

KRISTIN K. MAYES
Attorney General
Firm Bar No. 14000
2005 North Central Avenue
Phoenix, AZ 85004-1592
Tel.: (602) 542-8099
Fax: (602) 542-4377
Email: consumer@azag.gov

Plaintiff

*Additional counsel for Plaintiff on
signature page*

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA
IN AND FOR THE COUNTY OF MARICOPA

STATE OF ARIZONA *ex rel.* KRISTIN
K. MAYES, Attorney General,

Plaintiff,

vs.

CBR SYSTEMS, INC.,

Defendant.

No. **CV2025-007742**

CIVIL COMPLAINT

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Plaintiff, State of Arizona *ex rel.* Kristin K. Mayes, Attorney General (the “State”), alleges the following for its Civil Complaint (the “Complaint”) against Defendant CBR Systems, Inc. (“CBR”).

I. NATURE OF THE CASE

1. The private banking of umbilical cord blood is a relatively new industry, having first emerged in the 1990s. Private cord blood banking has quickly become an active and profitable industry in the United States and is projected to grow into a \$45 billion per year market by 2026.¹

2. There are over two million umbilical cord samples privately stored² in the United States, across approximately 20 private cord blood banks.³

3. The dominant player in this new, multibillion dollar industry is CBR. For roughly 30 years, CBR has sold parents-to-be on a supposedly “once-in-a-lifetime” opportunity to protect their child’s health:⁴ preserving umbilical cord blood (and/or tissue) at birth. CBR promotes the idea that private storage of a newborn’s umbilical cord cells might provide the only means to cure or treat “many life-threatening diseases,” such as blood disorders, cancers, immune disorders, and metabolic disorders.⁵

¹ Joe Shen, *Understanding The Cord Blood Banking Industry*, Forbes (Nov. 15, 2021, 7:00 AM), <https://www.forbes.com/councils/forbesbusinessdevelopmentcouncil/2021/11/15/understanding-the-cord-blood-banking-industry/> [<https://perma.cc/ZPA9-F4GB>].

² Sarah Kliff & Azeen Ghorayshi, *Promised Cures, Tainted Cells: How Cord Blood Banks Mislead Parents*, N.Y. Times (July 18, 2024), <https://www.nytimes.com/2024/07/15/health/cord-blood-storage-contamination.html> [<https://perma.cc/EM7C-BKY3>].

³ *Family Cord Blood Banking in United States*, Parent’s Guide to Cord Blood Found., <https://parentsguidecordblood.org/en/family-banking/united-states> (last visited Jan. 28, 2025).

⁴ Kliff & Ghorayshi, *supra* note 2; *see also* *Preserve with CBR*, CBR Sys., Inc., <https://www.cordblood.com/> (last visited Jan. 30, 2025).

⁵ *FAQs – Current Treatments: Is cord blood being used in medical treatments?*, CBR Sys., Inc. <https://www.cordblood.com/faqs> (last visited Jan. 30, 2025); *see also* *The*

4. Preying on the protective instincts of expectant families, CBR advertises its services as a fleeting chance to preserve cells that “are successfully being used to save lives,”⁶ but will be lost forever after a baby’s delivery. CBR advertisements target expectant parents, a vulnerable group susceptible to emotionally-charged advertisements.⁷ These parents are overwhelmed by the desire to protect their new life. They are bombarded with choices about how to go about their new stage. And they fear missing a singular opportunity that could have lifelong consequences for their child.

5. For at least a decade, these advertisements have claimed that it is “trusted” and “recommended” by doctors in general, and OB/GYNs in particular. Among other claims, CBR has touted a cure for 80+ diseases and held out the promise of potential treatments for conditions that currently have no universally adopted cure. CBR boasts that its cord blood collection and storage services provide “access to the most cutting-edge science that medicine has to offer,” marketing to parents the potential of cures for autism, cerebral palsy, acquired hearing loss, pediatric stroke, and a host of other conditions.⁸

6. These claims are highly misleading to their target consumers, which primarily includes expectant parents.

7. CBR fails to disclose that the majority of the 80+ diseases and medical conditions that it claims are potentially cured through using its services are extremely rare. CBR also gives the misleading impression that privately banked cord blood samples are frequently used in a range of treatments that are in fact still experimental. Doing so blurs

science behind newborn stem cells, CBR Sys., Inc.,
<https://www.cordblood.com/science-in-action> (last visited Jan. 28, 2025).

⁶ *FAQs – Common Questions: What are stem cells?*, CBR Sys., Inc.,
<https://www.cordblood.com/faqs> (last visited Jan. 30, 2025).

⁷ Sarah Kliff, *What Parents Should Know About Cord Blood Banking*, N.Y. Times (July 18, 2024), <https://www.nytimes.com/2024/07/15/health/cord-blood-banking.html>
[\[https://perma.cc/5RCB-8E9X\]](https://perma.cc/5RCB-8E9X).

