiring “to stimulate lactation” by pumping for others.²⁹⁸ Donors are influenced, therefore, by a mix of self-centered and altruistic reasons which could lead to feelings such as benevolence, compassion, and gratefulness arising between donor and recipient families even in the absence of contact.²⁹⁹

Informal milk sharing may allow for amplified affective communication as it directly connects providers and recipients. Providers generally know the circumstances of their recipients, sometimes even meeting them in person, and vice versa. According to Palmquist and Doehler’s 2013–2014 study of milk sharing practices in the United States, among a sample of 661 donors and 206 recipients, the majority of the milk was delivered face-to-face and only 18 recipients reported buying milk, the others obtaining it for free.³⁰⁰ Palmquist and Doehler note that milk sharing is embedded in social relationships and often practiced along shared breastfeeding—11.9% of the donors surveyed reported breastfeeding the recipient baby in addition to donating their expressed milk.³⁰¹ Peer-to-peer milk sharing,

293. Tanya M. Cassidy, *Maternal Corporeal Generosity, Social Psychological Trust, and Value in Human Milk Exchange*, 3 J. MOTHERHOOD INITIATIVE 102 (2012).

294. See Emilie Azema & Stacey Callahan, *Breast Milk Donors in France: A Portrait of the Typical Donor and the Utility of Milk Banking in the French Breastfeeding Context*, 19 J. HUM. LACTATION 199, 201 (2003).

295. Karleen D. Gribble, “I’m Happy to Be Able to Help:” *Why Women Donate Milk to a Peer via Internet-Based Milk Sharing Networks*, 9 BREASTFEEDING MED. 251, 251 (2014) (reporting based on a study of online milk sharing networks in Australia that 71% of the “respondents stated that they were motivated to donate milk because they wanted to help someone. Many described milk donation as an empathic response to women with insufficient milk.”)

296. See Ana Claire Pimenteira et al., *The Human Milk Donation Experience: Motives, Influencing Factors, and Regular Donation*, 24 J. HUM. LACTATION 69, 71 (2008).

297. *Id.* at 75.

298. See Richard Osbaldiston & Leigh A. Mingle, *Characterization of Human Milk Donors*, 23 J. HUM. LACTATION 350, 353, 356 (2007).

299. See, e.g., Kate Boyer, *Of Care and Commodities: Breast Milk and the New Politics of Mobile Biosubstances*, 34 PROGRESS IN HUMAN GEOGRAPHY 5 (2010) (reflecting on human milk’s newfound mobility and how this is affecting its socio-cultural status); Tanya M. Cassidy, *Maternal Corporeal Generosity, Social Psychological Trust, and Value in Human Milk Exchange*, 3 J. MOTHERHOOD INITIATIVE 96 (2012) (arguing that though the giving of human milk is regarded as a natural, biological event, breastfeeding is invested within an economic paradigm).

300. See Palmquist & Doehler, *supra* note 162, at 280, 286.

301. See Palmquist & Doehler, *supra* note 162, at 283.

especially when it is long term, may even result in forming friendships between the families involved.³⁰²

3. *Symbolic Communication*

Finally, in addition to communicating literally and affectively, human milk operates a form of symbolic connection. In certain cultural contexts, milk transfers are thought to have a transformative effect on the nature of the recipients and their relations to others.³⁰³ Chloé Maillet writes that during the late Middle Ages, milk “was understood to create kinship, and as changing the very essence of the person who was drinking it.”³⁰⁴ At the height of the wet nursing profession in the eighteenth and nineteenth centuries, medical and religious authorities admonished parents about the corrupting influence of wet nurses on their charge. If the wet nurse was of a “difficult character,” for instance, suspected of being lustful, or if her physical complexion did not conform with the beauty standards of the day (say she was a redhead³⁰⁵), parents worried that their children would imbibe her moral and physical traits. Milk was also, and still is in some cultures, capable of bringing about special social bonds between the breastfeeder and her nurslings and among the nurslings themselves. As noted earlier,³⁰⁶ according to Islamic rules and practices, infants suckling from the same woman become related even when they are not blood relatives, giving rise to incest taboos.

* * *

What does milk’s relational identity mean from a legal perspective? By and large, American law has ignored this dimension, which if taken seriously, would require legal interventions to encourage and protect the breastfeeding relationship. According to this relational perspective, milk should not be thought of as a separate substance that could be regulated independently from those who produce it and those who consume it. In a number of countries, labor laws allow working women to breastfeed their children in the workplace, rather than merely expressing milk, suggesting that this relational aspect is valued.³⁰⁷ This is not the case in the United States where the law typically only requires that workers be able to *express* milk in the workplace.³⁰⁸ The right to breastfeed a child at work involves the recognition of human milk as a relation, not just as fungible substance that can be expressed and

302. See Palmquist & Doehler, *supra* note 162, at 286.

303. See Chloé Maillet, *More than Food: Animals, Men, and Supernatural Lactation in Occidental Late Middle Ages*, in MAKING MILK: THE PAST, PRESENT, AND FUTURE OF OUR PRIMARY FOOD 7 (Mathilde Cohen & Yoriko Otomo eds., 2017) (describing this effect in medieval Europe).

304. *Id.* at 8.

305. See REBECCA JO TANNENBAUM, HEALTH AND WELLNESS IN COLONIAL AMERICA 64 (Joseph P. Byrne ed., 2012).

306. See *supra* notes 176-78 and accompanying text.

307. One such example is France. See CODE DU TRAVAIL [C. TRAV.] [LABOR CODE] art. 224-2-3-4 (Fr.).

308. See Laufer-Ukeles & Renan Barzilay, *supra* note 25 (arguing in favor of laws supporting direct breastfeeding).

administered as distinct events. By contrast, the dominant American norms reduce milk to the status of a food, a medicine, or a bodily fluid that can be isolated from their context of production and distribution. The next Part explores the practical impact of categorizing human milk in one way or another.

IV. THE IMPACT OF CATEGORIZING MILK

Federal lawmakers have substantial power to mold legal categories such as “food,” “drug,” and “tissue” (or “biologics”) to advance desired policies. The determination of a product as a food, a drug, or a biological product controls the supervisory approach the FDA and other regulatory entities impose upon it. Categorization is a critical consideration given that the FDA’s authority is greater over certain products than others. At the same time, the simultaneous grouping of a product under multiple classifications is not unprecedented. For example, the FDA and the courts have long interpreted the 1906 Pure Food and Drugs Act to allow the dual classification of some articles as both food and drugs.³⁰⁹ Under the 1938 Food, Drug, and Cosmetic Act, the terms “food” and “drug” are not even mutually exclusive.³¹⁰ Should the federal government decide to provide a legal definition for human milk, it should carefully balance the impact of the proposed categorization on 1) the *supply* of milk; 2) the *cost* of milk; and 3) the *safety* of milk.

A. Supply

Categorizing human milk as a form of relationship is the most promising avenue to maximize the available supply. If the communicative dimension were recognized and valued by lawmakers, they may consider protecting the act of breastfeeding rather than focusing on health and safety rules applicable to a liquid dissociated from the human bodies who produce it. Emphasizing the relationship, rather than the substance would provide more people with the social and economic ability to breastfeed, to breastfeed longer, and to produce excess milk available for donation.

Cataloging human milk as a food may also have positive effects on supply. The FDA has less authority over foods than drugs and biological products.³¹¹ If the federal government declared human milk to be a food and preempted the few state laws that classify it as a tissue or a drug, it would become easier to create and run milk banks, as they would neither be subject to the Current Good Manufacturing Practice (CGMP) regulations applicable to drugs nor to tissue licensing requirements. A food law approach would have the additional benefit of allowing

309. See Lewis A. Grossman, *Food, Drugs, and Droids: A Historical Consideration of Definitions and Categories in American Food and Drug Law*, 93 CORNELL L. REV. 1091, 1103 (2008).

310. See *id.* (noting that until the mid-twentieth century, the boundary between food and drugs was porous, and to some extent still is: doctors continue to rely on the manipulation of diet to treat patients); see also *supra* note 240 (describing the federal definition of medical foods).

311. See 21 U.S.C. §§ 301-399 (1938); 42 U.S.C. § 262 (2017); Public Health Service Act § 361 (2018).

informal milk sharing to carry on legally, be it on the model of food donations or of so-called cottage food laws.³¹² People could continue to donate milk without running the risk of incurring liability under the Model Good Samaritan Food Donation Act³¹³ so long as they give their milk to non-profit organizations³¹⁴ catering to families who cannot afford banked milk. In 1996, Congress passed the Act “[t]o encourage the donation of food and grocery products to non-profit organizations for distribution to needy individuals.”³¹⁵ The Act’s definition of food is broad enough to encompass human milk as it includes “any raw, cooked, processed, or prepared edible substance, ice, beverage, or ingredient used or intended for use in whole or in part for human consumption.”³¹⁶ The Act exempts individuals and non-profit organizations from civil and criminal liability when donating “apparently wholesome food” “in good faith” “for ultimate distribution to needy individuals.”³¹⁷ The only exception is gross negligence or intentional misconduct resulting in injury or death of the food recipient.³¹⁸

Families donating or selling milk peer-to-peer could also be treated as small food producers, that is, people who donate or sell their homegrown or homemade goods under state “cottage food laws.”³¹⁹ Cottage food laws allow home chefs and bakers to run businesses out of their homes without requiring special licenses or compliance with health and food safety regulations.³²⁰ These laws vary from state to state and involve restrictions such as maximum annual sales, exclusions of hazardous foods, special labeling obligations, and so on. Under cottage food laws, the states could condition milk providers’ exemption from seeking a food business license on the obligation that they periodically undergo serological testing for transmissible diseases and send out their milk for bacteriological, adulteration, and contaminant testing.

By contrast, classification of human milk as a drug or tissue would make it more burdensome for milk banks to operate. If human milk were categorized as a tissue, milk banks and hospitals would need to obtain a specific tissue bank license

312. See generally Nina W. Tarr, *Food Entrepreneurs and Food Safety Regulation*, 7 J. FOOD L. & POL’Y 35, 58–59 (2011).

313. See Model Good Samaritan Food Donation Act, Pub. L. No. 104-210, 110 Stat. 3011 (1996).

314. For the purpose of the Act, a “non-profit organization” is broadly defined, as it can be either an incorporated or unincorporated entity that “operat[es] for religious, charitable, or educational purposes; and does not provide net earnings to, or operate in any other manner that inures to the benefit of, any officer, employee, or shareholder of the entity.” 42 U.S.C.A. § 1791(b)(9) (West 2013). A community organization dedicated to collecting and distributing human milk to needy families would meet the definition.

315. Model Good Samaritan Food Donation Act § 110 at 3011–12.

316. 42 U.S.C.A. § 1791(b)(4) (West 2013).

317. “This legislation eliminates the threat of liability, except in instances of intentional harm and gross negligence . . .” 143 Cong. Rec. H10089 (daily ed. Sept. 5, 1996) (statement of Rep. Goodling); see also 42 U.S.C.A. § 1791(c)(1) (West 2013).

318. 143 Cong. Rec. H10089.

319. See generally Tarr, *supra* note 312 at 54–66.

320. See *id.* at 58.

from their state to collect, process, store, and distribute human milk.³²¹ They would also be subject to the equivalent of Current Good Tissue Practice (CGTP) requirements that would cover milk source recovery, donor screening and testing, processing controls, equipment and facility requirements, environmental controls, storage conditions, and require milk banks to meet labeling requirements.³²² Due to the burden of complying with these requirements, milk collection and distribution may become the prerogative of a few highly medicalized institutions that have the staff and administrative departments to handle it. While HMBANA banks and commercial milk companies have been able to operate under this regime in the states that define milk as a tissue, community milk banks would probably disappear if it were generalized nationally. Peer-to-peer markets would become unlawful, as a tissue classification would turn unlicensed milk donors and recipients into offenders on the model of organ harvesters and recipients.³²³ Under federal law, any person or organization seeking to “introduce or deliver for introduction into interstate commerce any biological product must have a ‘biologics license.’”³²⁴ Women have cross-nursed for millennia, that is, they have breastfed each other’s babies on a regular or occasional basis, be it as part of a paid childcare arrangement or for free.³²⁵ Under this new tissue paradigm, they would no longer be able to donate or sell their milk peer-to-peer as procuring a “biologics license” typically requires the submission of pre-clinical studies, clinical studies, and proposed labeling.³²⁶ This could have a chilling effect on people’s willingness to donate or sell their milk peer-to-peer, thus decreasing the existing supply.

Classifying human milk as a drug would have similar downsides. It would require physicians seeking to use it to submit a time-consuming Investigational New Drug (IND) application.³²⁷ This demand could restrict access to human milk for premature babies and other critically ill infants, judging by a similar scenario which unfolded around fecal microbiota transplantation—an experimental procedure in which fecal matter is collected from a healthy tested donor and placed in a patient for therapeutic purposes.³²⁸ In 2013, the FDA announced that it would regulate

321. As is already the case in California, Idaho, Indiana, Maryland, New York, and Virginia. *See supra* note 95 and accompanying text.

322. FDA Current Good Tissue Practice, 21 C.F.R. § 1271(D) (2001).

323. The National Organ Transplant Act makes the selling of human organs a federal crime. National Organ Transplant Act, Pub. L. No. 98-507, 98 Stat. 2339 (codified as amended at 42 U.S.C. §§ 273–274(e) (1988)).

324. 42 U.S.C. § 262(a) (2017).

325. *See* Virginia Thorley, *Sharing Breastmilk: Wet Nursing, Cross Feeding, and Milk Donations*, 16 BREASTFEEDING REV. 25, 26 (2008).

326. 21 C.F.R. § 601.2(a) (2018); *see also id.* §§ 600–80.

327. *See* Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BOARD FARM. MED. 362, 364–66 (2001) (describing the process of developing and bringing new drugs to market).

328. *See generally* Rachel E. Sachs & Carolyn A. Edelstein, *Ensuring the Safe and Effective FDA Regulation of Fecal Microbiota Transplantation*, 2 J.L. BIOSCIENCES 396, 415 (2015) (examining FDA’s approach to fecal microbiota transplantation).

human feces as a drug for the purpose of transplantation.³²⁹ The therapy had shown great promise in the fight against a number of antibiotic-resistant infections, but FDA's sudden move to categorize it as a drug meant that expensive and labor-intensive safety testing would be required before further clinical use. As a result, "patients, physicians and representatives of the Centers for Disease Control and Prevention and several professional medical societies voiced concern about restricting access to care for these increasingly prevalent infections. Six weeks later, the FDA revised its position."³³⁰ It granted an exception to the new rule, allowing doctors to continue transplanting fecal microbiota for *C. difficile* infections, which can be lethal and have been shown to be improved by fecal transplantation.³³¹ Analogously, classifying human milk as a drug could halt its dissemination in NICUs and diminish its availability, especially on the official markets as neonatologists would need to invest considerable resources in preparing Investigational New Drug applications. A drug definition would also have the effect of proscribing informal milk markets. Peer-to-peer milk donors, sellers, and recipient families would become drug dealers or users in the eyes of the law.

Classifying human milk as a drug or a tissue could therefore compromise its supply and accessibility, making it harder for milk banks to operate, for physicians to prescribe it, for donors to donate it, and for recipients to obtain it. It may also result in outlawing peer-to-peer markets, which fulfill a useful social function for recipients who do not fit within milk banks' priority schedule and/or lack the financial ability to obtain it through them.

