

# Liquid Gold: Antitrust and Consumer Protection in the Human Milk Industry

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## I. Introduction – What is Human Milk

Human milk is both food and living tissue.<sup>1</sup> The composition of human milk is complex, and this complexity makes replication next to impossible.<sup>2</sup> Human milk contains macronutrients and micronutrients that are unique footprints to mother and child.<sup>3</sup> Not only does human milk contain proteins, fats, and vitamins essential for development, the lactating mother also transfers stem cells, hormones, bacteria, and antibodies to boost the baby's immunity.<sup>4</sup> By this measure, human milk has no suitable alternative for mothers who decline to supplement with formula or other mammal milk such as goat or cow milk. The American Association of Pediatrics (AAP) recommends mother's milk and/or milk from a human donor as the preferred food for infants.<sup>5</sup>

The benefits to infants extend beyond base nutrition and immunity. The AAP in their 2012 policy on breastfeeding,<sup>6</sup> indicates that human milk consumption by infants reduces the number of children developing diabetes, celiac disease, bowel complications, obesity, and childhood leukemia.<sup>7</sup> Citing studies published by the *Lancet*, the AAP also suggests that human milk advances brain development in infants compared with formula alternatives.<sup>8</sup> The American Dietetic Association (ADA) states that promoting breastfeeding is a public health strategy for

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<sup>1</sup>Malgorzata Witkowska-Zimny and Ewa Kaminska-El Hassan, *Cells of Human Breast Milk*, Cell Mol Biol Lett (2017), <https://doi.org/10.1186/s11658-017-0042-4>.

<sup>2</sup>American Academy of Pediatrics, *Breastfeeding and the Use of Human Milk*, (2012), <https://pediatrics.aappublications.org/content/pediatrics/129/3/e827.full.pdf>

<sup>3</sup>Olivia Ballard, *Human Milk Composition: Nutrients and Bioactive Factors*. Pediatric Clinics of North America (2013) <https://pubmed.ncbi.nlm.nih.gov/23178060>.

<sup>4</sup>*Id.*

<sup>5</sup>AAP, *supra* note 2.

<sup>6</sup>The act of breastfeeding in this paper is synonymous with infants receiving pumped human milk from the biological mother or donor.

<sup>7</sup>AAP, *supra* note 2.

<sup>8</sup>Cesar Victoria, et al., *Association Between Breastfeeding and Intelligence, Educational Attainment, and Income at 30 Years of Age: A Prospective Birth Cohort Study from Brazil*, The Lancet (2015), [https://doi.org/10.1016/S2214-109X\(15\)70002-1](https://doi.org/10.1016/S2214-109X(15)70002-1).

improving infant and child health survival, improving maternal morbidity, controlling health care costs, and conserving natural resources.<sup>9</sup> Thus, human milk use is not only advantageous for health outcomes, but economical. Over the course of the first year of life, breastfeeding a baby compared with formula use, saves families as much as \$3,163.86.<sup>10</sup> Additionally, every dollar spent on donor milk saves between \$11 and \$37 in medical spending.<sup>11</sup>

## II. Regulation of the Human Milk Industry

The human milk industry is largely self-regulated by nongovernment agencies.<sup>12</sup> In the United States, there is no federal regulation or oversight in the collection of human milk from donor mothers.<sup>13</sup> Additionally, there is no regulation that extends to the private individual in donating or buying and selling milk over the internet.<sup>14</sup> It is not illegal for women to donate or sell their breast milk. However, nonprofit and for-profit milk businesses are held to different standards and are required to hold tissue-bank licensure in some states.<sup>15</sup>

The FDA, despite its lack of regulations over the industry, posts safety information regarding the use of private donor milk on its website.<sup>16</sup> “Human milk may be dangerous to babies because it can carry infectious diseases including HIV and drug contaminants from the donor.”<sup>17</sup> The FDA recommends against acquiring milk from unknown sources online due to

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<sup>9</sup> James DC, Dobson B, *Position of the American Dietetic Association: Promoting and Supporting Breastfeeding*, Journal of American Diabetes Assoc. (2005) [https://jandonline.org/article/S0002-8223\(05\)00329-9/fulltext](https://jandonline.org/article/S0002-8223(05)00329-9/fulltext).

