Review of Human Tissue Laws
Australian Law Reform Commission

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Dear Commissioners,

Submission in response to the ALRC Discussion Paper on Regulation of Human Tissues

Thank you for the opportunity to comment on the proposed law reforms outlined in the Review of Human Tissue Laws: Discussion Paper (Discussion Paper 90), released in November 2025. This submission responds to the proposals concerning the legal status of "human milk" and recommends a practicable, rights-respecting regulatory model for Australia that promotes equitable access.

I am an economist with more than two decades of academic research experience in public health and health services. My work has focused extensively on the regulation of markets in human milk, and I have developed a substantial research record in this field. I have held **two Australian Research Council Fellowships directly related to this topic**: FT140101260, *Enhancing measurement, understanding and policy regulatory approaches to emerging markets and trade in mothers' milk*, and DP0451117, *The economics of mothers' milk and the market for infant food*.

- In 2018, I **led a scientific evidence review**[1] commissioned by the Australian Department of Health on interventions to increase breastfeeding—including human milk banking and milk sharing—which informed the development of the *Australian National Breastfeeding Strategy 2019 and Beyond*.
- I also **participated as an invited member of the Oxford–PATH Human Milk Working Group**, which produced the *Call to Action for Equitable Access to Human Milk for Vulnerable Infants*, a landmark document addressing ethical, policy, and safety gaps in human milk banking to support safe and equitable access for vulnerable infants.[2]

[1] J. P. SMITH, et al., Review of effective strategies to promote breastfeeding: an Evidence Check rapid review brokered by the Sax Institute for the Department of Health, May 2018 (Sax Institute ed., 2018).
[2] K. ISRAEL-BALLARD, et al., *Call to action for equitable access to human milk for vulnerable infants*, 7 Lancet Glob Health, (2019).

An annotated bibliography of my publications related to this topic is attached.[3,4,5,6,7,8,9,10,11,12]

My research[13] directly informed development of UNICEF's 2025 *Operational Guidelines on Wet Nursing in Emergencies and Disasters*,[14] and I have served as an advisor to the World Health Organization on the marketing of complementary foods for infants and young children. Prior to my academic career, I worked as a senior economist for the Australian and New Zealand governments in the Departments of Treasury, Finance, and Prime Minister & Cabinet, and in the Commonwealth Parliamentary Library Research Service.

I am also a breastfeeding counsellor with more than twenty years' experience supporting women to overcome breastfeeding challenges, served for nearly a decade on the board of the Australian Breastfeeding Association, and am an associate member of the Lactation Consultants Association of Australia and New Zealand.

Specific recommendations are set out below, followed by some **broader comments** to put these in context.

Recommendations

Proposals 7–9: Definition of Human Tissue

— "Human milk" should not be included within the scope of new human tissue laws. It is a unique food secreted by specialised glandular tissues in an organ of the female body, and contains living cells, but human milk is **not a tissue or cell nor an organ that is "extracted," "removed," or "transplanted"** in the sense contemplated by human tissue law.

— If human milk is nevertheless brought within the scope of the proposed law, it should be **defined narrowly as *donor human milk* provided by lactating mothers specifically for use in milk banking within structured, formal health or medical settings for the purpose of feeding infants or young children aged 0-36 months ("infant nutrition")**. This would preclude diversion of human milk donations for adults,[15] even to adult patients, as available human milk supplies should be prioritised for infants and young children.[16]

— Should human milk be included in the definition of human tissue, the legislation must explicitly **exclude breastfeeding, breastmilk, and informal milk sharing for the purpose of infant**

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[3] J. P. SMITH, *Mothers' milk and markets*, 19 Australian Feminist Studies 369, (2004).

[4] J. P. SMITH, *Markets, breastfeeding and trade in mothers' milk*, 10 Int Breastfeed J, (2015).

[5] J. P. SMITH, *Without better regulation, the global market for breast milk will exploit mothers*. (2017), at https://theconversation.com/without-better-regulation-the-global-market-for-breast-milk-will-exploit-mothers-79846.

[6] J. P. SMITH, *Markets in mothers milk. Virtue or vice, promise or problem*, *in* Making milk. The past, present and future of our primary food, (Mathilde Cohen & Yoriko Otomo eds., 2017);id. at.

[7] SMITH, et al.

[8] ISRAEL-BALLARD, et al.

[9] J. P. SMITH & ALESSANDRO IELLAMO, *Wet nursing and donor human milk sharing in emergencies and disasters: A review*, 28 Breastfeeding Review, (2020).

[10] J. P. SMITH, et al., *Behind moves to regulate breastmilk trade lies the threat of a corporate takeover*. (2021), at https://theconversation.com/behind-moves-to-regulate-breastmilk-trade-lies-the-threat-of-a-corporate-takeover-152446.

[11] L SALMON & J. P. SMITH, *Sharing human milk: challenging Australian regulatory regimes* Broad Agenda *at* https://www.broadagenda.com.au/2024/sharing-human-milk-challenging-australian-regulatory-regimes/;id. at.

[12] J. P. SMITH, *Valuing human milk: Applying economic pricing to measure lactation in national accounts*, 36 The Economic and Labour Relations Review 450, (2025).

[13] SMITH & IELLAMO.

[14] UNICEF, Guidelines on wetnursing and donor milk in emergencies (2025).

[15] CHANTALLE FORGUES, et al., *The Paradox of Human Milk Doping for Anti-Doping*, Performance Enhancement & Health (2017).

[16] M. R. TULLY, *Recipient prioritization and use of human milk in the hospital setting*, 18 J Hum Lact, (2002).

nutrition. This is essential to avoid creating barriers to accessing breastfeeding or breastmilk, or generating unintended harms that could undermine breastfeeding practices.

— Any human tissue law reform that has human milk in its scope should include **'good Samaritan principles** to protect mothers who provide their milk to others for infant nutrition in disaster and emergency situations.

— Any change to the definition of human tissue that would encompass human milk should **only occur through legislation passed by Australian parliaments**. This safeguard is necessary to prevent arbitrary interference with the human rights and bodily autonomy of breastfeeding or lactating women engaged in private, non-medical activities.

Proposal 5: Objects of Human Tissue Laws

— **Tissue laws are not well suited to regulating breastfeeding practices**, nor is existing regulation in urgent or compelling need of modernising, adapting or making more uniform; milk banking policy has been reviewed[17] and **suitable operational guidelines for milk banks developed that remain fit for purpose**.[18] Reflecting the biological and social complexity of human milk and breastfeeding, these guidelines draw on food law as well as tissues law.

— If human milk is to be included within the scope of new human tissue legislation, the objects of the law should explicitly include the aim "to better enable breastfeeding." **Donor human milk used in formal health or medical settings should function as a bridge to breastfeeding** or as a supplement to mothers' own milk, and not be used as a substitute for it.

— States and territories should be encouraged to advance equitable access by adopting health policies that **mandate the availability of donor human milk in all maternal and newborn care facilities** for when breastfeeding is not possible or when mothers' own milk is unavailable. In some settings, organising for suitable wet nurses in line with WHO recommendations could be more a appropriate technology than establishing milk banks.[19]

— Promoting equitable access to human milk donation, distribution, and use should **require health and medical services to address structural and systemic barriers that prevent mothers from breastfeeding** in accordance with health authority recommendations. This includes barriers within health facilities, workplaces, and other environments that determine or shape women's breastfeeding decisions.

— **Donor human milk should only be permitted to be used in facilities that meet WHO/UNICEF Baby Friendly Hospital Initiative (BFHI) / Ten Steps quality-of-care standards, including** maintaining strong policies, procedures, monitoring systems, and accountability mechanisms to ensure donor milk does not displace direct breastfeeding or the use of mothers' own milk.