⁸ *Newborn Stem Cell Preservation 101*, CBR Sys., Inc.,
<https://www.cordblood.com/newborn-stem-cells-101> (last visited Jan. 28, 2025).

1 CBR's claims regarding sample use to give the impression that privately banked samples
2 are highly effective for use in the event of a serious disease or diagnosis. It does not disclose
3 that advertised experimental treatments are only in the very preliminary research stage.
4 CBR's advertisements are thus designed to give the misleading impression that a child's
5 privately banked cord blood cells are likely to be used for a wide range of diseases, when
6 in fact recognized uses are rare, if currently available at all.

7 8. Similarly, CBR heavily promotes the idea that private cord blood banking
8 provides a unique benefit because a newborn's privately stored umbilical cord cells will
9 always be a "perfect match" or "100% match" genetically for a transplant to such child
10 (known as an autologous transplant). But CBR fails to disclose that privately banked cord
11 blood has been successfully used in autologous transplants only a handful of times over the
12 past decade. Nor does CBR disclose that one's own cells cannot be used to treat certain
13 conditions, and that donor cells are required (especially for young children).

14 9. Although CBR claims to be endorsed by doctors, in reality the national
15 medical associations including the American Academy of Pediatrics ("AAP"), the
16 American College of Obstetricians and Gynecologists ("ACOG"), and the American
17 Medical Association ("AMA") actively discourage private cord blood banking.⁹ Upon
18 information and belief, no prominent United States medical organization endorses or
19 recommends private cord blood banking generally, much less CBR.

20 10. CBR's deceptive conduct extends beyond its false and misleading medical
21 claims for the use of umbilical cord cells and tissue. CBR portrays its services as providing
22 the "highest quality" protection for samples, including safe and secure transport to its
23
24

25 ⁹ Paul L. Martin *et al.*, *Umbilical Cord Blood: A Guide for Primary Care Physicians*, 84
26 Am. Fam. Physician 661–66 (2011), <https://www.aafp.org/pubs/afp/issues/2011/0915/p661.pdf>.

1 “trusted and recommended” storage facility in Tucson, Arizona.¹⁰ To convince new parents
2 to purchase its high-priced goods and services, CBR claims to offer reliable processing and
3 testing of samples, communication about the results, as well as support and education for
4 new parents.

5 11. The reality is different. CBR does not disclose that many cord blood samples
6 are unusable from the time of collection and that many other samples become contaminated
7 during transport. While touting the supposed safety of its storage process, CBR does not
8 disclose the risk of contamination at its facility either, which has drawn the attention of the
9 U.S. Food and Drug Administration (“FDA”). And—rather than communicating with new
10 parents about the quality of their baby’s samples—CBR keeps many families in the dark
11 about their samples’ viability to continue collecting exorbitant yearly storage fees from
12 them.

13 12. CBR has expertly marketed its services as providing expectant parents a
14 unique, one-time opportunity to create something akin to a biological insurance policy in
15 the event that a serious diagnosis occurs within their family.¹¹ CBR seeks to exploit new
16 parents’ desire to protect their children, through claims that are false and misleading in
17 several ways.

18 13. The negative effects of CBR’s conduct extend past the vulnerable parents it
19 targets. CBR has disparaged public cord blood banking—the preferred and doctor-
20 recommended alternative. They thus undercut the reputation and efficacy of public cord
21 blood banks nationwide, in turn reducing the number of donations that those blood banks
22 receive. In disparaging public cord blood banking, CBR prioritizes its corporate profits
23
24

25 ¹⁰ *Why preserve with CBR?*, CBR Sys., Inc., <https://www.cordblood.com/why-cbr> (last
26 visited Jan. 28, 2025).

¹¹ Kliff & Ghorayshi, *supra* note 2.

1 over the interests of public health, while also unfairly concealing accurate information
2 about the benefits of public cord blood banking from consumers.

3 14. While CBR’s conduct affects parents nationwide, the State of Arizona has
4 become the locus for private cord blood banking in the United States. CBR now holds a
5 dominant position in the market for privatized cord blood banking, an industry that is
6 projected to grow into a \$45 billion per year sector by 2026.¹² CBR stores *half of all*
7 *privately banked cord blood samples* in the United States—over one million samples—all
8 in its Tucson facility.

9 15. Accordingly, the State brings this action to rectify CBR’s ongoing pattern of
10 unfair, misleading, and fraudulent conduct, to protect families victimized by CBR’s
11 conduct, and to protect the public.

12 II. JURISDICTION AND VENUE

13 16. Venue is proper in Maricopa County pursuant to Ariz. Rev. Stat. Ann. § 12-
14 401(17).

