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The commodification of human milk: Analysing corporate practices and policy implications using the UCSF Industry Documents Library

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ABSTRACT

Commercialising human milk-based products (HMBPs) poses complex public health, ethical, and regulatory challenges for governments around the world. This study investigates the corporate strategies of the HMBP industry through a qualitative analysis of industry documents obtained from the University of California, San Francisco's Industry Documents Library. The analysis identifies how HMBP companies construct markets by positioning their products as essential to neonatal care and leveraging scientific narratives and professional networks to expand market dominance. These practices include embedding corporate interests in public health messaging and knowingly competing with non-profit milk donation systems. The findings reveal tensions between profit-driven innovation and equitable access to healthcare. The study highlights parallels with other health-related industries, where intellectual property (IP) and market control can deepen inequity. To address these issues, the study emphasises the need for stronger regulatory oversight, enhanced transparency in corporate practices, and support for public milk banking systems. By situating HMBPs within the Commercial Determinants of Health framework, this research provides policymakers and public health advocates with critical insights to safeguard equity in maternal-infant healthcare.

1. Introduction

Commercialising[1] human milk-based products (HMBPs) represents a profound transformation in how human milk, historically regarded as an essential societal resource, is valued and utilised globally. Recognised as the gold standard for infant nutrition, human milk[2] offers unparalleled benefits, including supporting immune system development, reducing the risk of chronic diseases across the life course, and promoting optimal physical and cognitive growth in infants (World Health Organization [WHO], 2025). For those who breastfeed, studies identify a reduced risk of developing certain cancers and cardiovascular diseases, improving long-term health outcomes (Masi and Stewart, 2024). Despite these well-documented advantages, breastfeeding rates remain suboptimal worldwide, impeded by systemic barriers such as inadequate maternity leave policies, insufficient workplace accommodations, cultural stigmas, and medical and healthcare practices that undermine breastfeeding such as routine mother–infant separation and limited lactation support (Zhu et al., 2025). Meanwhile, medical and public demand for expressed donor human milk often exceeds supply (Battersby et al., 2018). Against this backdrop, a range of HMBP products—including pasteurised donor

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[1] In this article, we use 'commodification' to refer to the transformation of human milk into a tradable good governed by market logics, while 'commercialisation' denotes the broader introduction of market relations into its production, distribution, and marketing, and 'corporatisation' highlights the role of corporate actors in organising and profiting from these processes.

[2] We use gender-neutral language to recognise that people of different genders lactate and donate milk. At the same time, we differentiate between breastfeeding and human-milk feeding when referring to evidence: most established health outcomes in the literature derive from studies of breastfeeding dyads, whereas evidence relating solely to the provision of expressed or donor human milk reflects a different set of practices and pathways. This distinction is retained for accuracy while ensuring inclusive terminology throughout.

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milk supplied through hospital or commercial channels, human milk-derived fortifiers produced through industrial processing of pooled donor milk, and powdered or concentrated formulations containing human milk components, with fortifier production in particular requiring large volumes of pooled donor milk—are being sold around the world, both to healthcare providers and, in some settings, to caregivers directly (Steele and Cooke, 2024; Shenker et al., 2024).

Initially developed in the 1990s for use in Neonatal Intensive Care Units (NICUs), HMBPs were promoted as critical interventions to reduce risks such as necrotising enterocolitis (NEC), a severe condition primarily affecting preterm infants. More recently though, companies have begun marketing these products beyond healthcare providers, selling directly to caregivers, framing HMBPs as essential and even superior feeding options (Newman and Nahman, 2022). Reliable global estimates of the size of the HMBP market and the relative contribution of non-profit versus for-profit providers remain limited, reflecting the opacity of this emerging sector.

Notably, however, these business practices have raised and are raising pressing ethical, economic, and regulatory concerns, particularly as the growing HMBP industry may disrupt breastfeeding practices, strain non-profit milk banks, and commodify an intimate and biologically unique human resource (Steele and Hernandez-Salazar, 2020). Both for-profit and non-profit arrangements for supplying donor human milk can contribute to inequity in access, depending on how milk banking and health financing systems are organised; however, for-profit HMBP companies are distinctive in their reliance on shareholder-driven growth, intellectual property strategies, and cross-border market expansion (Smith et al., 2021; Baker et al., 2023). Notably, the International Code of Marketing of Breast-milk Substitutes, adopted by the WHO in 1981 (WHO, 2017), was designed to restrict marketing practices that undermine breastfeeding. Subsequent guidance has indicated that the Code may also apply to certain HMBPs, yet national interpretations and implementation remain uneven, and HMBPs often sit at the margins of Code-related policy and enforcement (Cohen, 2019; Topothai et al., 2024).

Indeed, studies of for-profit companies in the human milk space have identified that HMBPs are governed by heterogeneous and often incomplete regulatory arrangements, with most countries in Europe, for example, lacking comprehensive policies governing the collection, processing, and distribution of human milk for commercial sale (Klotz et al., 2022). Outside Europe, regulatory responses to HMBPs have varied widely. For instance, India, Australia, and Cambodia have regulated aspects of commercialising human milk, such as the sale, export, and/or import (Shenker et al., 2024). Still, research suggests these regulations are often limited and open to challenge, and many companies in the space seek to operate across multiple markets to remain profitable in any event (Shenker et al., 2024). More broadly, jurisdictions classify human milk and HMBPs in divergent ways—as foods, tissues, drugs, or medical products of human origin (MPHO)—with each approach carrying different implications for donor protection, product safety, pricing, and marketing (Cohen, 2019; Smith et al., 2021). Such observations underscore the need for coordinated yet context-sensitive regulatory approaches to HMBPs, informed by technical, market, and ethical studies and attentive to the risks of unchecked commercialisation (Shenker et al., 2024; Baker et al., 2023). These developments are unfolding alongside the rapid expansion of the commercial milk formula sector, estimated at around US$55 billion globally, whose marketing strategies targeting parents, health professionals, and regulators are now well documented as powerful commercial determinants of breastfeeding practices (Baker et al., 2023; Rollins et al., 2023).