— State governments should be encouraged to **develop health policy guidelines supporting arrangements for directed donation of human milk** across all maternal and newborn care facilities. This would help reduce barriers and inequities in access to the benefits of human milk exchange.

Proposals 40–44: Prohibiting Reward and Advertising for Human Milk Exchange, and Permitting Reimbursement or Cost Recovery

— Prohibiting reward and advertising for human milk exchange can meaningfully contribute to the **safety of donations and help prevent financial gain from encouraging clinical overuse** of donor human milk. Such **prohibitions are particularly relevant in organised or structured**

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[17] AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, Donor Human Milk Banking in Australia- Issues and Background Paper (Department of Health. 2014).

[18] Operational Guidelines for Milk Banks in Australia and New Zealand. pt. (2022).

[19] A. COUTSOUDIS, et al., *Wet Nursing and Human Milk Sharing: Reviving Sustainable Systems to Prioritise Breastfeeding*, 22 Matern Child Nutr.

settings, including hospitals, non-profit milk banks, and commercial entities; it is especially in these settings that financial rewards and commercial incentives for cost cutting and market expansion risk driving widespread unethical and exploitative practices.[20]

— Guidance on reimbursable or recoverable expenses associated with donated human milk should clearly describe **what constitutes reasonable compensation for donors**. This may include reimbursement for inconvenience, time, travel, or lost earnings. European regulatory approaches **distinguish legitimate cost compensation from payment that results in financial gain**. Internationally, donors in some contexts receive compensation valued at approximately US$1 per ounce, provided either as direct reimbursement or through in-kind support such as equipment or supplies.[21]

— Allowing reimbursement or cost recovery for human milk donation can **broaden access to donation opportunities for mothers who might otherwise be unable to participate**, thereby increasing the availability of donor human milk for infants who need it.

— Activities related to breastfeeding and informal milk sharing for the purpose of feeding infants or young children **should be explicitly excluded from the scope of human tissue law.** If human milk is included within the new legislative framework, there is a risk that breastfeeding, breastmilk, and informal milk sharing outside healthcare or medical settings **could be inadvertently captured by prohibitions** on reward or advertising. Clear exclusions are essential to avoid unintended restrictions on private, non-commercial feeding practices.

— There is a long and well documented history of wetnursing and cross nursing, including in Australia.[22] Such **peer-to-peer milk sharing practices can help mothers overcome breastfeeding challenges**, and are normal practice in some cultures and Australian communities. **As with both altruistic and commercial surrogacy**, this can be coercive and harmful to women and children. Historical and modern day concerns about wet-nursing relate to potential risks of exploitation due to women's poverty, and risk of specific disease transmission. If there was an impetus to regulate significant problems in this area, **wetnursing could be suitably regulated in other ways,[23] including in Australia through labour law, and public health law**, which together with sex discrimination and occupational health and safety laws, could protect mother and child health, and prevent exploitative or unsafe work conditions and wages for occupational wetnursing. Studies in other high income countries provide relevant data for integrating the reality of informal milk sharing into policies.[24]

Proposals 15–22: Consent and Authorisation by Living Persons

— If human milk is included within the definition of human tissue, careful consideration is needed to ensure clarity in the definitions of "donor," "recipient," "removal," "transplantation," and "use." Human rights frameworks concerning **the breastfeeding dyad recognise that human milk is produced within a biosocial relationship**. In the context of "removal," the mother is generally the "donor," and her infant the "recipient." When a mother provides her milk to

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[20] H. C. RUSI, et al., *Conceptualizing the Commercialization of Human Milk: A Concept Analysis*, 40 J Hum Lact.

[21] A. H. GROVSLIEN & M. GRONN, *Donor milk banking and breastfeeding in Norway*, 25 see id. at.

[22] VIRGINIA THORLEY, *Boarded-out-babies_(JHL_2021).pdf*>;V. THORLEY, *Sharing breastmilk: wet nursing, cross feeding, and milk donations*, 16 Breastfeed Rev, (2008);V. THORLEY, *Breasts for hire and shared breastfeeding: wet nursing and cross feeding in Australia, 1900-2000*, 10 Health History, (2008);V. THORLEY, *Mothers' experiences of sharig breastfeeding or breastmilk co-feeding in Australia 1978-2008*, 17 Breastfeed Rev, (2009);V. THORLEY, *Human milk use in Australian hospitals, 1949-1985*, 20 Breastfeed Rev, (2012);V. THORLEY, *Milk siblingship, religious and secular: History, applications, and implications for practice*, 27 Women Birth, (2014);VIRGINIA THORLEY, *A mother, yet not 'mother': the occupation of wet-nursing*, 21 Journal of Family Studies 305, (2015);VIRGINIA THORLEY, *Milk Kinship and Implications for Human Milk Banking: A Review*, 3 Women's Health Bulletin, (2016);VIRGINIA THORLEY, *Selection criteria wetnurses &Sioda_2016.pdf*>, (2016).

[23] COUTSOUDIS, et al.

[24] E. PRESENT, et al., *Exploring human milk donation: A cross-sectional study*, 11 Public Health Pract (Oxf).

another recipient, this may benefit her, yet her own infant may also be understood as an affected "donor," given that the milk originates from a relationship centred on meeting the infant's nutritional needs.

— Proposed definitions that classify an "adult" as a person aged 18 years or older—or that address consent and authorisation for adults who lack decision-making capacity—risk **unintentionally excluding mothers under 18 from the benefits of donating human milk for their own infant or another child**. Similarly, young mothers and their infants could be **inappropriately denied access to donor human milk as recipients. These issues may arise in complex circumstances**, such as when a mother gives birth while incarcerated or when milk is provided for an infant placed in foster care. Ensuring valid consent and authorisation in these contexts requires careful, equitable consideration to avoid disadvantaging young mothers and their children.

Proposals 32-34: Consent for research

— Valid consent for the use of donated human milk in research should be defined explicitly, **ensuring that donors can clearly indicate their non-consent for any research use—including research involving milk that would otherwise be classified as waste or destined for disposal**. Donors typically provide human milk with the intention of supporting other mothers and infants, not for it to be diverted into research activities. Many would object to their milk being used in **studies that could enable commercial entities to claim patents over human milk components or to generate comparative marketing claims** between human milk and commercial formula products.[25] Clear, specific consent requirements are essential to respect donor intentions and maintain public trust.

The broader regulatory context

The stated object of modernising, adapting and improving consistency of Australian regulation of medical tourism, blood products, or organ transplantation **barely applies** to the exchange of human milk, and the discussion paper makes **no substantive case** for including it in scope of human tissue law. **Human milk exchange is not new** in either healthcare or community settings, nor are technologies such as breast pumps, pasteurisation or freezing particularly novel. Inclusion of human milk in the scope of tissues law reform **does not address the complexities of increasing breastfeeding or improving milk sharing practices**.[26] It is important to recognise that p**asteurising donor milk introduces added contamination risks and destroys important characteristics of human milk**; breastfeeding remains the normative standard for women's and children's health.[27] [28]

Where human milk exchange is regulated, it may be treated as a food, a tissue, or a medical product of human origin. In some Australian jurisdictions, human milk has been regulated as a human tissue to ensure maximum safety in establishing milk-banking systems—not because it is inherently a tissue. However, **human tissue law is too narrow a framework for regulating the full complexity of human milk exchange**. Human tissue legislation is designed for much more invasive and potentially harmful exchanges involving organs and tissues, whereas human milk exchange encompasses a far broader range of specifically female activities related to breastfeeding, including informal milk sharing with relatives, peers, or through online networks of mothers.

