Milk from Mars. The Challenges of Regulating Lab-Produced (Human) Milk

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ABSTRACT

For over a century, pediatricians, scientists, and industry players have sought to create an infant formula that would be as close as possible to human milk. Until recently, their efforts focused on "humanizing" cow's milk by making its composition more similar to human milk. But in the past few years, new technologies have led some companies to culture mammary cells or yeast in the lab. The resulting lab-produced components have been claimed to be identical to those found in human milk. One goal behind this new technology is to manufacture an infant formula that is more nutritionally adapted for newborns than conventional breastmilk substitutes. What impact might this new lab-produced milk have on infant feeding and regulation? Will it benefit parents and their children or represent a threat for lactation and donor human milk support? Could it precipitate a new regulatory regime for human milk itself? Given the many unknowns in this area, this Article hypothesizes various outcomes, examining their potential costs and benefits. What is certain, however, is that the legal regime eventually accorded to lab-produced milk will shape not only the products on the market, but also who will get access to them and at what cost.

I. INTRODUCTION

We are in a moment when science fiction seems to meet reality. In 1894, Marcellin Berthelot, one of the most renowned chemists at the time, addressed leading chemical industrialists and businesspeople about the future of chemistry at a banquet. He predicted that by 2000 there would no longer be any "agriculture, herders, plowers."[1] Solar energy and advances in chemistry would allow people to "manufacture food

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[1] Marcellin Berthelot, *En l'an 2000, Discours prononcé au banquet de la Chambre Syndicale des Produits Chimiques, le 5 avril 1894*, PAGES CHOISIES, 1923, at 58, 60.

from scratch" from carbon, hydrogen, nitrogen, and oxygen.[2] In an interview given the same year, he declared, "[t]here is no reason, . . . since we are making artificial butter, why we should not before long make artificial milk," adding that "ass's milk, goat's milk, or any other milk desired could be furnished from the same laboratory as easily as cow's milk."[3] Despite his prescient pronouncements, Berthelot did not seem to anticipate that by the 2020s, humans' primary food—human milk—might be developed in the laboratory.

Producing milk with one's body is hard work.[4] Parents may have difficulties feeding their children with their own milk for a variety of reasons, whether economic, medical, or social.[5] For millennia, the only alternative to maternal breastfeeding was nursing by another woman,[6] be it as part of a kin relationship, paid employment, or forced labor.[7] In the nineteenth century, the development of industrial dairy production, animal milk—particularly cow's milk—was increasingly seen as a viable substitute.[8] Leading pediatricians, scientists, and industry players endeavored to modify cow's milk to create a "formula" that would be as similar as possible in composition to human milk—hence the expression "infant formula."[9] At the turn of the century, these efforts focused on "humanizing" cow's milk by reducing its proportions of certain

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[2] *Id.* at 62.

[3] Henry J.W. Dam, *Foods in the Year 2000. Professor Berthelot's Theory That Chemistry Will Displace Agriculture*, MCCLURE'S MAG., 1984, at 303, 310.

[4] *See, e.g.*, KIMBERLY SEALS ALLERS, THE BIG LETDOWN: HOW MEDICINE, BIG BUSINESS, AND FEMINISM UNDERMINE BREASTFEEDING 120–50 (2017) (highlighting some of the difficulties of lactation and arguing that as a form of embodied labor, it should be compensated).

[5] *See generally* U.S. Dep't Health & Hum. Servs., *Barriers to Breastfeeding in the United States*, *in* THE SURGEON GENERAL'S CALL TO ACTION TO SUPPORT BREASTFEEDING (2011).

[6] Please note that though I use gendered language such as "breastfeeding," "breast milk," "woman," and "mother" in recognition that lactation is a gendered practice, I do not mean to exclude the lactating people who do not identify as women or mothers.

[7] *See* Barry S. Hewlett & Steve Winn, *Allomaternal Nursing in Humans*, 55 CURRENT ANTHROPOLOGY 200, 200 (2014) (showing that "allomaternal nursing," that is, women other than mother nursing infants, occurs in the vast majority of cultures); Tanya M. Cassidy & Abdullahi El-Tom, *Comparing Sharing and Banking Milk: Issues of Gift Exchange and Community in the Sudan and Ireland*, *in* GIVING BREAST MILK: BODY ETHICS AND CONTEMPORARY BREASTFEEDING PRACTICE 110, 110 (Alison Bartlett & Rhonda Shaw eds., 2010) (discussing two examples of unpaid milk sharing, one from Ireland and one from the Sudan); VALERIE FILDES, BREASTS, BOTTLES AND BABIES: A HISTORY OF INFANT FEEDING (1985) (offering a history of breastfeeding and wet nursing focusing on the period from 1500 to 1800); RIMA D. APPLE, MOTHERS AND MEDICINE: A SOCIAL HISTORY OF INFANT FEEDING, 1890–1950 (1987) (analyzing the shift from breastfeeding to bottle-feeding); GEORGE D. SUSSMAN, SELLING MOTHER'S MILK: THE WET-NURSING BUSINESS IN FRANCE 1715–1914 (1982) (analyzing two centuries of wet-nursing in France where the practice was more widespread than in other countries); Stephanie Jones-Rogers, *'[S]he Could . . . Spare One Ample Breast for the Profit of her Owner': White Mothers and Enslaved Wet Nurses' Invisible Labor in American Slave Markets*, 38 SLAVERY & ABOLITION 337 (2017) (examining the market White mothers created for enslaved wet nurses in the United States).

[8] *See* E. MELANIE DUPUIS, NATURE'S PERFECT FOOD: HOW MILK BECAME AMERICA'S DRINK 46–66 (2002).

[9] *See* Jacqueline Wolf, *The Origin of 'Formula': State of the Science, 1890s*, 36 J. HUM. LACTATION 410, 410 (2020) (telling the origin story of infant formula and describing how pediatricians devised "mathematical 'formulas' that represented instructions to chemists on how to 'humanize' cow's milk for the needs of a particular infant").

components, such as casein or fat; diluting it with water; and/or adding ingredients such as sugar, cream, sodium chloride, and bicarbonate of soda.[10]

Today, globally, about 60% of infants younger than six months are not exclusively breastfed.[11] Researchers and technicians continue to develop products that more closely mimic human milk to supplement or supplant lactation. For example, in the last few years, infant formulas containing sugars called "human milk oligosaccharides" became available.[12] However, human milk remains the gold standard for infant nutrition. Human milk feeding—that is, feeding on the breast or chest or feeding expressed human milk—benefits all infants, especially the most vulnerable, lowering the risk of certain complications and death in premature and sick babies.[13] The COVID-19 pandemic has led to renewed evidence of the protective effects of human milk on infants, in part through its immunological properties.[14] An entire sector, known as donor human milk services, is dedicated to the collection, processing, and distribution of human milk for infants who cannot be breastfed by their parents.[15] But securing human milk for babies, primarily preterm and medically fragile babies, can be challenging. Not all hospitals use donor human milk,[16] and it can

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[10] T.B. Mepham, *"Humanizing Milk": The Formulation of Artificial Feeds for Infants (1850–1910)*, 37 MEDICAL HIST. 225, 235 (1993).

[11] *Exclusive Breastfeeding (% of children under 6 Months*), THE WORLD BANK, https://data.worldbank.org/indicator/SH.STA.BFED.ZS [https://perma.cc/8M3A-L4WX]; *see also* Nigel C. Rollins, Nita Bhandari, Nemat Hajeebhoy, Susan Horton, Chessa K. Lutter, Jose C Martines, Ellen G Piwoz, Linda M. Richter & Cesar G. Victora, *Why Invest, and What it Will Take to Improve Breastfeeding Practices?*, 387 LANCET 491, 491–92 (2016).

[12] Philippe Alliet, Giuseppe Puccio, Elke Janssens, Cinzia Cajozzo, Giovanni Corsello, Bernard Berger, Peter Sperisen, Francois-Pierre Martin, Norbert Sprenger & Philippe Steenhout, *Term Infant Formula Supplemented with Human Milk Oligosaccharides (2'fucosyllactose and lacto-N-neotetraose) Shifts Stoom Microbiota and Metabolic Signatures Closer to That of Breastfed Infants*, 63 J. PEDIATRIC GASTROENTEROLOGY & NUTRITION S55 (2016); Nicole Wetsman, *The "Arms Race" to Build a Better Baby Formula*, WALL ST. J. (Oct. 31, 2019), https://www.wsj.com/articles/the-arms-race-to-build-a-better-baby-formula-11572533852 [https://perma.cc/C4WY-9ZN6]; Jennifer T. Smilowitz, Carlito B. Lebrilla, David A. Mills, J. Bruce German & Samara L. Freeman, *Breast Milk Oligosaccharides: Structure-Function Relationships in the Neonate*, 34 ANNUAL REV. NUTRITION 143, 144–45 (2014) (These oligosaccharides are not digested by infants, but seem to contribute to healthy bacteria in the digestive tract.).

[13] *See* Allan Walker, *Breast Milk as the Gold Standard for Protective Nutrients*, 156 J. PEDIATRICS (SUPPLEMENT 1) S3 (2010).

[14] *See* Emilia Vassilopoulou, Gavriela Feketea, Lemonica Koumbi, Christina Mesiari, Elena Camelia Berghea & George N. Konstantinou, *Breastfeeding and COVID-19: From Nutrition to Immunity*, FRONTIERS IMMUNOLOGY, Apr. 2021, at 1, 7 (reviewing the information available regarding the transmissibility of SARS-Cov-2 through or while breastfeeding and the protection against infection that human milk might provide).

[15] *See generally* TANYA M. CASSIDY & FIONA DYKES, BANKING ON MILK: AN ETHNOGRAPHY OF HUMAN MILK EXCHANGE RELATIONS (2019) (offering an ethnography of human milk banking in the United Kingdom and beyond).

[16] *See* Maryanne T. Perrin, *Donor Human Milk and Fortifier Use in United States Level 2, 3, and 4 Neonatal Care Hospitals*, 66 J. PEDIATRIC GASTROENTEROLOGY & NUTRITION 664 (2018).

be hard to obtain on an outpatient basis.[17] Even when available, it can be expensive, as it is rarely covered by insurance, especially for outpatient babies.[18]

In recent years, new technologies have led a few biotech startups to attempt to develop a human milk analog in the laboratory.[19] These companies use different techniques, including culturing mammary cells or yeast, to secrete components of human milk.[20] Their hope is to market a nutritionally identical product to human milk, which is thus more digestible than conventional breastmilk substitutes, and potentially also richer in beneficial micro-components, such as secretory antibodies, microbiota, and other bioactive factors. Although these technologies are still in development, they raise a number of social and legal questions. As Bruno Latour and other anthropologists and philosophers of science have shown, laboratory discoveries (and science in general) are not neutral, but are socially and culturally framed.[21] They change reality around them. Science and technology transform society, redefining its aims and practices; at the same time, society can frame how science and technology are understood, exchanged, and used.

In this Article, we reflect on the possible effects of the emergence of human milk analogs produced in the laboratory, what we are calling "lab-produced milk," on infant feeding practices and the law. Among other questions, we ask: Will these new substitutes offer a beneficial option for babies who currently cannot be fed human milk, or could they contribute to the existing under-recognition and lack of support for lactation and donor human milk services? As for the legal implications of introducing these products, human milk itself is currently regulated under different legal regimes throughout the United States.[22] This may begin to change as a bill introduced in Congress in 2022 would classify banked donor human milk a special type of infant formula.[23] For now, the lack of a baseline legal framework to fall back on—or depart from—may pose difficulty for the regulators tasked with addressing new human milk products. The stakes are high, as the legal classifications ultimately adopted will have

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[17] *See generally* Allison T. Rose, Emily R. Miller, Margaret Butler, Claire Eden, Jae H. Kim, Shetal I. Shah & Ravi M. Patel, *US State Policies for Medicaid Coverage of Donor Human Milk*, J. PERINATOLOGY (2022), https://doi.org/10.1038/s41372-022-01375-9 (documenting the current haphazard nature of coverage on an in- or outpatient basis under Medicaid).

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

[19] *See* Sarah Zhang, *A Bold and Controversial Idea for Making Breast Milk*, ATLANTIC (Feb. 27, 2020), https://www.theatlantic.com/science/archive/2020/02/lab-grown-breast-milk/606955/ [https://perma.cc/54PA-96FH].

[20] *Id.*; Christine Hall, *Helaina's Latest Round Brings It Closer to Market with Human Milk-Equivalent Baby Formula*, TECHCRUNCH (Nov. 19, 2021, 7:00 AM), https://tcrn.ch/3x0B28V [https://perma.cc/L5XA-FWU4].

[21] Bruno Latour, *Give Me a Laboratory and I will Raise the World*, *in* SCIENCE OBSERVED. PERSPECTIVES ON THE SOCIAL STUDY OF SCIENCE 141, 141–69 (Karin D. Knorr-Cetina & Michael Mulkay eds., 1983). *See also* BRUNO LATOUR & STEVEN WOOLGAR, LABORATORY LIFE (1979).

[22] *See* Mathilde Cohen, *Should Human Milk Be Regulated?*, 9 U.C. IRVINE L. REV. 557, 569–70 (2019).

[23] *See* Donor Milk Safety Act (2022), https://delauro.house.gov/sites/delauro.house.gov/files/documents/DeLauro_Donor%20Milk%20Safety%20Act.pdf [https://perma.cc/6BS8-QHFR] (bill that would amend the Federal Food, Drug, and Cosmetic Act to mandate that "donor human milk which has undergone any bioburden reduction process" follow "exempt infant formula" requirements); *see also* 21 C.F.R. § 107.3 (defining an "exempt infant formula" as one "for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems").

major implications for the development, funding, and distribution of lab-produced milk, including issues of affordability and accessibility. Conversely, lab-produced milk scientists, companies, and investors will shape their research, products, and discourses in ways that could affect the regulatory assessment.

The Article proceeds in three Parts. First, it describes how lab-produced milk is developed in the laboratory and marketed. Second, it discusses the advantages and disadvantages of adopting this new technology. Finally, it hypothesizes the various ways in which it could become regulated in the United States, which will in turn have implications globally.

II. WHAT IS LAB-PRODUCED (HUMAN) MILK?

Human milk produced from a human body is notoriously hard to define legally, as it can be thought of alternatively as a food, a tissue, a drug, a relationship, or all of the above.[24] As this Part argues, this polysemy is also at work in the futuristic lab-produced products emulating human milk currently under development.

A. Milk from Mars?

In the past few years, a handful of biotech companies from different countries began to create human milk components in the laboratory.[25] Their proprietary, rapidly evolving technologies make it difficult to describe with precision what they do, but this section offers a brief summary of what is publicly known at the time of writing.[26] North Carolina startup BIOMILQ cultures and nurtures mammary cell lines in a bioreactor, which is a device for growing organisms under controlled conditions.[27] In 2020, the company announced that it had successfully produced two key human milk components: the sugar lactose and the protein casein.[28] In 2021, BIOMILQ declared that it had gone further by "produc[ing] the world's first cell-cultured human milk outside of the breast," which "has macronutrient profiles that closely match the expected types and proportions of proteins, complex carbohydrates, fatty acids and other bioactive lipids that are known to be abundantly present in breastmilk."[29] Three other companies also seek to produce human milk from cells, while a fourth uses yeast. Colostrupedics (aka 108Labs), another North Carolina startup founded by a former BIOMILQ partner, uses commercially available mammary cells as well as donor human milk to develop "whole-human infant formula."[30] The company describes the

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[24] 21 C.F.R. § 107.3.

[25] *See* Zhang, *supra* note 19.

[26] Given the dearth of peer-reviewed research outlining this new technology, our description paints with a broad brush though we do not foresee that more specific details and individual variations would alter the substance of our argument and conclusion.

[27] *How It Works*, BIOMILQ (last visited June 17, 2021), https://www.biomilq.com/our-science [https://perma.cc/9KJD-3QX4].

[28] *See* Zhang, *supra* note 19.

[29] *BIOMILQ Has Successfully Made Human Milk: From Proof of Concept to Proof of Complexity*, BIOMILQ (June 1, 2021), https://biomilq.medium.com/biomilq-has-successfully-made-human-milk-ae3649571e69 [https://perma.cc/Q9C2-BU4N].

[30] *108Labs Introduces Colostrupedics™ Whole-human Infant Formula with Secretory IgA*, 108LABS (last visited Mar. 21, 2022), https://108labs.net/colostrupedics/ [https://perma.cc/EF8N-43TT] [hereinafter *108Labs Introduces Colostrupedics™*].

product as including human sugars, lipids, proteins, and "secretory antibodies."[31] Singapore-based TurtleTree Lab selects mammary cells and feeds them micronutrients, which are "convert[ed] . . . into milk."[32] Israeli firm BioMilk also produces human (and cow) milk from mammary cells.[33] Finally, New York startup Helaina employs yeast to feed a fermentation process that results in microflora secreting specific components of human milk, such as proteins.[34] So far, no standardization of processes and results have emerged, generating ambiguities in terms of nomenclature—with some calling the resulting products "lab-grown milk" and others, "synthetic," "cultured," "cell-based," "cellular," or "fermented" milk, among other labels.[35] This Article uses the expression "lab-produced" milk because at this juncture, it appears to be the most descriptive, even if eventually this type of milk would be manufactured in factories and other food processing facilities rather than labs.

Human milk is a complex fluid whose full range of properties are still "largely unexplored territory."[36] Researchers continue to identify previously unknown human milk components, "and the functionality of those components [is] under active investigation in many laboratories worldwide."[37] These identified components include antibodies, hormones, antiviruses, anti-allergens, anti-parasites, growth factors, enzymes, and hundreds of strains of probiotic bacteria and prebiotic oligosaccharides.[38] Despite scientific uncertainty as to the function and mechanism of action of various nutritional and bioactive human milk constituents,[39] lab-produced milk has received significant media and financial attention.[40] Though initially self-

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[31] *Id.*; *see generally Who Is 108Labs*, 108LABS (last visited May 7, 2021), https://108labs.net/history/ [https://perma.cc/A75V-HUAX].

[32] *Same Milk, Different Method*, TURTLETREE (last visited May 11, 2021), https://turtletree.co/process [https://perma.cc/P79F-W5TB].

[33] BIOMILK (last visited June 17, 2021), https://www.biomilk.com [https://perma.cc/T2KJ-TTA6].

[34] Samantha Sanders, *Breast Milk Start-Up Helaina Aims to Improve Upon an Old Formula*, PROTEIN REPORT (June 3, 2020), https://www.proteinreport.org/breast-milk-start-helaina-aims-improve-upon-old-formula [https://perma.cc/A8SZ-R24Y].

[35] *Id.*; *see generally* Press Release, U.S. Dep't of Agric., USDA Seeks Comments on the Labeling of Meat and Poultry Products Derived From Animal Cells (Sept. 2, 2021), https://www.usda.gov/media/press-releases/2021/09/02/usda-seeks-comments-labeling-meat-and-poultry-products-derived (seeking input from consumers and others as to how the new meat products should be called) [https://perma.cc/QS4P-W66B].

[36] Lily Rothman, *Desperate Women, Desperate Doctors and the Surprising History Behind the Breastfeeding Debate*, TIME (July 31, 2018), https://time.com/5353068/breastfeeding-debate-history/ [https://perma.cc/K967-K67N] (interviewing historian Jacqueline H. Wolf).

[37] Olivia Ballard & Ardythe L. Morrow, *Human Milk Composition: Nutrients and Bioactive Factors*, 60 PEDIATRIC CLINICS N. AM. 49, 61 (2013).

[38] *See Workshop on Bioactive Ingredients in Infant Formula*, NAT'L INSTS. OF HEALTH (Sept. 23, 2021), https://www.nichd.nih.gov/about/meetings/2021/092321 [https://perma.cc/RW4C-T53S].