Against these calls for research and regulation, the Commercial Determinants of Health (CDoH) framework offers a tool for exploring the systemic influence of private-sector interests on public health outcomes (McKee and Stuckler, 2018; Maani et al., 2021, 2023). The CDoH framework, interested in the methods and tactics employed by the private sector to advance products and behaviours that impact health, has expanded in recent years in light of calls to analyse a broader range of industries and practices (Maani et al., 2023, p.4). Recent scholarship has highlighted corporations' sophisticated strategies to entrench their influence across policy, public perceptions, and knowledge production (Maani et al., 2023, p.4). These strategies include lobbying for favourable regulatory environments, shaping public narratives to normalise the use of even harmful products, and funding research to obscure or minimise the risks associated with their goods and services (Maani et al., 2021).

The CDoH framework, thus, provides a critical lens through which to examine the structural and systemic mechanisms of corporate influence across diverse industries. By identifying common strategies —such as market construction and control, policy and regulatory influence, information and narrative management, and constituency-building—the CDoH framework highlights the pervasive and multifaceted nature of private-sector interests in shaping health outcomes and societal inequity (Mialon et al., 2015; Gómez, 2022; Maani et al., 2023). Notably, the CDoH framework also reveals how public-private partnerships allow corporations to reframe harmful practices by placing themselves as allies in addressing global health and nutrition challenges while embedding their influence in policymaking processes (Crosbie and Carriedo, 2022).

Consequently, this study positions the HMBP industry within the broader CDoH framework to highlight how corporate strategies impact public health, policy, and healthcare practices. It examines internal industry documents from the University of California, San Francisco's Industry Documents Library (UCSF-IDL) to uncover patterns of lobbying, marketing, and public relations activity. Specifically, the research examines how HMBP companies construct narratives about their products, shape regulatory frameworks, and interact with healthcare systems and consumer markets. This research aims to provide policymakers, healthcare professionals, and public health advocates with a nuanced understanding of the opportunities and risks associated with HMBPs. Accordingly, this article addresses three research questions: firstly, how do corporate actors involved in HMBPs construct and expand markets for human milk-based products? Next, we asked how do they seek to influence regulation, professional practice, and public narratives around human milk and neonatal care? Finally, what implications do these strategies have for breastfeeding, donor human milk provision, and health equity as understood through a CDoH lens?

2. Methods

This study investigates the commercialisation of HMBPs and their impact on health systems, public narratives, professional practices, regulatory frameworks, and health equity. To address these elements we undertook a systematic search and qualitative document analysis of documents identified in the UCSF-IDL, a well-established public health and social science research methodology, particularly in studies examining corporate practices and the CDoH (Baker et al., 2021; McKee and Stuckler, 2018). Following Bowen and O'Leary, we treat documents as socially situated artefacts that both reflect and construct institutional realities, making them well suited to examining how corporate actors frame problems, propose solutions, and position themselves in neonatal care and infant feeding systems (Bowen, 2009; O'Leary, 2014). We explored the interplay of narratives, policies, and practices that are not immediately quantifiable but are critical to understanding systemic impacts (Bowen, 2009). This text-based approach allows for interpreting meaning, context, and relationships within the textual sources – an approach that is particularly valuable for unpacking the complexities of the HMBP industry activities, including its marketing strategies, ethical considerations, and regulatory challenges (O'Leary, 2014). Indeed, by systematically analysing industry documents, this study offers insights into corporate strategy, lobbying efforts, and marketing practices in the HMBP sector.

2.1. Data sources

The primary data source for this study was the UCSF Industry Documents Library (UCSF-IDL), a publicly accessible digital archive hosted by the University of California, San Francisco Library. Established in 2002 following the landmark litigation against the tobacco industry during the 1990s, the UCSF-IDL originated with the Minnesota Settlement and the 1998 Master Settlement Agreement, which made millions of internal tobacco industry documents publicly available (University of California, San Francisco, 2025). Over time, the UCSF-IDL expanded to include a broader range of documents from industries influencing public health, including opioids, pharmaceuticals, chemicals, food, and fossil fuels, with a mission to identify, collect, curate, preserve, and provide open access to these materials (University of California, San Francisco, 2025). As of December 2024, the UCSF-IDL comprises over 128 million pages across 22 million documents, organised into collections such as the Truth Tobacco Industry Documents Library (the largest with over 104 million pages), the UCSF-JHU Opioid Industry Documents Archive, and smaller collections for the chemical, drug, food, and fossil fuel industries (University of California, San Francisco, 2025). The archive has been cited in over 1000 publications and is a widely recognised source of information on industry activities (University of California, San Francisco, 2025). The database is freely accessible worldwide without institutional affiliation, and all documents can be searched and downloaded via the UCSF-IDL website (University of California, San Francisco, 2025).

The research team leveraged the UCSF-IDL to examine HMBP companies and explore their corporate activities. The UCSF-IDL's collections support identifying historical and contemporary corporate practices that impact public health. The library's inclusion of documents disclosed during litigation—such as technical reports, internal communications, and marketing plans—allowed this study to assess the role of industry tactics in shaping health systems, public narratives, and related policies, professional practices, regulatory frameworks, and, to some degree, health outcomes. However, because the archive is litigation-driven and relies on voluntary or legally mandated disclosure, it represents a convenience sample that over-represents companies involved in legal disputes and cannot be assumed to be comprehensive or industry-wide. Although the UCSF-IDL contains material relating to multiple countries, the HMBP-related documents retrieved for this study predominantly concern one United States–based company and its expansion into high-income markets. These findings were supplemented by Internet and literature searches to triangulate industry practices where possible.