15 III. PARTIES

16 17. Plaintiff is the State of Arizona *ex rel.* Kristin K. Mayes, the Attorney
17 General of Arizona, who is authorized to bring this action under the Arizona Consumer
18 Fraud Act (“CFA”), Ariz. Rev. Stat. Ann. § 44-1521 – 34.

19 18. Defendant CBR Systems, Inc. is a California corporation with its principal
20 place of business at 1200 Bayhill Drive, San Bruno, California 94066.

21 19. CBR was founded in 1992. Since its inception and throughout a series of
22 corporate transactions, CBR has remained the world’s largest umbilical cord blood stem
23 cell collection and storage company, and the national leader in umbilical cord blood
24 storage. It keeps more than half of all privately stored cord units in the United States.

25
26 ¹² Shen, *supra* note 1.

20. In 2015, CBR was sold by private equity firm GTCR to AMAG Pharmaceuticals, Inc. (“AMAG”) for \$700 million. AMAG’s announcement noted CBR’s “sophisticated, consumer-driven marketing capabilities.”¹³

21. In 2018, CBR was acquired by private equity firm GI Partners for \$530 million. GI simultaneously acquired California Cryobank. California Cryobank provided frozen donor sperm and egg services, as well as umbilical cord blood banking through its “Family Cord” branch.¹⁴ The merger created Generate Life Sciences.

22. In September 2019, CBR acquired Natera’s Evercord™ Cord Blood Business, considered to be the first major acquisition of a competitor by CBR.¹⁵

23. Furthering consolidating the private cord blood banking industry, in 2021, The Cooper Companies, Inc. (“Cooper”) acquired Generate Life Sciences for approximately \$1.6 billion.¹⁶ Two-thirds of the acquisition’s value was attributed to cord blood storage.¹⁷ Cooper encompasses two distinct lines of business: CooperVision, a prominent eyewear and ophthalmology company, and CooperSurgical, which is focused on women’s health and gynecology. CBR is now a brand of CooperSurgical. Along with

¹³ AMAG Pharmaceuticals Completes Acquisition of Cord Blood Registry, Fierce Pharma (Aug. 18, 2015, 8:57 AM), <https://www.fiercepharma.com/pharma/amag-pharmaceuticals-completes-acquisition-of-cord-blood-registry> (citation omitted).

¹⁴ GI Partners to Acquire and Simultaneously Combine Cord Blood Registry and California Cryobank, GI Partners (June 15, 2018), <https://www.gipartners.com/news/gi-partners-to-acquire-and-simultaneously-combine-cord-blood-registry-and-california-cryobank>.

¹⁵ Cade Hildreth, *Cord Blood Industry Consolidation Escalates in 2025*, BioInformant (Dec. 21, 2024), <https://bioinformant.com/cord-blood-industry/>.

¹⁶ CooperCompanies Completes Acquisition of Generate Life Sciences, CooperSurgical (Dec. 17, 2021), <https://fertility.coopersurgical.com/coopercompanies-completes-acquisition-of-generate-life-sciences/>.

¹⁷ Kliff & Ghorayshi, *supra* note 2.

1 CBR's private cord blood banking, CooperSurgical also directly markets Paragard, a non-
2 hormonal copper IUD, to end-payer consumers.¹⁸

3 24. CBR's sole storage laboratory is located at 6550 South Bay Colony Drive,
4 Suite 100, Tucson, AZ 85756. All samples collected by CBR in the United States are
5 shipped to and stored in the Tucson facility. CBR stores the largest number of stored
6 samples of any private cord blood bank in the United States.

7 25. For at least 10 years, CBR has featured its Tucson storage laboratory in the
8 company's advertisements and actively marketed its Tucson facility and benefits of its
9 location as a reason to prefer the company's services over its competitors and public cord
10 blood banks.

Storage

Our safe and secure lab is located in Tucson, Arizona, which
historically is not impacted by hurricanes, tornadoes, and
earthquakes.