[39] Parul Christian, Emily R. Smith, Sun Eun Lee, Ashley J. Vargas, Andrew A. Bremer & Daniel J. Raiten, *The Need to Study Human Milk as a Biological System*, 113 AM. J. CLINICAL NUTRITION 1063, 1064 (2021).

[40] *See, e.g.*, Rachel Hall, *Lab-Grown Dairy Is the Future of Milk, Researchers Say*, THE GUARDIAN (July 31, 2021), https://www.theguardian.com/food/2021/jul/31/lab-grown-dairy-is-the-future-of-milk-researchers-say [https://perma.cc/BW5Y-5P9G].

funded, firms such as TurtleTree[41] and BIOMILQ[42] have obtained, or are in the process of brokering, substantial investments. Similarly, BioMilk has gone public in Israel.[43] Demographically, lab-produced milk businesses appear more diverse than traditional formula companies—BIOMILQ, BioMilk, and Helaina were founded by White American and Israeli women and TurtleTree was cofounded by a Singaporean woman.[44] Some of the companies use the language of female solidarity and empowerment to promote the message that their products offer more choice to parents.[45]

Lab-produced milk products are not the first foods or bodily substances manufactured from lab-grown cells. They are but one facet of a broader movement toward cellular agriculture—the production of agricultural products from cell cultures[46]—and regenerative medicine—the branch of medicine that develops methods to regrow, repair, or replace damaged or diseased cells, organs, and tissues.[47] In the early 2000s, NASA toyed with the idea of lab-produced meat with the goal of allowing astronauts to produce their own food in space.[48] In 2013, the first cell-based burger was unveiled in London with great fanfare.[49] Since then, the fervor for lab-produced food has soared.[50] Cellular agriculture now includes the production of meat, seafood, egg, animal milk, and leather from cell cultivation.[51] Regenerative medicine

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41 *TurtleTree Launches Turtle Tree Scientific, Will Help Make Cell-Based Affordable*, VEGCONOMIST (Jan. 6, 2021), https://vegconomist.com/science/turtletree-launches-turtle-tree-scientific-will-help-make-cell-based-affordable/ [https://perma.cc/D9FE-A853].

42 *BIOMILQ Raises $3.5M to Create a More Nutritious and Sustainable Option for Feeding Babies*, BIOMILQ (June 16, 2020), https://biomilq.medium.com/biomilq-raises-3-5m-to-create-a-more-nutritious-and-sustainable-option-for-feeding-babies-50bed8d0ac09 [https://perma.cc/K2LX-DXUV].

43 Simona Shemer, *Israeli Firm BioMilk Is World's First Cultured Milk Company to Go Public*, NO CAMELS (Apr. 19, 2021), https://nocamels.com/2021/04/israel-biomilk-cultured-public-ipo/?utm_source=Newsletter&utm_medium=email&utm_campaign=biomilk [https://perma.cc/7K3Z-LYC4].

44 *Fengru Lin, Co-Founder and CEO of TurtleTree Labs—Clean Milk for People and Planet Via Cell-Based Methods!*, ASIATECHDAILY (Sept. 18, 2020), https://www.asiatechdaily.com/fengru-lin-ceo-and-co-founder-turtle-tree-labs/ [https://perma.cc/6ERT-LWDK].

45 *See, e.g.*, *BIOMILQ Has Successfully Made Human Milk*, *supra* note 29.

46 *See* Alexandra E. Sexton, Tara Garnett & Jamie Lorimer, *Framing the Future of Food: The Contested Promises of Alternative Proteins*, 2 NATURE & SPACE 47 (2019) (critically examining "alternative proteins" derived from cellular agriculture).

47 *See* Gianluca Sampogna, Salman Yousuf Guraya & Antonello Forgion, *Regenerative Medicine: Historical roots and Potential Strategies in Modern Medicine*, J. MICROSCOPY & ULTRASTRUCTURE 101 (2015) (reviewing the history and practice of regenerative medicine).

48 Paul Shapiro, *Lab-Grown Meat Is on the Way*, SCIENTIFIC AM. (Dec. 19, 2017), https://blogs.scientificamerican.com/observations/lab-grown-meat-is-on-the-way/ [https://perma.cc/3PBV-8TX9].

49 Henry Fountain, *A Lab-Grown Burger Gets a Taste Test*, N.Y. TIMES (Aug. 5, 2013), https://www.nytimes.com/2013/08/06/science/a-lab-grown-burger-gets-a-taste-test.html [https://perma.cc/743U-YV89].

50 Hallam Stevens, *Lab-Grown Meat Is on the Rise. It's Time to Start Asking Tough Questions*, THE GUARDIAN (June 17, 2021), https://www.theguardian.com/food/2021/jun/17/lab-grown-meat-no-kill-food [https://perma.cc/33NL-P3G6].

51 *Cellular Agriculture: The Future of Food*, CELLULAR AGRIC. (Dec. 22, 2017), https://www.cell.ag/blog/cellular-agriculture-future-of-food [https://perma.cc/M6HA-3JMA].

is seen as a new frontier of research,[52] but the idea of creating artificial organs dates back to the 1930s.[53] Combining cell technology and tissue engineering, human cells (often stem cells), tissues, and organs are developed into fluids such as blood or specialized tissues such as heart muscle, bladders, and tracheas.[54] The resulting materials may serve to create patches for organs and perhaps someday as functional replacements to ease chronic shortages of transplantable organs.[55]

Lab-produced (human) milk is thus at the intersection of futuristic food and medical experiments, reflecting the multifaceted dimensions of human milk itself.

B. The Intersection of Cellular Agriculture and Regenerative Medicine

This section discusses where lab-produced milk can be situated within the fields of cellular agriculture and regenerative medicine.

The idea behind cellular agriculture is to replace the majority of animal foods (in particular meat, seafood, eggs, and dairy) with foods produced in the lab that are "biologically equivalent or near-equivalent replacements."[56] Lab-produced foods for adults provide "an imagined food future where humanity can still enjoy the products that have resulted from generations of nature's pacification, but without the guilt that comes with awareness of the negative consequences."[57] With lab-produced human milk, however, the goal is ostensibly *not* to replace lactation, but rather to supplement it.[58] Unlike lab-grown food companies premised on a critique of the existing food system,[59] lab-produced human milk makers do not think that there is anything

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[52] *See* 21 U.S.C. § 356(g)(8) (stating that "the term 'regenerative medicine therapy' includes cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products" with a few exceptions).

[53] Sampogna et al., *supra* note 47, at 101.

[54] *Id. See also Lab-Grown Blood: Realistic Science Fiction Still Awaiting a Major Break-Through: Interview with Marieke von Lindern*, SANQUIN (Dec. 18, 2018), https://www.sanquin.org/news/2018/dec/lab-grown-blood-realistic-science-fiction-still-awaiting-a-major-break-through#; Lars Noah, *Growing Organs in the Lab: Tissue Engineers Confront Institutional "Immune" Responses*, 55 Jurimetrics 297 (2015).

[55] *See* Noah, *supra* note 54.

[56] *See, e.g.*, Zsofia Mendly-Zambo, Lisa Jordan Powell & Lenore L. Newman, *Dairy 3.0: Cellular Agriculture and the Future of Milk*, 24 FOOD CULTURE & SOC'Y 675, 677 (2021) (analyzing the fermentation-based production of animal-free milk for marketing to the general population as dairy products, some of which are already commercially available in the United States, albeit on a very limited scale).

[57] Michael J. Mouat & Russell Prince, *Cultured Meat and Cowless Milk: On Making Markets for Animal-Free Food*, 11 J. CULTURAL ECON. 315, 316 (2018).

[58] *See, e.g.*, *The Perfect Balance of Milk, Nature & Science*, TURTLETREE, https://turtletree.co [https://perma.cc/KS2Y-S3PA] ("There is nothing like mother's milk. That is never going to change."); *BIOMILQ Has Successfully Made Human Milk*, *supra* note 29 ("We have no intention to replace chestfeeding, so we're comfortable with the differences between our product and breastmilk. Instead, we intend to offer parents another supplemental feeding option to nourish healthier babies, empower parents through choice, and contribute to a healthier planet."); Sanders, *supra* note 34 ("Unlike the advertising of the 50s and 60s, what Helaina is working on doesn't position itself as a better alternative to breast milk. No matter how perfect a milk the lab can create, it can't replicate a mother's immunity or hormones that can be transferred during nursing.").

[59] *See, e.g.*, Kate Aronoff, *Lab to Table*, NEW REPUBLIC (Sept. 29, 2021), https://newrepublic.com/article/163554/lab-meat-save-planet [https://perma.cc/2V3Z-SWEY] (discussing some of these companies).

inherently problematic with lactation. On the contrary, they see themselves as breastfeeding advocates endeavoring to support parents and children by offering a breastmilk substitute that is closer in composition to human milk than conventional formulas.[60] They present their product as serving to "close the gap between the infant formula offered today and the goodness of natural human milk," as TurtleTree puts it.[61] They do join the rest of cellular agriculture, however, in distancing themselves from infant formula, which is a product of conventional agriculture.[62] The main ingredients of infant formula are cow's milk and/or commodity crops such as soy and corn.[63] Lab-produced milk products are thus meant to replace a *substitute* to human milk—infant formula—not human milk itself. Functionally, their use would be similar, if not identical, to standard breastmilk substitutes—that is, to supplement or replace human-milk feeding. If that is the case, lab-produced milk is infant formula 2.0 rather than an alternative to infant formula.

Champions of cellular agriculture worry about the appeal of its harvest to consumers.[64] Existing studies on consumer acceptance suggest that although a substantial portion of people would be receptive to lab-grown food, many would also be wary "perhaps because it originates in labs, imagined as spaces where unnatural and potentially dangerous non-humans are negotiated by biohazard suit wearing technicians."[65] To the best of the authors' knowledge, no studies exist to date on consumer demand for (and acceptance of) lab-produced human milk. However, it can be hypothesized that parents might be more likely to endorse lab-produced human milk than regular consumers would lab-produced foods. A majority of families already use infant formula, be it as their children's primary food or as supplementation.[66] Formulas are devised in the lab before being mass produced.[67] Many contain ingredients incomprehensible to laypeople, such as maltodextrin, whey protein concentrate, galactooligosaccharides, or protein hydrolysate.[68] These products are already enigmatic, lab-made substances that blur the distinction between food and medicine, conventional agriculture and science.[69] Accordingly, it would not be a major stretch for families to switch from conventional formula to lab-produced milk-based

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[60] *See, e.g.*, *How It Works*, *supra* note 27.

[61] TURTLETREE, https://turtletree.com (last visited May 7, 2021) [https://perma.cc/7JUD-J5PU].

[62] *See* Sanders, *supra* note 34.

[63] VICTOR OLIVEIRA, ELIZABETH FRAZÃO & DAVID SMALLWOOD, U.S. DEP'T OF AGRIC., RISING INFANT FORMULA COSTS TO THE WIC PROGRAM: RECENT TRENDS IN REBATES AND WHOLESALE PRICES (2010), https://www.ers.usda.gov/webdocs/publications/46369/8164_err93_1_.pdf?v=3733.8 [https://perma.cc/GH5N-WUPW].

[64] Neil Stephens, Lucy Di Silvio, Illtud Dunsford, Marianne Ellis, Abigail Glencross & Alexandra Sexton, *Bringing Cultured Meat to Market: Technical, Socio-Political, and Regulatory Challenges in Cellular Agriculture*, 78 TRENDS IN FOOD SCI. & TECH. 155, 155 (2018).

[65] Mouat & Prince, *supra* note 57, at 317.

[66] Lauren M. Rossen, Alan E. Simon & Kirsten A. Herrick, *Types of Infant Formulas Consumed in the United States*, 55 CLINICAL PEDIATRICS 278, 278 (2015).

[67] *See, e.g.*, Michael G. Schwab, *Mechanical Milk: An Essay on the Social History of Infant Formula*, 3 CHILDHOOD 479, 488 (1996).

[68] *See* MINGRUO GUO, HUMAN MILK BIOCHEMISTRY AND INFANT FORMULA MANUFACTURING TECHNOLOGY 172–210 (2014).

[69] *See generally* Infant Formula Act of 1980, P.L. No. 94-359, 94 Stat. 1190 (stating that infant formula is classified as a food).

formula—unlike, say, consumers swapping minimally processed cow's milk for lab-produced cow's milk, or sausages made of animal flesh for cell-based sausages as their staple breakfast. Additionally, at least one company works on offering custom-made lab-produced milk prepared from each customer's own cells, which could facilitate acceptance.[70]

The goal of regenerative medicine is to cure patients with difficult-to-treat diseases and physically impaired tissues using cell therapy, tissue engineering, and human and tissue products.[71] Lab-produced milk may have medical applications for adults and children,[72] but it is primarily envisioned (at least for now) as a food to nourish infants, rather than as a biological drug to treat diseases. It is also unlikely that the Food and Drug Administration (FDA) would view lab-produced milk products as cell therapy products.[73] That said, lab-produced human milk bears similarities to blood substitutes developed to provide alternatives to donor blood transfusion. Both blood and milk are replenishable body fluids, which can be lifesaving. They are currently collected, processed, and distributed by hospitals and specialized biobanks.[74]

The U.S. donor human milk banking system is growing, but the federal government neither financially nor logistically supports it, nor is it integrated into the healthcare system as in other countries such as Brazil, France, Norway, or the United Kingdom.[75] Human milk banks in the United States are private, for- or not-for-profit organizations that must rely on their own funds and sales.[76] Few states require health insurance

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[70] *See How It Works*, *supra* note 27.

[71] L. F. Rose, E. J. Wolf, A. Cernich, W. K. Dean, C. L. Dearth, M. Grimm, A. Kusiak, R. Nitkin, K. Potter, B. J. Randolph, F. Wang & D. Yamaguchi, *The Convergence of Regenerative Medicine and Rehabilitation: Federal Perspectives*, 3 NPJ REGENERATIVE MED., no. 19, Oct. 2018, at 1, 3; *see also*, 21 U.S.C. § 356(g)(8).

[72] *See* TURTLETREE, *supra* note 61 (declaring that milk's bioactive compounds "are not just essential for infant development but also vital for everyone's nutrition. Brain development, gut health and immune boosting are just some of their benefits and we're barely scratching the surface"); Shemer, *supra* note 43 (reporting that the company has plans to use its lab-grown milk "to develop pharmaceutical alternatives (pills, additives, and more)"). Also note that a growing body of research has identified stem cells in human milk which could be used for regenerative therapy down the line. *See, e.g.*, Foteini Hassiotou, Adriana Beltran, Ellen Chetwynd, Alison M. Stuebe, Alecia-Jane Twigger, Philipp Metzger, Naomi Trengove, Ching Tat Lai, Luis Filgueira, Pilar Blancafort & Peter E. Hartmann, *Breastmilk is a Novel Source of Stem Cells with Multilineage Differentiation Potential*, 30 STEM CELLS 2164 (2012), Natalia Ninkina, Michail S. Kukharsky, Maria V. Hewitt, Ekaterina A. Lysikova, Larissa N. Skuratovska, Alexey V. Deykin & Vladimir L. Buchman, *Stem Cells in Human Breast Milk*, 32 HUMAN CELL 223 (2019).

[73] *See* U.S. FOOD & DRUG ADMIN., EXPEDITED PROGRAMS FOR REGENERATIVE MEDICINE THERAPIES FOR SERIOUS CONDITIONS: GUIDANCE FOR INDUSTRY (2019), https://www.fda.gov/media/120267/download (stating that regenerative medicine therapy may include allogenic, autologous, or xenogeneic cells) [https://perma.cc/C748-Q8U6].

[74] *See* KARA SWANSON, BANKING ON THE BODY: THE MARKET IN BLOOD, MILK, AND SPERM IN MODERN AMERICA (2014).

[75] Carolyn Prouse, *Social Reproductive Metabolisms of Human Milk Banking in Brazil*, 121 GEOFORUM 105 (2021); Jasmine Shafquat, *The World Health Organization Has Global Guidelines on Handling Cells, Tissue, Blood and Semen—So Why Is Breast Milk Left in the Dark?*, 29 MICH. ST. INT'L LAW REV. 139 (2021); Mathilde Cohen, *Regulating Milk: Women and Cows in France and the United States*, 65 AM. J. COMP. LAW 469 (2017); Anne Hagen Grøvslien & Morten Grønn, *Donor Milk Banking and Breastfeeding in Norway*, 25 J. HUM. LACTATION 206 (2009); CASSIDY & DYKES, *supra* note 15, at 75 (studying U.K. human milk banks that are part of the National Health Service (NHS)).

[76] *See* Linda C. Fentiman, *Commodification of Breastfeeding and the New Markets for Breast Milk and Infant Formula*, 10 NEVADA L. J. 29, 63–67 (2013).

companies to cover the cost of donor human milk, and when they do, it is typically prioritized for hospitalized premature and sick infants for a relatively short duration.[77] This often leaves parents of outpatients and term babies who need human milk with the alternative of using formula or procuring donor human milk peer-to-peer through friends or dedicated groups and websites.[78]

It is unclear to what extent lab-produced human milk is destined to become the universal formula of the future—widely available for all babies—or a designer product tailored to the needs of specific infants or groups of infants.[79] It could also find applications in older children and adults. After all, a human milk-based supplement is now marketed for adults,[80] promoted as beneficial for "optimum digestion," "immune system support," "mental health," and "better sleep."[81] It is conceivable that scientific and technological advances could enable the development of a lab-produced version of this supplement, as well as other lab-produced milk products for adults, such as foods, drugs, and cosmetics.

Different companies may have different goals with their lab-produced milk. BIOMILQ initially specialized in personalized lab-produced milk, but is now also working on a product for the general infant population. Initially, its motto was: "Your cells. Your nutrition. Your peace of mind."[82] The personalized milk program works by collecting mammary cell samples from individual parents and creating milk products for these specific parents.[83] It is analogous to "precision medicine"—medicine focused on targeted diagnoses and treatments based on patients' genetic profiles. In this instance, lab-produced milk shares in the highly individualized approach of regenerative medicine and the "right to try" movement.[84] It is also a cousin

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[77] *See* Yeon Bai & Jennifer Kuscin, *The Current State of Donor Human Milk Use and Practice*, J. MIDWIFERY & WOMEN'S HEALTH 1, 5 (2021).

[78] *See, e.g.*, SHANNON K. CARTER & BEATRIZ REYES-FOSTER, SHARING MILK: INTIMACY, MATERIALITY AND BIO-COMMUNITIES OF PRACTICE (2020) (exploring the growing milk sharing practices in the Global North).

[79] There are similarities here with direct-to-consumer genetic and microbiome-based testing companies that market their products with the idea that their recommendations will include a custom-tailored diet or dietary supplement.

[80] Press Release, Aventa Bioscience, Adventa Bioscience® Announces Launch of Trulacta® (July 13, 2021), https://www.prnewswire.com/news-releases/adventa-bioscience-announces-launch-of-trulacta-301332222.html [https://perma.cc/CQA7-LW54].

[81] *Why Trulacta®*, TRULACTA, https://www.trulacta.com/pages/why-trulacta [https://perma.cc/U4NN-8SC9]; *see also Hereditum® Probiotics*, BIOSEARCH LIFE, https://www.biosearchlife.es/en/hereditum lc40/ [https://perma.cc/945Q-W27K] (presenting a line of products called Hereditum® derived from human milk probiotics which are recommended for mothers and their babies); Carmen Romero-Bachiller Pablo & Santoro, *Hybrid Zones, Bio-Objectification and Microbiota in Human Breast Milk Banking*, 40 TECNOSCIENZA 33, 40 (2018) (discussing one of Biosearch Life's products—a probiotic supplement made of bacterial strains found in human milk, which is marketed for lactating people as a cure for mastitis but also for its "benefits for the immune system and intestinal flora of both mother and child").