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[25] VALERIE MCCLAIN, *Patents on life: a brief view of human milk component patenting* 9World Nutrition, (2018).
[26] M. TYEBALLY FANG, et al., *Human milk banks: a need for further evidence and guidance*, 9 Lancet Glob Health, (2021).
[27] COUTSOUDIS, et al.
[28] J. Y. MEEK & L. NOBLE, *Technical Report: Breastfeeding and the Use of Human Milk*, 150 Pediatrics;J. Y. MEEK, et al., *Policy Statement: Breastfeeding and the Use of Human Milk*, see id. at.

The overarching policy approach should recognise the diverse contexts in which human milk is exchanged and the wide- ranging ethical issues involved, and tailor regulatory responses accordingly; **the central policy goal should remain protecting, promoting, and supporting breastfeeding for maternal and child health**.[29] Adequate monitoring systems including data registries are crucial underpinning for evaluating and informing policies on breastfeeding including human milk exchange. Human milk and its use is **intrinsically about female lactating bodies**, and invokes **fundamental issues around bodily autonomy,** and women's economic, reproductive and health rights.[30]

The amount of **human milk exchanged in Australia though organised milk banking – at most a few thousand litres a year – is trivial** compared to the provision of ~**35-45 million** litres of milk a year by breastfeeding women.[31]

A **more suitable human-rights-based policy framework** for human milk regulation—rather than a new tissue law—would integrate with the Australian National Breastfeeding Strategy.[32] A regulatory regime specific to human milk would better reflect its unique characteristics and could provide the legislative foundation for mandating the **Operational Guidelines for Milk Banking** in Australia.[33] These guidelines already draw on both food and tissue law, although they do not address the wider context of human milk supply.

A broader policy framework would enable more consistent regulation to prevent exploitation and unethical marketing, while ensuring safety and public health in relation to the **comparative risks of both human milk and commercial formula products**.[34] In particular, it would recognise the need for **different regulatory approaches for different contexts** of milk sharing, as illustrated for the US.[35]

Despite multiple mass recalls of contaminated commercial milk formula products and global concern over the unethical marketing practices of a US$55-billion industry, regulatory attention continues to focus disproportionately on the far lower risks associated with human milk exchange—such as exploitation, advertising, or cost reimbursement—or, as seen in the early days of the coronavirus pandemic, on the rare possibility of disease transmission through breastfeeding.[36]

Recognising the reality of informal milk sharing, suitable guidance should be developed—led by the NHMRC in consultation with the Australian Breastfeeding Association, the Lactation

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[29] M. TYEBALLY FANG, et al., *Developing global guidance on human milk banking*, 99 Bull World Health Organ.

[30] UNITED NATIONS OFFICE OF HUMAN RIGHTS (UNOHR), Statement by the UN Working Group on discrimination against women and girls - Responses to the COVID-19 pandemic must not discount women and girls (2020);UNITED NATIONS OFFICE OF THE HIGH COMMISSIONER [OHCHR], *Joint statement by the UN Special Rapporteurs on the Right to Food, Right to Health, the Working Group on Discrimination against Women in law and in practice, and the Committee on the Rights of the Child in support of increased efforts to promote, support and protect breast-feeding*. (2016), at https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=20871;J. GALTRY, *Strengthening the human rights framework to protect breastfeeding: a focus on CEDAW*, 10 Int Breastfeed J;JUDITH GALTRY, *Extending the "bright line" feminism, breastfeeding, and the workplace in the United States*, 14 Gender & Society.

[31] JULIE P. SMITH, *Human milk supply in Australia*, 24 Food Policy 71, (1999);J. P. SMITH, *"Lost milk?": Counting the economic value of breast milk in gross domestic product*, 29 J Hum Lact, (2013);J. P. SMITH, et al., *The volume and monetary value of human milk produced by the world's breastfeeding mothers: Results from a new tool*, 11 Front Public Health, (2023).

[32] AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, *Australian National Breastfeeding Strategy*, (2019).

[33] . pt.

[34] K. D. GRIBBLE & B. L. HAUSMAN, *Milk sharing and formula feeding: Infant feeding risks in comparative perspective?*, 5 Australas Med J, (2012).

[35] M. COHEN, *Should Human Milk Be Regulated*, 9 UC Irvine Law Review (2019). GEORGE KENT, *How Should Human Milk Banks be Regulated?**, 10 World Nutrition ;COUTSOUDIS, et al. PRESENT, et al.

[36] KARLEEN GRIBBLE, et al., *First do no harm overlooked: Analysis of COVID-19 clinical guidance for maternal and newborn care from 101 countries shows breastfeeding widely undermined*, 9 Frontiers in Nutrition, (2023).

Consultants of Australia and New Zealand, and the Breastfeeding Medicine Network Australia/New Zealand—to strengthen breastfeeding support, **expand access to safe human milk sharing** in both community and clinical settings, **facilitate directed donor-milk sharing within facilities**, and affirm milk sharing as a **normal and appropriate response in emergencies and disasters**. Guidance for **cost reimbursement of donors should also be developed**. In the longer term, a dedicated regulatory framework for human milk exchange should be developed that reflects its unique characteristics as a product of the breastfeeding relationship between a woman and her child.

Policy development should also take into account **conflicts of interest and potential anti-competitive behaviour within the milk-banking sector**. Scaling up milk banking to expand sales in healthcare settings and achieve economies of scale can align with advocacy to restrict informal milk sharing and channel altruistic donations to milk banks. It can also **motivate de-legitimising reasonable cost reimbursement of donors**, and expanding the market for banked milk in ways that undermine breastfeeding and the use of mothers' own milk. Such advocacy is particularly evident in the United States, where the Academy of Breastfeeding Medicine has nevertheless issued **evidence-based guidance supporting safe informal milk sharing**,[37] to assist mothers in exchanging human milk outside the narrow constraints set by the formal not-for-profit milk-banking association

I would be pleased to elaborate further on these comments and the rationale for my recommendations in a further submission. I can provide a more detailed list of references if that would be of value to this Review.

Conclusion

Taken together, these recommendations reflect a coherent and evidence-based approach to safeguarding breastfeeding, supporting equitable access to human milk, and ensuring that regulatory confusion and overreach does not inadvertently undermine the health and rights of mothers and infants to breastfeeding.

Human milk occupies a unique place in public health, clinical care, and family life, and any regulatory response must recognise its distinct biological, relational, and social significance. A carefully scoped, proportionate, and rights-respecting framework—one that protects breastfeeding, enables safe access to donor milk for infant nutrition where clinically indicated, and avoids unnecessary intrusion into community practices—offers the most effective and ethical path forward for Australia.

Yours sincerely,

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[37] ACADEMY OF BREASTFEEDING MEDICINE, *Position Statement on Informal Breast Milk Sharing for the Term Healthy Infant*, (2017).

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L SALMON & J. P. SMITH, *Sharing human milk: challenging Australian regulatory regimes* Broad Agenda *at* https://www.broadagenda.com.au/2024/sharing-human-milk-challenging-australian-regulatory-regimes/.

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1. Smith, J. (2004). "Mothers' milk and markets." Australian Feminist Studies 19(45): 369-379.