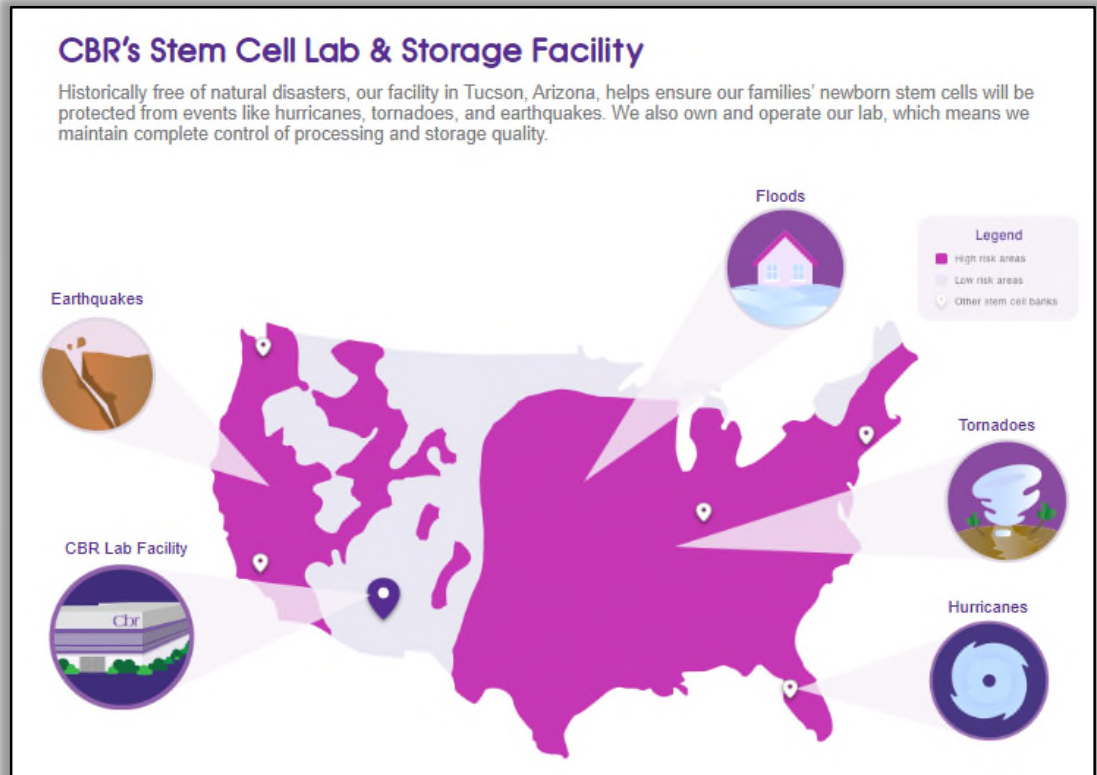


Safe, secure facility

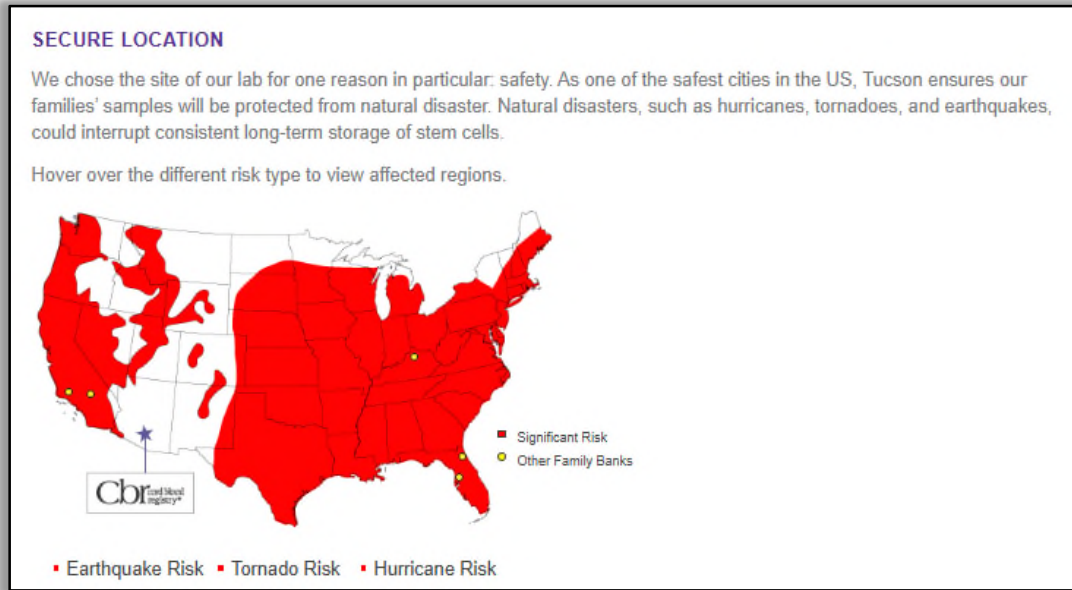
Our laboratory and storage facility located in Tucson, Arizona is built to help ensure the long-term safety of your baby's newborn stem cells.

18 The Cooper Companies, Inc., Annual Report (Form 10-K) at 7, 9 (Dec. 8, 2023),
19 <https://investor.coopercos.com/static-files/87af40d1-dab4-40fe-9696-bc36012008b7>.

26. Previous iterations of CBR's website similarly promoted the location of its Tucson facility as a reason to prefer the company's services. CBR has made the same or substantially similar representations touting its Tucson lab, such as these representations from in or around 2017 through 2021, which described the area as free of natural disasters like hurricanes, tornadoes, and earthquakes:



27. CBR's previous website similarly highlighted the safety of its Tucson facility from at least 2015 forward, again noting the absence of natural disasters like hurricanes, tornadoes, and earthquakes:



28. CBR actively markets for parents around the country to ship their children's samples for storage at its Tucson facility, making this controversy and CBR's misconduct of particular importance to the State of Arizona.