[82] *See How It Works*, *supra* note 27.

[83] *Id.*

[84] Christine Coughlin, Nancy M.P. King & Melissa McKinney, *Regenerative Medicine and the Right to Try*, 18 WAKE FOREST J. BUS. & INTELL. PROP. L. 590, 598 (2018) (note that a major difference is that drugs are highly regulated compared to human milk and formula).

of "nutrigenomics," that is, personalized nutrition informed by an individual's genetic makeup in order to achieve health.[85]

The idea of personalized artificial milk for infants is not new. At the end of the nineteenth century, American pediatrician Thomas Rotch developed the "theory that even very slight changes in the relative proportions of fat, protein and sugar in the feed mixture could have important effects on the infant's growth and development. He claimed that instructions for preparing feeds should be written as precisely as drug prescriptions."[86] In 1891, he established the first milk modification laboratory in Boston, which made daily deliveries of personalized cow's milk to customers based on physicians' prescriptions.[87]

By contrast, other lab-produced milk companies aim to offer the formulas of the future without embarking on a customized route. For instance, TurtleTree states on its website, "[e]very infant deserves the best nutrition, regardless of their situation."[88] There may eventually be a range of different products on the market, with some companies offering lower-cost versions that are seen and treated as standard infant formula and others manufacturing higher-cost, personalized products closer to therapeutics.

The potential bifurcation of lab-produced milk between products for the general infant population and specialty products geared toward specific infants (or groups of infants based on their condition or disease) tracks human milk itself. Unlike donor blood, which must be matched to a recipient's blood group, any human's milk can be consumed by any baby—with a few exceptions, for example, when an infant develops a reaction to allergens consumed by the milk producer.[89] At the same time, research on lactation continues to reinforce the understanding that the composition of human milk is dynamic, evolving in response to lactating people's situations, the needs of their nurslings, and their environment.[90] Milk is responsive to factors such as diet, bacteria and viruses, seasons, weather, and time of the day; it changes as a baby grows, during growth spurts and illnesses, but also from day to night and throughout a feeding.[91] If lab-produced milk products can someday emulate some of these adaptive quality, infants who cannot be breastfed or fed expressed human milk could, in theory, receive the personalized breastmilk substitute nineteenth century doctors imagined.

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[85] *See generally* Lorraine Brennan & Baukje de Roos, *Nutrigenomics: Lessons Learned and Future Perspectives*, 113 AM. J. CLINICAL NUTRITION 503 (2021) (discussing the state of precision nutrition science).

[86] *See* Mepham, *supra* note 10, at 227, 236. *See also* Thomas M. Rotch, *A Historical Sketch of the Development of Percentage Feeding*, 85 N.Y. MED. J. 532 (1907) (outlining the "percentage feeding" method); Jacqueline H. Wolf, *Historical Research: The Origin of 'Formula': State of the Science, 1890s*, 36 J. HUM. LACTATION 410 (2020) (telling the story of the development of infant formula in the United States, including Rotch's role).

[87] *Id.* at 236.

[88] *The Perfect Balance of Milk, Nature & Science*, *supra* note 58.

[89] *See* Maria Flora Martín-Muñoz, Fernando Pineda, G. García Parrado, Daiana Guillén, Daniela Rivero, T. Belver & Santiago Quirce, *Food Allergy in Breastfeeding Babies. Hidden Allergens in Human Milk*, 48 EUR. ANNALS ALLERGY & CLINICAL IMMUNOLOGY 123 (2016).

[90] *See* Christian et al., *supra* note 39.

[91] *See* Foteini Hassiotou, Anna R. Hepworth, Tracey M. Williams, Alecia-Jane Twigger, Sharon Perrella, Ching Tat Lai, Luis Filgueira, Donna T. Geddes & Peter E. Hartmann, *Breastmilk Cell and Fat Contents Respond Similarly to Removal of Breastmilk by the Infant*, 8 PLOS ONE e78232 (2013).

In sum, lab-produced human milk products are still in development, but they may eventually be marketed along a spectrum from an expensive, niche, druglike product to infant formula for all babies, including products designed for older children and adults. The next Part reflects on the advantages and disadvantages of adopting the lab-produced milk technology.

III. WHY LAB-PRODUCED HUMAN MILK?

Arguments can be made both in favor of and against lab-produced human milk—some of which track the debate over cellular agriculture and regenerative medicine.

A. Arguments in Favor of Lab-Produced Human Milk

The primary benefits of lab-produced human milk fall into several categories: ethical, environmental, health and safety, economic, social, and gender equality.[92] Note that although we draw comparisons between lab-produced milk, conventional infant formula, and donor human milk, we do not put donor human milk on the same continuum as lab-produced milk and conventional formula.[93] Human milk is a unique biological system that nourishes, communicates, and protects.[94] As such, it should remain the gold standard to feed infants who are not breastfed.[95]

1. Ethical

Lab-produced meat "is often described in media and academic discussions as a more humane or ethical way to produce animal flesh for human consumption as it reduces animal suffering."[96] Similarly, lab-produced human milk companies say their products positively impact animal welfare.[97] The primary ingredient in most conventional infant formula is cow's milk, though certain specialized formulas employ

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[92] *See* Annika Lonkila & Minna Kajlonen, *Promises of Meat and Milk Alternatives: An Integrative Literature Review on Emergent Research Themes*, 38 AG. & HUM. VALUES 625, 629 (2001) (noting a trend in the literature on meat and milk alternatives toward analyzing the industry's "promissory narrative" "as one of 'techno-salvation', nothing less than a kinder, healthier, fairer, tastier, safer, and more sustainable food system for all").

[93] *See* Tanya M. Cassidy, *More Than Milk: The Origins of Human Milk Banking (HMB) Social Relations*, 38 J. HUM. LACTATION 344 (2022) (emphasizing that donor human milk should not be viewed on the same continuum as human milk substitutes).

[94] *See* Bridget Young, *Reimagining the Impact of Milk Components on Infant Health*, Presentation at "*Breastmilk Ecology: Genesis of Infant Nutrition (BEGIN) Meeting Series: Working Group 2: Human Milk Composition"* (Jan. 29, 2021), https://videocast.nih.gov/watch=40152 (at 16 min 50s) [https://perma.cc/D2AS-EPR3].

[95] *See, e.g.*, Ann R. Spevacek, Jennifer T. Smilowitz, Elizabeth L. Chin, Mark A. Underwood, J. Bruce German & Carolyn M. Slupsky, *Infant Maturity at Birth Reveals Minor Differences in the Maternal Milk Metabolome in the First Month of Lactation*, 145 J. NUTRITION 1698, 1698 (2015) (pointing out that human milk is the gold standard of nutrition for infants); *see also* WORLD HEALTH ORG., GUIDELINES ON OPTIMAL FEEDING OF LOW BIRTH-WEIGHT INFANTS IN LOW- AND MIDDLE-INCOME COUNTRIES 3 (2011) https://www.who.int/publications/i/item/9789241548366 (recommending that the first option when parents are unable to breastfeed their child is the use of donor human milk) [https://perma.cc/G5RY-GFUU].

[96] James Painter, J. Scott Brennen & Silje Kristiansen, *The Coverage of Cultured Meat in the US and UK Traditional Media, 2013–2019: Drivers, Sources, and Competing Narratives*, 162 CLIMATIC CHANGE 2379, 2383 (2020).

[97] *See, e.g.*, *Positive Environmental Impact*, BIOMILK, https://www.biomilk.com [https://perma.cc/7EGD-LRV2].

other animals' milk—goat's milk in particular[98]—and still others are entirely plant-based.[99] Animals farmed for their milk live in conditions of extreme abuse, particularly those in large industrial farms.[100] If a lab-produced substitute can, indeed, replace the need for animal milk, the concomitant animal suffering could be significantly reduced. Additionally, some commentators might argue that lab-produced human milk, which relies on a very limited amount of initial mammary cells or human milk samples, could bypass some of the ethical questions surrounding the collection and use of donor human milk.[101]

2. Environmental

Proponents of cellular agriculture often point to its environmental advantages, arguing that it represents a solution to the significant environmental impacts associated with animal agriculture[102] and commodity crops production. Conventional agricultural practices use large amounts of energy, land, and water, and are major contributors to CO_2 greenhouse gas emissions.[103] Infant formula plays a substantial role in these environmental harms.[104] Cellular agriculture, by contrast, is described as using minimal amounts of energy, feed, emissions, and land.[105] Cell or cultured technology could also reduce the waste that occurs in the dairy industry due to withdrawal of certain animals for veterinary treatment, parlor infrastructures, lapses in management routine, contamination, and spoilage.[106] It could have similar benefits with respect to

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[98] Colin G. Prosser, *Compositional and Functional Characteristics of Goat Milk and Relevance as a Base for Infant Formula*, 86 J. FOOD SCI. 257, 257 (2021).

[99] *See* OLIVEIRA, FRAZÃO & SMALLWOOD, *supra* note 63, at 9.

[100] *See generally* KATHRYN GILLESPIE, THE COW WITH EAR TAG #1389 (2018) (critiquing the treatment of animals raised for milk).

[101] Some of these ethical issues include donors' and recipients' informed consent, donor compensation, milk price, and allocation decisions. *See generally* Donna J. Miracle, Kinga A. Szucs, Alexia M. Torke & Paul R. Helft, *Contemporary Ethical Issues in Human Milk-Banking in the United States*, 128 PEDIATRICS 1186 (2011) (discussing ethical considerations at stake in human milk banking in the United States).

[102] Painter, Brennen & Kristiansen, *supra* note 96, at 2382.

[103] *See Sources of Greenhouse Gas Emissions*, U.S. ENV'T PROT. AGENCY (Apr. 14, 2022), https://www.epa.gov/ghgemissions/sources-greenhouse-gas-emissions [https://perma.cc/U37Q-XBN8] (attributing 11% of total U.S. greenhouse gas emissions to agriculture in 2020).

[104] *See generally* Julie P. Smith, *A Commentary on the Carbon Footprint of Milk Formula: Harms to Planetary Health and Policy Implications*, 14 INT'L BREASTFEEDING J. 49 (2019) (arguing for an urgent investigation of the environmental costs of formula feeding, including greenhouse gas implications); Karin Cadwell, Anna Blair, Cindy Turner-Maffei, Maret Gabel & Kajsa Brimdyr, *Powdered Baby Formula Sold in North America: Assessing the Environmental Impact*, 15 BREASTFEEDING MED. 671, 671 (2020) (finding that in 2016, the greenhouse gas emissions (in tons of CO_2 eq.) attributable to sales of powdered formula for the United States was 655,956).

[105] *See, e.g.*, Natalie R. Rubio, Ning Xiang & David L. Kaplan, *Plant-Based and Cell-Based Approaches to Meat Production*, 11 NATURE COMMC'NS 6276 (2020).

[106] *See, e.g.*, Margaret D. March, Luiza Toma, Bethan Thompson & Marie J. Haskell, *Food Waste in Primary Production: Milk Loss with Mitigation Potentials*, 6 FRONTIERS NUTRITION 173, 173 (2019) (2018 survey of dairy farms in Scotland finding that "milk losses occurred due to withdrawal periods for veterinary treatment, parlor infrastructure, and lapses in management routine").

donor human milk, as a portion of the milk that human milk banks collect is discarded before it can be used, most often because of its high bacterial count.[107]

3. Health and Safety

Lab-produced human milk could have some safety advantages because its mode of production arguably allows for greater control over inputs.[108] Unlike cow's milk and infant formula, it could be made free from pesticides, growth hormones, and antibiotic residues.[109] Its nutritional profile would be closer to that of human milk.[110] It could also be adapted to meet the needs of certain populations—for example, some believe that premature babies should consume higher-protein milk, and some infants have conditions requiring fat to be removed from human milk.[111] Lab-produced milk products could also include non-nutritive, yet beneficial agents, such as immune factors, hormones, and microbiota lacking in conventional breastmilk substitutes.[112] In principle, lab-produced milk would also be free of harmful bacteria responsible for foodborne illness because their components are grown in a sterile environment—though there would still be potential for postharvest cross contamination via surfaces, workers, clothing, and the air.[113]

Some might argue that lab-produced milk has advantages over human milk itself in that it could be made free of milk-transmissible viruses, chemicals, allergens, and alcohol and drug residues[114]—but numerous voices have reaffirmed that the benefits

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[107] *See e.g.*, Crespin C. Adjidé, André Léké & Catherine Mullié, *Bacillus Cereus Contamination of Pasteurized Human Milk Donations: Frequency, Origin, Seasonal Distribution, Molecular Typing of Strains and Proposed Corrective/Preventive Actions*, J. MATERNAL-FETAL & NEONATAL MED. 1 (2020) (finding that 37.7% of pasteurized donor human milk in France was discarded due to Bacillus cereus contamination).

[108] *See* Alexandra E. Sexton, Tara Garnett & Jamie Lorimer, *Framing the Future of Food: The Contested Promises of Alternative Proteins*, 2 NATURE & SPACE 47, 56 (2019) (critically presenting the argument according to which alternative protein products "offer greater control in terms of the inputs and methods involved in production").

[109] *See generally* Bianca Figueiredo de Mendonça Pereira, Cristine Couto de Almeida, Katia Christina Leandro, Marion Pereira da Costa, Carlos Adam Conte-Junior & Bernardete Ferraz Spisso, *Occurrence, Source, and Pathways of Chemical Contaminants in Infant Formulas*, 19 COMPREHENSIVE REVS. FOOD SCI. & FOOD SAFETY 1378 (2020) (reviewing the various sources of contamination in infant formula).

[110] *See, e.g.*, *BIOMILQ Has Successfully Made Human Milk*, *supra* note 29 ("We can now confirm that BIOMILQ's product has macronutrient profiles that closely match the expected types and proportions of proteins, complex carbohydrates, fatty acids and other bioactive lipids that are known to be abundantly present in breastmilk.").

[111] *See, e.g.*, Emma A. Amissah, Julie Brown & Jane E. Harding, *Protein Supplementation of Human Milk for Promoting Growth in Preterm Infants*, 6 COCHRANE DATABASE SYST. REV. (2018), https://www.cochrane.org/CD000433/NEONATAL_protein-supplementation-human-milk-promoting-growth-preterm-infants (reviewing studies on the common supplementation of human milk with extra protein and finding that it may increase short-term growth but no evidence about effects on later health) [https://perma.cc/KGJ8-7Q3N]; Gary M. Chan & Ellen Lechtenberg, *The Use of Fat-Free Human Milk in Infants with Chylous Pleural Effusion*, 27 J. PERINATOLOGY 434 (2007).

[112] *See* Christine Couto Almeida, Bianca Figueiredo Mendoça Pereira, Katia Christina Leandro, Marion Pereira Costa, Bernadete Ferraz Spisso & Carlos Adam Conte-Junior, *Bioactive Compounds in Infant Formula and Their Effects on Infant Nutrition and Health: A Systematic Literature Revie*w, INT'L J. FOOD SCI., 15 May 2021.

[113] Natalie R. Rubio, Ning Xiang & David L. Kaplan, *Plant-Based and Cell-Based Approaches to Meat Production*, 11 NATURE COMMC'NS 6276, 6–7 (2020).

[114] *See BIOMILQ Has Successfully Made Human Milk*, *supra* note 29 ("[B]ecause BIOMILQ's product is produced outside the body in a sterile controlled environment, our milk will be free from the environmental

of lactation outweigh the risks of exposure to contaminants present in human milk.[115] Lab-produced milk could also be made consistent, while donor human milk varies from batch to batch due to human milk's ever-changing composition.[116] This standardization would make lab-produced milk easier to use, but not necessarily more beneficial for babies.[117] Finally, unlike conventional formula, some versions of lab-produced milk might not need to be pasteurized, preserving their nutritional properties (as well as immunological, if any).[118]

4. Economic

A different argument for lab-produced milk is economic. Although secreting human milk components in the lab is presently more costly than producing conventional infant formula and banked donor human milk, it may eventually become cost-efficient with technological improvements and scaling.[119] If lab-produced milk someday becomes widely available and affordable, and can be proven more beneficial to infants' clinical outcomes than standard breastmilk substitutes, it would offer a higher-quality infant formula option for babies who cannot be breastfed.[120] Its price point may depend on

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toxins, food allergens, and prescription medications that are often detected in breastmilk."). On some of the undesirable components that can found in human milk, see Guomao Zheng, Erika Schreder, Jennifer C. Dempsey, Nancy Uding, Valerie Chu, Gabriel Andres, Sheela Sathyanarayana & Amina Salamova, *Per- and Polyfluoroalkyl Substances (PFAS) in Breast Milk: Concerning Trends for Current-Use PFAS*, 55 ENV'T SCI. & TECH. 7510 (2021) (finding in samples of human milk from American women toxic chemicals known as PFAS found at levels nearly 2,000 times superior than what is considered safe in drinking water); *see also* M. Caminoa, M.F. Martín-Muñoz, F. Pineda de la Losa, G. García-Parrado García, I. Bobolea, J. Larco, J. Diaz- Pena & S. Quirce, *Hidden Allergens in Breast Milk*, 125 J. ALLERGY & CLINICAL IMMUNOLOGY AB221 (2010) (concluding based on five case studies that human milk should be considered a source of hidden allergens). *But see* MAIA BOSWELL-PENC, TAINTED MILK: BREASTMILK, FEMINISMS, AND THE POLITICS OF ENVIRONMENTAL DEGRADATION (2006) (framing toxins in human milk as a form of class, race, and gender-based environmental injustice).

[115] *See, e.g.*, M. Nathaniel Mead, *Contaminants in Human Milk: Weighing the Risks Against the Benefits of Breastfeeding*, 116 ENV'T HEALTH PERSPS. A427, A430–A431 (2008).

[116] *See, e.g.*, Laura Galante, Mark H. Vickers, Amber M. Milan, Clare M. Reynolds, Tanith Alexander, Frank H. Bloomfield & Shikha Pundir, *Feasibility of Standardized Human Milk Collection in Neonatal Care Units*, 9 SCI. REPORTS 14343 (2019) (reporting on the difficulty of collecting human milk "according to a standardized protocol" in light of its dynamicity).

[117] *See, e.g.*, Kimberly A. Lackey, Janet E. Williams, Courtney L. Meehan, Jessica A. Zachek, Elizabeth D. Benda, William J. Price, James A. Foster, Daniel W. Sellen, Elizabeth W. Kamau-Mbuthia, Egidioh W. Kamundia, Samwel Mbugua, Sophie E. Moore, Andrew M. Prentice, Debela Gindola K., Linda J. Kvist, Gloria E. Otoo, Cristina García-Carral, Esther Jiménez, Lorena Ruiz, Juan M. Rodríguez, Rossina G. Pareja, Lars Bode, Mark A. McGuire & Michelle K. McGuire, *What's Normal? Microbiomes in Human Milk and Infant Feces Are Related to Each Other but Vary Geographically: The INSPIRE Study*, FRONTIERS NUTRITION, Apr. 17, 2019, at 17 (putting forward evidence of within- and among-population differences in human milk suggesting that "milk may be tailored not only to infants in a given environment, but also specifically to the needs of individuals," which calls into question the idea that a standardized version of human milk would be beneficial).

[118] *See, e.g.*, Xiaomeng Sun, Cuina Wang, Hao Wang & Mingruo Guo, *Effects of Processing on Structure and Thermal Properties of Powdered Preterm Infant Formula*, 83 J. FOOD SCI. 1685, 1685 (2018).

[119] As far as we know, there is no research on this issue in relation to human milk, but commentators have discussed it in relation to cultured meats which are further ahead. *See, e.g.*, Nicolas Treich, *Cultured Meat: Promises and Challenges*, 79 ENV'T & RES. ECON. 33, 39 (2021).