2.2. Search strategy and data retrieval

A systematic search was conducted across the UCSF-IDL and supplemental sources, employing a combination of targeted keywords and Boolean operators, with a limitation that documents must be dated after 1999, the year the first products came to market. Search terms included general phrases such as ("human milk products" OR "expressed breastmilk" OR "donor milk" OR "milk fortifiers"), as well as specific brand names: NeoKare (UK-based), Prolacta Bioscience (USA-based), Medolac (formerly USA-based, now closed), BioMilq (USA-based, producing cell-cultured human milk), Vyarna (UK-based Kickstarter campaign), Neo-Lacta (formerly India-based, previously operating in Australia), Ambrosia Labs (previously USA-based, now discontinued), BestMilk (formerly UK-based, now closed), Lactare (Brazil-based), "Ni-Q" (USA-based), and LactaLogics (USA-based). This search list was devised using existing studies and Internet searches to update the list of known HMBP companies identified by Shenker and colleagues (2024). Documents were excluded if they were not: 1) in English; 2) dated before 1999; and 3) explicitly addressed HMBP.

An initial search of the UCSF-IDL's 128,045,817 pages in 22,459,816 documents in December 2024 yielded 758 results, which were then screened for relevance. One company name, Ni-Q, accounted for a large volume of erroneous results stemming from the coding of documents containing this phrase, which was irrelevant to the company itself, and 697 scanned documents were removed as unrelated. After removing apparent duplicates, 44 documents were reviewed, of which 16 directly pertained to HMBPs and were included in the analysis (see Fig. 1).

2.3. Coding framework and validation process

The coding framework was developed iteratively using a grounded theory approach to capture recurring themes and emergent patterns within the dataset (Charmaz, 2014). Using this approach, we initially conducted an open coding phase in which we reviewed a subset of documents to identify preliminary codes. This phase was guided by the study's research questions, focusing on themes such as corporate narratives, market strategies, and policy influence. Codes were then categorised into broader thematic groups aligned with the CDoH framework. Specifically, we grouped codes into four domains adapted from existing CDoH work: (1) market construction and control; (2) policy and regulatory influence; (3) information and narrative management; and (4) constituency-building with professionals, patients, and civil society (Mialon et al., 2015; Gómez, 2022; Maani et al., 2021, 2023).

To ensure robustness, the preliminary coding framework underwent validation by two independent coders, and discrepancies were resolved through discussion, leading to refinements to reduce ambiguity. The coding team included both junior and senior researchers. Initial coding was conducted independently, and consensus meetings were structured to allow junior researchers to present alternative readings before themes were finalised, to minimise hierarchical influence on interpretation. To further enhance validity, the framework was triangulated with external sources, including non-government organisation (NGO) reports, government policy documents, industry websites, and social media. Findings from the UCSF-IDL were systematically cross-referenced with these supplemental sources to ensure consistency and validity.

2.4. Researcher reflexivity and addressing interpretative biases

Given the interpretive nature of qualitative analysis, the research team recognised the importance of reflexivity to mitigate potential biases. Each research team member brought distinct academic and professional backgrounds and expertise in public health, ethics, law, government, and policy analysis, which informed their perspectives on the data. To address the risk of interpretative bias, the team engaged in regular reflexive discussions throughout the coding and analysis process. These discussions focused on how individual assumptions and disciplinary lenses can influence data interpretation. For example, some researchers noted a tendency to critique corporate practices more harshly due to pre-existing views on commercialisation in healthcare. Acknowledging this bias prompted a more balanced approach, where researchers sought corroborating evidence and considered alternative explanations for corporate strategies. Triangulation further counteracted biases by grounding interpretations in diverse data sources beyond the industry documents.

2.5. Document analysis

We followed a thematic coding framework informed by the CDoH as outlined above. Undertaking close reading, the research team coded documents for recurring themes such as:

- Corporate Narratives: Framing of HMBPs as superior nutritional solutions and their alignment with healthcare guidelines [market construction and control].
- Policy Influence: Lobbying efforts to shape regulations and secure public funding for HMBPs [policy and regulatory influence].

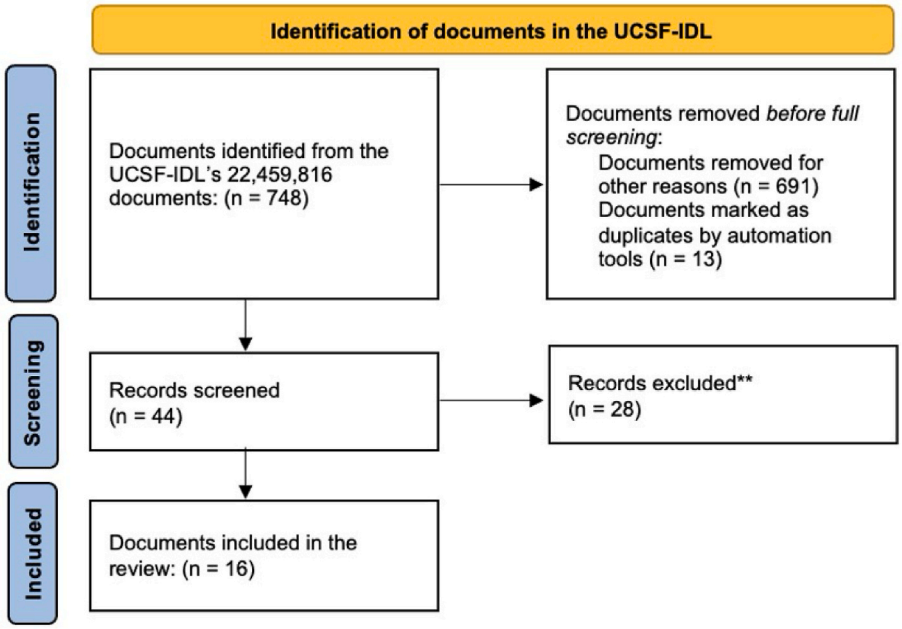

Fig. 1. Overview of document filtering and selection procedures applied to UCSF-IDL search results.

- Market Practices: Direct-to-consumer marketing, pricing strategies, and targeting of healthcare professionals [information and narrative management].
- Ethical and Social Impacts: Effects on vulnerable populations, healthcare professionals, and altruistic milk donation systems [constituency building].