<sup>10</sup> Kelly Bonyata, *Financial Costs of Not Breastfeeding*, Kellymom.com (Dec. 7, 2020, 3:49PM), <https://kellymom.com/pregnancy/bf-prep/bfcostbenefits/>.

<sup>11</sup> Olivia Campbell, *When Babies Need Donated Breast Milk Should States Pay?* (2016) <https://www.scientificamerican.com/article/when-babies-need-donated-breast-milk-should-states-pay/>.

<sup>12</sup> Jenine Kenna, *Got Milk - A Call for Federal Regulation and Support of Human Donor Milk*, 36 WOMEN's Rts. L. REP. 435, 437 (2015).

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> U.S. Food and Drug Administration, <https://www.fda.gov/science-research/pediatrics/use-donor-human-milk> (last visited Nov. 13, 2020).

<sup>17</sup> *Id.*

such safety risks.<sup>18</sup> The FDA suggests women procure donor milk from milk banks in their home states through the Human Milk Banking Association of North America's (HMBANA) network of milk banks.<sup>19</sup> The FDA has shied away from becoming more involved in the human milk industry. However, considering the growing trend of internet sales and the for-profit sector, some groups are calling for more regulation.<sup>20</sup>

### III. Antitrust in the Nonprofit Sector

The nonprofit sector of the human milk industry is largely represented by a network of associated milk banks under the umbrella of the HMBANA. This paper takes the position that the HMBANA participates in per se illegal behavior under Section 2 of the Sherman Act by regulating the behavior of its member milk banks to the point of price-fixing. The monopoly behavior of HMBANA includes price-fixing models, control over geography, lack of alternatives for consumers, and control of the milk supply. HMBANA was founded in 1985 out of growing concerns of HIV transmission through donor milk.<sup>21</sup> HMBANA is a nonprofit association that oversees member thirty milk banks across the United States and Canada.<sup>22</sup> HMBANA member milk banks accept human donor milk from vetted donors, screen and pasteurize the milk, then distribute it to consumers.<sup>23</sup>

HMBANA secured substantial market power by exclusively holding the market on “certified” milk banks.<sup>24</sup> Because there is no federal regulation overseeing independent milk

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<sup>18</sup> *Id.*

<sup>19</sup> U.S. Food and Drug Administration, *supra* note 16.

<sup>20</sup> Mikaela Conley, *FDA Weighs in on Breast Milk Sharing As Breast Milk Sharing Becomes Increasingly Popular, the FDA Deliberates Safety*, abcnews.go.com (Dec. 7, 2020 5:18PM), <https://abcnews.go.com/Health/breast-milk-fda-weighs-risks-human-milk-banks/story?id=12327503>.

<sup>21</sup> Interview with HMBANA Naomi Bar-Yam, HMBANA, Exec. Dir. Mothers' Milk Bank Northeast (Oct. 28, 2020) (Email, notes with author).

<sup>22</sup> HMBANA, <https://www.hmbana.org/about-us/> (last visited Dec. 7, 2020).

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

banks, hospitals contract almost exclusively with HMBANA affiliated banks.<sup>25</sup> There is a lack of data for HMBANA's percentage of both the nonprofit sector and the human milk industry as a whole, however in 2014, the organization held eighteen milk banks.<sup>26</sup> In 2020, just six years later, that number has grown to thirty.<sup>27</sup> The organization's affiliated banks distributed about 4.4 million ounces of human milk to hospitals last year, up from less than half that amount as recently as five years ago.<sup>28</sup>