[120] *See* Angela Johnson, Rosalind Kirk, Katherine Lisa Rosenblum & Maria Muzik, *Enhancing Breastfeeding Rates Among African American Women: A Systematic Review of Current Psychosocial Interventions*, 10 BREASTFEEDING MED. 45, 46 (2015) (highlighting the many barriers to breastfeeding

whether it is manufactured as a standard substitute for all infants or as a personalized milk for a narrow group of infants or specific recipients. Presumably, the more customized the milk, the more expensive.

5. Social

Because lab-produced milk more closely approximates human milk than does conventional infant formula, some lab-produced human milk companies claim that their products could alleviate the feeling of guilt or shame some parents feel when formula feeding.[121]

6. Gender Equality[122]

David Fontana and Naomi Schoenbaum have argued that the gender exclusivity of pregnancy—as opposed to the carework associated with pregnancy—persists well after babies are born.[123] They call for the separation of pregnancy as a biological condition and gender in order to achieve uniformity in the sharing of pregnancy and childcare labor between different sex parents. In her subsequent scholarship, Schoenbaum has shown that lactation is similar to pregnancy: In most cases, it is a gendered biological practice that sets the conditions for the gendered division of labor in dual-gender households well after children are weaned.[124] Lab-produced human milk, if proven safe and superior to conventional infant formula, could offer a tool to "unsex" infant feeding and disrupt the gendered division of labor it sets into motion. This unsexing could even take a literal form, given that lab-produced milk could be made out of male mammary cells, realizing the long-held vision of male lactation.[125] As one lab-produced milk company, 108Labs, observes, its "mother's milk personalization project has transformed into gender-neutral personalized mammary cell therapeutics."[126]

To summarize, if lab-produced milk were successfully manufactured and accessible to all families who want it, some of the inequities currently characterizing formula

among African American women); Katherine M. Jones, Michael L. Power, John T. Queenan & Jay Schulkin, *Racial and Ethnic Disparities in Breastfeeding*, 10 BREASTFEEDING MED. 186, 189 (2015) (reviewing the literature on racial and ethnic disparities in breastfeeding rates and practices); Aloka L. Patel, Tricia J. Johnson & Paula P. Meier, *Racial and Socioeconomic Disparities in Breast Milk Feedings in US Neonatal Intensive Care Units*, 89 PEDIATRIC RESEARCH 344 (2021) (reviewing some of the racial and disparities in human milk donor use for premature infants); Christina Szalinski, *Why US Parents Are Choosing European Baby Formula*, N.Y. TIMES (Mar. 12, 2021), https://www.nytimes.com/wirecutter/blog/us-parents-european-baby-formula/ [https://perma.cc/6ZCX-M75J] (reporting on American parents who purchase European formulas at a premium).

[121] *See* Zhang, *supra* note 19.

[122] I am grateful to Courtney Cahill for this point.

[123] *See generally* David Fontana & Naomi Schoenbaum, *Unsexing Pregnancy*, 119 COLUM. L. REV. 309 (2019).

[124] *See generally* Naomi Schoenbaum, *Unsexing Breastfeeding*, 107 MINN. L. REV. (forthcoming, 2022) (critiquing the sexed law of breastfeeding and arguing for its unsexing through the application of heightened scrutiny under the U.S. Supreme Court's equal protection jurisprudence).

[125] Mathilde Cohen, *The Lactating Man*, *in* MAKING MILK: THE PAST, PRESENT AND FUTURE OF OUR PRIMARY FOOD 141 (Mathilde Cohen & Yoriko Otomo eds., 2017).

[126] *Who Is 108Labs*, 108LABS, https://108labs.net/history/ (last visited June 23, 2021) [https://perma.cc/9GVF-2QDX].

feeding could be alleviated. Having reviewed these potential benefits of lab-produced milk, the next section examines its potential disadvantages.

B. Arguments Against Lab-Produced (Human) Milk

Lab-produced milk and other products of cellular agriculture and regenerative medicine have received substantial financial and media attention despite their uncertain future impact.[127] A 2020 study of the media in the United States and the United Kingdom found that "much of the coverage is prompted by the industry sector, whose representatives are also the most quoted. Positive narratives about cultured meat are much more prominent than cautionary ones."[128] Against this backdrop, two main lines of critique of lab-produced milk could be developed—the first centering on the speculative nature of some of its benefits; the second on the argument that even if it met its promises, it might become another type of technology displacing lactation.

1. Uncertain Impact

First, because lab-produced milk is in its infancy, there is significant uncertainty about its ability to realize its ethical, environmental, economic, health and safety, social, and gender equality promises.[129]

i. Ethics and the Environment

The environmental benefits of cellular agriculture in general are hypothetical, particularly when compared, in the case of lab-produced milk, with lactation.[130] Lactation and human milk sharing are the most sustainable and cruelty-free methods of infant feeding.[131] Lactating parents are walking food plants with integrated storage and packaging systems. When ingested at the breast or chest, human milk requires no land and water use, animal farming, power, packaging, storage, or transportation—but it does require that the lactating person consume more food and water than usual.[132]

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[127] *See* Aditi Roy, *Bill Gates' Climate Change Investment Form on Lab-Produced Breast Milk*, CNBC (June 16, 2020), https://www.cnbc.com/2020/06/16/biomilq-raises-3point5-million-from-bill-gates-investment-firm.html [https://perma.cc/B72T-YC3L] (announcing that BIOMILQ raised "$3.5 million [] from Breakthrough Energy Ventures, Bill Gates' investment firms focused on climate change"); Douglas Yu, *TurtleTree Raises $30 Million In Series A To Expedite Full Commercialization Of Cell-Based Milk*, FORBES (Oct. 29 2021), https://www.forbes.com/sites/douglasyu/2021/10/29/turtletree-raises-30-million-in-series-a-to-expedite-full-commercialization-of-cell-based-milk/?sh=2bc36f0f1249 [https://perma.cc/BT3M-VDV5] (Oct. 29, 2021); Treich, *supra* note 119 (discussing the environmental promises of cultured meat, but also its uncertainties).

[128] Painter, Brennen & Kristiansen, *supra* note 96, at 2379; *see also* Sexton, Garnett & Lorimer, *supra* note 108, at 49 (analyzing the "promissory narratives" of cellular agriculture according to which alternative proteins will secure a better future food system).

[129] *See* Lonkila & Kajlonen, *supra* note 92.

[130] *See* Painter, Brennen & Kristiansen, *supra* note 96, at 2382–83; Hanna L. Tuomisto, *The Eco-Friendly Burger: Could Cultured Meat Improve the Environmental Sustainability of Meat Products?*, 20 EMBO REPS. e47395 (2019); Carolyn S. Mattick, Amy E. Landis, Braden R. Allenby & Nicholas J. Genovese, *Anticipatory Life Cycle Analysis of In Vitro Biomass Cultivation for Cultured Meat Production in the United States*, 49 ENV'T SCI. & TECH. 11941 (2015).

[131] *See* Farryl M. W. Bertmann & Amy L. Yaroch, *Role of Breast Milk and Breastfeeding Within the Context of a Sustainable, Resilient Food System*, 11 J. HUNGER & ENV'T NUTRITION 242 (2016).

[132] *Maternal Diet*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/breastfeeding/breastfeeding-special-circumstances/diet-and-micronutrients/maternal-

Feeding an infant expressed human milk has a larger environmental impact than breast or chestfeeding, as it typically relies on breast pumps, storage bags and bottles, refrigeration, and transportation, but it is likely considerably less polluting than using breastmilk substitutes.[133] Yet another question is whether scaled-up lab-produced milk would be more or less polluting and energy-consuming than expressed human milk. What materials will be used to feed the cells in the lab and in what quantities? How will these materials be grown? How much energy will be required to run the bioreactors? Additionally, some observers question the economic model behind cellular agriculture, raising the concern that a few companies may end up having control over the world's food supply.[134] Similarly, the argument would be that a few lab-produced milk companies might end up with a monopoly over the infant formula of the future.

ii. Health and Safety

It is also uncertain whether lab-produced milk will, in practice, provide a form of nourishment that even approximates human milk.[135] As mentioned earlier, human milk is a complex, dynamic liquid containing immune factors, proteins, lipids, sugars, hormones, microbes, and vitamins, among other components.[136] Even if human milk components produced in the lab were biological analogs to those secreted by humans, little is known at this juncture about the impact of secreting, extracting, and recombining them. Further, assuming that lab-produced milk could replicate human milk's nutritional profile, it might still be deprived of key constituents such as antibodies, hormones, anti-inflammatory factors, and certain bacteria, among others.[137] Human milk is highly variable, changing from parent to parent, from day to day, and from the beginning until the end of a single feed.[138] It would be hard, at least in the near future, for lab-produced milk to mimic this adaptive quality given that, for example, the immune factors or hormones secreted in milk are time-, place-, and people-dependent.[139] Lab-produced milk would thus present similar risks to those of

diet.html (recommending an additional 450 to 500 calories per day to lactating parents) (last visited August 4, 2021) [https://perma.cc/82FZ-Z569].

133 Note that I have not been able to find an empirical study comparing the environmental costs of feeding infants expressed human milk versus feeding them infant formula, so this point is speculative.

134 Hallam Stevens & Yvonne Ruperti, *Lab-Grown Meat Is on the Rise. It's Time to Start Asking Tough Questions*, THE GUARDIAN (June 17, 2021), https://www.theguardian.com/food/2021/jun/17/lab-grown-meat-no-kill-food?.

135 *See* Cecília Tomori, *New Technologies Claiming to Copy Human Milk Reuse Old Marketing Tactics to Sell Baby Formula and Undermine Breastfeeding*, CONVERSATION (June 14, 2021), https://theconversation.com/new-technologies-claiming-to-copy-human-milk-reuse-old-marketing-tactics-to-sell-baby-formula-and-undermine-breastfeeding-159771 [https://perma.cc/W8SE-NEAS].

136 *See* Ballard & Morrow, *supra* note 37 (providing an overview of the composition of human milk).

137 *See, e.g.*, *BIOMILQ Has Successfully Made Human Milk*, *supra* note 29 ("But let's be clear, it's not bio-identical to mother's milk—we're not confident it can be. Hormonal changes, baby's cues, skin-to-skin contact, and environment all affect the dynamic complexity of breastmilk.").

138 *See* Ballard & Morrow, *supra* note 37.

139 *See* Lackey et al., *supra* note 117.

conventional infant formula use.[140] Furthermore, it is unknown whether lab-produced milk could pose yet unforeseen short- and long-term health problems.[141]

iii. Economics and Equity

Given the millions of infants who are not fed human milk and the incertitudes about lab-produced milk, another question is whether synthesizing milk in the lab is the best use of resources. As medical researcher and cofounder of the Hearts Milk Bank in England Natalie Shenker asks, "[w]hy go through the expensive, unproven process of growing cells to make milk in a bioreactor . . . when we already know how to get actual milk—nutritionally complete—from a donor? The problem is not a lack of breastmilk on Earth, but a lack of access and distribution."[142] If governments and investment firms allocated the same amounts of monies to donor human milk as they do to lab-produced milk,[143] some of these distributional problems could be solved. In some respects, the unequal rates of lactation and donor human milk access in the United States and abroad mirror the problem of world hunger: Poverty is the main cause of undernutrition and malnutrition, not the scarcity of food.[144] Analogously, most birthing parents (and some non-birthing parents[145]) have the ability to lactate and produce enough milk to feed a child—and sometimes more than one.[146] Some of the major obstacles in the way of lactation are economic and social,[147] representing a form of gender, race, and class inequity.[148] Parents are inadequately supported to lactate, and even less so to lactate

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[140] *See, e.g.*, Alison Stuebe, *The Risks of Not Breastfeeding for Mothers and Infants*, 2 REVS. OBSTETRICS & GYNECOLOGY 222, 222 (2009) (stating that for "infants, not being breastfed is associated with an increased incidence of infectious morbidity, as well as elevated risks of childhood obesity, type 1 and type 2 diabetes, leukemia, and sudden infant death syndrome").

[141] One concern, for instance, is whether lab-produced human milk could pose a risk of alloimmunization, that is, the "induction of immunity in response to foreign antigen(s) encountered through exposure to cells or tissues from a genetically different member of the same species," given that products currently developed would include endogenously produced proteins. *See* Hemchandra Pandey, Sudipta Das & Rajendra Chaudhary, *Red Cell Alloimmunization in Transfused Patients: A Silent Epidemic Revisited*, 8 ASIAN J. TRANSFUSION SCI. 75, 75 (2021) (discussing alloimmunization risks in the context of blood transfusion).

[142] Zhang, *supra* note 19.

[143] *See* Roy, *supra* note 127.

[144] *See* AMARTYA SEN, POVERTY AND FAMINES: AN ESSAY ON ENTITLEMENT AND DEPRIVATION (1981) (offering a theory to explain famine based on the concept of entitlement according to which hunger has to do with rights and power).

[145] *See* ALYSSA SCHNELL, BREASTFEEDING WITHOUT BIRTHING (2013) (guide for parents through surrogacy, adoption, same sex partnership, and other circumstances showing that lactation can be triggered in the absence of pregnancy and birth).

[146] *See, e.g.*, Jo Watt & Jo Mead, *What Paediatricians Need to Know About Breastfeeding*, 23 PAEDIATRICS & CHILD HEALTH 362, 365 (2013) (listing some of the most common causes for the inability to lactate or to produce enough milk, before adding that "almost all women are physiologically capable of producing enough milk to feed their baby").

[147] *See, e.g.*, U.S. DEP'T OF HEALTH & HUMAN SERVICES, THE SURGEON GENERAL'S CALL TO ACTION TO SUPPORT BREASTFEEDING 10–15 (2011).

[148] *See, e.g.*, Paige Hall Smith, *Breastfeeding and Gender Inequality*, 34 J. WOMEN POL. & POL'Y 371 (2013) (framing the lack of policies to support breastfeeding as a form of gender inequality); *see also* Andrea Freeman, *Unmothering Black Women: Formula Feeding as an Incident of Slavery*, 69 HASTINGS L.J. 1545 (2018) (arguing that racial disparities in breastfeeding originated in laws and policies impeding Black mothers' ability to breastfeeding during slavery); Kelly M. Boone, Jaclyn M. Dynia, Jessica Logan & Kelly Purtell, *Socioeconomic Determinants of Breastfeeding Initiation and Continuation for Families in Poverty*,

for the six months of exclusive breastfeeding recommended by leading international and U.S. public health organizations.[149] They may be discriminated against, lack the resources to be well-nourished themselves, to stay home with their baby (assuming they have a home) without having to engage in wage work inside or outside the home or to obtain lactation accommodations at work, and may not have access to competent and culturally appropriate lactation support.[150] They may also lack the social and emotional support as well as the encouragement crucial to sustain lactation labor. Donor human milk is not a widespread option, especially for otherwise healthy, non-hospitalized babies, because of insufficient funding and lack of integration of milk banks into the health system.

iv. Social

Will lab-produced milk have a "substitution effect," whereby it would replace conventional infant formula, or will it have a cumulative effect, whereby global consumption of breastmilk substitutes (lab-produced and conventional infant formula) will increase?[151] If the latter, lab-produced milk could reinforce the formula-feeding norm, perpetuating the idea that infant formula is inevitably desirable. Lab-produced milk could therefore become a new, improved type of infant formula that distracts from the urgency of supporting lactation.[152] Arguably, the very project of lab-produced milk would not exist without an established market for infant formula, that is, in the absence of a consumer culture in which bottle feeding is common.[153] Without this preexisting practice, there would be little motivation to develop new human milk substitutes. Some may thus object to lab-produced milk that it is another technological fix that does little to address the central social and economic issues that give rise to lactation difficulties and suboptimal human milk feeding in the first place.

144 PEDIATRICS 272 (2019) (study confirming the lower rates of breastfeeding initiation and continuation in low-income populations).

149 *See, e.g.*, Am. Acad. of Pediatrics, *Breastfeeding and the Use of Human Milk*, 129 PEDIATRICS e827 (2012) (policy statement reaffirming the American Academy of Pediatrics' recommendation for exclusive breastfeeding for six months, followed by continued breastfeeding for one year or longer).

150 *See* SEALS ALLERS, *supra* note 4 (analyzing barriers to breastfeeding in the United States).

151 *See* Neil Stephens, Lucy Di Silvio, Illtud Dunsford, Marianne Ellis, Abigail Glencross & Alexandra Sexton, *Bringing Cultured Meat to Market: Technical, Socio-political, and Regulatory Challenges in Cellular Agriculture*, 78 TRENDS FOOD SCI. & TECH. 155, 162 (2018) (highlighting that positive narratives about lab-produced meat rely on an unsubstantiated assumption of "substitution effect" according to which their dissemination will lead to a decline in consumption of animal flesh).

152 *See Protecting, Supporting and Promoting Breastfeeding*, WORLD HEALTH ORG., https://www.who.int/westernpacific/activities/protecting-supporting-and-promoting-breastfeeding [https://perma.cc/99AN-GCBG] (noting that "[p]rotecting, promoting and supporting breastfeeding will save more lives of babies and children than any other single preventive intervention").

153 *See Breastfeeding Report Card United States*, Table 1, CTRS. FOR DISEASE CONTROL & PREVENTION (2020), https://www.cdc.gov/breastfeeding/data/reportcard.htm [https://perma.cc/D2BA-NZXR] (showing that only 46.9% of infants born in 2017 were breastfed exclusively through three months and only 25.6% through six months).

v. Gender Inequality

Breastfeeding, as a gendered, embodied practice, has long divided feminists, some of whom argue that it collides with the ideal of gender-equal parenting[154] while others point out that in a truly gender equal culture, people should be supported to breastfeed, given its benefits for parents and children.[155] According to the former, lactation is constraining; for the latter, it can be a form of empowerment and a source of pleasure.[156] Delving into this debate would take us too far afield, but suffice it to say that inasmuch as lab-produced milk functionally parallels conventional infant formula, it is unlikely to shift the existing gendered division of labor.

2. Human Milk as the Sum of Its Parts?

Assuming that lab-produced milk can provide the convenience of formula feeding with some of the benefits of human milk, the drawback might be the displacement of lactation. Employers and law- and policymakers might be tempted to revoke the lactation accommodations they offer their employees, reasoning that lab-produced milk is a fine alternative. But feeding a child human milk—be it at the breast or chest, with a parent's expressed milk or with donor human milk—can be seen as a relational practice involving affect and social bonds that cannot be equated to nutrients and bioactive components in a bottle.[157] As Pamela Laufer-Ukeles and Arianne Renan Barzilay have argued, severing nutrition from nurture in the context of infant feeding amounts to prioritizing "separation strategies" between parents and children, rather than programs allowing them to spend time together, at least for the first months or years after birth.[158]

The concept of lab-produced milk relies on a biomedical conception of human milk that privileges its macro- and micronutrient and other properties.[159] It furthers the idea that human milk can become a disembodied, medicalized substance. Kate Boyer has argued that with advances in lactation technologies, human milk has become a "mobile biosubstance."[160] With lab-produced milk, human milk analogs could assume the form of hypermobile biosubstances made and transported in the absence of lactating bodies. In a way, lab-produced milk would fulfill the aspiration of feeding infants without any lactating human. Paul Emmerson, one of the Boston doctors at the forefront of the first American donor human milk services in the 1920s, wrote that "wetnurses are trouble

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[154] *See, e.g.*, ELIZABETH BADINTER, THE CONFLICT (2010) (arguing that contemporary norms of breastfeeding such as "on-demand" breastfeeding are antifeminist).