This approach's flexibility enabled the study to explore emergent themes, capturing unexpected patterns and contradictions within the data. Guided by the CDoH lens and critical work on commodification and intellectual property, we interpreted these themes with particular attention to how documents constructed markets for human milk, framed human milk as a resource, and invoked regulation and intellectual property to shape competition and access.

2.6. Ethical considerations

This study adhered to ethical guidelines for qualitative research, emphasising transparency and accountability in data collection and analysis. The primary data source, the UCSF-IDL, is a comprehensive and publicly accessible repository, which allows documents to be accessed and analysed under the Fair Use provisions of U.S. Copyright Law and encourages rigorous adherence to ethical and legal standards in both the collection and use of industry data (University of California, San Francisco, 2025). The ethical use of UCSF-IDL is ensured by its public accessibility and by documents obtained through litigation, FOI requests, or whistleblowers. These documents are classified as public-interest materials and are free of personally identifiable or confidential information as this has been redacted prior to upload (University of California, San Francisco, 2025). As such, research utilising this library is excluded from institutional review board requirements, as the library itself has already been subject to review and is intended for research and review.

3. Results

Of the 16 documents that directly pertained to HMBPs, none of these documents were prepared by HMBP companies themselves but were located within collections arising from: litigation with Mallinckrodt Pharmaceuticals (Opioid Industry Document Library; n = 9), McKinsey Documents (Opioid Industry Document Library; n = 3), the Insys Therapeutics documents (Opioid Industry Document Library; n = 1), Teva and Allergan documents (Opioid Industry Document Library; n = 1), US Right to Know's (USRTK) Food Industry Collection (Food Industry Document Library; n = 1), and JUUL Labs Collection (Truth Tobacco Industry Document; n = 1) (see Table 1).

Taken together, these third-party materials provide a limited but revealing window into how private-sector actors and their advisors describe the HMBP sector, assess its market potential, and anticipate interactions with health systems. Three overarching themes emerged: 1) market construction and control; 2) leveraging personnel, networks and influence; and 3) embedding corporate interests in public health narratives. Each theme illustrates aspects of the CDoH framework by showing the nuanced interplay between corporate practices and public health objectives.

3.1. Market construction and control

A key theme emerging from the documents is how pharmaceutical companies and their advisors strategically construct and control markets to drive demand, dominate supply chains, and secure competitive advantages. By positioning HMBPs as essential to neonatal care, for example, Mallinckrodt Pharmaceuticals identified significant growth opportunities in a market assessment that examined one U.S.-based HMBP company. It notes that "80 % of the addressable market remains untapped, providing an attractive opportunity to grow the market" in the U.S. (see IDL_Doc_1). In the same document, the company further observed the need to consider systemic barriers to adoption, such as Medicare and Medicaid coverage (see IDL_Doc_1), which may impede market growth. Other documents reveal that consulting companies were engaged to assess the "portfolio attractiveness" of this same U.S.-based entity (see IDL_Doc_10, 15–16). While notably, the scoring assessment criteria and reports are not captured in the UCSF-IDL disclosures (see IDL_Doc_10), other documents suggest the U.S. company did not provide an "anchor product"— a cornerstone product driving revenue and brand identity (Kotler and Keller, 2016)—in another merger and acquisition assessment (see IDL_Doc_16).

Beyond these initial assessments of market viability, the documents show how the HMBP market is framed as both underdeveloped and ripe for expansion through clinical integration. For instance, while initial

Table 1
Documents included.

Document Reference	Title	Date	Collection	Source	URL
IDL_Doc_1	PowerPoint Presentation	2017 September 08	Mallinckrodt Litigation Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/gfvk0247
IDL_Doc_2	PowerPoint Presentation	2017 September 25	Mallinckrodt Litigation Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/qghd0238
IDL_Doc_3	Application for District Sales Manager from Aisha LuVert	2014 February 20	Insys Litigation Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/fhmn0280
IDL_Doc_4	4541 (3-3-2020) Aff. of L. Saldana Exhibit 77.pdf	2016 May	Teva and Allergan Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/lfgv0312
IDL_Doc_5	[Email from Abbott Nutrition Regarding ANHI Resources for You & Your Patients]	2018 November 28	USRTK Food Industry Collection	Food Industry Document	https://www.industrydocuments.ucsf.edu/docs/rswf0269
IDL_Doc_6	Pharma Priority News Brief - (2/24/17)	2017 February 24	Mallinckrodt Litigation Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/txhy0236
IDL_Doc_7	Pharma Priority News Brief - (2/15/17)	2017 February 15	Mallinckrodt Litigation Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/rzgy0236
IDL_Doc_8	868 articles from Meltwater News	2010 December 08	Mallinckrodt Litigation Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/rslb0240
IDL_Doc_9	Mallinckrodt Daily News Report 24 February 2017	2017 February 24	Mallinckrodt Litigation Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/ynwy0237
IDL_Doc_10	Purdue_Assessment of Private Equity Funded Companies_Screening_DRAFT 01292015 v8.xlsx	2015 January 09; 2015 January 29	McKinsey Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/qphj0256
IDL_Doc_11	PowerPoint Presentation	2015 July 02	Mallinckrodt Litigation Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/gnnc0253
IDL_Doc_12	Mallinckrodt Daily News Report 15 February 2017	2017 February 15	Mallinckrodt Litigation Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/gjgc0237
IDL_Doc_13	Practical Law - 4 full text items for PUBLIC BENEFIT CORPORATION.RTF	2017 April 06	JUUL Labs Collection	Truth Tobacco Industry Document	https://www.industrydocuments.ucsf.edu/docs/flwk0298
IDL_Doc_14	Mallinckrodt Daily News Report 13 February 2017	2017 February 13	Mallinckrodt Litigation Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/zfxk0241
IDL_Doc_15	Windhover deals.xlsx	2014 February 26; 2014 October 15	McKinsey Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/trxj0256
IDL_Doc_16	20151013 - Master Company list vClientF3.xlsx	2015 September 30; 2015 October 16	McKinsey Documents	Opioid Industry Document	https://www.industrydocuments.ucsf.edu/docs/hjfm0256