Breastfeeding is rarely seen as an economic issue. Many would find the idea of placing a dollar value on mothers' milk as quite repugnant. Breastfeeding is not an economicrelationship. It is a complex, physiological, emotional and social relationship between mother and child, intricately related to the nature of society, community and family shelives in. Economics is not well equipped to deal with this. Its models rely on ideas of scarcity, selfishness, price and competition between individuals to maximise human satisfaction. In the case of breastfeeding, the main factors determining resource availability and allocation are not price but altruism, dependency, and breastfeeding knowledge and skills; and the 'costs' and 'benefits' of breastfeeding fall not just on individuals but on society as a whole. Yet in a world where not valuing something in dollar termsmeans it is not valued at all, this economic invisibility can have major consequences for the 'market' for mother's milk, for infant and maternal health and well-being, and for appropriate public policy. This article provides a feminist economic analysis of breastfeeding. It is broad ranging, uses cross-disciplinary evidence and draws on a variety of frameworks including a human rights approach. It builds on a growing feminist economic literature that argues that conventional approaches to public policy rest on misleading measures and concepts of economic efficiency. It seeks to highlight the imperfections within the market for infant food, with the main 'products' in this market broadly comprising: mothers' own milk (fed from the breast or expressed) or other mothers' milk (milk banks or wet nurses); commercial baby foods including infant milks (formula) and complementary foods and juices (referred to as 'breastmilk substitutes'). It shows that the dominant share of this market for infant food is accounted for by commercial baby foods and argues that the dominance of commercial baby food at the expense of breastmilk and breastfeeding reflects ignorance of scientific evidence on the health risks associated with consumptionof formula milk; agency problems arising from the mother necessarily making decisions on behalf of the infant; a pricing structure which does not recognise or incorporate thenegative externalities associated with consumption of formula milk (for example, health related costs incurred by individuals and society later on in life); and the unfair competitive and marketing advantage that commercial producers of breastmilk substitutes (private companies) have over other suppliers to the market (in this case mothers). The article uses a market analysis to demonstrate that unrecognised social costs and information failures, agency problems and unequal power relationships, along with unfair competition in the market for infant food, lead to a series of market failures that result in economically inefficient (and unfair) outcomes for society. Furthermore, this article argues the undervaluing and mis-valuing of mother's milk and the subsidisation and mis-valuing of formula milk underpins the current public policy approach, and proposes a new policy approach. The first section shows that themarket share of mothers' milk in Australia has been stagnating, if not declining, and the dominant share of the market is held by commercial baby foods. The second sectionanalyses the market for infant food within an economic framework to illustrate that the usual conditions for consumer sovereignty (informed, rational choice, consumer bears allcosts and benefits) may not apply. In such circumstances, social costs ('externalities') may arise. The third section establishes empirically that these social costs are large, significantfor public policy, but not recognised by conventional measures and approaches to public policy.

2. Smith, J. P. (2015). "Markets, breastfeeding and trade in mothers' milk." Int Breastfeed J 10: 9.

This introduction to a special issue on the economics of breastfeeding draws attention to the lack of economic justice for women. Human milk is being bought and sold. Commodifying and marketing human milk and breastfeeding risk reinforcing social and gender economic inequities. Yet there are potential benefits for breastfeeding, and some of the world's poorest women might profit. How can we improve on the present situation where everyone except the woman who donates her milk benefits? Breastfeeding is a global food production system with unsurpassed capacity to promote children's food security and maternal and child health, but it is side-lined by trade negotiators who

seek instead to expand world markets for cow's milk-based formula. Regulators focus on potential risks of feeding donated human milk, rather than on health risks of exposing infants and young children to highly processed bovine milk. Similarly, policymakers aspire to provide universal health care access that may be unaffordable when two thirds of the world's children are not optimally nourished in infancy, resulting in a global double burden of infectious and chronic disease. Universal breastfeeding requires greater commitment of resources, but such investment remains lacking despite the cost effectiveness of breastfeeding protection, support and promotion in and beyond health services. Women invest substantially in breastfeeding but current policy - epitomised by the G20 approach to the 'gender gap' - fails to acknowledge the economic value of this unpaid care work. Economic incentives for mothers to optimally breastfeed are dwarfed by health system and commercial incentives promoting formula feeding and by government fiscal policies which ignore the resulting economic costs. 'The market' fails to protect breastfeeding, because market prices give the wrong signals. An economic approach to the problem of premature weaning from optimal breastfeeding may help prioritise global maternity protection as the foundation for sustainable development of human capital and labour productivity. It would remove fiscal subsidies for breast milk substitutes, tax their sale to recoup health system costs, and penalise their free supply, promotion and distribution. By removing widespread incentives for premature weaning, the resources would be available for the world to invest more in breastfeeding.

3. Smith, J. (2017). Markets in mothers' milk: Virtue or vice, promise or problem? Making Milk. M. Cohen. Bloomsbury, London.

In 2015, a company called Ambrosia Milk began buying human milk from mothers in Cambodia to sell in the United States (Jackson 2015; Clark 2016). American mothers would feed it to their newborns a!er they returned to paid employment while Cambodian mothers would secure a better standard of living. "ere are reports of commercial wet- nursing and human milk exchange and trading as far afield as China and North America (Fowler and Ye 2008; "orley 2008a; "orley 2008b; Akre, Gribble, and Minchin 2011; Dutton 2011; Medo 2013; "orley 2015; Cohen 2017b).

Markets in mothers' milk have both problems and promise—for infants and mothers, for community health and welfare, and for gender equity. Trade and exchange of human milk might disempower women, and displace the breastfeeding relationships between mother and baby. While consuming human milk contributes to child nutrition and health, maternal breastfeeding confers a multitude of physiological and psychological benefits for the child, and protects the reproductive health of the lactating mother (Labbok 2001). Distributional concerns are profound, as market exchange may redistribute mothers' milk away from vulnerable consumers (children) with biological claims to it, to those most able and willing to pay—including adults seeking sexual gratification. "There is potential for the exploitation of lactating women due to gender inequality in wealth and income, weak or unequal bargaining power within households and markets, and inadequate human rights protections of women and children.

Furthermore, if we look at examples such as the trade in human milk in Cambodia (to the United States), there is a worrying reproduction of imperial food relations that requires further analysis. "e most willing producers—selling the cheapest milk—may be the more desperate or dishonest suppliers, rather than those offering the most suitable milk. Markets can systematically disadvantage purchasers over sellers of certain kinds of products because of unequal information on product characteristics such as whether a used car is a "lemon" or whether milk is diluted or contaminated (Akerlof 1970). Market prices can provide misleading signals about the societal value of products that distorts decision- making about what is produced or consumed. Market prices fail, for example, to incorporate negative health and environmental cost externalities of milk formula consumption, or the social benefits of parental investments in children (Folbre 1994; Smith 2004; Dadhich et al. 2015)

Making Milk

On the other hand, expanded markets in mothers' milk could improve its availability, benefit nutrition and health, and contribute to greater economic justice for women (Smith 2015). Breastfeeding and breastmilk production is well below its biologically potential capacity in many countries (Smith 2012; Smith 2013). "e sale or donation of surplus human milk could improve the nutrition and health of those children otherwise deprived of it. Lactating women might gain health and financial benefit from increased breastfeeding, while mothers able to secure breastmilk through trade or exchange may be more than willing to pay for the personal satisfaction as well as for better nutrition and health for their child. "e commercial model for milk exchange or wet- nursing has become uncommon in Western countries but the economic inequity of the contemporary donative market in the United States, where "everyone except the woman who donates her milk benefits," has been questioned (Fentiman 2009: 66).