B. Cost

Human milk is considerably more expensive than animal milk or plant-based infant formula. The price of banked donor milk, in particular, makes it out of reach to many families, creating inequitable access to a therapy that is life saving for pre-term, low birth weight, and medically fragile babies. This is a social justice issue, as human milk's lack of affordability disproportionately affects children born to low-income and minority parents who tend to experience higher rates of premature births.³³² Due to its steep price, some of the infants most likely to need donor

329. FOOD & DRUG ADMIN., FECAL MICROBIOTA FOR TRANSPLANTATION: SCIENTIFIC AND REGULATORY ISSUES, CENTER FOR BIOLOGICS, EVALUATION AND RESEARCH (FDA) AND THE NATIONAL INSTITUTE FOR ALLERGY AND INFECTIOUS DISEASES (NIH) 309 (2013), <http://www.fda.gov/downloads/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/UCM352903.pdf> [<https://wayback.archive-it.org/7993/20170113133556/http://www.fda.gov/downloads/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/UCM352903.pdf>].

330. Mark B. Smith et al., *How to Regulate Faecal Transplants*, 506 NATURE 290, 290 (2014).

331. See Els Van Nood, et al., *Duodenal Infusion of Donor Feces for Recurrent Clostridium Difficile*, 368 NEW ENGLAND J. MED. 407, 414 (2013).

332. See NEW YORK STATE AMERICAN ACADEMY OF PEDIATRICS, MEMO OF SUPPORT FOR A.9353/S.6583: INSURANCE COVERAGE FOR DONOR BREAST MILK FOR HIGH RISK NEWBORNS 2 (2016), <http://nysaap.org/pdf/2016MOSDonorBreastMilk.pdf> [<http://nysaap.org/pdf/2016MOSDonorBreastMilk.pdf>] (noting that 70% of premature babies in New York are born to "poor

human milk are the least likely to receive it. Explanations for disparities in birth outcomes include racial discrimination, less and lower quality prenatal care, poorer nutrition, greater exposure to accumulated chronic stressors, including crowded home environments, unemployment, teenage pregnancies, single-parent households, less social support, and financial problems.³³³ Low-income mothers are also less likely to enjoy the financial and social support necessary to breastfeed successfully.³³⁴ Their conditions of employment are typically such that they rarely have jobs offering paid maternity leave; cannot afford to forfeit their pay while pumping at work given that many are hourly workers; often lack access to adequate lactation rooms, qualified, affordable lactation consultants; and can seldom count on high quality and affordable childcare providing them with the time to express milk and the option to send their children to daycare with bottles of expressed milk.³³⁵

Additionally, not all NICUs have access to human milk or use it.³³⁶ When they do carry human milk, nearly all obtain it from HMBANA non-profit banks.³³⁷ But not all states have milk banks, requiring imports from out-of-state. According to a 2012 study, cost is a major barrier to the use of donor milk in hospitals, especially safety-net hospitals catering to low income and/or uninsured populations.³³⁸ Yet another obstacle to human milk use, especially for low-income families, is the fact that it is not systematically covered by insurance. Only a few states allow the use of Medicaid to access it from milk banks, though the numbers are growing.³³⁹ Many private insurances do not provide full coverage. And when covered, it is typically

mothers”); *see also* Joyce A. Martin & Michelle J.K. Osterman, *Describing the Increase in Preterm Births in the United States, 2014–2016*, 312 NCHS Data Brief 3, fig. 3 (Jun. 2018), <https://www.cdc.gov/nchs/data/databriefs/db312.pdf> [<https://perma.cc/K6SF-HNLK>] (showing racial disparities in preterm birth by race with “non-Hispanic black[s]” and “Hispanic[s]” experiencing higher rates of premature births).

333. *See generally* Michael S. Kramer et al., *Socio-Economic Disparities in Pregnancy Outcome: Why Do the Poor Fare So Poorly?*, 14 PAEDIATRIC & PERINATAL EPIDEMIOLOGY 194, 200–01 (2000) (reviewing the evidence bearing on socio-economic disparities in pregnancy outcome).

334. *See* Margaret M. McDowell et al., *Breastfeeding in the United States: Findings from the National Health and Nutrition Examination Survey, 1999-2006*, 5 NCHS Data Brief 1, 3 (Apr. 2008) (finding that breastfeeding rates in 1999-2006 were significantly higher among those with higher income (74%) compared with those with lower income (57%)).

335. *See* Kramer et al., *supra* note 333.

336. *See* Margaret G.K. Parker et al., *Pasteurized Human Donor Milk Use Among US Level 3 Neonatal Intensive Care Units*, 29 J. HUM. LACTATION 381, 385 (2013) (showing based on a 2012 survey of US level 3 NICUs—which care for very low birth weight infants most at risk for NEC—that only 45% of NICUs administer human milk, but that use is growing rapidly).

337. *See id.* at 386.

338. *See id.* at 387.

339. *See* Anna Berry, *Liquid Gold: 6 States Allow Medicaid Access for Breast Milk*, NON PROFIT Q. (Apr. 27, 2017), <https://nonprofitquarterly.org/2017/04/27/liquid-gold-6-states-allow-medicaid-access-breast-milk/> [<https://perma.cc/CS67-CEVJ>] (noting that “New York’s law could be the most far-reaching, since it provides for such milk for as long as it’s medically necessary, no matter the infant’s age.”).

restricted to critically ill infants and for a short duration, based on extensive and burdensome documentation, and not as a long-term food.

Could legal reform remove the economic barriers to accessing human milk? On the assumption that complying with food regulations is less expensive than complying with drug or tissue banking regulations, classifying human milk as a food could keep the production costs down. The drawback is that health insurance providers may be less likely to cover it given that they are in the business of covering therapies and drugs, not nourishment. A recurrent tune in the insurance industry is that third party payers do not reimburse for “special foods.”³⁴⁰ Naomi Bar-Yam, the founder of the Mothers’ Milk Bank Northeast and current HMBANA director thus observes, “[t]he [FDA] considers donor milk to be a food; insurance companies cover medicine, not food.”³⁴¹ The dilemma, therefore, is that categorizing human milk as a drug or a tissue would make human milk costlier to produce (by requiring additional screening, testing, approvals, etc.), but more affordable for insured patients to obtain because it would have a higher likelihood of being covered by insurance. According to a 2011 Maryland legislature working group that examined the possibility of granting coverage for donor human milk at the state level,

most insurance companies do not cover banked milk as a line item. It is considered part of the hospital’s bundled costs for room and board. Hospitals in other states where banked milk is classified as a tissue have traditionally “written off” the additional costs of banked milk because of the known benefits in terms of decreased morbidity and mortality. . . . Since the Federal government does not recognize banked human milk formally, it must be rolled into the bundled room and board rates.³⁴²

This mode of reimbursement shifts “the onus to the hospital to make the cost-benefit decision,”³⁴³ knowing that in “most hospitals, infant formulas . . . are provided free of charge by the manufacturers.”³⁴⁴ By contrast, if milk were classified as a drug or a tissue, it could be itemized as a line item in bills and hospitals would

340. See, e.g., Valerie Gregg, *Food Fight. Newborns with Metabolic Disorders Struggle Not Only for Insurance Coverage but Also Their Lives*, EMORY HEALTH (2008), http://whsc.emory.edu/_pubs/hsc/08fall/hs08_food_fight.html [<https://perma.cc/6CLR-KSPR>] (reporting that insurance companies often refuse to cover the necessary special foods for babies who suffer from certain genetic disorders).

341. Olivia Campbell, *When Babies Need Donated Breast Milk, Should States Pay?*, STAT NEWS (Oct. 4, 2016), <https://www.statnews.com/2016/10/04/breast-milk-laws-premature-babies/> [<https://perma.cc/R6VX-P3UP>] (quoting Naomi Bar-Yam).

342. See MD. H. OF DELEGATES HEALTH AND GOV’T OPERATIONS COMM., Work Group Report to the Maryland House of Delegates Health and Government Operations Committee on House Bill 180; The Premature Infant Survival Bill, at 8 (2011).

343. TAYLOR & LABBOK, *supra* note 80, at 35; Emily C. Taylor & Miriam H. Labbok, *Donor Human Milk Access and Use in the United States: Findings and Recommendations*, in CGBI FOR WKKF 35 (Kristin P. Tully ed., 2014).

344. *Id.* at 36.

no longer need to bury it among their bundled costs to get it covered.³⁴⁵ It would become harder for insurers to deny coverage. This is the approach Kentucky adopted since 2013.³⁴⁶ Human milk fortifiers, which the FDA classifies as exempt formulas, are now covered as drugs in the state for eligible beneficiaries to supplement a mother's expressed milk or donor milk.³⁴⁷

C. Safety

Due to the health risks associated with using unscreened donor milk, any regulatory project must address quality assurance and safety. Treating milk as a food would call for the application of food safety laws, including Hazard Analysis and Critical Control Points (HACCP), a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards.³⁴⁸ When properly implemented, this system has been shown to be an effective food safety strategy.³⁴⁹ Milk banks, whether for profit or non-profit, already follow HACCP protocols, when they do not go further.³⁵⁰ Accordingly, it is debatable whether there would be any added safety advantage in treating milk as a drug or a tissue.

Classifying milk as a drug would impart stricter safety protocols, but it would also raise production costs, as milk processors and distributors would need to fund large clinical trials, file Investigational New Device Applications (IND) with the FDA,³⁵¹ and produce a standardized product via a strictly defined process. This form of regulation could stifle milk use or prove counter-productive given the inherent variability in human milk compared to synthetic drugs' consistent list of ingredients and manufacturing processes.³⁵² There seems to be more promise in categorizing milk as a tissue considering that, like for blood, the oversight should focus on controls for transmissible diseases and dangerous bacteria.³⁵³ Unlike a drug classification, a tissue classification would not require premarket approval so long

345. See TAYLOR & LABBOK, *supra* note 80, at 36 (noting that Prolacta advises hospitals to bill its products as "medical/surgical supply, sterile supply, or general pharmacy" rather than donor milk or fortifier).

346. See KY. REV. STAT. ANN. § 304.17A-139 (West 2017).

347. See 2013 Ky. Acts 304.17A-139(4)(b).

348. See generally Martin W. Bucknavage & Catherine Nettles Cutter, *Hazard Analysis and Critical Control Points*, in MICROBIOLOGICALLY SAFE FOODS 435, 435 (Jose Santos Garcia, ed., 2009) (describing the seven principles of Hazard Analysis and Critical Control Points).

349. See generally Sara Mortimore, *How to Make HACCP Really Work in Practice*, 12 FOOD CONTROL 209 (2001) (arguing that the effectiveness of HACCP crucially depends on the training and education of those who develop and operate the program).

350. See Susan Landers & Ben T. Hartmann, *Donor Human Milk Banking and the Emergence of Milk Sharing*, 60 PEDIATRIC CLINICS NORTH AM. 247, 255 (2013).

351. Investigational New Drug Application Rule, 21 C.F.R. § 312 (2018).

352. See *supra* Section III.B.

353. See generally WORLD HEALTH ORG., SAFE BLOOD AND BLOOD PRODUCTS INTRODUCTORY MODULE: GUIDELINES AND PRINCIPLES FOR SAFE BLOOD TRANSFUSION PRACTICE (2009), http://www.who.int/bloodsafety/transfusion_services/Introductory_module.pdf [<https://perma.cc/VE82-T6ME>] (offering guidelines on safe blood banking practices).

as the milk is “minimally manipulated.”³⁵⁴ One benefit of considering milk a tissue is that it is compatible with its continued unprocessed or hardly processed use. The tissue paradigm could facilitate milk banks’ dispensing of raw human milk for those physicians or patients who prefer it to pasteurized milk.³⁵⁵ At present, U.S. milk banks typically do not offer raw milk, though other countries do.³⁵⁶ In Norway, where human milk is considered “both biologically active tissue and nutritional support,”³⁵⁷ banks deliver it raw. They save on the time and expense required for pasteurizing all the while offering an arguably superior product (assuming the validity of the arguments according to which raw milk is superior immunologically and perhaps even nutritionally to pasteurized milk³⁵⁸). If American neonatologists and pediatricians were confident that human milk were collected and processed in a standardized way on the model of a tissue, they may feel more comfortable prescribing it unpasteurized.

* * *

This Part described the costs and benefits of classifying human milk as a food, a drug, a tissue, and a relationship. The relationship account comes out as primary so as to allow any breastfeeding and milk production to happen and become the object of regulation. What about the food, drug, and tissue categories? The preceding analysis suggests that prioritizing supply cuts in favor of regulating human milk as a food product, while maximizing safety in the sense of securing a trialed, consistent, and germ-free product, counsels in favor of the drug model. As for tissue regulation, it appears to strike a balance between cost and safety, but does not address supply issues.

In the next Part, I neither advocate regulating milk along a food, drug, or tissue paradigm, nor do I champion any particular legal definition of milk. To reflect human milk’s complex identity, a flexible regulation should be preferred to a one-size-fits-all approach. The current market is segmented in peer-to-peer, non-profit, and for-profit purveyors, serving different needs for different consumers who can choose how much control they want to retain. Distinct regulatory regimes could be

354. See FOOD & DRUG ADMIN., REGULATORY CONSIDERATIONS FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS: MINIMAL MANIPULATION AND HOMOLOGOUS USE GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF, 3–4 (2017), <https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecompliance/regulatoryinformation/guidances/cellularandgenetherapy/ucm585403.pdf> [<https://perma.cc/SFD2-WRXG>] (clarifying what counts as a minimally manipulated tissue exempting from IND, clinical trials, and drug-like regulations).

355. See N.Y. COMP. CODES R. & REGS. tit. 10, § 52-9.7(b)(3) (2017). New York, one of the states that defines human milk as a tissue, also allows its distribution in unpasteurized form.

356. See HUMAN MILK BANKING ASS’N OF N. AM., GUIDELINES FOR THE ESTABLISHMENT AND OPERATION OF A DONOR HUMAN MILK BANK 41, 45 (2018) (indicating that donor milk is ordinarily dispensed pasteurized, but can be delivered unpasteurized at a “healthcare provider[s] request”).

357. Anne Hagen Grøvslien & Morten Grønn, *Donor Milk Banking and Breastfeeding in Norway*, 25 J. HUMAN LACTATION 206, 207 (2009).

358. See *supra* notes 173–75 and accompanying text.

articulated based on milk's providers, recipients, and uses. Donor milk's potential safety hazards vary depending on the populations it serves. The risks are at their highest for sick, premature infants and at their lowest for otherwise healthy children and adults. Correspondingly, safety regulation should be at its strictest for milk dispensed to the former and at its most lenient for milk distributed to the latter. The onus of regulation also weighs differently on private citizens versus non-profit organizations versus commercial ventures. To reflect these differences, rules could be tailored to milk's particular production and distribution chain, which often overlaps with the categories of recipients or indications at play. Milk could thus be regulated as a drug as applied to commercial milk manufacturers (and pharmaceutical companies that may someday enter milk markets), as a tissue as applied to non-profit milk banks, and as a food as applied to community and peer-to-peer milk exchanges.