29. This importance is further underscored by CBR's market dominance. The single largest storage facility in the United States for private cord blood samples is CBR's 80,000 square foot laboratory in Tucson,¹⁹ where approximately half of all privately banked cord blood samples in the United States are stored.²⁰ CBR stores its over one million samples in its Arizona laboratory, nearly double the number of samples stored by the next largest private bank.²¹

¹⁹ *FAQs – CBR's process: Where are my baby's cord blood stem cells stored, and how do I know they are stored safely?*, CBR Sys., Inc., <https://www.cordblood.com/faqs> (last visited Jan. 28, 2025).

²⁰ *Comparison Guide*, CBR Sys., Inc., <https://www.cordblood.com/comparison-guide> (last visited Jan. 28, 2025).

²¹ *Id.*

30. CBR’s behemoth laboratory has room to house many more samples. It is only at 20% capacity, with the capacity to hold five million cord blood samples.²²

IV. ALLEGATIONS

A. CBR Dominates the Private Cord Blood Banking Industry in the United States.

31. CBR’s backing from Cooper has afforded the private cord blood bank market recognizability and stability. Coupled with the volume of samples already banked at its Tucson facility and aggressive market growth, CBR financially dominates the United States private cord blood banking market.²³

32. Private cord blood storage is an expensive venture, typically marketed to consumers who are often overwhelmed when expecting the birth of a child, a time in their lives when money is often tight, and become customers of CBR by virtue of wanting to protect their family.

33. Since at least April of 2016, CBR has engaged in deceptive and misleading advertising stating that “your initial payment is not due until after your baby is born.”²⁴

34. From at least May of 2015 through November 2016, CBR engaged in similar deceptive and misleading advertising stating that “[w]e won’t charge you for processing or storage until your sample has been safely stored” and “[y]ou will be charged after your baby is born.”²⁵

²² *FAQs – CBR’s process: Where are my baby’s cord blood stem cells stored, and how do I know they are stored safely?*, CBR Sys., Inc., *supra* note 19.

²³ *CooperCompanies Announces Third Quarter 2024 Results*, Cooper Cos. Inc. (Aug. 28, 2024), <https://investor.coopercos.com/news-releases/news-release-details/cooper-companies-announces-third-quarter-2024-results>.

²⁴ *Enroll*, CBR Sys., Inc., <https://www.cordblood.com/enroll> (last visited Jan. 29, 2025).

²⁵ *Pricing*, CBR Sys., Inc., <http://www.cordblood.com/pricing> (as existed May 27, 2016–Nov. 11, 2016).

35. In fact, CBR requires parents to make a deposit before the blood sample can be collected and evaluated.²⁶

Annual storage <small>After your initial payment, you will be charged on an annual basis for storage fees.</small>		18 year storage <small>Paying upfront for 18 years of storage saves you 19% vs. annual payments.</small>		Lifetime storage <small>Paying upfront for lifetime storage saves you 69% vs. annual payments.</small>	
Processing Fees	\$1,330	Processing Fees	\$1,330	Processing Fees	\$1,330
Shipping Fees*	\$170	Shipping Fees*	\$170	Shipping Fees*	\$170
Storage Fees	\$205	Storage Fees	\$2,995	Storage Fees	\$4,995
Process Discount	(\$750)	Process Discount	(\$750)	Process Discount	(\$750)
Total:	\$955	Total:	\$3,745	Total:	\$5,745
Annual fee:	\$205	Annual fee:	\$0	Annual fee:	\$0
Select storage		Select storage		Select storage	

36. The fees that expectant parents must pay before birth (and collection) typically include a storage deposit, processing, shipping, and storage fees, ranging from \$955 to \$5,745 for cord blood alone (that is, not including cord tissue).²⁷ CBR's higher-cost plans are for long-term pre-paid storage plans, which the company markets as beneficially providing overall savings as compared to paying storage fees on an annual basis.²⁸ Parents who have elected an annual storage plan (instead of pre-paid plans) are currently charged an annual storage fee of \$205.²⁹

37. CBR charges some of the most expensive prices for private cord blood storage in the United States. CBR's main competitors are Cryo-Cell International and ViaCord, two of the other leaders in the United States private umbilical cord blood banking market. Cryo-Cell International charges a base fee of \$895 for its standard cord blood

²⁶ FAQs – CBR's process: Where are my baby's cord blood stem cells stored, and how do I know they are stored safely?, CBR Sys., Inc., *supra* note 19.

²⁷ Enroll, CBR Sys., Inc., *supra* note 24.