Because conventional economics deems unpaid household production including breastfeeding to be a non- economic phenomenon—and therefore excludes it from GDP—the existence of markets in human milk provides important evidence that economic rewards and market prices affects its supply and demand, strengthening the case for measuring it in GDP. Feminist critiques have long emphasized that how we measure GDP reflects a gender- biased interpretation of economic progress and development. Rather than being "positive" or "objective," economics reflects and privileges male experience. For example, economics has overlooked the differing experience of the female to that of the male during economic development and ignored the vital social and economic role of reproduction, care, and nurture (Boserup 1970). As Marilyn Waring (1988) famously illustrated, economic statistical conventions systematically excludes much of women's economic activity from measurement in GDP. Feminist economists have promoted an alternative approach based on "social provisioning" (Power 2004), which incorporates domestic work and unpaid care work as fundamental to economic analysis and which evaluates economic process or performance on how well it achieves sustainable human development (Benería, Berik, and Floro 2015). However, women's crucial reproductive and productive work remains invisible in conventional economic statistics, perpetuating bias in economic measurement and policy perspectives that disadvantages women and perpetuates gender inequality.

An important weakness of economic analysis is that it takes little or no account of gender power relations and their wider social institutional context. Social institutions, public regulations and policies perpetuate elements of deep- rooted pre- capitalist patriarchal systems that have served to coerce women's availability for unpaid reproductive and productive work. Economic exploitation of women's willingness to are for children is facilitated by entrenched false dichotomies between "altruistic" and "market" motivations for work (Folbre and Nelson 2000; England 2005). Similarly, the "breadwinner" focus of welfare capitalism during the past 200 years is not well designed to respond to economic risks to women in the modern economy arising from their investments in child- raising (Orloff 1993). As Nancy Folbre (1994) has pointed out, children have features of "public goods." As the benefits of investing in children are increasingly socialized, parenting becomes a public service.

Breastfeeding exemplifies the need to properly account for women's unpaid caring and reproductive work in economic statistics, and for the households' creation of human capital. Although all commodities including human milk are within the scope of GDP as defined by international agreement since 1993,1 standard national accounting practices exclude measurement of human milk production. An important reservation by national accountants is about whether "economic pricing" is important for demand and supply in these markets, that is, whether breastfeeding and trade in human milk meets the test of "sensitivity to economic rewards" (Kravis 1957).

This chapter explores the potential for the contemporary emergence of markets in breastmilk and breastfeeding to improve the recognition of women's unpaid breastfeeding work, by reviewing whether economic rewards influence breastfeeding, and using contemporary market prices for breastmilk to compare the economic value of breastmilk and milk formula for selected countries in Asia, Europe, and North America.

4. Smith, J. P. (2017). "Without better regulation, the global market for breast milk will exploit mothers." The Conversation Retrieved 19 July, 2023.

Markets in mothers' milk could be a good or a bad thing for women and their children, depending on how governments respond. Making breast milk more easily available may help more mothers breastfeed, and improve the economics of the situation for women. With maternal breastfeeding now promoted as a choice rather than a biological imperative, it is hypocritical and duplicitous for governments to authorise companies to sell breast milk without strengthening the rights of women to breastfeed, sell or share their own milk. Markets in mothers' milk could be a good or a bad thing for women and their children, depending on how governments respond. Making breast milk more easily available may help more mothers breastfeed, and improve the economics of the situation for women. With maternal breastfeeding now promoted as a choice rather than a biological imperative, it is hypocritical and duplicitous for governments to authorise companies to sell breast milk without strengthening the rights of women to breastfeed, sell or share their own milk.

Global trade in breast milk

The international market for breast milk has grown from both demand and supply factors, and from difficulties common to new mothers worldwide. The huge accumulation of scientific evidence on the importance of breastfeeding for both women and babies has resulted in an increase in market demand for milk. This is led by health professionals treating medically vulnerable babies. Potential bacterial or viral contamination of traded breast milk can be avoided by pasteurisation. The risks are comparable to those associated with cow milk infant formula. The buyers for breast milk in the United States include women having trouble breastfeeding, especially after difficult childbirth. Lack of paid maternity leave for women after childbirth also increases demand for breast milk in the US. Bodybuilders also buy it for sports nutrition. On the supply side, new technologies are helping lactating women in the US and elsewhere to extract, store and exchange their milk safely and independently. Exchange increasingly occurs online. For some, selling surplus milk makes maternity leave affordable. Others provide milk to babies of relatives and friends through informal networks. However, breast milk is in short supply where formula is cheap and breastfeeding rates are low. Only a small number of companies are involved in the global trade, the biggest being Prolacta. The US company has been collecting milk through milk banks for around US$30 a litre and turning into a commercial product sold to US hospitals for nearly US$300 a litre. Alongside the not-for-profit breastmilk banks, several million ounces of breastmilk are processed in North America each year. The Australian government recently approved a local dairy entrepreneur, Neolacta, to import and sell breast milk. Neolacta has attracted controversy in India around plans to collect milk without remuneration from poor mothers at a Bangalore hospital and sell it publicly for US$300 a litre, in return for donating some of the processed milk to a hospital neonatal unit. Another company, Ambrosia Milk, was selling breast milk in the United States. Unlike the Indian proposal, the company paid Cambodian mothers for their milk, so they earned at least twice the local wage. Ambrosia's scheme barred mothers from contributing milk until babies had been breastfed for six months, and required health checks. Offering women around US$15 a litre for breast milk, Ambrosia found willing suppliers. However, Cambodian officials shut down the trade this year, declaring:

Even though we are still poor, we are not so poor that we have to sell human breast milk.

Why would women get involved?

To date, the policy debate around the market for breast milk has focused on exploitation, any health risks and milk banking, without exploring the bigger picture of economic incentives and gender inequalities. Governments have neglected to recognise the economic value of women's "lactation work" or to provide legitimacy, guidance and safety to informal breast milk exchange. The work involved in breastfeeding is rarely acknowledged, although it can takes considerable time, skill and energy. International authorities including the World Bank, recently called for better resourcing of breastfeeding, including by paid maternity leave. More information must be given to mothers involved in exchanging breast milk. Breastfeeding image from www.shuttershock.com

US and Australian regulators have helped dairy industry players to position themselves in a commercialised breast milk supply chain, but individual women are discouraged from trading by legal ambiguities about rights and responsibilities. Selling breast milk is probably not illegal and buyers may sue over unsafe milk. Businesses selling food must be licensed and meet food safety standards. Laws in different jurisdictions differ, depending on whether breast milk is considered a food or a human tissue, or even a therapeutic good. Mothers involved in exchanging breast milk are alternatively praised or stigmatised, raising issues about institutionalising medical control of women's bodies and economic choices. Health researchers are already experimenting with financial rewards to improve breastfeeding rates. In fact, various studies have shown governments' own budgets would benefit if more women breastfed. Lower rates of infectious illness and later life chronic disease for breastfeeding mothers and children reduces health care costs. Maternal breastfeeding and breast milk could be made safer and more accessible to women in both rich and poor countries if governments were innovative and courageous in acknowledging women's economic and health rights, and if governments acted to protect maternal breastfeeding through comprehensive policies.