The price of human milk from a milk bank is not dictated by the market's natural supply and demand. In the year 2000, milk banks were charging on average, \$2.50 per ounce.<sup>29</sup> In 2020, one ounce of breast milk from a HMBANA milk bank is on average, \$4 per ounce, a 37% increase in price over 20 years.<sup>30</sup> Consider, an infant aged 1 to 6 months consumes an average of 25 ounces per day between the ages of 1 month and 6 months.<sup>31</sup> Babies in that same age range vary greatly in the amounts they take per day, with a range as low as 19 ounce, and as high as 30 ounce.<sup>32</sup> This pricing structure results in a cost as much as \$120 per day for donor milk. HMBANA member banks offer financial assistance to "all babies with a medical need for human milk," however applicants must disclose employment status and income, and the prioritization of sick infants means that mothers who wish to secure milk for a *healthy* infant are often rejected.<sup>33</sup>

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<sup>25</sup> Kenna, *supra* note 12 at 444.

<sup>26</sup> Eryn Kaiser Brown, *Inside the Growing Business of Mothers' Milk*, PBS.org, (Dec. 7, 2020, 3:04PM), <https://www.pbs.org/newshour/health/inside-growing-business-mothers-milk>.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> Sarah E. Waldeck, *Encouraging a Market in Human Milk*, 11 Colum. J. Gender & L. 361, 379 (2002).

<sup>30</sup> Judy Dutton, *Liquid Gold: The Booming Market for Human Breast Milk*, Wired.com (Dec. 7, 2020, 3:04PM), <https://www.wired.com/2011/05/ff-milk/>.

<sup>31</sup> Kelly Bonyata, *How much expressed milk will my baby need?* kellymom.com (visited Dec. 7, 2020), <https://kellymom.com/bf/pumpingmoms/pumping/milkcals/#:~:text=The%20research%20tells%20us%20that,%2D900%20mL%20per%20day>).

<sup>32</sup> *Id.*

<sup>33</sup> Mother's Milk Bank Austin, <https://www.milkbank.org/financial-assistance> (last visited Dec. 7, 2020).

HMBANA milk banks are registered nonprofits and have a consistent structure of costing. First, HMBANA milk banks must abide by the policy that milk donors will not receive compensation.<sup>34</sup> HMBANA's operating income is derived from milk sales, grants, and member bank association fees.<sup>35</sup> HMBANA does not coordinate or communicate prices between their affiliated milk banks, however HMBANA's states that each milk bank applies the same costs in calculating their price.<sup>36</sup> These are divided into the categories of "Direct and Indirect Milk Processing Costs." Direct costs include donor screening, shipping milk to the bank location, and milk processing. Indirect costs include research, overhead, and money reserved for free milk to individuals in need.<sup>37</sup> Consistent costing among banks may be considered concerted action leading HMBANA to fix prices across its member banks. If a consumer visits various HMBANA member bank websites, it is difficult to discern the current price of their milk without applying for outpatient services.<sup>38</sup> A consumer is not necessarily restricted to the HMBANA bank in its region and may "shop around" for the best price. However, that is not practical based on HMBANA's geographic restrictions.

#### IV. Antitrust in the For-profit Sector

There are limited players in the for-profit sector of the human milk industry but that is likely to change. Scientific data on the benefits of breast milk for infants has inspired non-formula alternatives that use breast milk as the main ingredient.<sup>39</sup> For-profit companies begin with the same raw material, human milk, then use that milk to create a pharmaceutical product

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<sup>34</sup> See HMBANA, *supra* note 22.

<sup>35</sup> *Id.*

<sup>36</sup> Interview *supra* note 21.

<sup>37</sup> Naomi Bar-Yam, *Why is Donor Milk So Expensive?*, lactationmatters.org (visited Nov. 10, 2020), <https://lactationmatters.org/2013/11/08/why-is-donor-milk-so-expensive/>.

<sup>38</sup> See HMBANA, *supra* note 22.