²⁸ *Id.*

²⁹ *Id.*

1 service, and \$1,245 for its premium cord blood service.³⁰ ViaCord's cord blood banking
2 service requires a payment of \$895.³¹

3 38. CBR offers auxiliary services that parents are encouraged to tack onto the
4 baseline cord blood plan, including storage of umbilical cord tissue and genetic testing.³²
5 CBR suggests that the addition of these upsold tests will give families the benefit of early
6 detection of genetic conditions and predispositions, which can lead to a "positive
7 difference" in the child's health.³³ These tests range from \$395 to \$1,195.³⁴ But, CBR does
8 not disclose the limitations on these genetic tests.³⁵

9 39. CBR's practices are deceptive with respect to both the timing and cost of its
10 services, and deceptive insofar as they seek to collect storage fees for unusable samples,
11 causing harm to consumers by eliciting payments unfairly.

12 **B. CBR Targets New Parents, a Vulnerable Group Susceptible to Emotionally-**
13 **Charged Advertisements.**

14 40. Through advertisements via online platforms, celebrity endorsements, and
15 physical marketing in OB/GYN offices, CBR has aggressively marketed its private cord
16 blood banking services directly to its vulnerable target customers: expectant parents.

17 41. CBR also markets directly to expectant parents through its website,
18 <https://www.cordblood.com>. Among other things, CBR hosts a virtual webinar every
19 month for interested parents. Attendance is rewarded with discounted pricing on cord blood
20 and tissue preservation.³⁶

21 _____
22 ³⁰ *Cost of Cord Blood Banking*, Cryo-Cell Int'l, <https://www.cryo-cell.com/cord-blood-banking-costs> (last visited Jan. 29, 2025).

23 ³¹ *Cord Blood Banking*, ViaCord, <https://www.viacord.com/shop/newborns/cord-blood-banking> (last visited Jan. 29, 2025).

24 ³² *Enroll*, CBR Sys., Inc., *supra* note 24.

25 ³³ *Id.*

26 ³⁴ *Id.*

³⁵ *Id.*

³⁶ *Events*, CBR Sys., Inc., <https://learn.cordblood.com/events> (last visited Jan. 29, 2025).

42. CBR markets its goods and services directly to consumers through various social media platforms including, upon information and belief, targeted advertisements on Meta Platforms (including Facebook, Instagram, Messenger), Google Search, Google Shopping, Google Maps, YouTube, Reddit, and other platforms. CBR’s social media advertisements link to the CBR website, <https://www.cordblood.com>. CBR employs social media family and lifestyle “influencers”—often with no medical backgrounds—to push its product, including Chrissy Teigen and Shawn Johnson East. It also offers giveaways through Instagram and uses other means of direct advertising.

43. CBR employs salespeople to visit obstetrics and gynecology practitioners around the country to pitch the company’s offerings. These salespeople provide financial inducements for doctors’ participation. Seeking to enlist physicians in its marketing efforts, CBR offers them free lunches, gift cards, and “collection fee” kickbacks up to \$700 per sample.³⁷ CBR thereby works to recruit the participation of the professionals who, for many expectant parents, are the most trusted resource for information in preparing for the arrival of a new baby, but it doesn’t tell parents that physicians are compensated with kickbacks to participate in CBR’s marketing efforts.³⁸ This practice is unfair and harmful to consumers insofar as it misleads and is designed and intended to mislead consumers about physician backing and/or approval of its services.

44. As a demographic, parents, especially new parents, can be exploited through targeted advertising regardless of their sophistication level or background. They are also, as a group, particularly vulnerable to guilt and fear-based marketing making CBR’s conduct particularly exploitative.³⁹

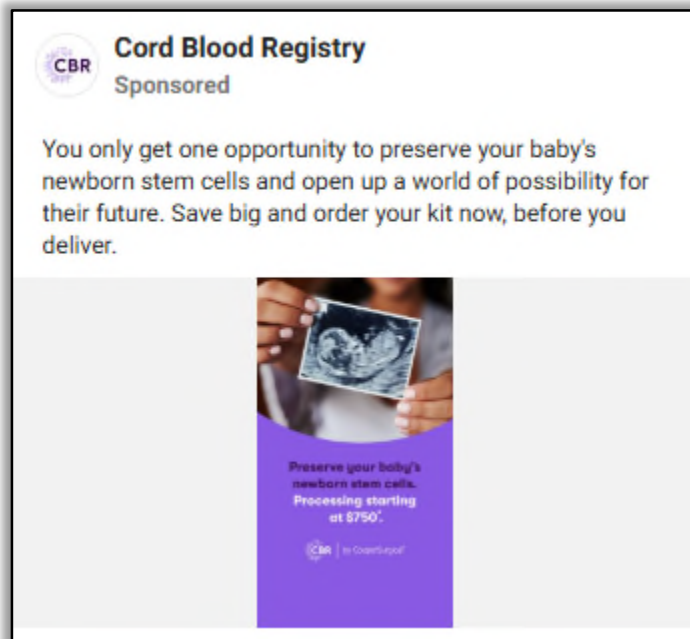
³⁷ Kliff & Ghorayshi, *supra* note 2.