[155] *See, e.g.*, Penny Van Esterik, *Breastfeeding and Feminism*, 47 INT'L J. GYNECOLOGY & OBSTETRICS S50 (1994) (arguing that "[b]reastfeeding empowers women and contributes to gender equality").

[156] *See, e.g.*, FIONA GILES, FRESH MILK: THE SECRET LIFE OF BREASTS (2006) (offering a feminist celebration of lactation).

[157] *See generally* CASSIDY & DYKES, *supra* note 15.

[158] Pamela Laufer-Ukeles & Arianne Renan Barzilay, *The Health/Care Divide: Breastfeeding in the New Millennium*, 35 COLUM. J. GENDER & L. 264, 268 (2018).

[159] *See, e.g.*, Sandeep Ravindran, *The Promises and Challenges of Producing Human Milk in the Lab*, MILK GENOMICS CONSORTIUM (2021), https://www.milkgenomics.org/?splash=the-promise-and-challenges-of-producing-human-milk-in-the-lab [https://perma.cc/E8YR-W77V] (highlighting the focus on milk components).

[160] Kate Boyer, *Of Care and Commodities: Breast Milk and the New Politics of Mobile Biosubstances*, 34 PROGRESS HUM. GEOGRAPHY 5, 5 (2010).

makers, and perhaps it is just as well that the number is limited."[161] Today, informal milk sharing is often depicted as dangerous in the media.[162] In the milk banking context, health professionals screen donors scrupulously, testing them for infectious diseases and their milk for bacterial contamination, as well as instructing them on how to collect and store their milk.[163] With lab-produced milk, these complications—human temperaments and germs—would be eluded. Cells procured from biobanks—or yeast—need not be recruited, interviewed, screened, and monitored, let alone counseled, thanked, or compensated. The concern, however, with this approach is that it eliminates human milk's relationality, that is, its social role as a "liquid bridge" that connects people within and outside the family unit.[164]

There is an analogy between, on the one hand, the difference between lab-produced milk and human milk produced by humans and, on the other hand, the contrast identified by Latour between "the obsessively clean Pasteurian laboratory" and the "dirty, smelling, noisy, disorganized nineteenth-century animal farm."[165] Few activities are as foreign to one another as that of producing milk compounds in an immaculate and impersonal lab (or factory) and lactation, an "intensely embodied" form of care work and emotional bond embedded in culture and relationships.[166] In the former, milk's micro-components are made hyper visible to the observer's eye, analyzed, measured, and recombined. In the latter, milk remains invisible, at least when it moves straight from nipple to mouth, escaping evaluation and fragmentation. When fed at the breast or chest, a two-way exchange occurs, with babies ingesting milk and its myriad components (including those present on their feeder's skin) while transmitting some of their own.[167] In the lab, milk is defined by the discrete micro-components uncovered by the scientific process.[168] In the field, it is the result of a relationship between humans. But scientists learn from the field—in this case, from lactation and its fluctuations—translating it into their own terms.[169] It may be precisely milk's variability that makes it an interesting object of study, prompting science and technology to claim their mastery of nature. In this sense, lab-produced milk technology is "post-Pasteurian," to use Heather Paxson's account of "microbiopolitics"—the social regulation that is caried out through the control of

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[161] Paul W. Emerson, *The Collection and the Preservation of Human Milk. Preliminary Report*, 78 JAMA 641, 641 (1922).

[162] *See* Shannon K. Carter, Beatriz Reyes-Foster & Tiffany L. Rogers, *Liquid Gold or Russian Roulette? Risk and Human Milk Sharing in the US News Media*, 17 HEALTH, RISK & SOC'Y 30 (2015) (showing that the media presents milk sharing as dangerous and imprudent).

[163] *See, e.g.*, Katherine Carroll, *Breastmilk Donation as Care Work*, *in* ETHNOGRAPHIES OF BREASTFEEDING: CULTURAL CONTEXTS AND CONFRONTATIONS (Tanya Cassidy & Abdullahi El Tom eds., 2015) (analyzing milk donors' hygienic practices as a form of care work).

[164] *See* CASSIDY & DYKES, *supra* note 15, at 4, 6, 101.

[165] *See* Latour, *supra* note 21, at 145.

[166] *See, e.g.*, Penny Van Esterik, *Contemporary Trends in Infant Feeding Research*, 31 ANN. REV. ANTHROPOLOGY 257, 265 (2002).

[167] *See* Su Yeong Kim & Dae Yong Yi, *Analysis of the Human Breast Milk Microbiome and Bacterial Extracellular Vesicles in Healthy Mothers*, 52 EXPERIMENTAL & MOLECULAR MED. 1288 (2020).

[168] *See* Christian et al., *supra* note 39.

[169] *Id.*

microbial life.[170] Biotech firms produce milk in the lab while moving beyond "antiseptic attitude[s]" embracing the idea that real milk is an unpasteurized fluid with living bacteria and other microorganisms.[171]

There is a parallel with lab-produced meat, too. Garrett Broad argues that, "[t]he dominant conceptual metaphor of meat as a product that is manufactured through a technological process highlights the individual components of meat as a focal point."[172] Both lab-produced milk and meat tend to rely on the ideology of nutritionism, that is, the understanding of nutrients as the key indicators of healthy food.[173] But, as a living, relational fluid, human milk may be much more than the sum of its individual parts.[174] A number of experts have called for a paradigm change in the way in which we think about it.[175] Rather than as a substance or an aggregate of discrete components, they argue that it should be seen as a "biological system that intersects and interacts with myriad internal (maternal biology) and external (diet, environment, infections) factors,"[176] in addition to social, cultural, and emotional aspects. A concern with lab-produced milk is that it might reinforce the nutritionist narrative according to which what infants really need—and parents should really want—are scientifically balanced cocktails of micro-components.[177] A related concern is that lab-produced milk could end up being touted as superior to milk from human bodies, for instance because it can be made free of viruses and contaminants, or richer in components considered desirable by some, such as iron.[178] Products already exist on the market that give the impression that human milk is somehow inadequate or should be fortified and closely monitored—for instance, probiotic supplements for

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[170] Heather Paxson, *Post-Pasteurian Cultures: The Microbiopolitics of Raw-Milk Cheese in the United States*, 23 CULTURAL ANTHROPOLOGY 15, 17 (2008).

[171] *Id.* at 18.

[172] Garrett M. Broad, *Making Meat, Better: The Metaphors of Plant-Based and Cell-Based Meat Innovation*, 14 ENV'T COMMC'N 919, 924 (2020).

[173] *See* GYORGY SCRINIS, NUTRITIONISM: THE SCIENCE AND POLITICS OF DIETARY ADVICE (2015) (presenting an ideological approach to food dubbed "nutritionism" that is popular with nutrition scientists, dieticians, and public health authorities and regards foods primarily in terms of their nutritional composition, drawing causal connections between particular nutrients and certain health outcomes).

[174] Note that BIOMILQ emphasizes this point in its marketing. *See BIOMILQ Has Successfully Made Human Milk*, *supra* note 29 ("Our core hypothesis has always been that milk is greater than the sum of its parts, which all work together as a dynamic system.").

[175] *See* Christian et al., *supra* note 39.

[176] Christian et al., *supra* note 39, at 1063.

[177] *See, e.g.*, Jamie Stang, Kathleen Hoss & Mary Story, *Health Statements Made in Infant Formula Advertisements in Pregnancy and Early Parenting Magazines: A Content Analysis*, 2 ICAN: INFANT, CHILD, & ADOLESCENT NUTRITION 16, 20 (2010) (noting that infant formula advertisements in parenting magazines often include statements about the addition of certain components claimed to be beneficial); *see also* Kathleen Parry, Emily Taylor, Pam Hall-Dardess, Marsha Walker & Miriam Labbok, *Understanding Women's Interpretations of Infant Formula Advertising* 40 BIRTH 117 (2013) (reporting that "some women perceive infant formula to have added 'vitamins,' beyond those found in human milk").

[178] *See supra* note 114 and accompanying text.

expressed milk[179] and analyzers that tell the nutritional content (or other data) of a sample of human milk in a few seconds.[180]

Courtney Cahill argues that the anxiety about lab-produced milk fragmenting the lactation relationship can be analogized to arguments raised against donor insemination decades ago and against surrogacy today.[181] In these scenarios, some of the opponents of the new technologies argued (and argue) that fragmenting the reproductive process is unnatural and unethical.[182] In this view, reproduction is seen as a relational process and nonsexual reproduction, as non-relational in a problematic way.[183] In the context of Assisted Reproductive Technology (ART), the fear of fragmentation led to the acceptance of new technologies when they approximate unfragmented traditional sex and reproduction.[184] Thus, although the use of ART by different-sex couples including a mother and a father using their own gametes is now widespread, legal, and generally considered legitimate, this is not the case for people who do not conform to traditional notions of the family, such as singles, LGBTQIA+ people, and/or those seeking to extend parenting or caregiving to more than two people.[185] Could some of the apprehension toward lab-produced milk be driven by the similar fear that it could fragment the traditional dyadic lactation relationship between a mother and a child, opening up infant feeding to non-birthing parents and caregivers? This is a possibility, but lactation differs from reproduction in that fragmenting lactation labor is far from new. Human milk feeding has been shared among multiple people for centuries in the form of wet nursing, cross nursing, and milk expression.[186] In other words, the reticence to lab-produced milk may not so much be motivated by the thought that it could fragment infant feeding, but rather that it could contribute to the lack of support for lactation and milk sharing, be it informally or via milk banks.[187]

To summarize, if it fulfilled its promises, lab-produced milk would have significant advantages over conventional infant formula. At the same time, it could run the risk of displacing lactation and exacerbating the insufficient protection it receives in laws

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[179] *See* Carolyn Prouse, *Mining Liquid Gold: The Lively, Contested Terrain of Human Milk Valuations*, ECON. & SPACE 958, 961, 968 (2021) (describing two types of products capitalizing on the idea of microbiome, which Prouse sees as similarly attempting to separate milk from the human: micro-components of human milk to add to formula and probiotics to add to expressed human milk).

[180] *See Reassuring Moms: Real-Time Breast Milk Diagnostics at Home*, MILKSTRIP, https://milkstrip.com (last visited July 22, 2021) (presenting a "first of its kind line of at-home breast milk tests that give moms nutritional and freshness information in minutes") [https://perma.cc/HRF3-N6AB].

[181] *See* Courtney Megan Cahill, *After Sex*, 97 NEB. L. REV. 1 (2018) (discussing donor insemination and surrogacy).

[182] *See id.*

[183] *See id.*

[184] *See id.*, at 18–42; *see also* Susan Appleton & Albertina Antognini, *Sexual Agreements*, 99 WASHINGTON L. REV. (forthcoming 2022).

[185] *See generally* Marcin Smietana, Charis Thompson & France Winddance Twine, *Making and Breaking Families—Reading Queer Reproductions, Stratified Reproduction and Reproductive Justice Together*, 7 REPROD. BIOMEDICINE & SOC'Y ONLINE 112 (2018) (examining some of the obstacles that LGBTQ+ people and other marginalized groups have faced in accessing reproductive care and services such as ART).

[186] *See* Hewlett & Winn, *supra* note 7; *see also* Mathilde Cohen, *The Right to Express Milk*, 33 YALE J.L. & FEMINISM 47, 54–55 (2021) (noting that milk expression may have been practiced since the Bronze Age).

[187] *See, e.g.*, Tomori, *supra* note 135.

and policies. Regardless of one's stance, however, lab-produced milk is likely to happen and to stay. The next Part examines the ways in which lab-produced milk could become regulated in the United States.

IV. HOW MIGHT LAB-PRODUCED MILK BE REGULATED?

Lab-produced milk raises the broader issue of how consumer products, in particular, those incorporated into the body as food or medicine, are regulated to protect public health when operating in scientific uncertainty. A major question is how lab-produced milk is likely to be regulated and whether it may affect the legal regime of human milk from humans.

In the United States, there is currently no statutory or regulatory statement of identity for human milk, let alone for lab-produced milk. The only statement of identity for milk is limited to cow's milk: "[T]he lacteal secretion . . . obtained by the complete milking of one or more healthy cows."[188] That said, under federal regulations, human milk banks must register as food facilities.[189] Furthermore, it has been proposed that banked milk fall under new federal food and drug laws. In April 2022, U.S. representatives Rosa DeLauro and Kim Schrier introduced the Donor Milk Safety Act in the U.S. Congress.[190] The "bill would require FDA to correctly classify any donor human milk that undergoes bioburden reduction – pasteurization or otherwise – as an exempt infant formula."[191] While most states do not regulate human milk per se, several have adopted dedicated legal regimes, alternatively defining it as a drug, a tissue, or a food, and specifying the conditions under which it can be collected, processed, and distributed.[192] This patchwork of laws does not provide a clear path forward for lab-produced milk, but other laws and regulations could be used as a blueprint. In what follows, we present how lab-produced meats are regulated, before examining other legal regimes that could be applied to lab-produced milk. The Part also considers how the regulation of lab-produced milk could have potential spillover effects on the law of human milk.

A. The Lab-Produced Meat Precedent

Regulatory authorities, industry players, and consumers have had the opportunity to engage in extensive debates over the regulation of lab-produced meat in the past years, given that it is the most developed product of cellular agriculture. Meat itself is a well-defined legal category, having been delineated by numerous U.S. and international laws as well as regulatory bodies such as FDA, the U.S. Department of Agriculture (USDA), the European Food Safety Authority, the Codex Alimentarius,

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188 21 C.F.R. § 131.110(a) (2005).

189 *See* Cohen, *supra* note 22; *see also* HUM. MILK BANKING ASS'N OF N. AM., HMBANA STANDARDS FOR DONOR HUMAN MILK BANKING: AN OVERVIEW 11 (Sept. 2020), https://www.hmbana.org/file_download/inline/95a0362a-c9f4-4f15-b9ab-cf8cf7b7b866 (noting that American milk banks are regulated and inspected as food manufacturers by FDA and their local health departments; all American milk banks must comply with the Food Safety Modernization Act (FSMA) and register with FDA as a food manufacturer bi-annually) [https://perma.cc/SGZ6-DCKX].

190 Press Release, U.S. Representative Rosa DeLauro, DeLauro, Schrier, Advocates Introduce Donor Milk Safety Act (Apr. 1, 2022), https://delauro.house.gov/media-center/press-releases/delauro-schrier-advocates-introduce-donor-milk-safety-act [https://perma.cc/8V2J-G6SH].

191 *Id.*

192 *See* Cohen, *supra* note 22.

and the Food and Agriculture Organization of the United Nations.[193] A common thread in those definitions is that meat comes from living animals. By challenging this understanding, lab-produced meat upsets the jurisdictional boundaries between the two federal agencies in charge of overseeing the American food supply—FDA and USDA.

The United States has a long history of meat regulation. The very notion that foods should be regulated at the federal and state levels stems in large part from issues around meat. For the United States to compete in the growing international meat trade, the first law requiring the inspection of meat products was passed in 1890, calling for USDA oversight.[194] In response to public outrage at the meat industry's exploitative and unsanitary practices exposed in Upton Sinclair's novel, *The Jungle*, Congress enacted the 1906 Pure Food and Drug Act, and FDA became a consumer protection agency.[195]

Today, FDA regulates drugs, tissues and cells, medical devices, food, food additives, and genetically modified organism (GMO) animals, among others, while USDA mainly oversees meat and eggs.[196] After a few years of incertitude as to how lab-produced meat would be addressed, the two agencies announced in 2019 that they would regulate it jointly.[197] Under their memorandum of understanding, FDA conducts premarket consultation processes, including "oversight of collection, cell lines and banks, and all components and inputs" and, "[a]t harvest, . . . provid[es] information necessary for USDA to determine whether harvested cells are eligible to be processed into meat or poultry products that bear the USDA mark of inspection."[198] USDA is responsible for inspecting "establishments where cells cultured from livestock and poultry . . . are harvested, processed, packaged or labeled" and ensuring "that the labeling of human food products derived from the cultured cells of livestock and poultry be preapproved and then verified through inspection."[199]

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[193] EFSA, Codex, and FAO define meat as "all parts of an animal that are intended for or have been judged as safe and suitable for human consumption." CODEX ALIMENTARIUS, ANIMAL FOOD PRODUCTION 7 (2008). USDA defines a meat product as "any product . . . made wholly or in part from any meat or other portion of the carcass." 21 U.S.C. § 601(j).

[194] *Our History*, USDA FOOD SAFETY & INSPECTION SERV., https://www.fsis.usda.gov/about-fsis/history (last updated Feb. 21, 2018) [https://perma.cc/6G25-T4PV].

[195] *See When and Why Was FDA Formed?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fda-basics/when-and-why-was-fda-formed (last updated Mar. 28, 2018) [https://perma.cc/38CD-H27N].

[196] *See What Does the FDA Regulate?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate [https://perma.cc/CHV5-MPDR] (Jan. 18, 2022); George Kimbrell & Paige Tomaselli, *"Fisheye" Lens on the Technological Dilemma: The Specter of Genetically Engineered Animals*, 18 ANIMAL LAW 75 (2011); *FDA or USDA Jurisdiction?*, FDA READER, https://www.fdareader.com/blog/fda-or-usda-jurisdiction [https://perma.cc/L4ZM-UFWM] (Feb. 27, 2019).

[197] Press Release, U.S. Dep't of Agric., USDA and FDA Announce a Formal Agreement to Regulate Cell-Cultured Food Products from Cell Lines of Livestock and Poultry (Mar. 7, 2019), https://www.usda.gov/media/press-releases/2019/03/07/usda-and-fda-announce-formal-agreement-regulate-cell-cultured-food [https://perma.cc/NV72-4PGY]; *see also* Formal Agreement Between the U.S. Department of Health and Human Services Food and Drug Administration and U.S. Department of Agriculture Office of Food Safety 2–4 (Mar. 7, 2019) [hereinafter *USDA and FDA Cultured Meat MOU*], https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/Formal-Agreement-FSIS-FDA.pdf.

[198] *USDA and FDA Cultured Meat MOU*, *supra* note 197, at 2.

[199] *Id.* at 3.

For now, lab-produced (human) milk is excluded from the arrangement, which applies to "human food produced using *animal* cell culture technology, derived from cell lines of *USDA-amenable species*,"[200] not to *human* cell lines. That said, it is likely that lab-produced milk will fall squarely under the authority of FDA. The agency has experience regulating emerging technologies, having worked with GMOs, food derived from animal cloning, and cell-culture technologies in other contexts.[201] FDA also regulates a number of products similar to lab-produced milk, including foods such as animal milk and infant formula, cells, tissues, organs, biologics, and drugs, among others.[202] Finally, FDA is already involved in the oversight of human milk banking, even if it does not, for now, directly regulate human milk.[203]

B. Legal Regimes for Lab-Produced Milk

Lab-produced (human) milk is likely to face higher scrutiny than other lab-produced foods because it is currently specifically designed for the most vulnerable category of consumers, infants, especially if intended for preterm or ill newborns. FDA appears to have already engaged in a reflection on lab-produced milk components for infants, having co-sponsored a National Institutes of Health (NIH) workshop on "biologically active human milk components and analogs" in September of 2021.[204] As noted earlier, it is possible that lab-produced milk products (such as supplements, foods, drugs, or cosmetics) will also be marketed for non-infants (i.e., older children and adults), but this consumer base does not appear to be industry leaders' current primary focus.[205] Lab-produced milk is a large category that may include both foods and drugs. Depending on the products' ingredients and intended use, FDA may take a variety of approaches to lab-produced milk—from the strictest, which would entail treating it as a drug or biologic, to the most lenient, which would consider it as a food, with intermediary regimes such as infant formula (a more stringently regulated subcategory of food) or a new hybrid category. The stakes of adopting any given classification for lab-produced milk are high. It could not only affect how the products are made—their ingredients, processes, packaging, and labeling, among others—but could also have distributional consequences in terms of cost and availability.