<sup>39</sup> Kenna, *supra* note 12 at 454.

derived from the milk known as a “human milk fortifier.”<sup>40</sup> The pharmaceutical product is then supplied to hospitals to feed infants in neonatal units.<sup>41</sup>

For-profit businesses have the capacity to raise more capital and create more product than the traditional methods. It is difficult to ascertain a price per ounce of these products. One source stated \$48<sup>42</sup> per ounce, another, \$184<sup>43</sup> per ounce. The average cost per day to feed a hospitalized infant with a milk fortifier product is \$200-\$300.<sup>44</sup> This variant is likely due to the cost relationships with the hospitals systems and insurance companies. Prolacta Bioscience, a for-profit milk product manufacturer, processed 2.4 million ounces, or 18,750 gallons of milk last year, and aimed to do 3.4 million in 2020.<sup>45</sup> That compares to the 3.1 million ounces dispensed in 2013 by all 18 nonprofit milk banks that belong to HMBANA.<sup>46</sup>

The For-profit sector is making headway to control the supply chain and squeeze out nonprofit milk banks through vertical integration. For-profit companies compete with nonprofit milk banks for milk supply. The industry for many years relied on women to donate their milk for free. Some for-profit businesses offer to pay women up to \$1 per ounce, a \$300 expense reimbursement,<sup>47</sup> and use similar emotional appeals as HMBANA does in their recruiting efforts.<sup>48</sup> Elena Medo, founder of Prolacta Bioscience, defended their recruiting efforts and

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<sup>40</sup> Prolacta Bioscience, [prolacta.com/en/](http://prolacta.com/en/) (last visited Dec. 7, 2020).

<sup>41</sup> Kenna, *supra* note 12 at 469.

<sup>42</sup> Marsha Austin, *Sides Clash Over Putting Price on Mothers' Milk*, [www.denverpost.com](http://www.denverpost.com) (May 8, 2016), <https://www.denverpost.com/2006/03/25/sides-clash-over-putting-price-on-mothers-milk/>.

<sup>43</sup> Linda C. Fentiman, *Marketing Mothers' Milk: The Commodification of Breastfeeding the New Markets for Breast Milk and Infant Formula*, 10 Nev. L.J. 29, 33 (2009).

<sup>44</sup> Brown, *supra* note 26.

<sup>45</sup> Fentiman, *supra* note 43.

<sup>46</sup> Ryan Stone, *Breast Milk Becomes a Commodity with Mothers Caught up in Debate*, [nytimes.com](http://nytimes.com) (visited Nov. 12, 2020), <https://www.nytimes.com/2015/03/21/business/breast-milk-products-commercialization.html>.

<sup>47</sup> Helping Hands Milk Bank, Operated by Prolacta Bioscience, <http://www.helpinghandsbank.com/> (last visited Dec. 7, 2020).

<sup>48</sup> Brown, *supra* note 26.

ethical concerns by stating: “We’re in a completely different market segment than the milk banks. If we have to be a for-profit to do it, so be it.”<sup>49</sup>

Prolacta has created their own network of twenty “milk banks” which act as depositories for donors, like HMBANA operations.<sup>50</sup> However, those that stand against the commercialization of milk donations claim Prolacta’s milk banks, like Tiny Treasures Milk Bank<sup>51</sup> and Helping Hands Bank<sup>52</sup> are “just a front” and not a “true milk bank.”<sup>53</sup> Medolac Laboratories, a competitor of Prolacta, was called out for a exploitive recruiting campaign aimed at African American mothers in Detroit.<sup>54</sup> After Medolac faced direct criticism by the Black Mothers’ Breastfeeding Association, it abandoned its plan.<sup>55</sup> Opponents of payments [for milk], worried about breast milk “farming,” stating the economic incentives could put women and their babies at risk.<sup>56</sup> Ethical questions remain in the operation of these for-profit producers, but most women would not know the difference between a HMBANA bank and a Prolacta bank.