³⁸ *Id.*

³⁹ Julie V. Stanton & Deirdre T. Guion, *Taking Advantage of a Vulnerable Group? Emotional Cues in Ads Targeting Parents*, 47 J. Consumer Aff. 485, 487–88 (2013), <http://www.jstor.org/stable/23859840> [<https://perma.cc/V2DD-8RAG>].

45. Research also shows that the most effective marketing strategies to promote consumption, especially consumption by expecting parents, are strategies that “engag[e] in tactics that alleviate the stress associated with such periods.”⁴⁰

46. Central to CBR’s emotional appeal is the deceptive impression that the banking of newborn cord blood is a “once in a lifetime” opportunity that will be forever lost after a baby’s delivery. For example, CBR’s current ads across multiple Meta platforms stress the fleeting opportunity.⁴¹



47. A video advertisement across certain Meta platforms tells parents “[t]here are some times that are once in a lifetime” and telling parents to enroll for their “chance of a lifetime.”⁴²

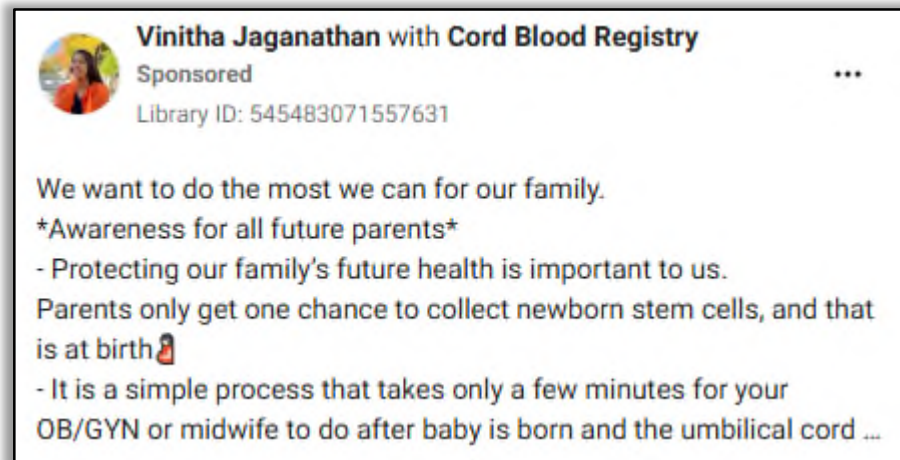
⁴⁰ John Hadjimarcou, *An Investigation of Informational Versus Emotional Advertising Appeals During Life Transitions*, 57 Int’l J. Mgmt. & Mktg. Rsch. 57, 55–65 (2012), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1957214 [<https://perma.cc/RGP9-VFW2>].

⁴¹ *Cord Blood Registry*, Meta Ads Libr. (Oct. 1, 2024), <https://www.facebook.com/ads/library/?id=1084165803304009>.

⁴² *Cord Blood Registry*, Meta Ads Libr. (Oct. 1, 2024), <https://www.facebook.com/ads/library/?id=1079942673702008>.

48. Similar advertisements on Meta from at least January of 2024 to present likewise refer to CBR cord blood banking as the “one opportunity to preserve your baby’s stem cells and open up a world of possibility for their future,”⁴³ the “one chance to collect newborn stem cells,”⁴⁴ or the “once in a lifetime” decision.⁴⁵

49. Partnering with Instagram “influencers,” CBR likewise extols the “one chance” to protect a “family’s future health,”⁴⁶ and the “oportunidad única en la vida.”⁴⁷



50. The theme of a once in a lifetime opportunity has been a consistent theme of CBR’s marketing over time.

⁴³ Cord Blood Registry, Meta Ads Libr. (Jan. 11, 2024), <https://www.facebook.com/ads/library/?id=897981468537558>.

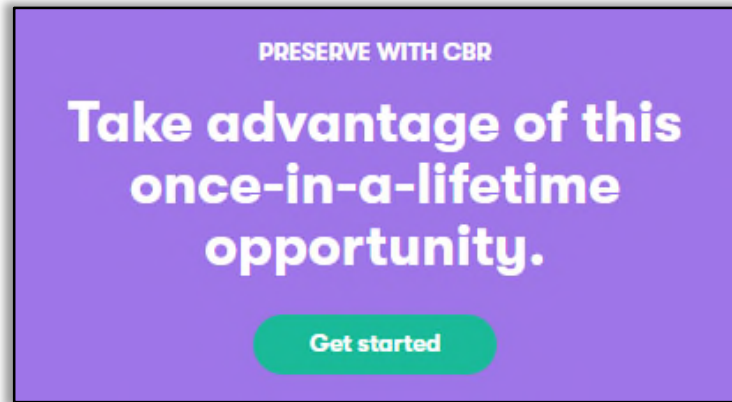
⁴⁴ Cord Blood Registry, Meta Ads Libr. (Nov. 5, 2024), <https://www.facebook.com/ads/library/?id=545483071557631>.