estimates on market projections are detailed in an internal PowerPoint document dated 8 September 2017 (see IDL_Doc_1), after Mallinckrodt initiated conversations with the company's management on 18 September 2017, a further internal document from 25 September 2017 (see IDL_Doc_2) provided detailed projections on the growth of the HMBP company within the U.S. market through 2024. These projections outlined an initial baseline with "no significant attitude change from [the] status quo", where there is "no wholesale conversion of those trialing the product" and "no major shift in reimbursement paradigm" to a strategic trajectory that leverages clinical worker support alongside growing institutional adoption to accelerate market growth (see IDL_Doc_2, p. 6; see IDL_Doc_1, p.14). The same documents go on to describe an even more favourable business case, in which "adoption accelerates as pilot accounts see value and benefit …" (see IDL_Doc_1, p.14). In this "better" case scenario, large Level 3 NICUs adopt the product "much more broadly and across the country", while smaller hospitals show "moderate adoption", bolstered by "continued positive hospital level clinical and health economic data" (see IDL_Doc_1, p.14). Importantly, these key growth drivers are projected to be effective even as "limited reimbursement support" [(presumably from Medicare and Medicaid)] is perceived to constrain the financial landscape (see IDL_Doc_1, p.14). This assessment highlights potential health equity concerns, as the reliance on institutional adoption, clinical support, and limited financial reimbursement may lead to unequal access to HMBPs.

Further to this, the modelling acknowledges that if a "competitor enters the market in a few years", it may "[help] to grow the overall size of the market", though they are also expected to "take their fair share of this larger market" (see IDL_Doc_1, p.14). The acceptance of competition as a driver of market growth suggests that market dynamics, rather than health outcomes, significantly influence decision-making. This underscores how profit motives and competitive strategies shape the availability and accessibility of health-related products, potentially prioritising market expansion over equitable health improvements.

Concurrently, the internal PowerPoint documents also explore the potential for market expansion across different geographical locations. They note, for example, that the company's products were used in fewer than 150 NICUs out of approximately 900 across the U.S., while detailing a projected $500 million market opportunity in Europe on account of the "beginning stages" of the company's presence in that region (see IDL_Doc_1, p.16). While such analyses may be expected in standard

business operations – particularly in the case of mergers and acquisitions – what is somewhat remarkable in this instance is the treatment of pooled human milk as an industrial input in a scalable, patent-protected product line. Although human milk has historically been exchanged and paid for through practices such as wet-nursing and informal milk markets (Golden, 1996), the documents depict a qualitatively different form of commodification, anchored in corporate ownership, proprietary processing, and transnational market growth. Such observations also chime with the suggestion by Shenker and colleagues (2024) that these companies must work across markets rather than simply within single countries to achieve sufficient profitability and be commercially viable in the long term.

Aside from the anticipated geographical expansion, market growth is envisaged to be achievable through product expansion and enhanced intellectual property protection. The documents emphasise that "ongoing label expansion studies" aiming to identify new clinical indications for the U.S.-based HMBP company's products could address unmet neonatal care needs while simultaneously driving "revenue growth" (see IDL_Doc_1, p.16) – a practice observed amongst pharmaceutical manufacturers which, particularly when combined with intellectual property protections in highly centralised markets, can be used reduce competition, inform pricing strategies, and boost market share (Le, 2023). With a robust portfolio of over 45 patents globally, the documents observe that the HMBP company can reinforce its market position. In this way, health innovation has been directly tied to profit. At the same time, the emphasis on patents highlights the role of intellectual property in consolidating market dominance, which may limit competition and potentially restrict access to these innovations in less-resourced settings, raising issues about equitable distribution and affordability.

Inequity in distribution becomes a further issue when the documents explicitly suggest that market growth will likely impact altruistic human milk donation systems. Potential competition with non-profit milk banks for donors could create reputational issues. For example, one document states:

> Volume growth of human milk products will require increased access to milk donors, which may result in competition with non-profit organisations for human milk donors, potentially representing future public relations challenges (IDL_Doc_1, p.16).

This tension highlights the ethical and systemic consequences of market-driven strategies, where profit motives risk undermining more equitable healthcare systems. The growth of commercial players may create a competitive donor landscape in which donors prioritise for-profit companies and sales over altruistic giving. This shift challenges the sustainability of non-profit milk banks and risks marginalising low-income families who depend on affordable or free access to donor milk–affirming scholarly calls to explore this market's equity and human rights dimensions (Steele and Hernandez-Salzar, 2020). At the same time, experiences from some health systems that reimburse donors modestly without apparent detriment to breastfeeding or non-profit supply suggest that donor compensation is not inherently harmful but depends on how recruitment and allocation are regulated (Smith et al., 2021). However, by framing the issue as a "public relations challenge" (see IDL_Doc_1, p.16), the documents focus on managing perceptions rather than addressing structural inequity. This reframing prioritises corporate image and reputation over the critical need for systemic solutions that ensure equitable access to donor milk, particularly for marginalised populations. Such strategies highlight the importance of examining how professional networks, including healthcare providers, lactation consultants, and policymakers, are engaged or co-opted by industry actors to help avoid negative public relations. The following section delves into the role of these professional networks, exploring how they shape narratives, influence consumer trust, and contribute to the evolving dynamics of the human milk market.

3.2. Leveraging personnel, networks and influence

The documents suggest that profitability and long-term growth are predicated on leveraging professional networks and regulatory influence to embed HMBPs within healthcare systems. A critical component of market expansion involves prioritising engagement with clinicians and healthcare providers, who play a pivotal role in shaping clinical practices and consumer trust. Two interrelated elements stand out in this approach: first, the 'revolving door' phenomenon, where executives and personnel move between roles across industries and from government and regulators, facilitating cross-sector influence; and second, the targeted efforts to co-opt clinical uptake through strategic involvement in clinical trials and research initiatives. These elements reflect a broader effort to institutionalise HMBPs within healthcare frameworks, blending corporate interests with clinical authority.