For-profit milk banks and commercial human milk companies have the resources to treat milk as a drug. Given that these organizations primarily sell to hospitals catering to premature and sick infants, the application of the exacting drug standards may be warranted. Neonatologists yearn for milk products that are standardized and precisely labeled in terms of nutritional and other content, which drug regulation would make a requirement.³⁵⁹ Non-profit banks and hospitals could function under the less exacting tissue banking model, which some already follow successfully, most notably in the states that require it.³⁶⁰ Finally, community banks and peer-to-peer milk markets could continue to operate unregulated—or minimally regulated as a food transaction—given that they primarily serve otherwise healthy babies or adults and that participants already mitigate many of the risks involved through screening and pasteurizing.³⁶¹

This is only an outline of what regulation of human milk along the lines of food, drug, and tissue could look like. As the next Part argues, however, the regulatory urgency lies in ensuring that American women have the resources and support they need in order to breastfeed successfully and to generate surplus milk that can be donated or sold. No amount of food, drug, and tissue safety legislation will, in and of itself, further that goal. What may help, however, are social policies that protect the relational dimension of milk via public health, work, and insurance law reforms, which is the focus of the next Part.

359. See Kate Kirby, *There is a Better Way to Supplement Breast Milk in the NICU*, MINI MAG. (Nov. 28, 2017), <http://www.mini-magazine.com/supplement-breastmilk-nicu-hmf-prolacta/> [<https://perma.cc/95MS-C49P>] (claiming that “NICUs nationwide choose Prolacta’s fortifiers because they know they are getting a safe, standardized donor milk product that is processed in a pharmaceutical-grade facility, under the industry’s most stringent quality and safety guidelines, to protect their most fragile patients”).

360. See *supra* note 96 and accompanying text.

361. See *supra* notes 200–195 and accompanying text.

V. WHAT IF HUMAN MILK WERE LIQUID GOLD?

In 2015, Canadian anthropologist Penny van Esterik posed a set of thought-provoking questions, “What would happen if human milk were really treated like liquid gold? What accommodations would be made for it and for its producers?”³⁶² This Part aims to answer her query within the context of American law and society. My premise is that legal reform projects ought to shift from considering human milk as a disembodied substance that can be regulated in abstraction from its producers to focusing on the people who make milk and the children who need it. The media and mainstream public health organizations regularly call for heightened safety regulation along the lines of food, drug, and tissue law.³⁶³ But regulating human milk as a substance decoupled from the conditions of the people who generate it and the families who procure it could prove counterproductive, deterring donors from donating, raising the costs of production, and not doing much to make milk more affordable.

Any regulatory scheme must start from the recognition that milk is a relational substance. For people to lactate, they typically need to breastfeed their own children.³⁶⁴ The key to securing an ample donor milk supply is to ensure that parents can breastfeed successfully and create surplus milk available for donation. It is vital that this surplus milk be made affordable to all children who need it, be it via government subsidization or health insurance reform. My claim, therefore, is that in order to maximize human milk’s availability, affordability, and safety, legal reform should concentrate on 1) providing lactating persons with the most favorable work and life conditions so as to breastfeed and make extra milk and 2) ensuring that donor human milk is affordable to all who need it.

After clarifying what aspects of the law need and do not need to be changed, this Part discusses three areas of promising legal and regulatory interventions: labor law, public health law, and insurance law. My proposals demand greater governmental intervention, but at the same time I seek to cabin this intervention to protect the autonomy of those who sell or donate their milk informally and that of families seeking to obtain it peer-to-peer.

A. Food and Drug Law

The two main existing modes of milk production and distribution—informal milk sharing and non-profit milk banking—already self-regulate effectively. Peer-

362. Penny van Esterik, *Foreword* to ETHNOGRAPHIES OF BREASTFEEDING: CULTURAL CONTEXTS AND CONFRONTATIONS xv, xx (Tanya Cassidy & Abdullahi El Tom eds., 2015).

363. See, e.g., Phoebe Ramsey, *The Breast Milk Market and the Need for Clearer Rules*, O’NEILL INSTITUTE (Oct. 23, 2013), <http://www.oneillinstituteblog.org/breast-milk-market-need-clearer-rules/> [https://perma.cc/B6SE-NXK5] (advocating in favor of regulating the donation and sale of human milk “to protect consumers from the purchase of tainted milk”).

364. See generally Sarah L. Wittig et al., *Induced Lactation: Gaining a Better Understanding*, 33 AM. J. MATERNAL CHILD NURSING 76 (2008) (finding that even women who induce lactation for their adoptive children cannot produce enough milk to exclusively breastfeed them.).

to-peer milk markets fill a vital need for those seeking human milk who cannot procure it from the formal markets, because it is in short supply, not considered medically necessary for them, or unaffordable. The risks associated with obtaining milk peer-to-peer can be mitigated in various ways.³⁶⁵ The absence of any reported case of contamination, while inconclusive in and of itself, suggests that overall these markets function satisfactorily. Conversely, several lawsuits have been initiated against hyper-regulated formula companies for contaminated products, confirming that FDA regulation is not a panacea.³⁶⁶

Commercial human milk manufacturers have criticized non-profit banks for not following some of their protocols (such as ensuring that the milk matches the donor's DNA or using Holder pasteurization).³⁶⁷ Yet, as neonatologist Susan Landers declared to the FDA during a 2010 pediatric committee meeting, "what we are doing [at the non-profit milk banks] is totally uncontrolled and unregulated, and it works beautifully."³⁶⁸ By which she meant that no documented cases of disease transmission from milk provided by a HMBANA-member bank has been reported since the association was founded in 1985. At the same meeting, her colleague Jatinder Bhatia added, "Isn't the question that we have used 1.5 million ounces of [banked] milk . . . [and] there's not a single donor breast milk-transferred infection[?]"³⁶⁹

The stakes are different when it comes to commercial milk banks and manufacturers. Unlike non-profit banks, these organizations do not provide a meaningful form of public service that would justify granting them the autonomy to self-regulate and be insulated from government scrutiny. Their organizational structure is typically that of privately-held companies with a CEO and a Board of Directors rather than HMBANA's "checks and balances, including a medical director and/or an advisory board with representatives of appropriate medical

365. See *supra* note 192–195 and accompanying text.

366. See, e.g., *Burks v. Abbott Labs.*, 917 F. Supp. 2d 902 (D. Minn. 2013) (parents suing because powdered infant formula was contaminated with *C. sak.*); see also *Korte v. Mead Johnson & Co.*, 824 F. Supp. 2d 877 (S.D. Iowa 2010) (parents alleging that human milk-based fortifier was contaminated with *C. sak.*).

367. See, e.g., Elena Taggart Medo, *Response to Sakamoto et al.*, 9 BREASTFEEDING MEDICINE 168, 168 (2014) (contending that her new company, Medolac uses better processing methods than nonprofit milk banks when it comes to eliminating *B. cereus*); Anna Petherick, *Milk Banking in the 21st Century*, SPLASH! MILK SCIENCE UPDATE (June 2015), <http://milkgenomics.org/article/milk-banking-in-the-21st-century/> [<https://perma.cc/YU6V-A2DD>] (pointing out that the CEO of for-profit company International Milk Bank "argues that his for-profit model provides the financial resources needed to screen and process milk in far more appropriate ways than nonprofit milk banks currently manage"); see also Lima et al., *supra* note 159, at 2, 4 (comparing the bacteria levels in 12 samples of raw human milk versus 12 samples of Holder pasteurized milk and 12 samples of shelf-stable human created using retort processing on the model of Medolac and finding that 1 raw milk 3 Holder pasteurized milk samples contained *B. cereus* while there were no detectable bacteria in the in the shelf-stable milk. However, the shelf-stable milk's bioactive components such as lysozyme and SIgA activity, which are important for immune protection, were far scarcer than the other two types of milk).

368. Food and Drug Admin., *supra* note 131 at 259.

369. *Id.* at 323.

fields.”³⁷⁰ They market products at high prices while paying their donors low fees, if they pay them at all. The going rate seems to be \$1 per ounce of expressed milk.³⁷¹ They ostensibly use proprietary methods and technologies,³⁷² making it difficult for medical professionals as well as the public to evaluate their products.³⁷³ In sum, the commercial sector may benefit from external and independent oversight and regulation which could take the form of food, drug, and tissue law in a way that is not equally warranted for informal milk markets and non-profit banks.

In what follows, I concentrate on the type of regulation that would promote human milk as a relationship, that is, legal initiatives that support milk collection and distribution efforts via a combination of work, public health, and insurance laws. These avenues for change are not themselves without flaws, as Meghan Boone has shown, pointing out that lactation laws can be problematic from a feminist perspective because they provide legal benefits and protections on adherence to culturally-defined expectations regarding women, gender, reproduction and motherhood.³⁷⁴

B. Work Law

1. Breastfeeding and Working

Without people breastfeeding and producing extra milk, there would be no donor milk available. Part of the case for donor milk is therefore a case for protecting and supporting breastfeeding. The idea of using employment law to promote breastfeeding is not novel, but, so far, the United States has lagged behind peer countries in realizing its declared commitment to breastfeeding through work law protections. Breastfeeding initiation and duration rates remain lower than in some other countries. According to the CDC, “[a]mong infants born in 2013, 4 out of 5 (81.1%) started to breastfeed, over half (51.8%) were breastfeeding at 6 months, and almost one third (30.7%) were breastfeeding at 12 months.”³⁷⁵ According to

370. TAYLOR & LABBOK, *supra* note 80, at 39.

371. See, e.g., *Find a Milk Bank*, PROLACTA, <http://www.prolacta.com/find-a-milk-bank/> [<https://perma.cc/R4KL-U4DL>] (noting that donors have the option of donating via the Tiny Treasures Milk Bank and “be compensated \$1 for your time and effort”); see also Kimberly Seals Allers, *Inviting African-American Mothers to Sell Their Breast Milk, and Profiting*, N.Y. TIMES: PARENTING (Dec. 3, 2014), <https://parenting.blogs.nytimes.com/2014/12/03/inviting-african-american-mothers-to-sell-their-breast-milk-and-profiting> [<https://perma.cc/BB9T-FS7W>] (critiquing Medolac for its Detroit milk collection program which relied on low-income African American mothers to provide milk for \$1 per ounce).

372. For instance, Ni-Q mentions its “proprietary processing system” on its website without providing additional information. See *About The Company: FAQs*, NI-Q, <https://www.ni-q.com/about-us/> [<https://perma.cc/5K5R-3PSX>].

373. See Lima, *supra* note 144.

374. See generally Meghan Boone, *Lactation Law*, 106 CALIF. L. REV. 1827 (2018) (critiquing lactation laws from a feminist perspective).

375. CTR. FOR DISEASE CONTROL & PREVENTION, BREASTFEEDING REPORT CARD 2 (2016), <https://www.cdc.gov/breastfeeding/pdf/2016breastfeedingreportcard.pdf> [<https://perma.cc/DGR4-4RM4>].

the US Department of Labor, 57% of women participate in the labor force.³⁷⁶ The numbers are even higher for mothers—70% of mothers work, including 62% of women who have given birth in the past 12 months, the most likely to breastfeed.³⁷⁷

The lack of a supportive legislative framework constitutes a structural barrier to workers seeking to combine breastfeeding and wage labor, and, down the line, to a more robust donor human milk supply. U.S. employers are not required to provide any paid leave after a worker gives birth or becomes a parent via adoption or surrogacy. One bright spot is the federal requirement that non-exempt employers³⁷⁸ offer eligible employees³⁷⁹ an appropriate location and job-protected time off from work to express milk for children under the age of one.³⁸⁰ This mandate is a product of the 2010 Patient Protection and Affordable Care Act, which amended the Fair Labor Standards Act (FLSA) by adding the Nursing Mothers Amendment.³⁸¹

In practice, the Nursing Mothers Amendment fails to effectively support breastfeeding workers in a number of ways, which have been the object of extensive critique in the legal scholarship.³⁸² Here, I focus on the fact that the Amendment does not require the lactation break to be paid.³⁸³ Under one interpretation this could be explained by a cost allocation decision: Congress simply did not want

376. Women's Bureau, *Data & Statistics: Women in the Labor Force*, U.S. DEP'T OF LAB., https://www.dol.gov/wb/stats/stats_data.htm [<https://perma.cc/LN36-HS2G>] (last visited Feb. 6, 2019).

377. *Id.*; Women's Bureau, *Data & Statistics: Fertility*, U.S. DEP'T OF LAB., <https://www.dol.gov/wb/stats/Fertility.htm> [<https://perma.cc/G8JP-USW3>] (last visited Feb. 6, 2019).

378. Employers are exempt if they employ less than 50 workers. 29 U.S.C. § 207(r)(3) (2012).

379. The mandate only applies to employees who work for hourly wages; it does not apply to school teachers, administrative employees, agricultural workers, or generally salaried employees. 29 U.S.C. § 213(b) (2012).

380. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 4207, 124 Stat. 119, 577 (2010). Section 4207 of the PPACA states that “[a]n employer shall provide a reasonable break time for an employee to express breast milk for her nursing child for one year after the child’s birth each time such employee has need to express the milk.” 29 U.S.C. § 207(r)(1)(A) (2012).

381. 29 U.S.C. § 207(r) (2012).

382. See, e.g., Marcy Karin & Robin Runge, *Breastfeeding and a New Type of Employment Law*, 63 CATH. U. L. REV. 329, 368–70 (2014) (critiquing the use of employment law for breastfeeding protection); Saru M. Matambanadzo, *The Fourth Trimester*, 48 U. MICH. J.L. REFORM 117, 117 (2014) (arguing that the law should prohibit discrimination on the basis of fourth trimester activities like breastfeeding, caring for newborn infants, or recovery); Nancy Ehrenreich & Jamie Siebrase, *Breastfeeding on a Nickel and a Dime: Why the Affordable Care Act’s Nursing Mothers Amendment Won’t Help Low-Wage Workers*, 20 MICH. J. RACE & L. 65, 65 (2014) (arguing that the Nursing Mothers Amendment falls short of guaranteeing all women the ability to work while breastfeeding); Andrea Freeman, *First Food: Justice, Racial Disparities & Infant Feeding as Food Oppression*, 83 FORDHAM L. REV. 3053, 3072–78 (2015) (denouncing inadequate workplace accommodations, breastfeeding laws and policies and their disproportionate harm on black women and children); Kiersten Jodway, *Pumping 9 to 5: Why the FLSA’s Provisions Provide Illusory Protections for Breastfeeding Moms in the Workplace*, 4 BELMONT L. REV. 217, 234–41 (2017) (proposing legislative reform that would amend the FLSA to advance workplace equality and offer meaningful protections for working mothers).