1. Drug or Biologic

Biologics and drugs are products intended for use in the cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body.[206] FDA could

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[200] *Id.* at 1 (emphasis added).

[201] *See What Does the FDA Regulate?*, *supra* note 196; *Animal Cloning*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/animal-veterinary/safety-health/animal-cloning [https://perma.cc/XB22-EDTV] (May 20, 2020); *Food Made with Cultured Animal Cells*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-ingredients-packaging/food-made-cultured-animal-cells [https://perma.cc/T8SX-65ND] (Oct. 6, 2020).

[202] *See What Does the FDA Regulate?*, *supra* note 196.

[203] *See* Cohen, *supra* note 22.

[204] *See Workshop on Bioactive Ingredients in Infant Formula*, NAT'L INSTS. OF HEALTH, https://www.nichd.nih.gov/about/meetings/2021/092321 (last updated Aug. 25, 2021) [https://perma.cc/6JA7-ZLTT].

[205] *See supra* notes 80–81 and accompanying text.

[206] U.S. FOOD & DRUG ADMIN., GENERAL NAVIGATION GUIDE FOR MANUFACTURERS OF FDA-REGULATED PRODUCTS AND START-UPS, https://www.fda.gov/media/79688/download (last visited Apr. 8, 2022) [https://perma.cc/9RUB-ABSH].

regulate lab-produced milk marketed for any of these objectives as a drug or biologic, which would be the most stringent form of regulation. FDA previously chose to regulate a cellular agriculture product, insulin—which is life-sustaining for people with diabetes—as a drug.[207] An article is typically considered a drug if it is a consistent product made up of small chemical molecules,[208] whereas biologics encompass variable materials made of large biological molecules and cells.[209] At this time, the biologic category appears more relevant than the drug category for lab-produced milk,[210] but as research progresses and new claims arise, the drug pathway might become more suitable, at least for some products. Regardless, either classification would require that lab-produced milk makers go through the rigorous investigational new drug (IND) application process and obtain a specific license.[211]

Although the federal government has already determined that infant formula is food,[212] certain claims on product labels require FDA authorization, or else can trigger FDA regulation of the product as a drug.[213] This is the case even if the product is marketed as a food, supplement, or cosmetic.[214] Such claims include statements indicating that the intended use of the product is to treat or prevent disease.[215] A review of lab-produced milk companies' websites suggests that they avoid such language, though some of their communications could come under federal scrutiny. For instance, one company says its product "[m]ay provide broad spectrum passive immunity against gastrointestinal and mucosal pathogens," which could be interpreted as a disease claim.[216] So-called "structure/function" claims are subject to a laxer regime than disease claims, and when properly used, they would not cause infant formula to

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[207] Jennifer Penn, *Cultured Meat: Lab-Grown Beef and Regulating the Future Meat Market*, 36 UCLA J. ENV'T. L. & POL'Y 104, 116 (2018).

[208] *See* Jordan Paradise, *Insulin Federalism*, 27 B.U. J. SCI. & TECH. L. 118, 136 (2021).

[209] *See What Are "Biologics" Questions and Answers*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers (last updated Feb. 6, 2018) ("Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources—human, animal, or microorganism—and may be produced by biotechnology methods and other cutting-edge technologies.") [https://perma.cc/LN3G-GKCT].

[210] *See Frequently Asked Questions About Therapeutic Biological Products*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/frequently-asked-questions-about-therapeutic-biological-products (last updated July 7, 2015) (noting that most proteins intended for treatment or prevention of disease will be treated as therapeutic biological products) [https://perma.cc/XX4M-7Z9Q].

[211] 21 U.S.C. § 355(b)(1)–(2), (j); 42 U.S.C. § 262(a)(2)(C)(II).

[212] *See* Infant Formula Act, 94 Stat. 1190.

[213] 21 C.F.R. § 101.93(g) (providing that so-called "disease claims" require prior approval by FDA and may be made only for approved drug products).

[214] *See Label Claims for Conventional Foods and Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (Mar. 7, 2022), https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements; *Cosmetic Labeling Claims*, U.S. FOOD & DRUG ADMIN. (May 25, 2022), https://www.fda.gov/cosmetics/cosmetics-labeling/cosmetics-labeling-claims.

[215] 21 C.F.R. § 101.93(g).

[216] *See 108Labs Introduces Colostrupedics™*, *supra* note 30; *see also* 21 U.S.C. § 343(r)(3)(B)(i) (authorizing health claims on food products if "there is significant scientific agreement . . . that the claim is supported by . . . [scientific] evidence"). A health claim *is* a disease claim that would render the product a drug, were it not for the special exception in 201(g). Here, the word "pathogens" could render the product a drug unless the company goes through the process of getting an authorization regulation.

be considered a drug.[217] These claims describe the effect of an infant formula on a structure of the body or a bodily function. For example, a trade article about another lab-produced milk company states that it is "in the process of producing a lab-made replica for breastmilk, which includes the production of complex carbohydrates found in human milk that support the development of the immune system."[218] This might be considered a structure/function claim.

Even if the primary purpose of lab-produced milk is nutrition, it could also be used as a potential delivery system for non-nutritive components such as immune factors or beneficial bacteria for the microbiome intended to prevent disease, for instance, in the form of an antibodies fortifier or a probiotic. In these scenarios, FDA could consider the product to be a drug or biologic. Should lab-produced milk products be developed for older children and adults, the drug/biologic pathway might become especially relevant given that human milk is not typically a food for non-infants.[219]

A determination that lab-produced milk is a drug or biologic would require that manufacturers conduct clinical trials to establish the safety and efficacy of their products.[220] But to what should lab-produced milk be compared? Special infant formulas, drugs used for sick and premature infants, or human milk from humans? The ethics of randomized controlled drugs trials affecting infant feeding is itself disputed considering the superiority of a 100% human milk diet, especially for the most fragile infants.[221] Leading voices in the breastfeeding community call for an overhaul on research on babies that would cause them to receive a breastmilk substitute until it is determined that there is a safe and ethical way to conduct it.[222] Others argue that, for

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[217] Infant formula and supplement companies can make structure/function claims for their products if they substantiate them based on "competent and reliable scientific evidence." *See* U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: SUBSTANTIATION FOR STRUCTURE/FUNCTION CLAIMS MADE IN INFANT FORMULA LABELS AND LABELING 6 (Sept. 2016), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-substantiation-structurefunction-claims-made-infant-formula-labels-and [https://perma.cc/LHP4-W242] [hereinafter FDA, SUBSTANTIATION FOR STRUCTURE/FUNCTION CLAIMS DRAFT GUIDANCE] (note that this is only draft guidance); *Structure/Function Claims*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-labeling-nutrition/structurefunction-claims (last updated Mar. 7, 2022) [https://perma.cc/FY3F-PF54].

[218] Shemer, *supra* note 43; *see also Helaina Is the Future of Nutrition*, HELAINA, https://www.my helaina.com/home (stating, "Helaina makes first-of-its-kind, nature-equivalent breast milk components that build immunity") (last visited Apr. 8, 2022) [https://perma.cc/MNB3-7WR6].

[219] *See* Sarah Steele, *Breast Milk Is a Marvel of Nature But that Doesn't Mean Adults Should Drink it to See off Disease*, THE CONVERSATION (Apr. 21, 2016), https://theconversation.com/breast-milk-is-a-marvel-of-nature-but-that-doesnt-mean-adults-should-drink-it-to-see-off-disease-57913[https://perma.cc/RW7R-WXAU].

[220] Note that the issue of how to design trials for lab-produced milk will also crop up if it were categorized as infant formula, so this discussion is relevant to the discussion below in the Article. *See infra* Section III.B.3.

[221] *See* Cesar G. Victora, Rajiv Bahl, Aluisio J.D. Barros, Giovanny V.A. França, Susan Horton, Julia Krasevec, Simon Murch, M. Jeeva Sankar, Neff Walker & Nigel Rollins, *Breastfeeding in the 21st Century: Epidemiology, Mechanisms and Lifelong Impact*, 387 LANCET 475 (2016); Katharine Jarrold, Mona Eskander, Helen Crawley, Jillian Trabulsi, Laura E. Caulfield, Gillian Duffy, Vanessa Garcia-Larsen, Deborah Hayward, Matthew Hyde, Suzan Jeffries, Mikael Knip, Jo Leonardi-Bee, Elizabeth Loder, Caroline J. Lodge, Adrian J. Lowe, William McGuire, David Osborn, Hildegard Przyrembel, Mary J. Renfrew, Paula Trumbo, John Warner, Barbara Schneeman & Robert J. Boyle, *Guidance for the Conduct and Reporting of Clinical Trials of Breast Milk Substitutes*, 174 JAMA PEDIATRICS 874 (2020).

[222] *See generally* Robert M. Ward & Catherine M.T. Sherwin, *Ethics of Drug Studies in the Newborn*, 17 PEDIATRIC DRUGS 37 (2015) (on the ethical challenges of drug studies in pediatric patients); *see also* Bartosz Helfer, Jo Leonardi-Bee, Alexandra Mundell, Callum Parr, Despo Ierodiakonou, Vanessa Garcia-

safety reasons, if premature and ill newborns are the target consumers for new products, they should also be one of the study populations involved in the trials.[223] But their "immaturity, small size and rapid developmental changes" make them a particularly high-risk and vulnerable group.[224]

Another difficulty is understanding the long-term consequences of any given compound or ingredient in a breastmilk substitute or a drug for infants and children, given that many clinical trials are of relatively short duration.[225] Some researchers argue that pediatric trials should thus extend for months, if not years, so that findings be generalizable to later outcomes.[226] Conducting such trials could be a lengthy, complicated, and costly process,[227] potentially leading some lab-produced milk companies to attempt to avoid a drug/biologic classification. Conversely, this very classification could be attractive to well-funded firms or companies seeking to partner with powerful players, such as formula or pharmaceutical companies. For these actors, the drug/biologic pathway, despite its time and financial investment, could maximize the likelihood of high legitimacy with the public and profits via data exclusivity and insurance coverage.[228] For consumers, a drug/biologic classification would mean a

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Larsen, Cynthia M. Kroeger, Zhaoli Dai, Amy Man, Jessica Jobson, Fatemah Dewji, Michelle Kunc, Lisa Bero & Robert J. Boyle, *Conduct and Reporting of Formula Milk Trials: Systematic Review*, 375 BRIT. MED. J. 2202 (2021) (arguing that most formula trials have a high risk of bias).

[223] *See* Dan Kabonge Kaye, *The Ethical Justification for Inclusion of Neonates in Pragmatic Randomized Clinical Trials for Emergency Newborn Care*, 19 BMC PEDIATRICS 218 (2019) (arguing that under certain conditions prospective randomized trials involving neonates should be ethically permissible).

[224] Robert M. Ward, Daniel Benjamin, Jeffrey S. Barret, Karel Allegaert, Ronald Portman, Jonathan M. Davis & Mark A. Turner, *Safety, Dosing, and Pharmaceutical Quality for Studies That Evaluate Medicinal Products (Including Biological Products) in Neonates*, 81 PEDIATRIC RSCH. 692, 693 (2017).

[225] *See* Lars G. Hemkens, *How Routinely Collected Data for Randomized Trials Provide Long-Term Randomized Real-World Evidence*, 1 JAMA e186014 (2018) (pointing out some of the problems with too short follow-up periods in randomized clinical trials). *See also* U.S. FOOD & DRUG ADMIN., GENERAL CLINICAL PHARMACOLOGY CONSIDERATIONS FOR NEONATAL STUDIES FOR DRUGS AND BIOLOGICAL PRODUCTS GUIDANCE FOR INDUSTRY (JULY 2019), https://www.fda.gov/media/129532/download [https://perma.cc/R7RF-PMCN] (suggesting that trials for neonates are by nature limited in time given that the neonatal period has typically been defined as twenty-eight days from delivery).

[226] *See* Kanecia O. Zimmerman, Brian Smith, Ann W. McMahon, Jean Temeck, Debbie Avant, Diane Murphy & Susan McCune, *Duration of Pediatric Clinical Trials Submitted to the US Food and Drug Administration*, 173 JAMA PEDIATRICS 60 (2019) (discussing the duration of pediatric trials, including trials with infants); *see also* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: E11 CLINICAL INVESTIGATION OF MEDICINAL PRODUCTS IN THE PEDIATRIC POPULATION 8–9 (Dec. 2000), https://www.fda.gov/media/71355/download (suggesting that long-term studies and follow-up studies "may be needed" or "may be important") [https://perma.cc/J6FR-JWRL]; Eunice Kennedy Shriver, National Institute of Child Health and Human Development, *Exploring the Science Surrounding the Safe Use of Bioactive Ingredients in Infant Formula: Considerations for an Assessment Framework (Day 1): Human Milk as a Reference for Safety/Function of Bioactive Ingredients*, NIH VIDEOCAST, at 2:29:34 (Sept. 23, 2021), https://videocast.nih.gov/watch=42545 (advocating for longitudinal studies on the impact of infant formula throughout childhood and postmarketing surveillance of bioactives used in those substitutes) [https://perma.cc/C7E5-RQFF].

[227] *See, e.g.*, Thomas J. Moore, Hanzhe Zhang, Gerard Anderson & Caleb Alexander, *Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015–2016*, 178 JAMA INTERNAL MED. 1451 (2018) (finding that clinical trials that support FDA's approval of new drugs have a median cost of $19 million).

[228] *See* 42 U.S.C. § 262(k). Once a company's new biologic is approved by FDA, the company is protected for a period of time from competitors' use of its safety and efficacy data to obtain their own FDA marketing approval. *See also* Caroline Park, *Data Exclusivity: What Is It and Why Does It Matter?*, SENSE & SUSTAINABILITY (Jan. 20, 2016), https://www.senseandsustainability.net/2016/01/20/data-exclusivity-

longer wait for products to reach the market, but with assurance that their safety and efficacy would be assessed more thoroughly. A drug/biologic categorization could also have distributional effects if health insurance plans systematically covered lab-produced milk products.[229]

Within the drug/biologic category, FDA also recognized a new class of "live biotherapeutic product" (LBP) for medicinal products for which the active substance is a living microorganism such as bacteria or yeast.[230] As for other biologics/drugs, LBPs' efficacy and safety must be proven via clinical trials before marketing, but specific regulations require, for example, strain identification and characterization through genome sequencing.[231] This category would exclude lab-produced milk made of human cells, but it could fit milk secreted from yeast.

2. Tissue or Cell

Lab-produced milk is typically derived from human cells, except for one company producing it from yeast,[232] raising the question of whether it could be regulated along with other tissues and cells. This pathway would only apply to products that meet the regulatory definition for "Human Cells, Tissues, and Cellular or Tissue Products" (HCT/Ps).[233] HCT/Ps consist of human cells or tissues "intended for implantation, transplantation, infusion or transfer into a human recipient."[234] HCT/P regulations aim at preventing communicable disease transmission and ensuring safe processing and handling, in addition to tracking samples, record keeping, adverse event reporting, and more.[235] Tissues and cells do not require an Investigational New Drug (IND), which includes lengthy and costly clinical trials. However, certain HCT/Ps must satisfy separate licensing requirements applicable to drugs, devices, or biologics, including HCT/Ps that are more than "minimally manipulated" and not intended for "homologous use," which would apply to lab-produced milk.[236]

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what-is-it-and-why-does-it-matter/ [https://perma.cc/7ZKH-WDRS]. During this time, FDA may not approve any "biosimilars" unless the manufacturer or sponsor has done its own safety and efficacy studies. *Id.*

[229] *See* Douglas Conway, *Adults Age 26 Had Highest Uninsured Rate Among All Ages, Followed by 27-Year Olds*, CENSUS (Oct. 26, 2020), https://www.census.gov/library/stories/2020/10/uninsured-rates-highest-for-young-adults-aged-19-to-34.html [https://perma.cc/KP27-URWB] (children are more likely to be insured compared to adults younger than sixty-five—the uninsured rate for those under ten was 5.7% in 2019).

[230] U.S. FOOD & DRUG ADMIN., EARLY CLINICAL TRIALS WITH LIVE BIOTHERAPEUTIC PRODUCTS: CHEMISTRY, MANUFACTURING, AND CONTROL (June 2016), https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Early-Clinical-Trials-With-Live-Biotherapeutic-Products--Chemistry--Manufacturing--and-Control-Information--Guidance-for-Industry.pdf [https://perma.cc/A5CS-4A3X].

[231] Sheila M. Dreher-Lesnick, Scott Stibitz & Paul E. Carlson, Jr., *U.S. Regulatory Considerations for Development of Live Biotherapeutic Products as Drugs*, 5 MICROBIOLOGY SPECTRUM, NO. 5:BAD-0017-2017, 2017, at 1, 5.

[232] *See* Sanders, *supra* note 34.

[233] HCT/Ps are regulated under 21 C.F.R. § 1271.3(d)(1) (2016) and the Public Health Service Act, 42 U.S.C.A. § 264.

[234] 21 C.F.R. § 1271.3(d) (2016).

[235] *See* 1 C.F.R. § 1271.3(d)(1) and Section 361 of the PHS Act.

[236] 21 U.S.C.A. § 355(c) (West 2021). Lab-produced milk would likely not qualify as homologous use, which is a prerequisite for falling under the framework. Homologous use is "repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic

Presently, FDA does not classify secreted body fluids such as human milk as HCT/Ps.[237] However, the agency has determined that *cells* from secreted body fluids are generally considered HCT/Ps.[238] Would cell-based lab-produced milk make the cut? It differs from other HCT/Ps in that it is generally intended to be *swallowed* rather than implanted, transplanted, infused, or transferred into a human recipient.[239] For lab-produced milk that uses human cells as its initial material, the HCT/P pathway could be used to regulate the donor aspects of cell retrieval, such as donor history and testing for pathogens. Based on the information available on their websites, lab-produced milk companies appear to purchase their initial cells from licensed biobanks, which must already comply with establishment registration, donor screening, and current good tissue practice requirements.[240] The HCT/Ps regime is thus unlikely to apply to lab-produced milk per se.

3. Food, Including Infant Formula

FDA has broad authority to regulate food, including "articles used for food or drink for man or other animals . . . [and] articles used for components of any such article."[241] Food regulations are more lenient than drug/biologic or HCT/Ps regulations given that they are typically post-market.[242] A new food can be sold for direct ingestion without prior FDA approval, and it would not be considered adulterated unless it was ordinarily injurious to health.[243] Human milk is humans' primary food and federal law regulates an extensive category of substances as food, be they general use foods or special types of foods.[244] In what follows, various subcategories of food regulation that could be pertinent to lab-produced milk are examined: Food additives, generally recognized as safe foods, the doctrine of substantial equivalence, infant formula, and dietary supplements.

i. Food Additives

If lab-produced milk components became components of another food, they could be treated as food additives requiring food additive regulation unless they were

function or functions in the recipient as in the donor[,]" 21 C.F.R. § 1271.3 (2016), which would not be the case for milk.

[237] 21 C.F.R. § 1271.3(d)(3) (2016).

[238] U.S. FOOD & DRUG ADMIN., REGULATORY CONSIDERATIONS FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS: MINIMAL MANIPULATION AND HOMOLOGOUS USE 15 (July 2020), https://www.fda.gov/media/109176/download [https://perma.cc/4L7A-T6DQ].

[239] But lab-produced milk for preterm infants would presumably also be fed intravenously or through a feeding tube, depending on their gestational age and complications, which could count as "transfer."

[240] *But see BIOMILQ Has Successfully Made Human Milk*, *supra* note 29 (securing cells from individual clients for whom milk is then custom-made).

[241] 21 U.S.C. § 321(f) (2018).