As the for-profit sector takes command of the supply chain, players simultaneously the engage in exclusionary conduct by racing to secure patents and pursuing litigation against one another. Prolacta is accused of predatory legal action against smaller competitors by asserting infringement claims on its patents.<sup>57</sup> NI-Q, a small competitor of Prolacta operating in Oregon,

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<sup>49</sup>Marsha Austin, *Sides Clash Over Putting Price on Mothers’ Milk*, [www.denverpost.com](http://www.denverpost.com) (May 8, 2016). <https://www.denverpost.com/2006/03/25/sides-clash-over-putting-price-on-mothers-milk/>.

<sup>50</sup>Fentiman, *supra* note 43 at 68.

<sup>51</sup>Tiny Treasures Milk Bank, Operated by Prolacta Bioscience, <http://tinytreasuresmilkbank.com/prolacta-bioscience> (last visited Dec. 7, 2020).

<sup>52</sup>Helping Hands Milk Bank, *supra* note 47.

<sup>53</sup>Stone, *supra* note 46.

<sup>54</sup>*Id.*

<sup>55</sup>*Id.*

<sup>56</sup>*Id.*

<sup>57</sup>Moms on Watch, *Moms on Watch Troubled by Allegations at Prolacta Bioscience Press Release*, [Bloomberg.com](http://Bloomberg.com) (June, 25, 2020), <https://www.bloomberg.com/press-releases/2020-06-26/moms-on-watch-troubled-by-allegations-at-prolacta-biosciences>.

holds seven patents for testing milk, while Prolacta holds thirteen.<sup>58</sup> Between 2017 and 2020, NI-Q and Prolacta were embroiled in ongoing litigation over patent infringement, ultimately culminating with NI-Q's allegations that Prolacta had violated antitrust laws under the Sherman Act. There will likely be more litigation like *NI-Q, LLC v. Prolacta Bioscience, Inc.* as more for-profit businesses enter the human milk market. Prolacta acquired significant market power in a relatively short period of time due to its innovation and investment capital early in the formation of for-profit human milk sector.

#### V. Consumer Protection in the Private Peer-to-Peer Transactions Sector

Peer-to-peer milk sharing is not a new concept.<sup>59</sup> Wet nursing, the act of a lactating woman breastfeeding a child not her own, was a known profession throughout civilization.<sup>60</sup> A variety of internet sites facilitate pairing buyer/seller and donor/receiver.<sup>61</sup> Between 2012 and 2015 online transactions for human milk doubled, totaling 55,000 in 2015.<sup>62</sup>

The peer-to-peer private transactions sector of the human milk industry enhances competition and allows women to drive the price and availability of their product. Some women are motivated altruistically, some financially. Regardless of their motivations, women benefit from an unregulated online market. While the unregulated market of human milk sales over the

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<sup>58</sup> U.S. Patent and Trademark Office, Search Feature (patent search NI-Q, results for NI-Q registered patents), <http://patft.uspto.gov/>. (last visited Dec. 7, 2020).

<sup>59</sup> The term milk sharing is used however most transactions involve payment. See Aunchalee Palmquist, *Demedicalizing Breast milk: The Discourses, Practices, and Identities of Informal Milk Sharing, Ethnographies of Breastfeeding: Cultural Contexts and Confrontations* (2015).

<sup>60</sup> Mathilde Cohen, *Regulating Milk: Women and Cows in France and the United States*, 65 Am. J. Comp. L. 469, 484 (2017).

<sup>61</sup> Zanolli, Lauren, *Mothers are Buying Breast Milk Online – Because they Don't Have Better Options*, theverge.com (visited Nov. 10, 2020), <https://www.theverge.com/2015/4/28/8504443/mothers-buying-breast-milk-online-donors-risks>.