383. Because the Amendment primarily targets hourly as opposed to salaried workers, it is most likely to apply to low income women for whom the loss of an hour or more of earnings per day would be unbearable.

employers to bear the additional cost (in additional hourly wages) of milk production, apart from the cost of the accommodation mandate. Under another interpretation, Congress assumed, much like the rest of the population, that producing milk is free for women.³⁸⁴ It is not. Breastfeeding can be painful and laborious—it requires skills, emotional and material support, an investment in equipment and accessories, and it has an opportunity cost, including the time not spent working inside or outside the home or doing other activities such as cooking, childcare, or unwinding.³⁸⁵ Breastfeeding and producing milk for donation also have long-term economic costs.³⁸⁶ As sociologists Phyllis Rippeyoung and Mary Noonan have shown, “mothers who breastfeed for six months or longer suffer more severe and more prolonged earnings losses than do mothers who breastfeed for shorter durations or not at all.”³⁸⁷ According to their observational data, this is due to the fact that “long-duration breastfeeders are more likely to be non-employed in the years following childbirth and they work fewer hours when they are employed.”³⁸⁸ One explanation for this is “the difficulty of combining breastfeeding and work,”³⁸⁹ resulting in great part from the lack of sufficient workplace accommodations.³⁹⁰

Though breastfeeding comes at an economic cost to women, they produce tremendous economic as well as non-economic value not only for their children, but also for potential recipients. Breastfeeding also benefits society as a whole, which receives short- and long-term benefits of better health outcomes associated with children who are fed human milk.³⁹¹ The value of breastfeeding is insufficiently acknowledged, like much of women’s embodied and affective labor, which too often remains invisible and unpaid.³⁹² The government, employers, insurers, and

384. In fact, some states encourage or require paid lactation breaks. *See, e.g.*, 802 Ill. Comp. Stat. § 260/10 (in 2018 Illinois amended its law to require employers to provide *paid* breaks to workers who breastfeed or express milk at work until their baby reaches the age of one); *see also* Sarah Andrews, *Lactation Breaks in the Workplace: What Employers Need to Know About the Nursing Mothers Amendment to the FSLA*, 30 HOFSTRA LAB. & EMP. L.J. 121, 142–46 (2012).

385. *See* Julie P. Smith & Robert Forrester, *Who Pays for the Health Benefits of Exclusive Breastfeeding? An Analysis of Maternal Costs*, 29 J. HUM. LACTATION 547, 547 (2013) (reporting based on a survey of Australian new mothers conducted in 2005–2006 that exclusively breastfeeding mothers spent seven hours extra weekly on milk feeding their infants compared to other mothers).

386. Phyllis L.F. Rippeyoung & Mary C. Noonan, *Is Breastfeeding Truly Cost Free? Income Consequences of Breastfeeding for Women*, 77 AM. SOCIOLOGICAL REV. 244, 260 (2012).

387. *Id.* at 244.

388. *Id.* at 260.

389. *Id.*

390. But the authors also recognize that other factors may be at play such as the pressure on women to engage in intensive mothering involving sacrificing “their work-lives and earnings to be (or even to be seen as) ideal mothers” or “class-bias[]” given that long-term breastfeeders tend to be privileged and therefore able to forgo paid labor to parent. *Id.* at 261.

391. *See* Lindsey Murtagh & Anthony D. Moulton, *Working Mothers, Breastfeeding, and the Law*, 101 AM. J. PUB. HEALTH 217, 218 tbl.1 (2011) (listing selected health and economic benefits of breastfeeding).

392. *See* Michael Hardt, *Affective Labor*, 26 BOUNDARY 2 89 (1999) (writing that affective labor “is better understood by beginning from what feminist analyses of ‘women’s work’ have called ‘labor

everyone else free rides on women's unpaid lactation work. Economist Julie Smith has shown that the economic worth of breastfeeding, and more generally of human milk, whether delivered from the breast or as donor milk, is rarely measured.³⁹³ Standard accounting practices include infant formula in Gross Domestic Product (GDP) calculations, which are widely used to measure the national economic activity, but exclude human milk in the calculations.³⁹⁴ Smith estimates the annual value of human milk produced from 2000-2010 in the United States to be at least \$4.47 billion, which reinforces the incongruity of an unpaid lactation break.³⁹⁵ Additionally, feeding babies human milk has considerable environmental benefits, which are rarely taken into account. Formula feeding, by contrast, has a negative impact on the environment given its reliance on dairy farming, industrial processing, storage, packaging, and shipping, among others.³⁹⁶

Beyond the question of whether lactation breaks should be paid, a broader issue is whether women providing milk to milk banks should be compensated.³⁹⁷ Currently, non-profit milk banks do not pay their donors while some for-profit banks do, albeit meagerly.³⁹⁸ This “giftification” of human milk, as sociologist Marisa Pineau calls it,³⁹⁹ is a relatively recent phenomenon. In the early days of milk banking, it was thought that women should legitimately profit from their reproductive labor by selling their milk. Historian Janet Golden writes that in the 1910s, the Boston Floating Hospital's “crew of milk sellers . . . earned approximately \$4.20 per week if they provided the one quart daily that was typical of women selling milk—a wage approximately half that received by live-in wet nurses but, nonetheless, a significant contribution to the family economy.”⁴⁰⁰ Some women were able to make an enviable income, and in one case, sufficient to purchase a home.⁴⁰¹ In 1943, the Committee on Mothers' Milk of the American Academy of

in the bodily mode.’ Caring labor is certainly entirely immersed in the corporeal, the somatic, but the affects it produces are nonetheless immaterial.”)

393. See Julie Smith, *Markets, Breastfeeding and Trade in Mothers' Milk*, 10 INT'L BREASTFEEDING J. 1, 3 (2015).

394. See Julie Smith, *Markets in Mothers' Milk: Virtue or Vice, Promise or Problem?*, in MAKING MILK: THE PAST, PRESENT, AND FUTURE OF OUR PRIMARY FOOD 117, 118–19 (Mathilde Cohen & Yoriko Otomo eds., 2017).

395. *Id.* at 133.

396. See generally JAI PRAKASH DADHICH ET AL., REPORT ON CARBON FOOTPRINTS DUE TO MILK FORMULA: A STUDY FROM SELECTED COUNTRIES OF THE ASIA-PACIFIC REGION (Arun Gupta ed., 2015), <http://ibfan.org/docs/Carbon-Footprints-Due-to-Milk-Formula.pdf> [<https://perma.cc/B4GJ-9QUW>] (report on the carbon footprint of infant formula in the Asia-Pacific region).

397. See Waldeck, *supra* note 25, at 362–63, 371–76 (arguing in favor of compensating milk donors).

398. See *supra* note 371 and accompanying text.

399. Marisa Gerstein Pineau, *Liquid Gold: Breast Milk Banking in the United States* (2012) (unpublished Ph.D. dissertation, UCLA), <https://escholarship.org/content/qt3r61618s/qt3r61618s.pdf> [<https://perma.cc/TH2B-9NCR>].

400. Janet L. Golden, *A SOCIAL HISTORY OF WET NURSING IN AMERICA: FROM BREAST TO BOTTLE* 194–95 (Charles Rosenberg ed., 1996).

401. *Id.* at 196.

Pediatrics stipulated in their standards of operation for milk bureaus that “[r]egular milk donors should receive compensation sufficient to insure good standards of living and relief from financial worry.”⁴⁰² In 1946, a milk bank director in New York could thus write, “[o]ne donor came to us originally in June 1939 and remained until June 1940, earning the sum of \$948.”⁴⁰³ Based on inflation, her earnings would amount to \$16,348.40 in today’s dollars.

Why are present-day milk providers no longer compensated? According to Marisa Pineau, “[b]eginning in the 1970s, milk banks in America began operating on a donor-based system in which women give their breast milk to the banks without remuneration.”⁴⁰⁴ The giftification of milk makes economic sense given banks’ high operating costs. Should banks internalize the costs of making milk by compensating providers and charging a higher price to recipients, their ability to survive and to serve a diverse clientele may be compromised. As for milk providers, it is possible that women’s massive entry into the workforce outside the home since World War II decreased the need for milk income.⁴⁰⁵

Yet, the giftification of milk is tied to its gendered, classed, and raced construction. These days milk banks can obtain milk for free in part because they mainly rely on middle-class white female donors who have been acculturated in “intensive motherhood,”⁴⁰⁶ a conception of appropriate mothering in which breastfeeding, nurturing, and unselfishness are considered a central component of a mother’s devotion to her infant.⁴⁰⁷ According to Marisa Pineau, today’s milk donors tend to be white, middle-class, and college-educated—a group that has

the cultural and economic resources to both define and engage in “good mothering”, and to breastfeed and pump milk, which is particularly time consuming. Breastfeeding has therefore become a potent symbol of both racial and class inequality, and these inequalities in turn influence breast milk banking.⁴⁰⁸

A 2007 survey conducted at the Mother’s Milk Bank at Austin, Texas, which included interviews with 87 donors, found that 91% were married, 87% white,

402. American Academy of Pediatrics, *supra* note 109, at 113.

403. Helen Leighty, *Operating a Mothers’ Milk Bureau*, 38 PUB. HEALTH NURSING 218, 218 (1946).

404. See Pineau, *supra* note 399, at 18.

405. See Amanda Weinstein, *When More Women Join the Workforce, Wages Rise*, HARV. BUS. REV. (Jan. 31, 2018), <https://hbr.org/2018/01/when-more-women-join-the-workforce-wages-rise-including-for-men> [<https://perma.cc/75XP-6K6H>] (noting that women’s participation in the labor market has nearly doubled from 1950 to 2016).

406. See SHARON HAYS, *THE CULTURAL CONTRADICTIONS OF MOTHERHOOD* 4 (1996) (identifying the ideology of intensive motherhood as the idea that “correct child rearing requires not only large quantities of money but also professional-level skills and copious amounts of physical, moral, mental, and emotional energy on the part of the individual mother”).

407. See generally LINDA M. BLUM, *AT THE BREAST: IDEOLOGIES OF BREASTFEEDING AND MOTHERHOOD IN THE CONTEMPORARY UNITED STATES* (1999) (explaining the resurgence of breastfeeding as a class-specific, culturally based phenomenon associated with the ideology of intensive motherhood).

408. See Pineau, *supra* note 399, at 170.

8% Asian, and 5% “other”; 83% had at least a college degree; and 40% reported a household income superior to \$100,000.⁴⁰⁹ Marisa Pineau’s own fieldwork, conducted at the San Jose Mothers’ Milk Bank in the early 2010s, revealed a similar pattern. Of the 19 donors she interviewed, 15 were married, 16 “were middle to upper income, while three were low income and received WIC benefits,” 16 had at least a college degree, 12 were white, 1 black, 2 Latina, 1 Asian, and 3 “mixed or other.”⁴¹⁰ This pattern is replicated in the informal market. Aunchalee Palmquist and Kirsten Doehler have found milk sharing to be prevalent among middle-class, college educated white women.⁴¹¹

2. *Easy Fixes and Structural Reform*

Given the paucity of labor protections for American mothers, breastfeeders, and milk donors, legal reform could make a meaningful difference. For instance, studies have shown an association between breastfeeding-friendly legislations across U.S. states, including laws permitting breastfeeding breaks at work, and breastfeeding initiation and duration.⁴¹² Workers with both adequate break time and a private space to express milk are 2.3 times more likely to exclusively breastfeed at 6 months after giving birth, and also most likely to donate their extra milk to banks or other outlets.⁴¹³ If human milk were treated like liquid gold, women would benefit from a number of legal protections enabling them to breastfeed their own children as well as to produce surplus milk for others. The financial and other burdens of protecting breastfeeding and milk donation should not exclusively fall on the shoulders of employers, as is too often the case in the United States, where accommodating and financially supporting breastfeeding and milk donation is treated as an employer’s responsibility rather than a social choice. For that to happen, a combination of easy fixes and structural reform is called for, including heightened government intervention in the form of regulation and subsidies.

First, I recommend amending the Nursing Mothers Amendment⁴¹⁴ to cover all workers, rather than only non-exempt employees under section 7 of the FLSA. In addition, I would limit employers’ discretion as to the amount of time available for pumping. The Department of Health and Human Services’

409. See Richard Osbaldiston & Leigh A. Mingle, *Characterization of Human Milk Donors*, 23 J. HUM. LACTATION 350, 351–52 (2007).

410. See Pineau, *supra* note 399, at 33–34.

411. Palmquist & Doehler, *supra* note 162 and accompanying text.

412. See, e.g., Michael D. Kogan et al., *Multivariate Analysis of State Variation in Breastfeeding Rates in the United States*, 98 AM. J. PUB. HEALTH 1872, 1877 (2008) (showing based on a nationally representative study of children aged six to seventy-one months that breastfeeding initiation rates were highest in states “that had enacted multiple pieces of legislation supportive of breastfeeding and lowest among states with no such legislation”); see also Murtagh & Moulton, *supra* note 391, at 217 (claiming that state laws generally supportive of breastfeeding correlate with higher rates of breastfeeding).

413. See Kathy B. Kozhimannil et al., *Access to Workplace Accommodations to Support Breastfeeding After Passage of the Affordable Care Act*, 26 WOMEN’S HEALTH ISSUES 6, 8 (2016).

414. 29 U.S.C. § 207(t).

recommendation of a fifteen-minute break every three hours, not including travel time to the lactation room, would give pause to anyone with some breastfeeding and pumping experience. Fifteen minutes is far too short of a break for most people, especially considering the time it takes to set up a pump and to dismantle and clean it after use.⁴¹⁵ More detailed statutory guidance on the minimum requirements for lactation rooms would also be welcome so as to rule out rooms partitioned with curtains in lieu of a separation from coworkers. Federal law should also align with the states that provide more advanced protections to employees who nurse, including a longer period during which employers must offer lactation breaks, the possibility of breastfeeding one's child at work (on-site breastfeeding), and encouraging or mandating employers to pay lactation breaks.⁴¹⁶

Second, lactation should be protected via anti-discrimination guarantees. The Pregnancy Discrimination Act (PDA) forbids discrimination on the basis of pregnancy or pregnancy-related medical conditions, but does not explicitly include protections for breastfeeding and lactation.⁴¹⁷ As Marcy Karin and Robin Runge point out, an

employee may only file a complaint with the Department if the employer denies or fails to provide the unpaid break time or location, and her potential damages are significantly limited. Consequently, the same group of women who are meant to benefit from the statute may be discriminated against because of their status as nursing mothers, without effective recourse.⁴¹⁸

Since lactation is typically a physiological result of pregnancy and childbirth, it should be covered by the PDA⁴¹⁹ as the Equal Employment Opportunity Commission⁴²⁰ and a number of federal courts have recognized.⁴²¹ Yet, as Pamela

415. See Genevieve E. Becker, Hazel A. Smith & Fionnuala Cooney, *Methods of Milk Expression for Lactating Women*, 9 Cochrane Database Syst. Rev. 2016 Art. No.: CD006170, at 20–21 (reviewing studies on the time taken to express milk, noting that the time used for pump cleaning and assembly was not reported and that a study of women using electric double pumps found a range of five to twenty-two minutes per session).

416. Andrews, *supra* note 384, at 142–46.

417. See 42 U.S.C. § 2000e(k) (2012). Breastfeeding, the courts have held, is not a “pregnancy-related medical condition” under the PDA, and breastfeeding discrimination is not illegal under Title VII because lactating women are not similarly situated to men. See, e.g., *Jacobson v. Regent Assisted Living, Inc.*, No. CV-98-564-ST, 1999 WL 373790, at *11, *15 (D. Or. Apr. 9, 1999); *Barrash v. Bowen*, 846 F. 2d 927, 931–32 (4th Cir. 1988); *Martinez v. NBC*, 49 F. Supp. 2d 305 (S.D.N.Y. 1999).

418. See Karin & Runge, *supra* note 382, at 368.

419. See Jodway, *supra* note 382, at 228–29.

420. See OFFICE OF LEGAL COUNSEL, EEOC ENFORCEMENT GUIDANCE ON PREGNANCY DISCRIMINATION AND RELATED ISSUES 15–17 (2015), https://www.eeoc.gov/laws/guidance/upload/pregnancy_guidance.pdf [<https://perma.cc/F5RN-7VZU>] (considering lactation to be a pregnancy-related condition).