First, the documents highlight how movement between the pharmaceutical, medical device, and other healthcare-allied industries lends one U.S.-based company credibility and greater investment interest, while its website further highlights the move from government bodies into executive roles. In its PowerPoint presentation, Mallinckrodt Pharmaceuticals notes, for example, that "7 out of 10 key executives are ex-employees of Baxter Healthcare, including the CEO" (IDL_Doc_1, p.12). Baxter is a leading global company in bioscience and medical products. The HMBP company's leadership website also emphasises this connection (Prolacta, 2025). The website also reveals that one board member's profile emphasises continued work in research-intensive and medical education institutions, another emphasises prior work within government departments, and others emphasise their clinical experience (Prolacta, 2025). Another document reveals movement out of the company into the broader industry, with a Clinical Sales Specialist applying for a District Sales Manager position at Insys Therapeutics (see IDL_Doc_3). The documents and the company's website reveal a clear pattern of personnel mobility that connects HMBP companies with allied healthcare industries, government agencies, medical institutions, and research organisations. This pattern exemplifies one element of the revolving door phenomenon: executives and personnel transition between roles in industry, regulatory bodies, and public institutions (Kanter and Carpenter, 2023). The literature acknowledges that such movements may enable companies to leverage individuals' insider knowledge, relationships with regulators and other government entities, and stakeholder networks to advance corporate interests (Kanter and Carpenter, 2023), although these examples do not map full flow of personnel and executives; a point which may require further study.

Notably, the documents emphasise the pivotal role of neonatologists in driving HMBP market growth, positioning their adoption as central to this growth (IDL_Doc_1, p.14). This strategy underscores the importance of professional trust in influencing clinical practice and consumer decision-making, as neonatologists often serve as gatekeepers in NICUs. As outlined in one document, market assessments focus not only on converting "pilot accounts" but also on achieving the "conversion of those trialing the product" (IDL_Doc_1, p.14). This suggests that a key strategy is targeting early adopters to establish credibility and leverage their influence to expand acceptance within the broader hospital and medical community. The documents outline the potential growth outcomes for the company regarding the issue of "attitude change" (IDL_Doc_1, p. 14). The emphasis suggests a deliberate effort to align clinical perceptions with the company's goals and indicates that growth is tied to including HMBPs in standard care protocols. These relationships and adoption strategies reveal how industry actors may strategically engage with healthcare professionals, hiring them into personnel and executive positions within the company while also co-opting professionals to embed their products within medical systems. In this way, HMBP companies may combine scientific authority with perceptions of market imperatives to drive growth; a theme further explored in the following section.

3.3. Embedding corporate interests in public health and medicine narratives

The documents provide a detailed account of how HMBP and wider infant feeding companies actively integrate their products and brands into public health messaging and consumer education initiatives. By leveraging partnerships, sponsorships, and trusted platforms, these companies may strategically shape perceptions of neonatal care, subtly influencing the behaviours of both consumers and healthcare providers.

One prominent strategy documented in the documents is the sponsorship of educational resources and platforms that support NICU families and professionals. Mallinckrodt Pharmaceuticals repeatedly publicises that it, alongside one U.S.-based HMBP company, sponsors the *Hand to Hold* podcast series dedicated to providing support and guidance to NICU families and staff (IDL_Doc_6, 7, 8,9, 12, and 14). These podcasts are directed to the neonatal care community, offering a platform for disseminating information and fostering shared experiences among families, caregivers, and professionals on Spotify, YouTube, and Apple Podcasts (Hand to Hold, 2024). Season 5, Episode 34, "When Breastfeeding is Complicated", for example, features a lactation consultant and focuses on challenges faced by families with medically fragile infants. By sponsoring this podcast, the HMBP company subtly aligned its brand with both evidence-based neonatal care and emotional support for vulnerable families. As the founder of *Hand to Hold* noted, the podcast serves as "a way for NICU families to share their stories", creating a space where families can connect, learn, and access resources (YouTube, 2023). By associating its brand with this mission, the HMBP company may amplify its presence within the neonatal care ecosystem, cementing its reputation as a trusted partner in the field, much as food corporations have done with food charities (Lambie-Mumford and Kennedy, 2025). For healthcare providers, the sponsorship may reinforce the HMBP company's commitment to evidence-based practices by aligning the company's products with trusted professional guidance.

Additionally, by financially supporting initiatives like podcasts, HMBP companies align themselves with professional development and education, which may create a perception of its products as indispensable components of neonatal health care. In another document, Abbott Nutrition advertises a Continuing Professional Development (CPD) session led by a registered dietician and Director of Clinical Research in a Department of Paediatrics (IDL_Doc_5). The session, titled "Advances in Human Milk Fortification: Evidence for Preterm Infants", appears designed to educate healthcare professionals on the nutritional challenges premature infants face and the use of various strategies and products to address these needs. The content promises to "review challenges and recommendations for meeting nutritional needs of premature infants", provide an overview of "various types of human milk fortifiers", and explore "different strategies for human milk fortification" (Abbott Nutrition Health Institute, 2018). While the CPD session ostensibly seeks to advance neonatal nutritional care, Abbott Nutrition, a major player in the infant formula industry, manufactures a dairy-based human milk fortification rather than an HMBP. However, while exploring the resources related to the session, we observed that the speaker has also hosted a podcast for a U.S.-based HMBP company, *Speaking of Human Milk*, which is available on Apple Podcasts, Spotify, Google Play, and Stitcher (Prolacta, 2024).