Regulating the trade in breast milk

The major risk of the emerging trade is that it will reduce maternal breastfeeding. If mothers are not breastfeeding, their own health is compromised, and the risks of breast cancer are higher. Feeding at the breast also benefits children's development and bonding, and reduces infection risk even compared to feeding breast milk. At the supplier end, in India or Cambodia, breastfeeding mothers may be persuaded to make more milk and lactate longer. However, they may unknowingly sell or donate too much of their own child's birthright. If mothers don't know the true worth of their breast milk, or have few decent work or leave options, they are easy targets for companies marketing cow's milk substitutes for breast milk. The overriding goal of regulating the selling or sharing of human milk should be to empower women to breastfeed their own children, while protecting maternal breastfeeding from economic incentives and markets that undermine it. Although health policymakers may think a market for breast milk solves the problem of breastfeeding, it doesn't. Markets work by holding costs down, and selling at a profit to those willing and able to pay, not to the children who most need it. Public health regulation supported the expansion of markets for infant formula last century. Comparable public health support is now needed to make breast milk more available and breastfeeding less costly for women. Markets increase the need for strong employment and consumer regulation to protect women and children worldwide. In Australia this could mean National Health and Medical Research Council guidelines to assist safe sharing, selling and buying of human milk. There also needs to be clarification of mothers' legal rights and responsibilities. Insurance and technical support could be provided for running women's breast milk cooperatives, focused on helping mothers with breastfeeding. Health services could screen and certify potential suppliers, and offer storage and logistics support. For example, in Brazil, the government implemented a comprehensive and integrated national strategy that incorporated community-based milk banking. The integrated strategy dramatically improved breastfeeding rates and children's health in the country. World Health Organisation guidance, including the International Code of Marketing on Breast Milk Substitutes, should extend its scope to commercialised breast milk. Import and export regulation for breast milk should include fair trade or fair pay requirements. Product labelling should certify that the women supplying the breast milk received fair pay and health protection. Governments also need to urgently implement the International Labour Organsation's conventions on paid maternity leave and lactation breaks. Breastfeeding takes time and "time is money" for women as well as men. If governments prioritise corporations over women's economic and health rights, sales of breast milk will result in everyone but mothers benefiting from trade.

5. Smith, J., et al. (2018). Review of effective strategies to promote breastfeeding: an Evidence Check rapid review brokered by the Sax Institute for the Department of Health, May 2018.

Sax Institute. https://www.saxinstitute.org.au/wp-content/uploads/Review-of-effective-strategies-to-promote-breastfeeding.pdf

6. Israel-Ballard, K., et al. (2019). "Call to action for equitable access to human milk for vulnerable infants." Lancet Glob Health 7(11): e1484-e1486.

Breastfeeding, which is an integral component of human reproduction, prevents the infant mortality associated with alternative feeding methods owing to the unique nutritional and immunoactive properties of human milk.1 UNICEF and WHO emphasise the crucial role of breastfeeding in addressing the Sustainable Development Goals (SDGs), including improving child nutrition (SDG 2), preventing child mortality and decreasing the risk of non-communicable diseases (SDG 3), and supporting cognitive development and quality education (SDG 4).

Although extensive evidence supports the importance of breastfeeding for infant health and development, many infants worldwide do not have access to breastfeeding or their own mother's milk because of maternal death, illness, or separation. Up to 40% of infants in neonatal intensive care units globally cannot access sufficient mother's milk during during the first days or weeks of life.2 These vulnerable infants—mainly preterm neonates with low birthweight—are at greater risk of morbidity and mortality from severe digestive complications, infections, and delayed growth or development than full-term or healthy infants. For these infants, WHO recommends safe use of donor human milk through human milk banks as a key risk reduction strategy.3

To address this need, over 600 human milk banks have been established in more than 60 countries, but most are in Europe, the USA, Asia, and Brazil, with a nationalised system of more than 230 human milk banks in Brazil alone.4 More of these banks are needed. Human milk banks serve a critical role by recruiting milk donors, and collecting, processing, screening, storing, and distributing safe donor human milk. Without ensuring a strong global breastfeeding culture and support system, not all vulnerable infants will have access to donor human milk. Global scale-up of human milk banks has been hampered by the absence of global policies and standards to guide donor programmes. For example, there is no consensus on the classification of human milk as a food, tissue, medicine, or other possible classification for regulatory purposes, which has important implications for how human milk banks are governed and legislated. To date, in most countries, human milk banks are developing operating systems and guidelines without systematic coordination or with limited guidance on global best practices.

There are a number of important ethical considerations that policymakers, regulators, health workers, and mothers must consider in facilitating and navigating supportive breastfeeding environments, including the provision of human milk within different socioeconomic contexts. Ethical challenges include the commercialisation of donor human milk for profit and exploitation of women in low-income settings selling breastmilk—where detrimental to their own child's health—for purchase by consumers in high-income settings;5 managing risks associated with peer-to-peer sharing and selling of unscreened human milk;6 weighing trade-offs for increasing screening of donors to ensure milk safety with increasing supply to address unmet need;7 potential risks that donor's own infants are not optimally breastfed; and determining how best to prioritise provision of donor human milk in times of scarcity.8 A crucial and overriding challenge is ensuring the appropriate use of donor milk so that it serves as a bridge to support breastfeeding, rather than displacing a mother's own milk and breastfeeding.9,10

To address these challenges, the Ethox Centre of the University of Oxford and PATH convened a working group—the Oxford-PATH Human Milk Working Group— of technical and policy experts in nutrition, human milk banking, human rights, bioethics, and maternal, newborn, and child health to develop ethical guidance in support of safe and equitable access to human milk and breastfeeding for vulnerable infants. Participants shared perspectives from Australia, France, Germany, India, Kenya, Malawi, Mexico, the Philippines, South Africa, UK, USA, and Vietnam. The working group identified cross-cutting ethical considerations and key actions that should be addressed as part of global and regional responses to donor milk policy and guideline development (panel).

7. Smith, J. P. and A. Iellamo (2020). "Wet nursing and donor human milk sharing in emergencies and disasters: A review." Breastfeeding Review 28(3).

During emergencies and disasters infant survival can depend on their access to breastfeeding or human milk. Wet nursing and donor human milk sharing are options endorsed by the World Health Assembly (WHA). This study looks at regulatory environments for wet nursing and donor human milk sharing and considers the wider food security and resilience implications.

Legislation and policies relating to wet nursing, donor human milk sharing and milk banking can support appropriate infant and young child feeding in emergencies responses (IYCF-E). However, in many countries there is a lack of legislative and regulatory clarity on protecting and supporting breastfeeding practices in these situations. This is true for all income country settings and geographic regions. High breastfeeding prevalence in a country can reduce exposure to food insecurity and risk for mothers and their children during emergencies. Regulatory clarity is also needed to protect safe wet nursing and donor human milk sharing, being an important step in developing protocols and plans for emergency preparedness and response. With human milk products becoming more available, there is also an urgent need to ensure full implementation of the IYCF-E Operational Guidance and the World Health Organization (WHO) International Code of Marketing of Breast-milk Substitutes and subsequent relevant WHA Resolutions.

8. Smith, J. P., et al. (2021). "Behind moves to regulate breastmilk trade lies the threat of a corporate takeover." The Conversation Retrieved 27 May, 2021, from https://theconversation.com/behind-moves-to-regulate-breastmilk-trade-lies-the-threat-of-a-corporate-takeover-152446.

The European Union is preparing to harmonise regulations governing the trade in human milk, which sounds like a good thing. But it won't be if it sidelines breastfeeding or makes informal human-to-human milk exchanges more difficult. Women and their families have exchanged human milk informally (including for money) throughout history, and still do. Until a century ago human milk was mainly delivered in person, breast-to-child, by friends, relatives or wet nurses if mothers couldn't provide it. As the paediatric profession developed, hospitals in Europe and the United States took over the process and began administering human milk by bottles, at first filled by volunteers, and later, in the lead-up to the second world war, by paid donors. Higher women's wages after the war made paying donors financially prohibitive, and most countries moved closer to a "gift economy" in which payment for products such as human milk and blood was seen as inappropriate, alongside a growing commercial market for formula and powder derived from cows milk. Donor milk collected by charities and non-profit organisations from screened donors is mostly pasteurised and tested to minimise risks of disease.

Biotech discovers breast milk

Things changed in 1999 when an American company, Prolacta, developed human milk-based products for fortifying breast milk fed to premature infants. At first Prolacta didn't pay donors, but it now pays about US$4 per 100ml for milk it uses to make products that sell for up to US$250 per 100 ml.