421. See *EEOC v. Houston Funding II, Ltd.*, 717 F.3d 425, 428 (5th Cir. 2013) (holding that “lactation is a related medical condition of pregnancy for purposes of the PDA,” in the context of a woman seeking to express milk at work); *Mayer v. Prof'l Ambulance, LLC*, 211 F. Supp. 3d 408, 417 (D.R.I. 2016) (finding that “lactation is a medical condition related to pregnancy, and therefore covered under Title VII and RICRA,” in the context of a woman seeking to express milk at work); *Grewcock*

Laufer-Ukeles and Arianne Renan Barzilay have argued, current legal protections separate the nutritional aspects of milk from the other benefits of breastfeeding and thus the focus on accommodating milk expression in the workplace as opposed to actual breastfeeding is inadequate.⁴²² Breastfeeding should not be treated merely as a “medical condition,” but also as a relationship between workers and their babies, entitling them to direct breastfeeding breaks during the workday and/or at work.⁴²³

Third, all new parents who are the primary caregiver and/or breastfeeder in their households, including freelancers, contractors, students, or unemployed individuals, should be guaranteed paid parental and breastfeeding leave regardless

v. Yale New Haven Health Servs. Corp., 293 F. Supp. 3d 272, 274 (D. Conn. 2017) (holding that “a nursing mother’s ability to engage in nursing-related activity like expressing breast milk is subject to protection from discrimination under both Title VII and CFEPA”); *Allen-Brown v. D.C.*, 174 F. Supp. 3d 463, 478 (D.D.C. 2016) and *Hicks v. City of Tuscaloosa*, 870 F.3d 1253, 1262 (11th Cir. 2017) (both holding that breastfeeding can be considered a “condition related to childbirth,” making it covered under the Pregnancy Discrimination Act, which means that employers must accommodate breastfeeding workers by allowing them and cannot dismiss them because they breastfeed).

422. See Laufer-Ukeles & Renan Barzilay, *supra* note 25, at 304–05.

423. There is movement in this direction, both in federal and state law. For federal case law, see *EEOC v. Houston Funding II, Ltd.*, 717 F.3d 425, 428 (5th Cir. 2013) and *id.* at 430–31 (Jones, J., concurring) (“[I]f providing a plaintiff with special accommodation to pump breast milk at work were required, one wonders whether a plaintiff could be denied bringing her baby to the office to breastfeed during the workday.”). *But see* *Falk v. City of Glendale*, No. 12-CV-00925-JLK, 2012 WL 2390556, at *3 (D. Colo. June 25, 2012) (“The language of the PDA focuses solely on the conditions experienced by the mother. While lactation is not per se excluded, Title VII does not extend to breastfeeding as a child care concern. Since the complaint asserts that Plaintiff’s desire to ‘continue to breast feed her infant daughter’ formed the basis for the alleged discrimination, her protected status is not established.”) (citations omitted); *Id.* at *4 n.7 (“A plaintiff could potentially succeed on a claim if she alleged and was able to prove that lactation was a medical condition related to pregnancy, and that this condition, and not a desire to breastfeed, was the reason for the discriminatory action(s) that she suffered.”); *Frederick v. New Hampshire*, No. 14-CV-403-SM 2016 WL 4382692 (D.N.H. Aug. 16, 2016) (suggesting that breastfeeding should be narrowly construed under PDA: employers must allow workers to *express* milk at work, but need not allow them to breastfeed their babies at work and/or during work hours). A few state statutes and regulations explicitly protect “breastfeeding” as part of their workplace discrimination (similar to the PDA) or accommodations laws (similar to the break time for nursing mothers provision in the Fair Labor Standards Act). See CAL. CODE REGS. tit. 2, § 11035(d) (2018); CONN. GEN. STAT. ANN. § 31-40w(a) (West 2018); HAW. REV. STAT. ANN. § 378-2(a)(7) (West 2018); 775 ILL. COMP. STAT. ANN. 5/2-102(J) (West 2018); NEB. REV. STAT. ANN. § 48-1102(11) (West 2018); N.J. STAT. ANN. § 10:5-12 (West 2018); OKLA. STAT. ANN. tit. 40 § 435(A) (West 2018); OR. ADMIN. R. 839-020-0051(2)(b) (2018); 23 R.I. GEN. LAWS ANN. § 23-13.2-1(a) (West 2018); UTAH CODE ANN. § 34A-5-106(1)(g) (West 2018); W. VA. CODE R. § 77-10-2.4 (2018). There is usually little or no guidance, however, as to what that term means in practice in the sense that nothing explicitly indicates whether breastfeeding, as opposed to lactation or expressing milk, is protected, even though the term is used specifically. The District of Columbia and Hawaii, however, are very explicit in their protection of direct breastfeeding. See D.C. Mun. Regs. tit. 4, § 518 (2018) (prohibiting discrimination and requiring accommodations for breastfeeding or expressing milk) and D.C. Mun. Regs. tit. 4, § 599 (2018) (defining “breastfeed” as “to provide breast milk from a mother’s breast or to express breast milk into a container or bottle.”); HAW. REV. STAT. ANN. § 378-2(a) (West 2018) (“It shall be an unlawful discriminatory practice: . . . (7) For any employer or labor organization to refuse to hire or employ, bar or discharge from employment, withhold pay from, demote, or penalize a lactating employee because the employee breastfeeds or expresses milk at the workplace. For purposes of this paragraph, the term ‘breastfeeds’ means the feeding of a child directly from the breast.”).

of their employment status, which could be both privately and publicly financed.⁴²⁴ In the United States, quantitative research shows a positive association between the length of maternity leave and breastfeeding rates.⁴²⁵ Once they return to work, in addition to paid lactation breaks, new parents should also have the option to take breastfeeding leaves to visit their babies during the day for nursing.⁴²⁶ Public health expert Jody Heymann and her colleagues showed that the rate of exclusive breastfeeding of infants younger than six months of age was 8.86 percentage points higher in countries that guaranteed paid breastfeeding breaks at work compared to those that did not.⁴²⁷ Neither benefit—lactation breaks and breastfeeding leaves—should be capped at twelve months after the birth of a baby. They should not be conditioned upon giving birth so that non-gestational parents who breastfeed, such as intended or adoptive parents, non-gestational lesbian mothers, transdads, or others, can receive them.⁴²⁸ Instead, they should be available to all parents of babies younger than two, the number of years of breastfeeding recommended by the World Health Organization.⁴²⁹ It is particularly important to support long-term breastfeeding so as to increase the supply of donor milk. Premature infants benefit most from milk produced in the earliest stages of lactation, but older babies thrive on milk produced at any stage of lactation.⁴³⁰ Breastfeeders are also more likely to donate at later stages in their lactation because by then their own children consume less milk, thus potentially creating a larger surplus.

Fourth, access to high quality and affordable childcare should be expanded. Among other barriers to breastfeeding is our nation's poor record when it comes to early childhood education options for low and middle-income families. It is often

424. See Laufer-Ukeles & Renan Barzilay, *supra* note 25, at 288, 322 (2018) (pointing out the current inequities of the current system whereby white women tend to benefit most from the existing leave system be it because they can afford to take unpaid leaves or because they tend to occupy positions more likely to come with paid leaves).

425. Sylvia Guendelman et al., *Juggling Work and Breastfeeding: Effects of Maternity Leave and Occupational Characteristics*, 123 PEDIATRICS e38–e46 (2009).

426. See Grovslien & Grønn, *supra* note 357, at 206 (reporting that Norway offers working mothers two hours off per day to nurse either at the office or at home); *Norway - The WHO Code and Breastfeeding: An International Comparative Overview*, AUSTL. GOV'T DEP'T OF HEALTH (May 3, 2012), <http://www.health.gov.au/internet/publications/publishing.nsf/Content/int-comp-whocode-bf-init~int-comp-whocode-bf-init-ico~int-comp-whocode-bf-init-ico-norway> [<https://perma.cc/E2BC-BFL3>].

427. Jody Heymann et al., *Breastfeeding Policy: A Globally Comparative Analysis*, 91 BULL. WORLD HEALTH ORGAN 398, 398 (2013).

428. California is a precursor here. See *Gonzales v. Marriott Int'l, Inc.*, 142 F. Supp. 3d 961 (C.D. Cal. 2015) (finding that neither the PDA nor California discrimination statutes were limited to claims involving the expression of milk for an employee's own children, so a woman who had been a surrogate and wished to continue expressing milk in order to donate it could state a claim for relief).

429. See Exclusive Breastfeeding, WORLD HEALTH ORG., http://www.who.int/nutrition/topics/exclusive_breastfeeding/en/ [<https://perma.cc/ZY9A-WJQB>] (last visited Feb. 7, 2019).

430. See generally Maryanne T. Perrin et al., *A Longitudinal Study of Human Milk Composition in the Second Year Postpartum: Implications for Human Milk Banking*, 13 MATERNAL & CHILD NUTRITION 1, 8 (2016) (examining the composition of human milk during the second year of lactation and finding stable or increasing concentrations of macronutrients and bioactive factors).

extremely hard for these families to find quality child care facilities at or near their workplace and the costs are often prohibitive.⁴³¹ Access to such facilities would allow a greater number of parents to breastfeed their children while working as they could visit their daycare centers during the workday.⁴³² Parents would also have more time to express milk thanks to shorter commutes and less pressure to work longer hours to pay for childcare.

Fifth, workers expressing their milk and/or donating it to milk banks should have the option of being compensated. If donors were compensated a living wage based on the actual time and expenses incurred (in terms of supplies and transportation in particular), producing milk could be recognized as a legitimate form of paid work. Several compensation schemes could be contemplated, be they based on the time spent pumping (such as the minimum living wage), the quantity of milk produced (price per ounce), or certain characteristics of the milk (for instance preterm milk is more valuable than term milk because it is specifically adapted to premature babies).⁴³³ Donors who have the time and financial ability to donate gratis would be able to carry on, but the new policy may encourage new groups of donors to jump on the bandwagon.⁴³⁴ More people across the demographics would have the opportunity to donate and benefit from the breastfeeding support and counseling that often accompany donations as well as the social capital earned by being seen as a do-gooder helping babies.

A major impediment to these various reform proposals is their cost. There is no denying that the proposals would require substantial public and private investments. However, on the employer side, there is evidence that savings can be made by setting up more robust breastfeeding support policies.⁴³⁵ Several authors

431. See Tonse N.K. Raju, *Continued Barriers for Breast-Feeding in Public and the Workplace*, 148 J. PEDIATRICS 677, 677 (2006) (listing the “inability to find a day care facility at or near the workplace; the high cost of day care and long waiting periods” as barriers to breastfeeding for working women); see also Laufer-Ukeles & Renan Barzilay, *supra* note 25, at 335 (discussing on-site daycare centers).

432. See Raju, *supra* note 431.

433. See Waldeck, *supra* note 25, at 397 (suggesting that earnings from the sale of milk should be tax free as in Denmark and that donors be able to deduct milk expression related expenses such as pumps, pumping supplies, and the extra nutrition they need); see also Bridget Crawford, *Our Bodies, Our (Tax) Selves*, 31 VA. TAX REV. 695, 719–23 (2012) (discussing whether taxpayers can deduct as charitable contribution the fair market value of their donated milk).

434. See Mary Rose Tully, *Currents in Human Milk Banking: Human Milk Banking in Sweden and Denmark*, 7 J. HUM. LACTATION 145, 145 (1991) (noting that milk bank directors in Sweden and Denmark, where women are paid for milk, report that compensation encourages women to contribute).

435. See U.S. DEP’T HEALTH & HUMAN SERVS., THE BUSINESS CASE FOR BREASTFEEDING, <https://www.womenshealth.gov/breastfeeding/breastfeeding-home-work-and-public/breastfeeding-and-going-back-work/business-case> [<https://perma.cc/N2FS-MABG>] (a program designed to educate employers about the value of supporting breastfeeding employees in the workplace); see also Lara M. Gardner, *A Step Toward True Equality in the Workplace: Requiring Employer Accommodation for Breastfeeding Women*, 17 WIS. WOMEN’S L.J. 259, 266–67, 271 (2002) (quoting a study finding that “[o]ne day absences were three times more common in the mothers of formula-fed infants”); Brit Mohler, Note, *Is the Breast Best for Business?: The Implications of the Breastfeeding Promotion Act*, 2 WM. & MARY BUS. L. REV. 155, 163 (2011) (noting that “notable employer benefits include fewer

claim that accommodating breastfeeding saves employers money by reducing employee absenteeism and the medical costs of employee mothers and their children.⁴³⁶ Another cost-saving argument is the inability of many new parents to return to workforce without the opportunity to express milk at work.⁴³⁷ Losing these productive employees and expending the costs to recruit, hire, and train new employees are themselves costly. On the banking side, offering to pay donors would certainly increase operating costs, especially in the case of commercial banks that pay more than the going \$1 per ounce rate. However, if the additional reforms suggested below are implemented, particularly the proposals pertaining to health insurance markets, these costs could be passed on to insurers as donor milk would become covered as a standard of care.

C. Public Health Law

Breastfeeding and donor human milk protection should not be confined to the workplace—many breastfeeders are unemployed or stay-at-home parents and nonetheless need legal protections to breastfeed successfully. The burden of supporting breastfeeding and milk donation should be considered a collective responsibility via public health law regulations, understood broadly to include the promotion of milk banking, the provision of physical accommodations for lactating people in public spaces, and the creation of public or subsidized milk banks alongside community-based milk sharing programs.

1. A National Strategy for Donor Milk

Developing a national strategy for human milk collection and distribution would be useful to coordinate the variety of existing initiatives and to support the creation of innovative milk sharing systems.

The current donor milk landscape in the United States is somewhat haphazard. For-profit and non-profit milk banks abide by different standards in terms of methods of collection, processing, testing, packaging, labeling, and distribution. While these variations are not problematic per se, some measure of standardization of human milk for premature infants' consumption could help broaden its distribution and facilitate its coverage by insurance companies. A number of neonatologists and other medical professionals have confided that in order to feel comfortable prescribing donor milk to premature or critically ill infants, they need

missed work days, reduced health care costs, fewer instances of employee turnover . . . increased employee loyalty?").

436. See Rona Cohen et al., *Comparison of Maternal Absenteeism and Infant Illness Rates Among Breast-feeding and Formula-feeding Women in Two Corporations*, 10 AM. J. HEALTH PROMOTION 148, 153 (1995) (“[W]omen who breast-feed their babies are less likely to be absent from work because of baby-related illnesses and less likely to have long absences when they do miss work . . .”); see also Melissa Bartick & Arnold Reinhold, *The Burden of Suboptimal Breastfeeding in the United States: A Pediatric Cost Analysis*, 125 AM. ACAD. PEDIATRICS e1048, e1052 (2010).

437. See U.S. Dep’t Health & Human Servs., *supra* note 435.

to trust that any given batch has been treated in a similar, or at least, predictable manner.⁴³⁸ Such standards includes consistency in defining preterm milk—specifically indicated for premature babies,⁴³⁹ as opposed to term milk, which is appropriate for babies born full term—and also in data collection, traceability, donor screening methods, milk processing (in particular the method of pasteurization used), bacteriological⁴⁴⁰ and nutritional analysis, bottling, labeling, storage, and shipping. Due to the variability across donors and between various stages of lactation in macronutrient content,⁴⁴¹ nutrition labels stating caloric value, fat, and protein content would be particularly valuable to medical professionals.⁴⁴² Such calibration would have the added benefit of facilitating insurance coverage as it would bring preterm donor milk closer to a drug or a biologic product.