[242] *See, e.g.*, Martha Dragich, *GRAS-Fed Americans: Sick of Lax Regulation of Food Additives*, 49 IND. L. REV. 305, 305 (2016).

[243] 21 U.S.C. § 342.

[244] *See generally* MICHAEL T. ROBERTS, FOOD LAW IN THE UNITED STATES (2016) (providing an overview of food regulation in the United States).

generally recognized as safe (GRAS).[245] Additives are defined in the Federal Food, Drug, and Cosmetic Act as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food," and not yet be GRAS.[246] Writing about lab-produced meat, Jennifer Penn observes that "the nutrient medium that is added to tissue samples to cause it to expand into what we would recognize as meat would qualify as a "food additive" because it is added to a food, namely a tissue sample, to cause that sample to change as the cells propagate."[247] Applied to lab-produced milk, this pathway would require manufacturers to submit a petition to FDA, including scientific documentation to support the safe use of their additives.[248]

ii. GRAS

The GRAS program is a notification/objection one, meaning that manufacturers may "notify FDA of a conclusion that a substance is GRAS under the conditions of its intended use."[249] The program would allow companies to get their lab-produced milk components on the market as food or infant formula ingredients relatively quickly, relying on a combination of existing studies and data and limited new trials.[250] FDA declined to follow this path for lab-produced meat, but in 2020, it recognized as GRAS the whey protein developed from fermented yeast by a company working on cow-free milk intended for consumption by the general public.[251] Similarly, if FDA deemed that the milk components produced in the lab such as lactose, casein, and secretory Immunoglobulin A are identical to their human-secreted original, it might declare them GRAS. In 2017, a new probiotic received GRAS status for infant formula,[252] but

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[245] United States v. 29 Cartons of * * * An Article of Food, 987 F.2d 33, 37 (1st Cir. 1993) (citing United States v. Two Plastic Drums, 984 F.2d 814 (7th Cir. 1993)) (finding that "in order to qualify as a food additive, a component must be added to a food in order to change that food's properties").

[246] 21 U.S.C. § 321(s).

[247] Penn, *supra* note 207; *see, e.g.*, U.S. FOOD & DRUG ADMIN., FDA-2018-N-2155, FDA PUBLIC MEETING: FOOD PRODUCED USING ANIMAL CELL CULTURE TECHNOLOGY 92, 151 (2018), https://www.fda.gov/media/115122/download [https://perma.cc/L8NT-Q924]. "[Y]ou could have the same chemical identity of a substance and yet the properties could change a great deal depending on the actual size of the particles of the substance in the food." *Id.* at 39.

[248] *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS ABOUT THE FOOD ADDITIVE OR COLOR ADDITIVE PETITION PROCESS (Apr. 2011), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-about-food-additive-or-color-additive-petition-process#answerC [https://perma.cc/T66H-9WGP].

[249] *See About the GRAS Notification Program*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/generally-recognized-safe-gras/about-gras-notification-program (last updated Jan. 4, 2018) [https://perma.cc/3RKR-EEUX].

[250] Note that if for food the GRAS program is voluntary, "only substances that may be used in an infant formula are substances that are safe and suitable for use in infant formula under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act; that is, a substance is used in accordance with the Agency's food additive regulations, is generally recognized as safe (GRAS) for such use, or is authorized by a prior sanction." *See* 21 C.F.R. § 106.40 (2014).

[251] *See* Letter from Susan Carlson, Dir., Div. of Food Ingredients, Off. of Food Additive Safety, Ctr. for Food Safety & Applied Nutrition, to Melvin S. Drozen, Keller & Heckman LLP (Mar. 25, 2020), https://www.fda.gov/media/136751/download (determining that the β-lactoglobulin produced by Perfect Day is GRAS and accepting the company's characterization that it is "identical to commercially available bovine-produced β-lactoglobulin") [https://perma.cc/V4FA-C57N].

[252] Adi Menayang, *Safe for Babies: FDA Has No Objections to GRAS Status of Ganeden's BC30 Probiotic Strain for Use in Infant Formula*, DAIRY REP. (Jan. 20, 2017), https://www.dairyreporter.

the bovine milk-derived whey protein osteopontin has so far not gained GRAS status in infant formula.[253]

iii. Doctrine of Substantial Equivalence

FDA could decide to apply the doctrine of substantial equivalence to lab-produced human milk components, as it has been proposed for lab-produced meat. The agency developed this doctrine in the 1990s to address genetically modified foods by focusing "on the specific product being proposed for approval rather than the means by which the product came to be."[254] FDA used this doctrine for GMOs when it concluded in 1992 that, in "most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food."[255] As a result, FDA "presumes that most [genetically engineered] foods are GRAS."[256] Under this approach, FDA could decide to treat lab-produced milk's components as substantially equivalent to those found in milk secreted by humans—and thus as GRAS.

These different variations on the food pathway might appeal to producers and some consumers, as the resulting products would likely be more affordable than drugs/biologics (discounting insurance coverage) as well as accessible over the counter. They would also be subject to significantly less scrutiny than if they were treated as drugs/biologics and would not be covered by insurance. The resulting products would also not be marketable as complete or partial substitutes for human milk, as this status is reserved for products following the infant formula regulatory program described below.[257]

iv. Infant Formula

Because manufacturers primarily present lab-produced milk as a breastmilk substitute, it is likely to be regulated as infant formula—that is, as a "food" that simulates "human milk or its suitability as a complete or partial substitute for human milk."[258] Infant formula is subject to more demanding standards than general types of food in recognition that it is often used as the sole source of nutrition for a vulnerable population during a critical period of growth and development.[259] Other than the

com/Article/2017/01/20/FDA-has-no-objections-for-GRAS-status-of-BC30-in-infant-formula [https://perma.cc/UC9Z-XXB5].

253 *See* Letter from Ray A. Matulka, Dir. of Toxicology, Burdock Grp. Consultants, to Paulette M. Gaynor, Deputy Div. Dir., Off. of Food Additive Safety, Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin. (July 6, 2017), https://www.fda.gov/media/110670/download [https://perma.cc/WP2Z-GYUY].

254 Jeffrey Burkhardt, *The Ethics of Food Safety in the Twenty-First Century: Who Keeps the Public Good?*, PHIL. FOOD 140, 155 (David M. Kaplan, ed., 2012).

255 Trevor Findley, *Genetically Engineered Crops: How the Courts Dismantled the Doctrine of Substantial Equivalence*, 27 DUKE ENV'T. L. & POL'Y F. 119, 123 (2016) (citing Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,985 (May 29, 1992)).

256 *Id.*

257 21 U.S.C.A. § 321(z) (West 2021).

258 21 U.S.C.A. § 321(z) (West 2021).

259 Infant formula must meet the requirements of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 321 (West 2021); the Infant Formula Act, 21 U.S.C.A. § 350a (West 1938); and associated regulations, 21 C.F.R. §§ 106–07 (2022). The Federal Food, Drug, and Cosmetic Act (FFDCA) defines infant formula as "a food which purports to be or is represented for special dietary use solely as a food for

requirement for premarket registration and notification,[260] FDA does not approve infant formulas, but rather reviews them based on their manufacturers' data, relaying concerns to them.[261] One requirement for "non-exempt" infant formula (i.e., formula for healthy term infants) demands the formula meet two quality factors before going to market: 1) clinical evidence that infants consuming the product maintain normal physical growth, and 2) sufficient biological quality of protein.[262] The federal government requires that new formulas follow the GRAS process for new ingredients, providing data from growth monitoring studies demonstrating that they offer adequate nutrition.[263] But much like clinical trials for drugs for newborns are contentious, the ethics of research on infant formula supplementation is contested, especially when research led by "high-income country [] investigators and funders" is conducted on babies in "low/middle-income countries."[264] In addition, manufacturers must follow good manufacturing practices and establish an audit plan, including annual FDA inspections, to ensure that their formula meets nutritional and safety standards.[265]

One normative question is whether some of these requirements are suitable to lab-produced milk products aspiring to be as close to human milk as possible. For instance, federal law requires conventional infant formula to contain a higher level of iron than

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infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk." 21 U.S.C.A. § 321(z) (West 2021). Internationally, infant formula is regulated under the Codex Alimentarius' voluntary standards as well as the WHO 1981 International Code of Marketing of Breastmilk Substitutes. *See* CODEX ALIMENTARIUS, STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (2020), http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B72-1981%252FCXS_072e.pdf. *See generally* WORLD HEALTH ORG., INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES (1981). The Codex adopted Codex Stan 72-1981 for formula in 1981, defining it as follows: "Infant formula means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding." CODEX ALIMENTARIUS, *supra* note 259, § A.2.1.1, at 2. According to the standard, "[i]nfant formula is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be suitable for infant feeding." *Id.* at § A.3.1.1, at 2.

[260] *See* 21 C.F.R. §§ 106.110, 106.120.

[261] Steven A. Abrams, *Is It Time to Put a Moratorium on New Infant Formulas That Are Not Adequately Investigated?*, 166 J. PEDIATRICS 756, 756 (2015).

[262] The quality factor for normal physical growth is demonstrated by conducting a growth monitoring study (GMS). *See* 21 C.F.R. § 106.96(b). A Protein Efficiency Rat (PER) bioassay must be conducted to demonstrate that the infant formula meets the quality factor of sufficient biological quality of protein. *See* 21 C.F.R. § 106.96(f).

[263] *See* Requirements for Quality Factors for Infant Formulas, 21 C.F.R. § 106.96 (2014); Quality Factor Assurances for Infant Formulas, 21 C.F.R. § 106.121 (2014) (requiring that manufacturers demonstrate that their infant formula supports normal physical growth in infants by conducting growth monitoring studies of their product).

[264] Tanya Doherty, Ingunn Marie S. Engebretsen, Thorkild Tylleskär, Kathy Burgoine, Anne Baerug, Raul Mercer, Phillip Baker, David Clark, Catherine Jane Pereira-Kotze & Max Kroon, *Questioning the Ethics of International Research on Formula Milk Supplementation in Low-Income African Countries*, 7 BMJ GLOBAL HEALTH e009181 (2022); *see also Help Stop Unethical Formula Research on Babies*, INT'L BABY FOOD ACTION NETWORK, http://www.babymilkaction.org/archives/32708 [https://perma.cc/A4Z3-48K2] (petition calling for immediate halt to a study "randomly allocating infant formula to exclusively breastfed low-birth-weight babies in Uganda and Guinea-Bissau").

[265] *See* Helen K. Hughes, Michael M Landa & Joshua M. Sharfstein, *Marketing Claims for Infant Formula Additives and Infant Formula*, 171 JAMA PEDIATRICS 105, 105 (2017).

is found in human milk.[266] Should lab-produced milk formulas be held to the same level of fortification, or should human milk be used as a reference for minimum and maximum nutrient and bioactive contents? Using human milk as a benchmark would not be without challenges given its dynamic nature. Similarly, should FDA alter current requirements for growth monitoring studies to account for lab-produced milk's greater similarity to human milk, and the resulting likelihood of differing growth patterns between infants consuming lab-produced milk and those fed conventional formula?[267] Finally, as for labeling, FDA has not issued guidance on "labeling claims that suggest that the product contains constituents found in breastmilk or that the product is 'closer' to breastmilk than other formulas."[268] According to Jennifer Pomeranz and Jennifer Harris, this is "a serious issue for infant formula."[269] Left unaddressed, this gap would allow lab-produced milk products to be labeled as identical to human milk from humans, misleading consumers into believing that these products are just as good as breastfeeding or feeding a baby expressed human milk.[270]

v. Exempt Infant Formula

FDA currently regulates formulas and fortifiers made from donor human milk as "exempt" infant formula.[271] As mentioned earlier, a federal bill recently introduced would also regulate most donor human milk under this category.[272] The exempt infant formula classification is intended for infants who have "an inborn error of metabolism or low birth weight or who otherwise [have] an unusual medical or dietary problem."[273] Regulators could decide to extend this classification to lab-produced milk inasmuch as it is intended for premature or sick infants, or those with allergies or intolerances to regular formula. But as noted above, some lab-produced milk companies aspire to eventually replace conventional formula for all infants, not just

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[266] *See* 21 C.F.R. § 107.100 (listing infant formulas' nutrient specifications).

[267] *See Growth Chart Training: Using the WHO Growth Charts*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nccdphp/dnpao/growthcharts/who/breastfeeding/index.htm (last update Feb. 3, 2022) (noting that the growth patterns of breastfed and formula-fed infants are different, with healthy breastfed infants typically putting on weight more slowly) [https://perma.cc/69XV-GV4B].

[268] *See* FDA, SUBSTANTIATION FOR STRUCTURE/FUNCTION CLAIMS DRAFT GUIDANCE *supra* note 217, at 5.

[269] *See* Jennifer L. Pomeranz & Jennifer L. Harris, *Federal Regulation of Infant and Toddler Food and Drink Marketing and Labeling*, 45 AM. J.L. & MED. 32, 45–46 (2019).

[270] *See, e.g.*, Roopal Luhana, *Abbott Faces New Class-Action Lawsuit Alleging Misleading Claims About Infant Formula*, N.Y. INJ. L. NEWS (Dec. 7, 2021), https://newyork.legalexaminer.com/legal/abbott-faces-new-class-action-lawsuit-alleging-misleading-claims-about-infant-formula/ [https://perma.cc/D47G-ZCSZ] (attorney discussing on-going litigation against a leading formula company based on the claim that consumers were misled by the claim that one of its products is "our closest formula to breastmilk").

[271] *See Exempt Infant Formulas Marketed in the United States by Manufacturer and Category*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/exempt-infant-formulas-marketed-united-states-manufacturer-and-category (last updated Dec. 3, 2019) [https://perma.cc/BG2U-97EQ].

[272] *See supra* note 23 and accompanying text.

[273] 21 C.F.R. § 107.50 (2016) (Exempt Infant Formulas are those "for use by an infant who has an inborn error of metabolism or low birth weight or who otherwise has an unusual medical or dietary problem.").

offer a niche product for certain infant populations.[274] For them, the exempt infant formula classification may not be a good fit.

The infant formula pathway (be it exempt or non-exempt) would be advantageous for lab-produced milk companies given its relative leniency and low compliance costs compared to a drug/biologic classification. This would likely allow these companies to innovate, change, and make their products available sooner. An infant formula classification would make lab-produced milk products eligible for inclusion in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)'s bidding process for purchasing formula.[275] WIC provides nutrition education, vouchers for food packages, and referrals to healthcare and other services to low-income women, infants, and children up to five years of age.[276] It is the single largest purchaser of infant formula in the United States, servicing over half of all infants.[277] As pediatrician and researcher Steven Abrams has asked, if novel breastmilk substitutes lead to improved clinical outcomes compared to traditional formula, should they be systematically included in WIC even if they are more costly?[278] In his view, equity requires that they be included so that under-resourced families can access them.[279] Applied to lab-produced milk, the argument would be that if lab-produced milk did fulfill its promises in terms of health and safety, it should be included in WIC.

From a consumer perspective, an infant formula classification would ensure that lab-produced milk products meet federal nutrient and labeling requirements (be they the current ones or new ones specifically devised for lab-produced milk) and reach the market sooner than a drug/biologic, potentially over the counter, and at a lower price point. However, they would also be less rigorously scrutinized than if classified as a drug or biologic. Additionally, unless the products were considered exempt infant formula or there is a medical need for their use justifying a prescription, insurance companies would typically not cover them, creating an affordability and accessibility issue.[280]

vi. Dietary Supplements

Dietary supplements are yet another subcategory of food under federal law that could be relevant if a lab-produced milk product, for example a probiotic, were

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[274] *See The Perfect Balance of Milk, Nature & Science*, *supra* note 58.

[275] STEPHEN CARLSON, ROBERT GREENSTEIN & ZOE NEUBERGER, CTR. ON BUDGET & POL'Y, WIC'S COMPETITIVE BIDDING PROCESS FOR INFANT FORMULA IS HIGHLY COST-EFFECTIVE, https://www.cbpp.org/research/food-assistance/wics-competitive-bidding-process-for-infant-formula-is-highly-cost (last update Feb. 17, 2017) [https://perma.cc/99AZ-GTNE].

[276] *See* VICTOR OLIVEIRA & ELIZABETH FRAZÃO, U.S. DEP'T OF AGRIC., THE WIC PROGRAM: BACKGROUND, TRENDS, AND ECONOMIC ISSUES, 2015 EDITION (2015), https://www.ers.usda.gov/publications/pub-details/?pubid=43927 [https://perma.cc/64K8-5AWL].

[277] Victor Oliveira & Elizabeth Frazão, *Most Infant Formula Purchased Through WIC*, U.S. DEP'T OF AGRIC. (Mar. 1, 2010), https://www.ers.usda.gov/amber-waves/2010/march/most-infant-formula-purchased-through-wic/ [https://perma.cc/ZWL6-TRUK].

[278] *See* Kennedy Shriver, National Institute of Child Health and Human Development, *supra* note 226 (raising the question of whether less-beneficial infant formulas should even be permitted in the marketplace).

[279] *Id.*

[280] *See* Joshua Bartlett, *Does Insurance Cover Formula? (With Info on Major Companies)*, NAT. BABY LIFE, https://naturalbabylife.com/does-insurance-cover-formula/ (last updated Sept. 20, 2020) [https://perma.cc/CPD8-QZHK].

intended to supplement the diet through ingestion by increasing the total dietary intake of a given substance.[281] If the ingredient was not used in supplements before October 15, 1994, it would have to go through a premarket clearance process.[282] A dietary supplement is considered "new" if it contains an ingredient not recognized as a food substance, unless it was sold as a supplement before October 1994.[283] Human milk itself is not new, but the question would be, as in the preceding section on food additives and the GRAS program, whether FDA would consider lab-produced milk components to be identical to human milk's and, therefore, not new substances. If determined to be new, lab-produced milk companies would need to provide FDA with reasonable evidence that the components are safe before lab-produced milk-based supplements could be marketed to the public.[284] Even if they were *not* considered new, the question would still arise (at least for cell-based milk) whether materials derived from the human body can be used as ingredients in dietary supplements.[285] The dietary supplement framework would thus be advantageous to firms that want to put on the market specific components of lab-produced milk for the general public and not for use as a conventional food or meal replacement. This pathway could also appeal to consumers who prefer a more accessible, over-the-counter product to a highly scrutinized, but potentially less accessible drug/biologic.

4. Path Forward

FDA could also apply aspects of its emerging lab-produced meat framework to lab-produced milk. Under the current MOU with USDA on lab-produced meat, FDA oversees the initial cell collection as well as the development and maintenance of qualified cell banks.[286] It ensures that companies follow current good manufacturing practices.[287] The agency is probably developing additional requirements to ensure that biological materials are safe and unadulterated as they leave the culture process.[288] These steps are likely to be analogous to those involved in lab-produced milk regulation. The major difference, however, is that for lab-produced milk, FDA could also be in charge of the tasks currently allocated to USDA for lab-produced meat, such as control over harvested cells and products.

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[281] Dietary Supplement Health and Education Act (DSHEA), 108 Stat. 4325 (1994). Note that a human-milk dietary supplement for adults was launched in 2021, so it is not impossible that lab-made versions may eventually be marketed; *see* Jim Cornall, *Adventa Bioscience Launches Trulacta Human-Milk Supplement*, DAIRY REPORTER (July 15, 2021), https://www.dairyreporter.com/Article/2021/07/15/Adventa-Bioscience-launches-Trulacta-human-milk-supplement [https://perma.cc/96X4-KHK5].

[282] U.S. FOOD & DRUG ADMIN., DIETARY SUPPLEMENTS: NEW DIETARY INGREDIENT NOTIFICATIONS AND RELATED ISSUES—GUIDANCE FOR INDUSTRY (Aug. 2016), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-new-dietary-ingredient-notifications-and-related-issues [https://permacc/4ZFJ-2NRN].