Prolacta human milk products

In 2015 a not-for-profit Utah-based company, Ambrosia Labs established clinics in Cambodia to collect milk for exporting to the United States. After the United Nations Children's Fund condemned the practice saying breast milk could be considered "human tissue" the Cambodian government banned it. Some mothers despaired at losing crucial income. A few years later in 2017 an Australian-Indian company Neolacta, was granted permission to sell milk collected from Indian mothers in Australia. In 2019 a related company, NeoKare, established a "state-of-the-art" plant in Europe making freeze-dried fortifier sourced from UK donors. These human milk product manufacturers are competing with cow-sourced product manufacturers such as Nestle and might soon be competing with start-ups growing new products that mimic human milk.

Industry backs new regulation

The harmonisation being considered by the European Union would extend to human milk the rules that already govern trade in blood, tissues and cells. Some member states in the European Union already apply tissue and cell rules to human milk, others apply food legislation, and at least 11 don't regulate it at all. Australian regulators will be watching closely, because Australian states and territories have similarly diverse rules. That formula companies are backing the idea provides cause for concern.

But it's women who matter

Health authorities have already expressed disquiet about commerce-free internet-based milk sharing. The proposal would give them greater powers to act against it. If these powers were applied heavily they could shut down the generally safe and self-regulated human-to-human trade.

And advancing the medical market for human milk products might delay the advances in social and employment protection policies needed to support breastfeeding at work, at home and in public.

Human milk is not simply a homogenised "commodity crop in a bottle".

Breastfeeding creates connections that are important for women's health and wellbeing and for their babies. Ironically, where governments fail to adequately protect, promote and support breastfeeding, mothers are often forced to turn to commercial formula for a quick fix. The proposals as drafted pay scant regard to the United Nations human rights commissioner's view that "states should do more to support and protect breastfeeding, and end inappropriate marketing of breast-milk substitutes".

A truly comprehensive set of laws would include protection from marketing and biomedical experiments and allow suitable recompense for donors. Serological testing would be easily available to donors along with guidance to support milk sharing outside of medical facilities

Such comprehensive laws would impose levies on commercial substitutes in order to fund better breastfeeding support in maternity and newborn facilities. They would have at their centre the needs and rights of women, who are both the main providers of human milk and (on their children's behalf) its biggest users.

9. Salmon, L. and J. P. Smith (2024) Sharing human milk: challenging Australian regulatory regimes. <u>Broad Agenda</u>

Women who share their milk may meet with social disapproval, but this ancient practice for feeding vulnerable babies and meeting breastfeeding challenges signals an adaptable decentralised nutrition system through which women collectively deliver basic food security and lifelong health to human populations. Although political power over access to food is increasingly centralised and globalised through market-based supply systems, greater prevalence of breastfeeding and milk sharing among women resists the effects of corporate power and climate change on the health and wellbeing of the most vulnerable.

How is human milk sharing regulated in Australia, and what are its implications for harming, or helping, breastfeeding? What organisational structures would put women in charge of breastfeeding, mothers' milk, and its distribution?

Nothing new in human milk sharing

The ways that infants are fed, and mothers are treated, are crucial issues for the health of individuals, societies and the planet. Breastfeeding is important for women's and children's health. It also contributes to maintaining planetary health. Sharing human milk has a long history in wet-nursing. In the past, infants who were not breastfed rarely survived. Wet nursing was and continues to be employed in many cultures, sometimes as a respectable and valued occupation. Breastfeeding may also be shared among relatives or friends, including to overcome breastfeeding challenges. More recently, expressed milk is shared through human milk banks and informal arrangements in the community, facilitated by new technologies. Recent research at ANU used Australia as a case study of these various forms of milk sharing, and their governance through legal and social norms. The study covered the period 2010 to 2022, which was a critical time for milk sharing in Australia, with the emergence of human milk banks, milk sharing via social media and international trade in human milk. These issues ignited media reports of milk banks saving premature babies, while

'black markets' in milk supplied body builders. These representations left donor milk caught in a 3-way competition —between breastfeeding and infant formula, raising deep legal and social questions about safety, ethics and women's reproductive rights.

What is 'regulation'?

How should we think about the 'regulation' of milk sharing? Broad theories of regulation can help, for example, thinking of regulation as the 'steering of events,' through the state and 'beyond the state,' by government and civil society actors.First, was the question of how laws and policies frame milk sharing. The second challenge was to identify how these legal factors influence milk sharing in practice, in hospitals and communities, by interviewing mothers, milk banks, health professionals and policy makers.

What 'regulates milk sharing'?

The research showed incoherence in regulation, with discontinuities between legal frameworks and actor knowledge, objectives, courses of action and feedback. This incoherence arose from several sources: contested legitimacy, multiple lines of and conflicting objects of regulation. Targeting these themes will help refocus regulation from milk as a resistance product, to milk sharing that supports breastfeeding systems. Milk sharing is empowering when its regulation includes mothers' voices in ways that respect individual autonomy, but uphold collective interests. Without these twin objectives, milk sharing risks reproducing social inequities in infant feeding. These complexities are exacerbated by the emergence of global trade in human milk, which has attracted controversy, and has limited value for women. While corporations increasingly trade in human milk products, and profit from it, women's costs for donating milk are poorly recognized and payment of donors is discouraged for fear of exploiting their vulnerability or incentivising unsafe practices. Meanwhile, the increased medicalisation of human milk for use in neonatal intensive care risks dispossessing women and their systems of knowledge that sustain breastfeeding . Regulations to harmonise the governance of global trade in human milk sounds like a good thing but won't be if it displaces breastfeeding or makes safe systems of informal milk exchange more difficult, or promotes an extractive industry.

'Saying this is a valuable commodity, so let's assign some money to it… that kind of economic argument, …that's just capitalism. I don't think good outcomes follow…. You know, someone's going to get exploited in there because that's the way that capitalism works. And it will be the woman who supplied the milk' (health professional).

For milk donation to support breastfeeding, it is important that consumers are not deceived about the potential benefits or harms of human milk products compared to breastfeeding. Like formula, using donor milk can displace a mother's own milk production, and evidence that pasteurised, homogenised human milk products are better than the mother breastfeeding is lacking. To prevent misleading marketing to the public and health professionals, Australian regulators should clarifying that donor human milk products are within the scope of the WHO International Code of Marketing of Breastmilk Substitutes. Similar concerns arise with the emergence of 'synthetic breastmilk', with Australian food regulators noting that such 'cell-based human milk products are unlikely to truly replicate the composition and health benefits of human milk, and are comparable from a function and regulatory perspective to infant formula products'.

Where to for mothers' milk sharing

Markets in human milk and other milk formula products increase the need for strong maternity protection and consumer regulation to protect women and children worldwide. Governments need to urgently implement the International Labour Organisation's conventions on paid maternity leave and lactation breaks. Breastfeeding takes time and "time is money" for women as well as men, but women who share breastmilk have nuanced views about payment, which is allowed in some countries, though donors do not generally receive payment in Australia:

'It would be an unfair system if it didn't benefit the donors in some way, because …it takes time. I don't know whether it should be an incentive or compensation. If it's a commercial arrangement, I

absolutely think the donating mothers should get a significant proportion of the profits, otherwise it's exploitation in my view' (donor and recipient mother).

'If I was donating for payment, especially if I was donating to a milk bank, I'd have ethical issues about the way that hospitals interfere with breastfeeding relationships in the first place. …I wouldn't feel comfortable …financially benefiting from that' (donor mother)

Structures are needed for human milk exchange that make mothers central in the governance of milk and build localized and national collaborative capacity.

'So having that involvement with my community, extended through milk sharing, gives me that sense of pride, …looking after other mums and each other. We should be empowering each other, we shouldn't be tearing each other down' (donor mother).