A national donor milk strategy could also encourage the continuation and the development of innovative milk collection and distribution systems. As mentioned before, there are different indications and recipient categories for human milk,⁴⁴³ calling for diverse models of milk movements. First, in-hospital milk banks, which used to dominate the field when milk banks were first established, but have nearly disappeared, should be revived. In 1945, about half of the twenty milk banks in existence in the United States and Canada were “located in hospitals or other public health agencies.”⁴⁴⁴ Hospital banks help keep the costs down given that the required facilities, staff, and potential donors are already present in a neonatology department. Typically, the only major piece of equipment purchased is a pasteurizer⁴⁴⁵ and the only additional expense is the cost of sending donors’ blood and milk samples for testing. There are no transportation costs as both donors and recipients are on premises and, for the same reason, there is little need for storage. Bottles can be reused as they do not leave the hospital.

438. See Margaret G.K. Parker et al., *Pasteurized Human Donor Milk Use among US Level 3 Neonatal Intensive Care Units*, 29 J. HUM. LACTATION 381 (2013) (finding that lack of knowledge by medical directors of accessibility, safety, and parental receptiveness may be barriers to the use of donor milk in NICUs).

439. See TAYLOR & LABBOK, *supra* note 80, at 40 (noting that there is currently no commonly accepted definition of pre-term milk).

440. Standards could be set across the industry to define the maximum bacteria count allowed on the model of dairy production.

441. See Francis B. Mimouni et al., *Preterm Human Milk Macronutrient and Energy Composition: A Systematic Review and Meta-Analysis*, 44 CLINICAL PERINATOLOGY 165, 168 (2017) (reviewing the macronutrient and energy composition of preterm human milk).

442. This explains why in 2016, ICCBBA, a nongovernmental organization associated with the World Health Organization created an ISBT 128 standard for the labeling of human milk products on the model of a similar specification for labeling blood products developed in 1995. See ISBT 128 Standard Labeling of Human Milk Products § 1.2 (ICCBBA Feb. 2016). The standard is purely voluntary but has already been adopted by HMBANA and the European Milk Banking Association (EMBA); *id.* at § 1.6.

443. See *infra* Part I.

444. See Leighty, *supra* note 403, at 222.

445. Arguably, pasteurization is not even necessary considering that the milk is usually collected in the hospital under medical supervision from screened donors.

Second, peer-to-peer milk sharing, which meets a market demand, should also be supported. A few recent community-based initiatives such as the DC Breastfeeding Center Milk Connection,⁴⁴⁶ Get Pumped!,⁴⁴⁷ and the Mothers' Milk Alliance⁴⁴⁸ are worth mentioning. These ventures share similar features in that they coordinate milk sharing by centralizing donors' screening and serological testing, providing information on safe milk expression and storage, and distributing the milk to local families in need.

The DC Breastfeeding Center Milk Connection is a non-profit organization that employs lactation consultants who follow HMBANA guidelines to review prospective donors' health histories and order lab tests. The Center collects and stores donated milk, "but in order to reduce the processing fees for recipients, . . . [it] do[es] not thaw, pool, pasteurize, and test"⁴⁴⁹ milk. Instead, lactation consultants "provide all families with instructions in easy, evidence-based flash-heat pasteurization at home."⁴⁵⁰ The major advantage, on the donor side, is that there is no minimal donation amount—non-profit and for-profit banks typically require at least 150 ounces of milk from each donor, which can be a deterrent for those worried that they will lack the time or supply to meet the threshold.⁴⁵¹ The drawback is that donors are expected to pay for the cost of their own lab work when they don't have full coverage health insurance. On the recipient's side, the primary benefit is the availability of screened milk at a reduced price. The only fee is a suggested donation of \$1 per ounce, which is about 4.5 times cheaper than standard banked HMBANA milk.

This model should be extended nationwide as it would help resolve two problems with donor milk: its high cost when obtained from milk banks and its questionable safety when procured peer-to-peer. Another path to consider would be for non-profit and community milk banks to become public organizations or to receive public subsidies. In 2014, the District of Columbia required its Department of Health to establish a "public breastmilk bank and lactation support center," which encouraged initiatives such as the DC Breastfeeding Center Milk Connection.⁴⁵² Unfortunately the provision was repealed due to a lack of funding

446. THE BREASTFEEDING CTR. FOR GREATER WASH., Breastfeeding Center Milk Connection, breastfeedingcenter.org/breastfeeding-center-milk-connection/ [https://perma.cc/S24B-FF5V] (last visited Feb. 7, 2019).

447. GET PUMPED!, getpumpedonline.org [https://perma.cc/S4VC-A8HW] (last visited Feb. 7, 2019).

448. WELCOME TO MOTHER'S MILK ALLIANCE OF MADISON, WISCONSIN!, mothersmilkalliance.org [https://perma.cc/CM6P-YXFM] (last visited Feb. 7, 2019).

449. BREASTFEEDING CENTER MILK CONNECTION, <http://breastfeedingcenter.org/breastfeeding-center-milk-connection/> [https://perma.cc/UND9-GK3K] (last visited Feb. 7, 2019).

450. *Id.*

451. *See, e.g., Donate Milk*, NEW YORK MILK BANK, <http://www.nymilkbank.org/donate-milk> [https://perma.cc/H92T-S7EY] (last visited Feb. 7, 2019) (listing among the requirements for prospective donors the ability "to donate at least 150 ounces of milk").

452. D.C. CODE § 7-881 (2017).

in 2018.⁴⁵³ Other states should experiment with public or publicly subsidized milk banks, especially considering that opening a new bank seems to have a virtuous effect, increasing breastfeeding rates by raising awareness about the benefits of human milk, which in turn widens the pool of potential donors.⁴⁵⁴

Going further, the United States could venture other innovative milk sharing systems, such as the Dutch milk sharing program. In 2005, a milk sharing database was created in the Netherlands to connect families with insufficient milk for their babies with families with an ample supply.⁴⁵⁵ Donors are rigorously screened before they are accepted and, where possible, families living near one another are matched. The overhead costs for the Dutch program are even lower than in the DC system. No milk collection, storage, or distribution are undertaken at all by the organization, which limits its role to that of an intermediary for donors and recipients. A 2.0 version of the Dutch initiative could take the form of a milk sharing app connecting pre-screened donors to recipients based on multiple criteria, including location, availability for direct breastfeeding, diet, and lactation stage. Another possibility would be for the government and the health care system to support the comeback of wetnurses, which has been reported among middle and upper class families.⁴⁵⁶ Some breastfeeders and some families in need of milk may welcome this resurgence as a way, for the former, to engage in waged labor (assuming that their pay is profitable and they are allowed to nurse their own children), and for the latter, to take full advantage of milk's adaptability to nurslings' needs when fed directly on the breast.

2. *Accommodating Breastfeeders and Pumpers*

The law should protect breastfeeding and expressing milk in all physical spaces, not just in the workplace. Lactating people only spend a fraction of their lives at work and many do not work outside the home, thus accommodating them should be a state's as well as an employer's responsibility. In order to maintain a full milk supply, breastfeeders need to nurse or express milk at regular intervals (at the same times that the baby would normally feed), which can be as often as every two hours for a newborn and every three to four hours until the end of the first year.⁴⁵⁷ Milk expression is not an activity that can be delayed or spaced out too long or else

453. The entire DC Breastmilk Bank and Lactation Support Act was repealed by the Fiscal Year 2018 Budget Support Act of 2017. The reason for this is that the original act was passed "subject to appropriation" and remained unfunded for two years. Rules for Org. and Procedure for the Council of the D.C., § 736.

454. See generally Alessandra DeMarchis et al., *Establishing an Integrated Human Milk Banking Approach to Strengthen Newborn Care*, 37 J. PERINATOLOGY 469 (2017) (arguing that milk banks and donor milk programs support breastfeeding by increasing the awareness of families and NICU staff of the value of breastfeeding).

455. See Thorley, *supra* note 245, at 8.

456. See Cohen, *supra* note 16, at 505–06.

457. See, e.g., JUDITH LAUWERS & ANNA SWISHER, COUNSELING THE NURSING MOTHER: A LACTATION CONSULTANT'S GUIDE 449 (4th ed. 2005).

women will see their supply diminish and run the risk of suffering a variety of uncomfortable symptoms and ailments, including breast swelling, pain, engorgement, and infections.⁴⁵⁸ For lactating people to be free and equal citizens—that is to be able to travel freely outside of the home—and to participate in the economic, social, political, and cultural life on equal terms to others, they must be able to not only breastfeed their babies, but also to express their milk wherever they may be physically. The current legal framework, however, helps constitute lactation as a disability in the socio-political sense.⁴⁵⁹ The lack of physical accommodations of breastfeeding and pumping, and the narrowing of the protections in the employment context, are part of the surrounding social context that turns lactation into a disability.⁴⁶⁰ Our built environment, which makes breastfeeding and pumping out of place but for in a limited range of spaces coded as private such as the home or designated lactation rooms, is an “instrument of exclusion” that can be “understood as a discriminatory force.”⁴⁶¹

Breastfeeding in public has grown in acceptance in the past years and a majority of states have made it a legally-protected right.⁴⁶² Federal and state lawmakers should consider extending breastfeeding protection legislation to milk expression. If women produce liquid gold, why should they do so secretively and uncomfortably? Granting legal protection to public milk expression may help turn it into a more socially acceptable activity. This cultural and legal change would greatly facilitate milk production as there may never be enough lactation rooms to accommodate lactating people wherever they are. Doing away with lactation rooms would also be emancipatory in that these rooms and other private nursing stations can be oppressive,⁴⁶³ leading “[w]omen [to] internalize prevailing norms about the appropriate ‘place’ of the breast (and by extension their body) by focusing on the comfort of those around them.”⁴⁶⁴ In that sense, lactation rooms are analogous to

458. *Id.* at 321, 326.

459. See Julie E. Maybee, *The Political Is Personal Mothering at the Intersection of Acquired Disability, Gender, and Race*, in *DISABILITY AND MOTHERING: LIMINAL SPACES OF EMBODIED KNOWLEDGE* 245, 245 (Cynthia Lewiecki-Wilson & Jen Cellio eds., 2011) (emphasizing that “[t]he social model of disability urges us to define disability as a category of identity that is socially constructed . . . people are not disabled by their bodies or impairments, but by the societies in which they live. Impairments do not disable people; society’s prejudice, discrimination, and oppression disable people with impairments.”).

460. See generally Jessica L. Roberts, *Accommodating the Female Body: A Disability Paradigm of Sex Discrimination*, 79 U. COLO. L. REV. 1297 (2008) (arguing that physical space promotes discrimination against people with disabilities and members of other protected groups).

461. *Id.* at 1300.

462. See *Breastfeeding State Law*, NAT’L CONFERENCE OF STATE LEGISLATURES (June 5, 2017), <http://www.ncsl.org/research/health/breastfeeding-state-laws.aspx> [<https://perma.cc/SV5N-Q3W9>] (presenting current state breastfeeding laws, including those pertaining to breastfeeding in public).

463. See Kate Boyer, *Affect, Corporeality and the Limits of Belonging: Breastfeeding in Public in the Contemporary UK*, 18 HEALTH & PLACE 552, 557 (2012) (arguing that lactation rooms can work to contain and compartmentalize breastfeeding).

464. Vanessa Mathews, *Reconfiguring the Breastfeeding Body in Urban Public Spaces*, SOC. & CULTURAL GEOGRAPHY 1, 5 (2018).

nursing covers, which Vanessa Mathews deems “representative of the discourse that women should protect others from feeling uncomfortable.”⁴⁶⁵ In practice, however, many people do not feel comfortable breastfeeding and expressing milk in public be it because of the inadequacy of public or semi-public spaces, modesty, or well-founded fear of onlookers’ reactions, among other reasons.⁴⁶⁶

For privacy and comfort, an extensive network of lactation rooms should be established, not just at work, but also in public and semi-public spaces that women visit or transit by, such as malls, transport hubs (bus terminals, train stations, airports, rest stops) and public transports themselves, such as long distance trains, public libraries, chain cafes, hotel, restaurants, parks, conference centers, courtrooms, museums, zoos, sporting and recreational facilities, universities, and hospitals, among others. The availability of public lactation rooms would not conflict with the idea of promoting public milk expression—to the contrary, their spread would make breastfeeding and pumping more visible thanks to logos, signage, and increased awareness that people lactate here, now, and everywhere. Minimum requirements for public lactation rooms should be similar to those in the work context.⁴⁶⁷ In addition to guaranteeing some level of privacy, they should include a place to sit, a table on which to place the pump, access to an electrical outlet, a sink for washing hands and pump attachments (or close access to facilities where washing can be done). Such a network would particularly benefit mobile or traveling workers who are not in a fixed place during their shift, such as drivers, delivery workers, law enforcement officers, EMTs, freelancers, those with extreme commutes, service workers, as well as students⁴⁶⁸ and employees not covered under the Nursing Mothers Amendment.⁴⁶⁹

In practice, a similar infrastructure is already developing unsystematically, as public institutions and businesses increasingly provide lactation rooms. It has become easier than ever to express milk since Vermont company Mamava, launched in 2013, began marketing “lactation pods,” which are freestanding and mobile prefabricated lactation suites that can be used in office or outdoor spaces.⁴⁷⁰

465. *Id.* at 7.

466. *See, e.g.,* Christen Clifford, *Pumping in Public*, HUFFINGTON POST (Mar. 2, 2009), https://www.huffingtonpost.com/christen-clifford/pumping-in-public_b_162713.html [<https://perma.cc/2BXW-F722>] (recounting the experience of pumping on a crowded New York subway or at a bar while being stared at by fellow passengers or at a bar).

467. *See* Reasonable Break Time for Nursing Mothers, 75 Fed. Reg. 80073, 80076 (Dec. 14, 2010) (commenting that minimum requirements must include “a place for the nursing mother to sit, and a flat surface, other than the floor, on which to place the pump” and access to electricity).

468. *See* Lauren M. Dinour & Nisha Beharie, *Lessons Learned from a Student-Led Breastfeeding Support Initiative at a US Urban Public University*, 31 J. HUM. LACTATION 341 (2015) (noting that students are typically not employed by their school and thus not protected by state and federal labor laws).

469. *See supra* notes 378–79 and accompanying text; *see also* LIZ MORRIS, JESSICA LEE & JOAN C. WILLIAMS, EXPOSED: DISCRIMINATION AGAINST BREASTFEEDING WORKERS 5 (2018) (pointing that over 9 million women are not covered by the federal break time provision).

470. *Mamava Original Lactation Pod*, MAMAVA, <https://www.mamava.com/original-mamava-lactation-suite/> [<https://perma.cc/BC6B-VK7P>] (last visited Feb. 7, 2019).

Mamava “has sold about 450 pods to airports, arenas, colleges, and large businesses such as Amazon and Walmart.”⁴⁷¹ A few breastfeeding and pumping mobile applications and lactation room locators⁴⁷² are available for those looking for “breastfeeding friendly places and nursing rooms.”⁴⁷³ However, legal interventions could go a long way to expand and improve the existing offering to ensure that the rooms are up to standard, easily accessible, and welcoming for all lactating persons.