<sup>62</sup> *Id.*

internet is free from monopoly concerns, ethical questions linger regarding consumer health, safety, and ethics.<sup>63</sup>

Transactions for milk over the internet occur in a few forms. Formalized networking services such as “Human Milk for Human Babies”<sup>64</sup> that operate on Facebook, restrict users to donating their milk, and ban any money exchanges. These networks encourage receivers to request a donor health screening before accepting milk.<sup>65</sup> The website “Only the Breast” allows the buying and selling of milk through a classifieds posting board.<sup>66</sup> Only the Breast recommends that buyers interview sellers and pasteurize milk prior to feeding it to their infants.<sup>67</sup>

Unfortunately, pasteurization removes some nutrients from the milk, causing some mothers to choose not to pasteurize purchased milk.<sup>68</sup> All of these sites, regardless of free milk or milk for a price, state that they do not take responsibility for any harm stemming from milk exchanged through their networks.<sup>69</sup> Rightfully so, since in a 2012 report by the BBC, out of 12 breast milk samples bought online, four contained E.coli, two contained candida, which causes thrush, and one contained pseudomonas aeruginosa, a bacteria linked to the death of four babies in neonatal

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<sup>63</sup> David Dawson, *Legal Commentary on the Internet Sale of Human Milk*, Public Health Rep. (2011), <https://pubmed.ncbi.nlm.nih.gov/21387944/>.

<sup>64</sup> Human Milk 4 Human Babies, <https://www.facebook.com/hm4hb/> (last visited Nov. 10, 2020).

<sup>65</sup> *Id.*

<sup>66</sup> Only the Breast, <https://www.onlythebreast.com/breast-milk-classifieds/browse-ads/> (last visited Nov. 10, 2020).

<sup>67</sup> Only the Breast, <https://www.onlythebreast.com/buy-sell-donate-breast-milk/buyer-tips/> (last visited Nov. 10, 2020).

<sup>68</sup> Natasa Fidler et al., *Effects of Human Milk Pasteurization and Sterilization on Available Fat Content and Fatty Acid Composition*, 72 J. Pediatric Gastroenterology & Nutrition 317, 321 (1998); Thomas Henderson et al., *Effect of Pasteurization on Long Chain Polyunsaturated Fatty Acid Levels and Enzyme Activities of Human Milk*, 132 J. Pediatrics 876, 877 (1998).

<sup>69</sup> Zanolli, *supra* note 61.

units in Belfast in 2012.<sup>70</sup> In a study published by the Journal of Pediatrics, 10% of the breast milk purchased online during their investigation was contaminated with cow's milk.<sup>71</sup>

Given that consumers understand these risks, peer-to-peer transactions are the solution to expensive milk banks who price out mothers. If a donor and recipient can be connected through a formal networking site, the cost may be free or limited to shipping of the milk verses a HMBANA bank which would charge \$4 per ounce. Milk sellers compete over this digital marketplace. Prices posted on Only the Breast are as low as \$.75 per ounce.<sup>72</sup>

## VI. Conclusion

Most human materials are commercialized, and human milk is no exception. A commercial enterprise under the Sherman Act legally demands freedom from constraints and fair competition. This paper has demonstrated that the human milk industry is not immune to antitrust and consumer protection issues. In order for the human milk industry to provide access to milk for a fair price to consumers, the industry must remain diversified and the nonprofit, for-profit, and private sales sectors must compete with one another.

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<sup>70</sup> Inside Out Reports, '*Why I Sell My Breast Milk to Strangers*', [bbc.com/news](https://tinyurl.com/y4m3dsf3) (visited Nov. 11, 2020), <https://tinyurl.com/y4m3dsf3>.

<sup>71</sup> Michaelen Doucleff, *Breast Milk Sold Online Contaminated with Cow's Milk*, [npr.org](https://www.npr.org/sections/health-shots/2015/04/07/397369416/breast-milk-sold-online-contaminated-with-cows-milk) (visited Nov. 11, 2020), <https://www.npr.org/sections/health-shots/2015/04/07/397369416/breast-milk-sold-online-contaminated-with-cows-milk>.

<sup>72</sup> Only the Breast, *supra* note 66.