[283] *Id.*

[284] 21 U.S.C. § 350b.

[285] *See Questions and Answers in Dietary Supplements*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements (last updated July 22, 2019) (stating that a dietary ingredient can include "substances such as enzymes, organ tissues, glandulars, and metabolites" but not saying whether human cells or tissues or substances derived from them can be considered dietary ingredients) [https://perma.cc/9SZS-VDWF].

[286] Feyza Sancar, *Agreement to Regulate Cell-Based Meat Products*, 321 JAMA 1449, 1449 (2019).

[287] *Id.*

[288] *Id.*

Another approach would be for FDA to devise a new, hybrid regulatory classification for lab-produced (human) milk in its various iterations. This could be especially useful for products that include multiple interactive components. The current FDA framework for foods and drugs leads to primarily assessing ingredients one by one for their safety (and where relevant, efficacy), rather than holistically.[289] But bioactive ingredients interact with one another in ways that may affect the function and the safety of the products.[290]

Finally, in addition to or instead of creating new regulatory pathway, the emergence of lab-produced milk technology could be the occasion to strengthen food regulation, in particular infant formula regulation, with a precautionary mission including a rigorous premarket review process and a moratorium on infant formula trials until a safe and ethical protocol is established. Numerous voices over the years have advocated for stricter requirements for breastmilk substitutes.[291] Some of the proposals are to base the approval process on a review of evidence, which would be made publicly available and look broadly at safety to children and the environment. Key stakeholders could also be included in the review, in particular, parent representatives, lactation experts, human milk scientists, and pediatricians. More exacting standards could be imposed on the clinical studies to be conducted before infant formulas can be marketed. As Abrams has argued, FDA should not only focus on the safety of infant formulas, but also on their "efficacy," that is, their expected benefits for infants, if any.[292]

Finally, the 1981 World Health Organization (WHO) International Code of Marketing of Breast-Milk Substitutes should be adopted and enforced in the United States, including to lab-produced milk for infants.[293] The Code is designed to protect and promote breastfeeding and to end the inappropriate marketing of infant formula and other foods and drinks intended for children up to age three.[294] Among other provisions of the Code that are not followed in the United States are the prohibition on advertising or promoting breastmilk substitutes[295] and on labeling that "may idealize the use of infant formula."[296] Additionally, since 1981, the World Health Assembly

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[289] *See, e.g.*, *Overview of Food Ingredients, Additives & Color*, U.S. FOOD & DRUG ADMIN. (Feb. 6, 2018), https://www.fda.gov/food/food-ingredients-packaging/overview-food-ingredients-additives-colors (distinguishing between different food components).

[290] *See* Eunice Kennedy Shriver National Institute of Child Health and Human Development, *Workshop on Bioactive Ingredients in Infant Formula*, NIH VIDEOCAST, (Sept. 23–24, 2021), https://www.nichd.nih.gov/about/meetings/2021/092321 [https://perma.cc/GY2Q-D6C].

[291] *See, e.g.*, George Kent, *Regulating the Nutritional Adequacy of Infant Formula in the United States*, 5 CLINICAL LACTATION 133, 134 (2014).

[292] *See* Steven A. Abrams, *Is It Time to Put a Moratorium on New Infant Formulas hat are not Adequately Investigated?*, 166 J. PEDIATRICS 756, 759 (2015).

[293] *See* WORLD HEALTH ORG., MARKETING OF BREAST-MILK SUBSTITUTES: NATIONAL IMPLEMENTATION OF THE NATIONAL CODE: STATUS REPORT 2020 (2020), https://www.who.int/publications/i/item/9789240006010 (WHO established the Code to end the inappropriate marketing of breast-milk substitute for infants and children up to age three, but it has not been implemented in the United States) [https://perma.cc/B6X6-UNKB]; *see also* WORLD HEALTH ORG., *supra* note 95, art. 3 (defining as "breast-milk substitute" "any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose").

[294] *See* Pomeranz & Harris, *supra* note 269, at 33.

[295] *See* WORLD HEALTH ORG., *supra* note 95, art. 5.1.

[296] *See id.* at art. 9.2.

has adopted a number of resolutions, including one urging member states "to ensure that nutrition and health claims are not permitted for breast-milk substitutes" due to concerns that these claims "may be used to promote breast-milk substitutes as superior to breastfeeding."[297] The resolution allows for an exception "where specifically provided for in national legislation."[298] As discussed above,[299] health claims (that is, claims that characterize the relation between an infant formula and the risk of a disease or health-related condition) are allowed in the United States so long as they undergo a premarket evaluation by FDA to ensure that there is significant scientific agreement on the relation in question.[300] Structure/function claims describe the effect of an infant formula on the structure of the body or on a bodily function; they must be truthful and not misleading but are not subject to premarket approval by FDA before use.[301] A number of voices have called for tighter regulations of these claims, in particular structure/function claims.[302] Another approach would be to follow the WHO guidance and the European Union's recent example of altogether banning nutritional and health claims on infant formula.[303]

In summary, a variety of regulatory regimes are conceivable for lab-produced milk. Some products could be food, including infant formula; some could be supplements; and some could be biological drug products. There is still too little certainty as to what lab-produced milk products will look like to envision a unique path forward. However, it is not too early to reflect on the possible impact of lab-produced milk on the regulation of human milk itself.

C. Potential Effects on the Regulation of Human Milk Itself

The impending availability and regulation of lab-produced milk may have regulatory effects that go beyond it. In particular, it could influence the law of human milk in areas such as FDA law, intellectual property, and international trade.

1. FDA Law

As mentioned earlier, currently the federal government does not have a dedicated legal framework for human milk from humans, even if FDA is involved in the oversight of human milk banks and a federal bill could classify donor human milk as

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[297] *See* WORLD HEALTH ORG., FIFTY-EIGHTH WORLD HEALTH ASSEMBLY: RESOLUTIONS AND DECISIONS WHA58.32, at 136–37 (2005), https://apps.who.int/gb/ebwha/pdf_files/WHA58-REC1/english/A58_2005_REC1-en.pdf.

[298] *See id.* at 137.

[299] *See supra* notes 227–28 and accompanying text.

[300] Food, Drug, and Cosmetic Act § 403(r)(1)(B), (3)(B), 21 U.S.C. § 343(r)(1)(B), (3)(B) (providing that FDA may issue an authorizing regulation for a claim only if it is supported by the "totality of publicly available scientific evidence . . . that there is significant scientific agreement" among qualified experts that the claim is supported by that evidence).

[301] John C. Wallingford, *Perspective: Structure-Function Claims on Infant Formula*, 9 ADVANCES NUTRITION 183, 183 (2018).

[302] *See, e.g.*, Hughes et al., *supra* note 265, at 106 (arguing for statutory change requiring submission of substantiating data or at least a voluntary process encouraging formula manufacturers to submit data).

[303] *See* Commission Regulation 2016/127, 2016 O.J. (L 25), supplementing Regulation (EU), 609/2013 2013 O.J. (L 181), as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (note the exceptions listed in Article 9 allowing for the statements "lactose free" and "contains DHA").

exempt infant formula in the future.[304] For the time being, most law on the books regarding human milk is state law; thus, rules significantly differ from state to state.[305] In one jurisdiction, human milk is considered a drug; in others, a tissue; in still others, a food; and in the majority, it is not defined at all.[306] Medical, public health, and human milk banking professionals have called for FDA to define human milk and/or to sponsor a uniform regulatory framework for it.[307] Going forward, lab-produced milk companies may be tempted to urge that donor human milk should be more stringently regulated.[308] In response, the federal government could opt for the status quo or decide to clarify its stance on human milk from humans. Should FDA be moved to act along those lines, it might use one of the regimes described above (drug/biologic, including tissue/cell; food/infant formula; or new hybrid category) to regulate human milk and another for lab-produced milk or devise a novel category encompassing regulation for both.

2. Intellectual Property

FDA law is not the only area of law in which the regulation of lab-produced milk is connected to the regulation of human milk from humans. Intellectual property law is another important field of regulation.[309] The science of human milk and its applications has resulted in the assignment of patents.[310] Patents are limited duration property rights for inventions granted by the U.S. Patent and Trademark Office in exchange for public disclosure of the invention, which must be "new, useful, and non-obvious."[311] In other words, milk scientists and businesses use intellectual property law as an incentive to innovate and to protect their economic interests from competition. This is not specific to human milk, but rather characteristic of technology industries, especially biotechnologies.[312] As Melissa Cooper has argued, the biotechnology revolution was

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[304] *See supra* note 233 and accompanying text.

[305] *See* Cohen, *supra* note 22, at 569–70.

[306] *Id.*

[307] *See, e.g.*, Prolacta Bioscience, Citizen Petition (Oct. 26, 2007), https://downloads.regulations.gov/FDA-2007-P-0292-0002/attachment_1.pdf [https://perma.cc/63WH-H7Z2] (petitioning FDA "to promulgate regulations defining human milk to be a food, and for the condition of neonatal prematurity, a medical food.").

[308] *Cf.* Diane E. Hoffmann, Felicia D. Langel, Francis B Palumbo & Erik C. von Rosenvinge, *The Future of Stool Banks: A Premature Death?* 76 FOOD & DRUG L.J. 524 (2022) (analyzing donor stool regulation and showing that the companies going through the drug approval process for their stool-based therapies argue that the natural stool product from stool banks should be more stringently regulated on the ground that there was not enough data on safety and effectiveness for *C. Difficile*).

[309] *See, e.g.*, Shunzo Majima, *A Brief Thought on the Future of Global Ethics: Military Robots and New Food Technologies*, 10 J. GLOB. ETHICS 53, 55 (2014) (arguing that a few global corporations could monopolize patents for in vitro meat production which may provide a blueprint for lab-grown milk given their similarities).

[310] *See generally* Valerie McClain, *Patents on Life: A Brief View of Human Milk Component Patenting*, 9 WORLD NUTRITION 57 (2018) (discussing the rise of patents on human milk components).

[311] *General Information Concerning Patents*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/basics/general-information-patents (last updated Mar. 24, 2022) [https://perma.cc/V3LN-6N38].

[312] *See, e.g.*, Aisling McMahon, *Biotechnology, Health and Patents as Private Governance Tools: the Good, the Bad and the Potential for Ugly?*, 3 INTELL. PROP. Q. 161 (2020) (emphasizing the various functions of patents in the context of health-related biotechnologies, including economic, incentivizing, and private governance).

"designed to relocate economic production at the genetic, microbial, and cellular level, so that life [would] become[], literally, annexed within capitalist processes of accumulation."[313] The former President of the European Milk Bank Association, Gillian Weaver, states that there are now "human milk component patents owned by infant formula companies, medical schools, universities, drug companies and the U.S. government."[314] These include human lactoferrin, human milk oligosaccharides, and the human milk probiotic Lactobacillus reuteri.[315] Geographer Carolyn Prouse has shown that commercial human milk companies have filed patents for their milk handling processes and testing and the composition of their products.[316]

Similarly, lab-produced milk companies that develop milk components out of human cells or yeast are regularly touted for their "patent-pending" technologies.[317] The language of intellectual property not only contributes to the presentation of their products as innovative, but also generates "a form of asset or property that the company holds, and which can accrue value in the future."[318] This approach has led to the criticism that milk scientists and industrialists attempt to profit from processes that are public knowledge and from micro-components that are products of nature and should remain outside the scope of intellectual property law.[319] The argument is that lactating people and their children are the true owners of human milk and should not be dispossessed of their property. In fact, under U.S. patent law, it is not possible to patent naturally occurring bodily fluids, proteins, cell lines, or genes, among others, unless they are modified or used in some novel process.[320] Valerie McClain thus uses the concept of "biopiracy" to describe efforts to patent human milk components,[321] analogizing them to the dispossession of people's bodily materials as in the infamous case of Henrietta Lacks, an African-American woman whose cancer cells were used unbeknownst to her by a White biologist to establish one of the most lucrative cell lines in medical research.[322]

To address both these concerns as well as the social need for infant feeding options when breastfeeding and human milk feeding is neither desired nor possible, public research and development should be supported in the area of infant feeding. It is important that independent research be conducted that does not depend on corporate

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313 MELINDA E. COOPER, LIFE AS SURPLUS: BIOTECHNOLOGY & CAPITALISM IN THE NEOLIBERAL ERA 19 (2008).

314 Gillian Weaver, *For-Profit Milk Banks: The Impact of New Companies Rising Worldwide* (May 27, 2021) (unpublished conference paper presented at the UKAMB Virtual Forum: How Should Human Milk be Regulated?).

315 *Id.*

316 *See* Prouse, *supra* note 179, at 966.

317 *See, e.g.*, Catherine Lamb, *BIOMILQ Has Grown the Main Components of Human Breastmilk in a Lab*, SPOON (Feb. 6, 2020), https://thespoon.tech/biomilq-has-grown-the-main-components-of-human-breast-milk-in-a-lab/ [https://perma.cc/M5CP-84YV].

318 Prouse, *supra* note 179, at 968.

319 *See id.* at 959, 964, 967, 971; *see also* McClain, *supra* note 310, at 63–64.

320 *See, e.g.*, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013) (holding that unmodified DNA sequences were not patent-eligible because "[l]aws of nature, natural phenomena, and abstract ideas are not patentable." (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293, 182 L. Ed. 2d 321 (2012) at 70)).

321 McClain, *supra* note 310, at 59.

322 *See generally* REBECCA SKLOOT, THE IMMORTAL LIFE OF HENRIETTA LACKS (2010).

funding. Parallel to Hallam Stevens and Yvonne Ruperti's argument in the context of lab-produced foods for adults, public monies could be invested to create a publicly available "commons" of both human-secreted and lab-produced milk compounds.[323] Others have proposed that a nutrition institute at NIH be established or that current institutes and mechanisms be used to study infant formula.[324] This new institute (or current Institutes) could also be tasked with evaluating the costs and benefits of lab-produced human milk products.

3. International Trade

Considering the so-called California and Brussels effects, future U.S. regulation of lab-produced milk is likely to influence other countries' regulation of the product, which could alternatively facilitate or impede international trade in human milk and human milk-based products such as fortifiers.[325] Currently, imports and exports of donor human milk are limited, not only by contrasting legal regimes in different countries, but also by ethical considerations.[326] The ethical argument is that donor human milk should stay within the communities where it was collected so as to prevent high-income countries from siphoning the human milk resources of lower-income countries.[327] The advent of a specific legal regime for lab-produced milk in countries that manufacture it—and the recognition that it does not pose the same ethical issues as donor human milk (even if it raises other issues)—could open the door to its global travel. The international fate of donor human milk is more uncertain. Uniform regulation in the United States and the European Union, for example—but also by the World Health Organization and the Codex Alimentarius—could either liberalize trade, or, quite the reverse, prohibit it on ethical or other grounds.[328]

To summarize, if there is doubt as to how lab-produced (human) milk will be regulated in the United States, it is possible that whatever regulation is adopted will influence the way in which donor human milk itself is regulated.

V. CONCLUSION

This Article has examined the advantages and disadvantages of lab-produced (human) milk technology and its possible regulatory pathways. The stakes of legal

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[323] Stevens & Ruperti, *supra* note 134.

[324] Steven A. Abrams & Stephen R. Daniels, Letter to the Editor, *Reply*, 216 J. PEDIATRICS 251 (2020).

[325] *See generally* ANU BRADFORD, THE BRUSSELS EFFECT: HOW THE EUROPEAN UNION RULES THE WORLD (2020) (developing the idea of "Brussels effect" similar to the "California effect," according to which the most stringent standards appeal to companies operating across multiple regulatory environments as they facilitate global production and exports).

[326] *But see FAQs*, PROLACTA, https://www.prolacta.com/en/prolacta-feed/faqs/ [https://perma.cc/69NN-RLBW] (U.S. human milk company stating that its products are used in Europe as well as the United States).

[327] *See* Kiersten Israel-Ballard, Jessica Cohen, Kimberly Mansen, Michael Parker, Cyril Engmann & Maureen Kelley, *Call to Action for Equitable Access to Human Milk for Vulnerable Infants*, 7 LANCET GLOB. HEALTH e1484, e1484 (2019).

[328] *See* Julie Smith, Tanya Cassidy & Mathilde Cohen, *Behind Moves to Regulate Breastmilk Trade Lies the Threat of a Corporate Takeover*, CONVERSATION, https://theconversation.com/behind-moves-to-regulate-breastmilk-trade-lies-the-threat-of-a-corporate-takeover-152446 (last updated May 27, 2021, 2:34 AM) [https://perma.cc/3FZB-EYSE].

intervention are high. The way in which lab-produced milk will be classified and regulated will inform the product design and safety, companies' business models, and have distributional consequences in terms of who gets to access it and at what cost.

Despite its novelty, lab-produced milk may not be the sci-fi-like milk from Mars some imagine it to be, but another earthling item. It could even be understood as continuing an old pattern of scientists and physicians developing technologies of human milk. In 1909, Ernst Mayerhofer and Ernst Přibram, two Austrian doctors also credited with creating the first human milk bank in Vienna, began to experiment with techniques to store and preserve the milk they collected from a network of mothers.[329] They applied the dairy science of the day to pasteurize, freeze, and freeze-dry it, adding a variety of more or less dangerous chemicals in it.[330] A decade later, as legal historian Kara Swanson has shown, "Boston physicians collaborated with engineers and industry, enlisting technology to make human milk itself into a technology."[331] This partnership resulted, among other outcomes, in a machine to powder human milk in 1922.[332]

Is lab-produced milk a new iteration of this quest for a primary food that would do away with humans? Today, the main argument is that lab-produced milk is needed because parents experience lactation failure or insufficiency and hold jobs that do not allow them to maintain their lactation.[333] Yet, both problems are partly the results of a political economy that privileges "productive" forms of labor over reproductive work and care work.[334] Lactation is not supported as a form of work itself. Regulation of lab-produced milk should therefore go hand in hand with legal reform to support parents with robust entitlements to lactation and human-milk feeding, including paid parental leave, high-quality and affordable healthcare comprising lactation support, and flexible work arrangements. Lactation rights should range from paid lactation leaves to the right to feed one's child on the breast or chest and to express milk in all locations where one is allowed to be, in addition to expanded (and paid) lactation breaks, lactation rooms, and support for donor human milk banking.

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[329] Special Correspondence, *Vienna. Feeding with Preserved Human Milk—The Dangers of Celluloid*, BRIT. MED. J. 1005 (1909) (describing the functioning of this human milk service).

[330] *See* Ernst Mayerhofer & Ernst Přibram, *Praktische Erfolge Ernährung mit konservierter Frauenmilch (Bericht über 100 Fälle)*, 3 ZEITSCHRIFT FÜR KINDERHEILKUNDE 525 (1912) (reporting on their experiments); *see also* Mathilde Cohen, *Freeze-Dried Bodies. The Return of Powdered Human Milk*, COUNTER MAG., no. 3, 2021, at 15 (on the past and present of powdered human milk).

[331] Kara W. Swanson, *Human Milk as Technology and Technologies of Human Milk: Medical Imaginings in the Early Twentieth-Century United States*, WOMEN'S STUD. Q., Spring 2009, at 20, 21.

[332] *Id.*

[333] *See, e.g.*, *The Making of Mother's Milk*, MEDIUM: BIOMILQ (Feb. 17, 2021), https://biomilq.medium.com/the-making-of-mothers-milk-b849d06f07e2 (highlighting that some parents struggle with low milk supply) [https://perma.cc/4ERZ-K997].

[334] *See, e.g.*, MARILYN WARING, IF WOMEN COUNTED: A NEW FEMINIST ECONOMICS (1988) (critiquing the exclusion of house and carework gendered as female from value in economic theory).