Such targeted media content offerings on human milk suggest companies may be using these platforms to embed their products into podcasts about clinical practice, framing them as essential tools for addressing neonatal nutritional challenges while also raising awareness amongst caregivers. Indeed, the U.S.-based company's own hosted podcast overtly leverages educational content to promote its products as professional development and clinical guidance, while also sponsoring other non-profit podcasts that provide less overt product promotion. We observed on the *Speaking of Human Milk* podcast that there is targeted messaging for healthcare professionals on using Prolacta's products as calorie boosters for preterm infants (Prolacta, 2024). Framing this product as a vital tool for neonatal care, the podcast blends educational insights with indirect marketing, which may encourage practitioners to incorporate Prolacta products into their feeding protocols. The dual function of these CPD programmes and podcasts—as vehicles for professional development and marketing tools—exemplifies a broader CDoH strategy where corporate actors blur the lines between education and promotion. The emphasis on evidence and professional accreditation may lend legitimacy to the sessions, while the underlying commercial sponsorship may subtly reinforce the sponsor's market presence.

The sponsorship may also enable companies to influence the broader narratives surrounding neonatal care, engaging in an established strategy of constituency-building (Gómez, 2022). By funding resources that shape perceptions of optimal care, companies indirectly position their products as essential to achieving these standards. The podcasts help normalise the use of these products while reinforcing their perceived value in addressing complex health needs. By sponsoring educational initiatives, the company may actively shape consumer behaviour, encouraging families and providers to view its products as indispensable, gradually ensuring their adoption and use. This influence is particularly significant in neonatal care, where decisions are often driven by urgency, trust in medical professionals, and the desire to provide the best possible outcomes for vulnerable infants.

4. Discussion

The findings of this study illuminate the complex and systemic ways in which the CDoH operate within the HMBP sector, embedding corporate interests into neonatal healthcare frameworks. By analysing 16 industry-related documents, this research reveals how private-sector actors construct markets and policy environments, leverage professional networks, and influence public health narratives to align clinical practices with market objectives. These dynamics prioritise profit and may exacerbate existing inequity by undermining collective solutions, such as non-profit milk banks, while obscuring other structural barriers to neonatal health equity, such as employing and funding lactation support for those who give birth to pre-term or unwell infants.

At the heart of these documents is the framing of the commodification of human milk as indispensable for the care of preterm infants. Companies construct their brand value by positioning their products as optimal care, aligning their branding with critical public health priorities, and associating their brands with health professionals. This strategy reflects a well-documented industry tactic in which market-based solutions are positioned as essential interventions, thereby creating demand and justifying high prices (Freudenberg, 2014). However, the documents also emphasise rapid scaling opportunities in the U.S. and Europe. This reveals how health needs are leveraged to construct profitable markets, mirroring trends in the infant formula industry, where companies globalised their operations to sustain growth, often prioritising high-income consumers while neglecting underserved populations (Moodie et al., 2013).

The documents show that industry acknowledges that market growth around HMBPs may impact the non-profit sector, thereby posing an inherent risk to health equity, yet pursues market growth anyway and promotes products as superior for neonatal care. Historically, non-profit milk banks have relied on altruistic donation systems to provide equitable access to donor milk, often serving vulnerable populations at little or no cost (Shenker et al., 2024). However, the expansion of for-profit markets may disrupt these systems by introducing financial incentives that divert donor supplies and increase healthcare providers' costs. At the same time, concerns have been raised about the treatment of those who express and sell milk by certain for-profit entities (Shenker et al., 2024). Evidence from some European systems—where modest donor reimbursement is routine—additionally suggests that compensation alone is not inherently harmful but depends on governance, transparency, and allocation policies (Smith et al., 2021). Patterns observed in other sectors, such as the privatisation of water and essential

medicines, do, however, suggest that market mechanisms can undermine collective welfare and deepen disparities; What is clear is that "commercial actors can shape our health as individuals and as populations, but beyond that, they can shape how we define ourselves, live our lives, interact with others, and how we perceive problems and solutions" (Maani et al., 2023, p.4).

Situating HMBPs within broader theoretical debates of CDoH can deepen our understanding of how corporate practices reshape healthcare ecosystems, particularly regarding resources with substantial cultural and ethical dimensions, such as human milk. We observe that adaptations to the CDoH framework are needed to reflect the distinctive characteristics of the HMBP industry. For instance, the commodification of human milk raises complex ethical and systemic issues that extend beyond traditional CDoH analyses (Steele and Hernandez-Salzar, 2020). These include the ethical trade-offs between the potential exploitation of vulnerable populations and threats to donor recruitment (Shenker et al., 2024). Integrating biological-resource industries into CDoH theory may therefore require conceptual refinements that incorporate embodied and reproductive labour, as well as the moral economies surrounding donation and care.

Such an exacerbation of inequalities connects to another critical finding of this study: the use of intellectual property to secure market dominance. The documents' emphasis on the U.S.-based company holding a portfolio of over 45 global patents further highlights how corporations wield intellectual property rights to limit competition and maintain high product prices while growing their domestic and international market. This dynamic exemplifies a broader CDoH pattern in which proprietary controls prioritise corporate profits over public health equity (Stuckler and Nestle, 2012; Freudenberg, 2014).

Meanwhile, more subtle means may achieve positive perceptions of the companies and their products. Sponsorship of educational content—including podcasts and CPD programmes—can serve as a soft-power mechanism through which HMBP companies are associated with professional authority and care, potentially fostering perceptions of trustworthiness and normalising their products within routine practice, while the company also appears altruistic though its donations. The U.S.-based HMBP company's sponsorship of the *Hand to Hold* and *Speaking of Human Milk* podcasts exemplifies this strategy, aligning the brand with evidence-based neonatal care and emotional support. These initiatives may engender credibility and trust, embedding corporate products within caregiving journeys and clinical practices. This dual function of education and marketing blurs the boundaries between public health advocacy and corporate promotion, raising ethical concerns about the objectivity of these resources. Such strategies are characteristic of market-driven health systems, where private entities position themselves as indispensable partners in addressing public health challenges while advancing commercial interests (Maani et al., 2021).

As such, we observe that the commodification of human milk exemplifies strategies well observed within the CDoH literature. This study offers one perspective on how corporate strategies reshape maternal and infant health systems by examining documents that position HMBPs at the intersection of market construction, intellectual property, and professional networks. Focusing on the erosion of non-profit milk banks adds a unique dimension to the analysis, highlighting the systemic trade-offs that arise when market logics infiltrate public health systems.