Finally, to facilitate the donation of human milk, refrigerated donation boxes and drop off points could be set up in stores, daycare centers, schools, hospitals, doctors’ offices, and other locations. Donating milk should be quick, easy, and cheap. Some milk banks already address some of the challenges of donation by paying for donors to ship their milk on dry ice or organizing home pick-ups by volunteers,⁴⁷⁴ but strengthening and broadening the range of milk depots would make milk donations not only more visible, but also more practical.

D. Insurance Law

While private and public medical insurance providers cover standard premature birth treatments and drugs such as ventilation, surgery, surfactants, antibiotics, or diuretics, donor milk is not automatically covered. Donor milk is even less likely to be covered for full-term infants, older babies, and adults. An essential step towards making human milk accessible to all those who need it lies in insurance reform. Not only should insurance providers cover the costs of milk production by picking up the tab for milk expression supplies, training, donor screening, and milk testing, but they should also cover recipient families’ expenditures to obtain milk.

1. Covering the Costs of Production

Since the passage of the Affordable Care Act (ACA) in 2010, insurance law has made strides toward supporting breastfeeding, and therefore, donor human milk. All “non-grandfathered” health insurance plans must now cover 100% of the costs of a breast pump, be it a rental or a bought unit.⁴⁷⁵ Some plans also cover pumping supplies, such as storage bags or bottles, and spare pump parts, which need to be replaced regularly, though some companies only cover 90 days’ worth of supply and only during the first year. This new set of requirements represents a

471. See Katie Johnston, *New Perk for Breastfeeding Moms: Lactation Pods Signal Changing Times (and Laws)*, BOS. GLOBE (Apr. 10, 2018), <https://www.bostonglobe.com/business/2018/04/09/new-perk-for-nusing-moms-workplace-lactation-pods-signal-changing-times-and-laws/4VDwVaSbpAC5k0qtbXGFAL/story.html> [<https://perma.cc/3KP6-Q588>].

472. For instance, the website Moms Pump Here functions as a lactation room locator. See MOMS PUMP HERE, <https://www.momspumphere.com/> [<https://perma.cc/DX62-PN7S>] (last visited Feb. 7, 2019) (one problem is that it provides the names and address of organizations that house lactation rooms without indicating their hours of operations or conditions of access).

473. *Moms Pump Here, LLC*, APP STORE PREVIEW, <https://itunes.apple.com/us/app/moms-pump-here/id992177877?mt=8> [<https://perma.cc/UY77-UY5E>] (last visited Feb. 7, 2019).

474. *Id.*

475. Affordable Care Act § 2719A, 42 U.S.C. §§ 300gg-19a (2012).

major improvement as expressing milk is essential for many to be able to breastfeed (for instance when their babies won't latch) and for most to maintain lactation when they are away from their children. It is also necessary to produce milk that can be donated. Yet milk expression can be a time-consuming and expensive activity. Electric double pumps cost anywhere from \$60 to several hundred dollars or more for hospital-grade pumps.⁴⁷⁶ Electric double pumps allow women to express both breasts simultaneously rather than having to express from one breast after the other, a crucial time saver. Yet, some insurers only cover the cost of a manual pump, which is typically good for occasional but not frequent use, as it can take up to an hour to pump manually from both breasts.⁴⁷⁷ Hand expression is free and can be fast for those who master the technique, but very few women do, as it is rarely taught—and the few experts command high fees for their training sessions.⁴⁷⁸ Additional expenses include adapters for pumping in cars, breast pads, nipple shields, nipple cream for cracked nipples, products for cleaning pump parts, nursing and pumping bras, transport coolers and ice packs, and adequate clothing.

Uninsured and low-income women can obtain a free pump through Medicaid, but only if a doctor deems it a medical necessity. In some states, the WIC program offers pumps for certified breastfeeding participants.⁴⁷⁹ Disparities in breastfeeding based on race and income level persist, however. Andrea Freeman has shown that breastfeeding laws and policies have been particularly harmful to black mothers and their children.⁴⁸⁰ She writes,

The factors contributing to racial disparities in breastfeeding are manifold, complex, and interconnected. They include comfort with formula; lack of information about infant behavior; cultural norms, including discouragement of breastfeeding; media influence; race-targeted marketing; disproportionate representation among the poor and in federal programs to assist women and children; unequal distribution of resources for new mothers; immigration status; and historical and present discrimination.⁴⁸¹

A study conducted in Maine between 2012-2014 concluded that the effect of the ACA breast pump provision was an eleven-fold increase in claims for pumps by women with private insurance, while less than a dozen women with Medicaid laid

476. This is an estimate range based on searching prices as of December 2017 on Amazon.com.

477. See Ehrenreich & Siebrase, *supra* note 382, at 97 n.170. Note however that new innovative products such as Freemie's double manual pump promise fast and easy manual pumping. See *Freemie Equality Double Manual Pump Set – S.A.L.E!!!*, FREEMIE, <https://freemie.com/collections/frontpage/products/freemie-equality-double-manual-pump-set-sale> [<https://perma.cc/EAH2-A3YB>] (last visited Feb. 7, 2019).

478. See generally FRANCIE WEBB, *GO MILK YOURSELF YOU HAVE POWER. EXPRESS IT!* (2017) (book manifesto about the advantages of hand expression over pumping and how to master the technique).

479. See Summer Sherburne Hawkins, *Effect of the Affordable Care Act on Disparities in Breastfeeding: The Case of Maine*, 107 AM. J. PUB. HEALTH 1119, 1120 (2017).

480. See Freeman, *supra* note 382, at 3075–78.

481. See Freeman, *supra* note 382, at 3065.

claims for free pumps.⁴⁸² Approximately 47% of all births are paid for by Medicaid, which makes the contrast all the more worrisome.⁴⁸³ The study concluded that without additional support for low-income women, differences in breastfeeding rates may increase. The Affordable Care Act did take the welcome step of requiring insurers to cover lactation support in the form of consultations with lactation consultants, which was anticipated to reduce these inequalities.⁴⁸⁴ Regrettably, lactation consultants are rarely accessible in-network and often not available at all for Medicaid recipients, leaving low-income women with little help when they run into breastfeeding difficulties, such as inadequate milk supply (and/or fears of inadequate milk supply), sore breasts, engorgement, or latching problems, among others.⁴⁸⁵ Women who encounter breastfeeding challenges are more likely to discontinue breastfeeding, indicating the importance of providing them with hands-on support.⁴⁸⁶ Individualized and interactional guidance from trained lactation professionals providing positive support, problem solving, and patient education has proven far more effective than dispensing theoretical education and distributing pamphlets and other reading materials.⁴⁸⁷ In addition, “[m]ore in-network service providers for lactation counseling”⁴⁸⁸ should provide “more consistent definitions of lactation support and counseling, including what level and type of training are required of lactation counselors”⁴⁸⁹ to ensure that women get advice from qualified lactation consultants.

Insurance reform could also play a leading role in incentivizing milk donations and making milk sharing safer by requiring that insurers cover the costs of screening and testing. In the context of organ donations, the recipient’s health insurance typically covers living donors’ medical expenses, such as the tests necessary to determine whether the donor is a good candidate, donation surgery, and post-operative care.⁴⁹⁰ Similarly, programs could be instituted whereby donors willing to give or sell their milk surplus peer-to-peer would undergo serological testing for infections transmissible via milk every six months at no out-of-pocket cost. The

482. *Id.* at 1119.

483. VERNON K. SMITH ET AL., IMPLEMENTING COVERAGE AND PAYMENT INITIATIVES: RESULTS FROM A 50-STATE MEDICAID BUDGET SURVEY FOR STATE FISCAL YEARS 2016 AND 2017 10 (2016), <http://files.kff.org/attachment/Report-Implementing-Coverage-and-Payment-Initiatives> [<https://perma.cc/9G6G-A9ND>].

484. Kaiser Family Found., Preventive Services Covered by Private Health Plans under the Affordable Care Act 6 tbl.1 (2015).

485. *See* Hawkins, *supra* note 478, at 1119, 1120.

486. *See, e.g.*, Elizabeth Brand et al., *Factors Related to Breastfeeding Discontinuation Between Hospital Discharge and 2 Weeks Postpartum*, 20 J. PERINAT. EDUC. 36, 37 (2011) (finding that the presence of a support system, whether it is personal or professional, is a greater influence than socioeconomic status on a woman’s decision to breastfeed and her ability to continue for a longer duration).

487. *See* Hawkins, *supra* note 478, at 1120.

488. *See* Hawkins, *supra* note 478, at 1121.

489. *See* Hawkins, *supra* note 478, at 1121.

490. *See Living Donation Costs*, TRANSPLANT LIVING, <https://transplantliving.org/financing-a-transplant/living-donation-costs/> [<https://perma.cc/MJ5F-BWY6>] (last visited Feb. 7, 2019).

periodical testing of their milk for nutritional content, bacterial count, and toxic contaminants would also be covered by the recipient's insurance. Test results would be available to donors and recipient families, helping the former address any health, hygiene, or environmental factor compromising the quality of their milk and the latter make informed decisions. Insurers could also provide recipient families with home pasteurizers for the milk. These steps could turn informal milk sharing into a practice nearly as safe as non-profit milk banking all the while keeping the production costs low as there would be no need for independent brick and mortar facilities, professional equipment, medical and administrative personnel, processing, packaging, storing, and transportation.

2. *Covering the Costs of Distribution*

In addition to supporting the production of human milk, insurance law could sustain its distribution costs. Banked milk is incorporated into national public health policy and regulation in many countries such as Canada, France, Brazil, Germany, Great Britain, and Scandinavian countries, where families do not pay out of pocket for their infant to receive it when medically indicated.⁴⁹¹ By contrast, in the United States, many are left paying for it out-of-pocket.⁴⁹² Human milk is most likely to be covered by insurance for NICU hospitalized, premature, and sick babies. For all other inpatients and outpatients, obtaining insurance coverage can be an uphill battle. In some cases, parents of outpatient babies report obtaining coverage for human milk on a limited basis, but this is not known to be the common experience.⁴⁹³ HMBANA milk banks maintain charitable programs, sometimes referred as "Milk Money Funds," which can help with the costs of donor milk for outpatients.⁴⁹⁴ Due to their limited resources they can only do so on a temporary basis and in the most urgent situations.⁴⁹⁵ These haphazard and unpredictable arrangements are not sustainable.

The United States should move toward a system in which non-profit banked milk is compulsorily covered for preterm and other medically fragile or at-risk full-term infants when a provider with prescriptive authority considers it medically necessary. This mandate would cover Medicaid plans, public insurance, and private

491. See Lois D.W. Arnold, *Global Health Policies that Support the Use of Banked Donor Human Milk: A Human Rights Issue*, 1 INT'L BREASTFEEDING J. 1, 1–2 (2006).

492. See TAYLOR & LABBOK, *supra* note 80, at 34–37.

493. See *id.*

494. See *Why Is Donor Milk So Expensive?*, LACTATION MATTERS: THE ILCA BLOG (Nov. 8, 2013), <https://lactationmatters.org/2013/11/08/why-is-donor-milk-so-expensive/> [<https://perma.cc/3S9Y-FL2W>]; see also Kimberly Horton Updegrove, *Donor Human Milk Banking: Growth, Challenges, and the Role of HMBANA*, 8 BREASTFEEDING MED. 435, 437 (2013) (noting that certain banks maintain charitable programs to assist outpatient families who lack resources).

495. See Carolina Buia, *The Booming Market for Breast Milk*, NEWSWEEK (May 23, 2015, 4:11 PM), <https://www.newsweek.com/2015/06/05/booming-market-breast-milk-335151.html> [<https://perma.cc/9LKP-FNMS>] (noting that "[i]n some cases, HMBANA gifts donor milk to outpatient babies who cannot get insurance coverage").

insurance. It would apply to outpatient as well as inpatient children, with an age limit of at least up to two years. As research on the benefits of human milk for grown-up patients progresses, the requirement could be extended to adults for certain indications. Commercial donor milk, which is more expensive, would not be obligatorily covered unless it were the only human milk available due to shortages or other problems. This arrangement would have the benefit of rewarding non-profit banks for their work and helping them grow. So far, HMBANA banks have lacked the resources to expand their activities to include research and the development of new products such as human milk-based fortifiers⁴⁹⁶ or freeze-dried milk. Presently the only 100% human milk-based fortifier available on the U.S. market is produced by for-profit company Prolacta.⁴⁹⁷ It should be covered for premature infants under the same general conditions as non-profit donor milk until HMBANA banks are able to develop their own version.

This proposal is not utopian. In fact, it is close to the frameworks in place in a few foreign countries and reflective of a number of local initiatives in the United States.⁴⁹⁸ A few jurisdictions have stepped in to ensure access to human milk for low-income parents of premature or sick babies. California has covered human milk for some low-income newborns since 1998.⁴⁹⁹ Texas followed suit in 2008,⁵⁰⁰ as did Missouri,⁵⁰¹ Kentucky in 2013,⁵⁰² the District of Columbia in 2014,⁵⁰³ Kansas⁵⁰⁴ and Utah in 2015,⁵⁰⁵ New York and Pennsylvania in 2017,⁵⁰⁶ and New Jersey in 2019.⁵⁰⁷

496. See Ekhard E. Ziegler, *Human Milk and Human Milk Fortifiers*, 110 WORLD REV. NUTRITION DIET 215 (2014) (explaining the need to fortify donor human milk for premature infants).

497. Pinkal Patel & Jatinder Bhatia, *Human Milk: The Preferred First Food for Premature Infants*, 4 J. HUM. NUTRITION FOOD SCI. 1, 2 (2016).

498. See, e.g., Maryanne Tigchelaar et al., *A Mixed-Methods Observational Study of Human Milk Sharing Communities on Facebook*, 9 BREASTFEEDING MED. 128, 132 (2014) (showing that on the American continent, the leader in milk banking is Brazil, which offers the most extensive network of public banks with over 200 banks (while the United States only has 23) delivering milk at no cost to infants with medical needs).

499. CAL. WELF. & INST. CODE § 14132.34 (West 2017); see also CAL. DEP'T OF HEALTH SERVS., MMCD POLICY LETTER 98-10 3-4 (Dec. 10, 1998), <http://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/PL1998/MMCDPL98010.pdf> [<https://perma.cc/38K2-55F8>].

500. TEX. HEALTH AND HUMAN SERVS., HUMAN DONOR MILK NEW REIMBURSEMENT (Mar. 1, 2017), <https://hhs.texas.gov/about-hhs/communications-events/news/2017/02/human-donor-milk-new-reimbursement> [<https://perma.cc/7T1ED-C2GH>].

501. MO. ANN. STAT. § 208.141 (West 2017).

502. KY. REV. STAT. ANN. § 304.17A-139 (West 2017).

503. D.C. Mun. Regs. tit. 29, § 10003 (2017).

504. KAN. STAT. ANN. § 39-7,121g (West 2017).

505. UTAH ADMIN. CODE r. 414-60-5 (2017).

506. N.Y. SOC. SERV. LAW § 365-a(2)(dd) (McKinney 2017); PA. DEP'T OF HUMAN SERVS., PASTEURIZED DONOR HUMAN MILK, MEDICAL ASSISTANCE BULLETIN, (Aug. 7, 2017), http://www.dhs.pa.gov/cs/groups/webcontent/documents/bulletin_admin/c_264241.pdf [<https://perma.cc/J95N-F539>].