Research in Australia shows that milk sharing is not just an example of a complex regulatory problem but an example of a complex solution: of women's lactating bodies as sites of production, power and resistance to the biopolitics of infant feeding at the global level. Public health support is needed to make breastfeeding less costly and more equitable for women, and breastmilk more available. In Australia, this could mean updated National Health and Medical Research Council guidelines to assist women and families in the safe sharing of human milk and a system to cover the costs of donation.

'I'd like to see [government] support it as a valid alternative to, or addition to formula.

Even as part of one of the possibilities on the spectrum of feeding and I guess normalising it… help break down stigma around it being dangerous or unhygienic. … I've seen guidelines on the web from other countries … there's ways to do it responsibly' (recipient mother).

A network of organisations controlled by women, for example women's breastfeeding cooperatives, could help mothers with breastfeeding and lactation, and also provide technical support, logistics and insurance for milk exchange, liaising with hospital milk banks and health services to screen suppliers and recipients. A population where breastfeeding is prevalent and wet-nursing is acceptable and practiced safely also has greater resilience to climate risks such as natural disaster events, or during disruptions to food supplies. International health agencies increasingly acknowledge the advantages of using donor human milk or a wetnurse when an infant cannot be breastfed by its mother, or as a bridge to breastfeeding amidst breastfeeding challenges. In emergencies, bottle feeding is unsafe and wet-nursing, as well as re lactation, may provide a lifeline, but are poorly recognised in agencies in many countries, including Australia. For example, in Brazil, the practical guidancefor relief government implemented a comprehensive national strategy that integrated hospital milk banks into local centres of expertise on breastfeeding. The strategy dramatically improved breastfeeding rates, children's health and health professional education in breastfeeding. In Australia, some health services may have policies which support breastfeeding but few facilitate milk sharing by relatives or friends to support hospitalised mothers who cannot provide sufficient milk for their newborn and provide a 'bridge to breastfeeding.'

'Directed donation' protocols exist but are not widely known, and mainly focus on helping manage risks to the health service. Concerns about risks to the infant of not being breastfed vary with the age of the infant, but rarely extend to ensuring all dyads access to donor human milk where the mother finds herself unable to breastfeed. Without the legitimization and collective structures that empower the women who produce and exchange milk, the emerging markets in breastmilk will continue to prioritise corporations over women's economic and health rights, and result in everyone but mothers benefiting from its exchange.

10. Smith, J. P. (2025). "Valuing human milk: Applying economic pricing to measure lactation in national accounts." <u>The Economic and Labour Relations Review</u> 36(2): 450-479.

Since the early 1950s, national statisticians have regarded unpaid work as non-economic, excluding it from GDP. Feminist scholars argue this exclusion reflects a gender-biased view of progress that renders women's non-market productivity invisible. As what gets measured drives policy priorities and resource allocation, breastfeeding highlights the need to account for women's unpaid care work

in economic statistics. This paper advances the Beyond GDP agenda by demonstrating how marketderived prices can improve the measurement and recognition of women's lactation labour. We first trace the historical displacement of breastfeeding by commercial formula and identify key economic drivers. Next, we review critiques ofGDP and debates over including non-market household services in the UN's System of National Accounts. We then present novel estimates of breast milk's economic value in selected countries. Our analysis shows that existing market prices can robustly proxy for breastfeeding work, correcting GDP's gender bias and realigning policy priorities. Including human milk production in core economic indicators not only reflects its true contribution but also promotes women's and children's rights and supports sustainable development through comprehensive truecost accounting.

11. Smith, J. P. (1999). "Human milk supply in Australia." Food Policy 24(1): 71-91.

This paper aims to place a monetary value on the actual and potential supply of human milk in Australia. It estimates the quantity of milk produced in 1992. It considers different bases for determining a 'shadow price' for breastmilk, and uses the method established by Oshaug and Botten (Food Policy 19(5), (1994), 479-482). It also calculates scenarios for different prevalences of breastfeeding, looking at the implications on the human milk supply of Australia achieving its National Health Targets, of all mothers breastfeeding according to the optimum regime recommended by the WHO and UNICEF in the Innocenti Declaration of 1990, or of a return to the 'human milk famine' of the early 1970s. It concludes that Australian women supplied 33 million kg of breastmilk in 1992, compared to 16 million kg in 1972. Valued at A$67 per litre (the price of expressed human milk) the 1992 production level was worth $2.2 billion. This is around 0.5% of GDP, or 6% of private spending on food. Achieving international standards for 'optimal' levels of breastfeeding, with breastfeeding continuing up to age two and beyond, would nearly triple the supply of human milk. (C) 1999 Elsevier Science Ltd. All rights reserved.

12. Smith, J. P. (2013). ""Lost milk?": Counting the economic value of breast milk in gross domestic product." J Hum Lact 29(4): 537-546.

BACKGROUND: The contribution of breastfeeding and mothers milk to the economy is invisible in economic statistics. OBJECTIVE: This article demonstrates how the economic value of human milk production can be included in economic statistics such as gross domestic product (GDP) and provides estimates for Australia, the United States, and Norway. METHODS: The contribution of human milk and lactation to GDP in these countries is estimated using United Nations (System of National Accounting) guidelines and conventional economic valuation approaches to measuring production in GDP. RESULTS: In Australia, current human milk production levels exceed $3 billion annually. The United States has the potential to produce human milk worth more than US$110 billion a year, but currently nearly two thirds of this value is lost due to premature weaning. In Norway, production valued at US$907 million annually is 60% of its potential value. CONCLUSIONS: The potential loss of economic value from not protecting women's lactation and milk production from competing market pressures is large. Failure to account for mothers' milk production in GDP and other economic data has important consequences for public policy. The invisibility of human milk reduces the perceived importance of programs and regulations that protect and support women to breastfeed. The value of human milk can be measured using accepted international guidelines for calculating national income and production. It is quantitatively nontrivial and should be counted in GDP.

13. Smith, J. P., et al. (2023). "The volume and monetary value of human milk produced by the world's breastfeeding mothers: Results from a new tool." Front Public Health 11: 1152659.

The Mothers' Milk Tool was developed to make more visible the economic value contributed to society by women's unpaid care work through breastfeeding infants and young children. This manuscript describes the development and display key features of the tool, and reports results for

selected countries. For the development, we used five steps: (1) defining the tool by reviewing existing tools and scholarly literature to identify uses, approaches, design features, and required data characteristics for a suitable product; (2) specifying the best open-access data available for measurement and easy updating; (3) analyzing development options; (4) testing predictive models to fill identified breastfeeding data gaps; and (5) validating the tool with prospective users and against previous research. We developed an Excel-based tool that allows working offline, displaying preloaded data, imputing data, and inputting users' data. It calculates annual quantities of milk produced by breastfeeding women for children aged 0-35.9 months, and the quantities lost compared to a defined biologically feasible level. It supports calculations for an individual mother, for countries, and global level. Breastfeeding women globally produce around 35.6 billion liters of milk annually, but 38.2% is currently "lost" due to cultural barriers and structural impediments to breastfeeding. The tool can also attribute a monetary value to the production. In conclusion, the Mothers' Milk Tool shows what is at risk economically if women's important capacity for breastfeeding is not protected, promoted, and supported by effective national policies, programs, and investments. The tool is of value to food and health policymakers, public officials, advocates, researchers, national accountants and statisticians, and individual mother/baby dyads, and will assist consideration of breastfeeding in food balance sheets and economic production statistics. The tool supports the 2015 Call to Action by the Global Breastfeeding Collective by facilitating the tracking of progress on breastfeeding targets.