However, several limitations warrant consideration. First, the UCSF-IDL constitutes a litigation-driven, convenience sample that disproportionately reflects companies involved in legal disputes. The resulting dataset of 16 documents—while analytically rich—captures only a narrow slice of industry activity and is more likely to foreground contentious or legally scrutinised practices than routine or potentially beneficial aspects of HMBP provision. Second, reliance on publicly accessible documents means covert, proprietary, or strategically sensitive practices—such as informal lobbying, undisclosed sponsorships, and internal market deliberations—remain largely invisible. Future research should aim to triangulate these findings with qualitative interviews, insider testimony, or whistleblower accounts to provide a more comprehensive understanding. Third, the dataset centres primarily on one U.S.-based company operating in high-income contexts, limiting the generalisability of findings across the broader HMBP industry. Practices, impacts, and stakeholder dynamics in other corporate entities remain insufficiently examined. Finally, the implications for low- and middle-income countries remain largely uncharted. Given differences in breastfeeding prevalence, regulatory environments, and health-system financing, the commercialisation of human milk may produce distinct, potentially more acute consequences in these settings. Future work should therefore investigate the HMBP market across diverse geopolitical and socioeconomic contexts to capture the full global complexity of this emerging industry.

However, the findings underscore the systemic trade-offs inherent in the commodification of neonatal care. While HMBPs may address legitimate gaps in neonatal nutrition, their market-driven promotion risks deepening health disparities by marginalising low-income populations, undermining non-profit systems, and shifting focus from structural barriers to maternal and infant health equity. Notably, the documents do not provide adequate evidence to verify the accuracy of clinical claims regarding product use in the United States or elsewhere, and such an evaluation was beyond the scope of this study. What is known, however, is that the reliance on altruistic donation systems for human milk has historically ensured broad access to donor milk, especially for vulnerable populations (Shenker et al., 2024). The documents themselves note that the competitive dynamics introduced by for-profit HMBP markets threaten these systems, creating a scenario in which public health objectives are subordinated to private interests.

Addressing these systemic challenges requires a multi-pronged approach. Policymakers must prioritise structural reforms that mitigate the influence of corporate interests on healthcare systems (Maani et al., 2021). This includes increasing transparency in corporate sponsorships, strengthening non-profit arrangements, and developing regulatory frameworks that balance innovation with equity. Some researchers suggest this involves further research on agents and power, as well as structural determinants, and the re-politicisation of the social determinants of health and health inequity at the international level, specifically within the WHO (Karatekin et al., 2024). Interdisciplinary research that bridges public health, ethics, law, and political economy will be essential for understanding how market-driven neonatal care affects maternal and infant outcomes and for informing responses by international bodies such as the WHO. Specific recommendations, therefore, include:

- *Enhancing Transparency*: Mandating clear disclosure of corporate sponsorships in educational and public health initiatives to safeguard the integrity of health narratives.
- *Strengthening Non-Profit Milk Banks*: Increasing funding and support for non-profit donor systems to ensure sustainable and equitable access to human milk.
- *Reforming Intellectual Property Policies*: Establishing mechanisms to limit monopolistic practices and promote access to proprietary health resources.
- *Mitigating Regulatory Capture*: Implementing stricter conflict-of-interest guidelines for professional networks and regulatory bodies.
- *Promoting Structural Reforms*: Addressing systemic barriers to breastfeeding and neonatal care through comprehensive public health policies prioritising collective solutions over market-driven interventions.

5. Conclusion

This study illustrates how companies can shape the production, promotion, and integration of HMBPs into neonatal care and broader infant-feeding systems. Through strategies that construct markets,

leverage professional networks, and embed products within public health narratives, HMBP companies may influence clinical practices, policy and regulatory systems, and consumer behaviours in ways that prioritise profit over equity. By situating these dynamics within a CDoH lens, this research contributes to understanding how market-driven strategies around a biologically and socially unique resource—human milk—generate ethical and systemic trade-offs in neonatal care.

The findings underscore the pressing need for a critical reassessment of corporate actors' role in neonatal care. Policymakers, researchers, and public health advocates must work collectively to ensure that neonatal care systems prioritise equity, sustainability, and public welfare over corporate interests. This requires regulatory reforms, strengthened non-profit infrastructures, and a commitment to transparency in public health initiatives. By addressing these challenges, public health policy and regulation can move societies toward a more equitable and sustainable approach to maternal and infant health, safeguarding the collective well-being of future generations.

CRediT authorship contribution statement

Sarah L. Steele: Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Noah C.A. Cooke:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation, Conceptualization. **David Stuckler:** Writing – review & editing, Writing – original draft, Methodology. **Adam Kamradt-Scott:** Writing – review & editing, Writing – original draft, Formal analysis.

Ethical approval Statement

This study used publicly available documents from the University of California, San Francisco's Industry Documents Library (UCSF-IDL). These documents were obtained through litigation, Freedom of Information requests, or whistleblower disclosures and are classified as public interest materials. As such, they do not contain personally identifiable or confidential information. The research adhered to ethical guidelines for qualitative studies, emphasising transparency and accountability in data collection and analysis. Since all data used in this study were already in the public domain and no human participants were involved, this research did not require Institutional Review Board (IRB) approval. The study follows the ethical principles outlined in the Declaration of Helsinki and relevant guidelines for conducting research with publicly available industry documents.

Data availability Statement

The data used in this study were obtained from the publicly accessible University of California, San Francisco's Industry Documents Library (UCSF-IDL). These documents are available for open access and can be retrieved using the search terms and strategies outlined in the Methods section of this manuscript. Table One provides links to all the documents we cite. No new datasets were generated or collected specifically for this study.

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Declaration of competing interest

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Data availability

These documents are available for open access and can be retrieved using the search terms and strategies outlined in the Methods section of this manuscript. Table One provides links to all documents.

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