507. N.J. STAT. ANN. § 17B:26-2.1kk (West 2018) (requiring health coverage of banked human milk).

These tend to be restrictive programs, as coverage is often limited to low-income, Medicaid-eligible hospitalized newborns for whom donor milk is deemed medically necessary. Coverage is sometimes capped with maximum age conditions—three months in Kansas and Missouri, six months in New Jersey, eleven months in Texas, Utah, and DC—and yearly cost caps (\$15,000 per infant per year in Kentucky⁵⁰⁸). Coverage is conditioned upon completed feeding trials required every 180 days in Texas, Utah, and DC. The District of Columbia, New Jersey, and Pennsylvania are among the few to mandate Medicaid to reimburse donor milk on an *outpatient* basis but for very limited indications.⁵⁰⁹ Legislators in other states have expressed interests in mandating the coverage of donor milk including to a broader range of recipients.⁵¹⁰ According to Emily Taylor and Miriam Labbok, federal law may further inequalities in access to donor human milk for outpatients, as “federal policy prohibits WIC coverage for donor human milk. Therefore, in the WIC program, infants with special healthcare needs can receive free specialty formulas, but they cannot receive free or reimbursed donor human milk.”⁵¹¹

In 2017, New York’s new provision on the Medicaid coverage of donor milk became effective.⁵¹² It represents a retreat from the original Senate bill introduced in 2016,⁵¹³ which would have been one of the most progressive schemes nationally, covering donor milk for as long as medically necessary no matter the infant’s age, on an outpatient basis as well as an inpatient basis, and for a wide range of indications, including “feeding intolerance” and babies who “otherwise require nourishment by breast milk.”⁵¹⁴ An otherwise healthy, non-hospitalized full-term baby or toddler participating in Medicaid would have been able to obtain donor milk covered by insurance on the sole ground that she failed to digest or thrive on formula. Unfortunately, Governor Cuomo vetoed the law, citing three reasons.⁵¹⁵ First, it only allowed reimbursement for outpatient infants.⁵¹⁶ Second, Cuomo found its language too broad, especially the clause “otherwise require nourishment by breast milk.”⁵¹⁷ He feared that it would have had the effect of “restrict[ing] an

508. KY. REV. STAT. ANN. § 304.17A-139 (West 2018).

509. D.C. Mun. Regs. tit. 29, § 10003 (2017); PA. DEPT OF HUMAN SERVS., *supra* note 506 (reserving coverage to infants recently discharged from the hospital and requiring a burdensome prior authorization process); *see also* TAYLOR & LABBOK, *supra* note 80, at 35 (stating that California and Texas also state that they will cover donor human milk in the outpatient setting).

510. *See, e.g.*, H.B. 156, 53rd Leg., 1st Sess. (N.M. 2017).

511. *See* TAYLOR & LABBOK, *supra* note 80, at 36. *But see* NAT. WIC ASS’N, *supra* note 17 (suggesting that the tide is turning on this issue at WIC).

512. N.Y. SOC. SERV. LAW § 365-a(2)(dd) (McKinney 2017).

513. S. 6583, 2017 Leg., 239th Sess. (N.Y. 2016).

514. S. 6583, 2017 Leg., 239th Sess. (N.Y. 2016).

515. Governor Andrew Cuomo, Veto Message No. 278 (full date) (vetoing S. 6583) (on file with author).

516. *Id.* Note that the drafters of the bill probably made this choice because inpatient donor milk is typically already reimbursed in New York as a bundled payment. *See supra* note 342 and accompanying text.

517. *See* Cuomo, *supra* note 515.

extremely scarce resource from those infants that need it most.”⁵¹⁸ Finally, no funding had been appropriated to achieve the legislative objectives.⁵¹⁹ As a response to Cuomo’s objections, the version of the law that was eventually enacted no longer covers milk for outpatient use.⁵²⁰ It narrowed down the eligibility criteria to premature infants who suffer a specific medical condition calling for human milk.⁵²¹ Feeding intolerances or the mere need for nourishment by human milk are no longer sufficient grounds to trigger the coverage provision.

Governor Cuomo’s apprehensions that broadening the coverage of donor human milk could result in shortages⁵²² and excessive fiscal liabilities are not uncommon. The preceding discussion has already examined issues of supply and affordability, but Cuomo’s specific fiscal concerns must be addressed. To that end, the next section examines whether the costs of covering human milk would outweigh its potential benefits.

3. *A Cost Saving Proposition*

Parties who have a stake in the expenditures associated with using donor human milk include healthcare providers who spend money to care for patients; insurers who may or may not cover donor milk; patients and their families who may end up paying out of pocket to obtain milk; and society as a whole, which must collectively bear the present costs of premature and sick babies and the future costs of illnesses and disabilities in children and adults who have failed to receive optimal infant nutrition and care in the form of human milk. Whether or not healthcare is publicly or privately funded, a growing number of studies suggest that the wider use of donor human milk may ultimately reduce costs for all of these stakeholders.

While in-depth research is lacking to evaluate the cost effectiveness of covering donor human milk for outpatients, studies show that covering it for NICU hospitalized infants is at least a zero-sum game, and possibly generate cost savings.⁵²³ A few states conducted fiscal analysis to determine the impact of

518. *See id.*

519. *See id.*

520. N.Y. SOC. SERV. LAW § 365-a(2)(dd) (McKinney 2017).

521. SOC. SERV. §365-a(2)(dd).

522. *See, e.g., There is a Critical Shortage of Donor Milk*, INT’L MILK BANK, <https://internationalmilkbank.com/about-us/> [<https://perma.cc/GRR4-3WZ9>] (last visited Feb. 7, 2019) (a commercial milk company claiming that “[c]urrently in the U.S. and around the world there is not enough banked milk to meet the demand even for those with the most critical need, the premature infants in neonatal intensive care units (NICU).”); *see also Donated Breast Milk Shortage Across the Nation*, CBS 46 (Nov. 16, 2011), <http://www.cbs46.com/story/16056475/donated-breast-milk-shortage-across-the-nation>.

523. *See, e.g.,* Tricia J. Johnson et al., *Economic Benefits and Costs of Human Milk Feedings: A Strategy to Reduce the Risk of Prematurity-Related Morbidities in Very-Low-Birth-Weight Infants*, 5 ADV. NUTR. 207, 209 (2014) (describing the costs of NICU hospitalization and prematurity-related morbidities and the incremental benefits and costs of human milk feedings during the NICU hospitalization); Tricia J. Johnson et al., *Cost Savings of Human Milk as a Strategy to Reduce the Incidence of Necrotizing Enterocolitis in Very Low Birth Weight Infants*, 107 NEONATOLOGY 271, 271 (2015)

mandating coverage of human milk for ill NICU patients. In 2011 and 2013 respectively, Maryland and Kentucky concluded that there would be no fiscal impact at all.⁵²⁴ A 2015 Kansas fiscal note issued in conjunction with the state's decision to mandate coverage of donor milk in some situations determined that the fiscal effect of the change would be negligible.⁵²⁵

Other studies go further, claiming that covering donor human milk for NICU hospitalized infants may lead to fiscal savings.⁵²⁶ The economic benefits of providing human milk feedings in this population are substantial and “higher doses of human milk provide greater risk reduction.”⁵²⁷ Infants born at very low birth weights (usually defined as below 1,500 grams) are some of the most expensive patients in hospitals due to intensive resource use (such as ventilation and surgery) and higher incidence of costly morbidities requiring additional days in the NICU.⁵²⁸ As a result of human milk consumption, hospital stays are shortened, the likelihood of surgical intervention is reduced, and overall incremental costs associated with complications are decreased.⁵²⁹ More specifically, there is mounting evidence that the provision of donor milk translates to substantial cost savings in the NICU due to reduction in necrotizing enterocolitis (NEC), a devastating disease that is

(finding that exclusive human milk feeding during the first 14 days of life is an effective strategy to reduce the risk of necrotizing enterocolitis and resulting NICU costs in very low birth weight infants).

524. See WORK GRP. REPORT TO THE MD. HOUSE OF DELEGATES HEALTH AND GOV'T OPERATIONS COMMITTEE on *House Bill 180, THE PREMATURE INFANT SURVIVAL BILL 8* (2011); *Prolacta Praises Landmark Legislation in Kentucky Mandating Human Milk Diet for Premies in Jeopardy of Intestinal Disease*, BUSINESS WIRE (May 7, 2013, 9:09 AM), <https://www.businesswire.com/news/home/20130507005810/en/Prolacta-Praises-Landmark-Legislation-Kentucky-Mandating-Human> [<https://perma.cc/KYG3-NY3P>] (“The analysis and Fiscal Impact Statement by the State’s actuary indicated that the legislation would not increase administrative expenses of the insurer, nor would it increase premiums. This complements a 2011 study conducted by Dr. Joel Hay with the department of clinical pharmacy & pharmaceutical economics & policy, from the University of Southern California, Los Angeles, California, demonstrating that a 100% breast milk diet which included a fortifier made exclusively from human milk for extremely premature infants may result in a net savings of medical care resources by reducing the incidence of NEC, when compared to feeding these infants HMF produced from cow milk.”).

525. KAN. DIV. OF THE BUDGET, SUPPLEMENTAL NOTE ON HOUSE BILL NO. 2149, 2-2149, 2015 Sess. (2015), http://www.kslegislature.org/li/b2015_16/measures/documents/supp_note_hb2149_00_0000.pdf [<https://perma.cc/3LYV-KHMT>].

526. V. Ganapathy et al., *Costs of NEC and Cost Effectiveness of Exclusive Human Milk-Based Products in Feeding Extremely Premature Infants*, 7 BREASTFEEDING MED. 29, 29 (2012).

527. Tricia J. Johnson et al., *Economic Benefits and Costs of Human Milk Feedings: A Strategy to Reduce the Risk of Prematurity-Related Morbidities in Very-Low-Birth-Weight Infants*, 5 ADV. NUTR. 207, 209 (2014).

528. See Stavros Petrou et al., *Structured Review of the Recent Literature on the Economic Consequences of Preterm Birth*, 96 ARCH. DIS. CHILD. FETAL NEONATAL ED. F225–32 (2011) (pointing out that in addition to health service costs incurred during the premature infant’s initial hospital stay, preterm birth can result in substantial costs to the health services throughout childhood and impose a substantial economic burden on special education and other services and on families).

529. Jennifer A. Bisquera et al., *Impact of Necrotizing Enterocolitis on Length of Stay and Hospital Charges in Very Low Birth Weight Infants*, 109 PEDIATRICS 423, 423 (2002) (studying the impact of NEC on the length of hospitalization and cost of care).

extremely costly to treat.⁵³⁰ Neonatologist Nancy Wight estimates that for every \$1 spent on donor milk, \$11 to \$37 could be saved in healthcare costs.⁵³¹ This includes, among other things, the costs of NEC, feeding intolerance, and infection. Feeding premature babies human milk not only reduces the incidence and severity of morbidities such as late-onset sepsis, bronchopulmonary dysplasia (BPD), necrotizing enterocolitis, renal failure, and retinopathy of prematurity, which require expensive treatments, longer stays in the NICU,⁵³² and increase the risk of long-term chronic illnesses and disabilities, but also it may directly reduce NICU hospitalization costs.⁵³³

Greater use of donor human milk in NICUs and beyond may have other cost-saving effects. The use of donor human milk as opposed to formula has been shown to improve women's own health outcomes by increasing their breastfeeding rates.⁵³⁴ Women whose infants receive donor milk in the NICU are more likely than formula-fed babies to initiate and continue breastfeeding.⁵³⁵ Using donor human milk outside of the hospital, be it obtained from banks or peer-to-peer, has also been associated with higher rates of breastfeeding initiation and duration, rather than the other way around, as some commentators have feared.⁵³⁶ It is well-known that breastfeeding generally promotes women's and children's health, lowering their health costs.⁵³⁷

530. See Johnson et al., *supra* note 526; see also Paula P. Meier & Lars Bode, *Health, Nutrition, and Cost Outcomes of Human Milk Feedings for Very Low Birthweight Infants*, 4 ADV. NUTR. 670 (2013).

531. Nancy E. Wight, *Donor Human Milk for Preterm Infants*, 21 J. PERINATOLOGY 249 (2001).

532. See Johnson et al., *supra* note 526, at 207.

533. See Aloka L. Patel et al., *Impact of Early Human Milk on Sepsis and Health Care Costs in Very Low Birthweight Infants*, 33 J. PERINATOLOGY 514, 514 (2013) (showing that providing human milk lowered the incidence of sepsis and NICU costs).

534. See generally Agata Kantorowska, *Impact of Donor Milk Availability on Breast Milk Use and Necrotizing Enterocolitis Rates*, PEDIATRICS, March 2016, at 1, 1 (showing that the availability of donor milk at California NICUs was associated with increased breastfeeding at NICU discharge and decrease in NEC rates); see also Karen L. Kamholz et al., *Implementing Change: Steps to Initiate a Human Donor Milk Program in a US Level III NICU*, 28 J. HUM. LACTATION 128, 128–29 (2012) (describing the hesitation of a group of neonatologists about introducing donor human milk in their NICU due to the fear that they “would see a decrease in mother’s own milk when donor milk was available” and the response by donor milk specialist and neonatologist Kathleen Marinelli, according to which “offering PDM increases awareness of the benefits of human milk and motivates mothers to pump more of their own milk rather than giving them an excuse to pump less often”).

535. See Sertac Arslanoglu et al., *Presence of Human Milk Bank Is Associated with Elevated Rate of Exclusive Breastfeeding in VLBW Infants*, 41 J. PERINAT. MED. 129 (2013).

536. Palmquist & Doehler, *supra* note 162, at 284 (“In fact, milk sharing recipients in the U.S. report higher rates of exclusive breast milk feeding 0–6 months and longer duration of any breastfeeding/breast milk feedings than the national averages”).

537. See generally Melissa C. Bartick, *Suboptimal Breastfeeding in the United States: Maternal and Pediatric Health Outcomes and Costs*, MATER. CHILD NUTR., 20 July 2016, at 1, 1 (discussing the connections between breastfeeding and maternal and pediatric health); see also OFFICE OF THE SURGEON GENERAL, *supra* note 17, at 3 (claiming that the United States would save about \$13 billion per year in medical costs if 90% of U.S. families breastfed their newborns for at least six months).

CONCLUSION

The demand for donor human milk is increasing. It is likely to continue to grow as medical and biological research reveals new facts about its components and applications. Popular culture and media are replete with characterizations of human milk as liquid gold. Yet these discourses are more rhetorical than reflective of our laws and society's treatment of women and children. Lactating women dissolve part of themselves, liquefying their bodies to produce milk,⁵³⁸ yet they must do that against all odds in a culture that discriminates against them and does not accommodate their needs and those of their children. Children born in low-income families, who are most likely to require donor human milk as infants, are also those that are least likely to obtain it, often due to its prohibitive cost. This Article asked what would happen if women were really treated as people who produce "liquid gold." It found that attempts at legal reform ought to shift from a single-minded focus on germs potentially transmitted by milk to putting the breastfeeding relationship between women and their children first. The human milk regulatory agenda should proceed from the following premises. First, there can be no sustainable donor human milk program without women who are economically, culturally, and medically empowered to breastfeed and to produce extra milk available for donation. Second, children deserve access to human milk regardless of their families' socio-economic status. It is not so much human milk itself, as a disembodied product, that should be regulated, but rather our work, public health, and insurance laws that should be reformed. In these and many other ways, the state could become not merely a partner, but also a leader in improving the health and lives of children and their families in a way that promotes rather than hinders women's autonomy.

538. See Garbes, *supra* note 283.