⁴⁵ Cord Blood Registry, Meta Ads Libr. (Oct. 1, 2024), <https://www.facebook.com/ads/library/?id=1079942673702008>.

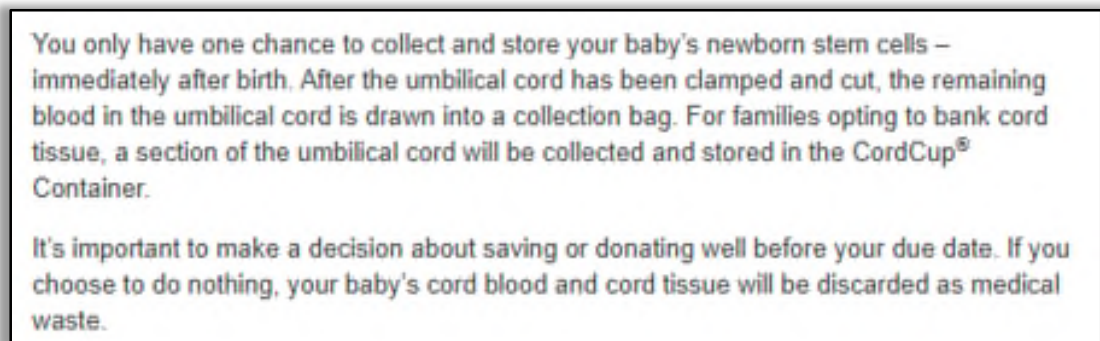
⁴⁶ Cord Blood Registry, Meta Ads Libr. (Nov. 5, 2024), <https://www.facebook.com/ads/library/?id=545483071557631>.

⁴⁷ Cord Blood Registry, Meta Ads Libr. (May 6, 2024), <https://www.facebook.com/ads/library/?id=333859299416703>.

51. From November 2021, for example, CBR’s website advertisements urged parents to seize the “once-in-a-lifetime opportunity” for its private cord blood banking services:



52. Similarly, this 2014 CBR advertisement stressed the “one chance” parents had to preserve cord blood before it becomes “medical waste”:

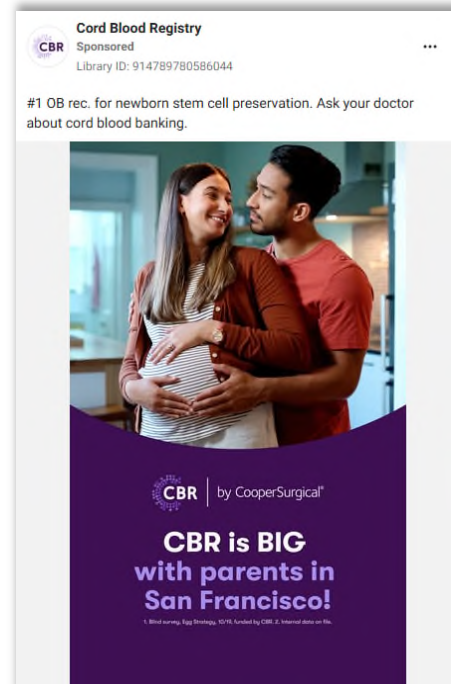
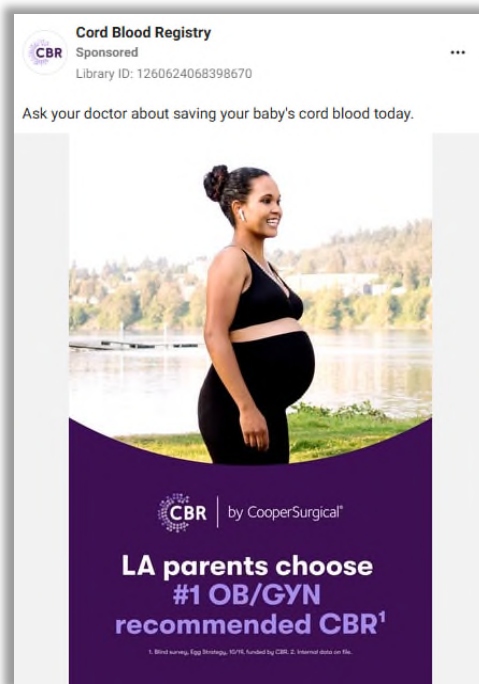


53. Upon information and belief, CBR targets its advertisements both to new parents as a demographic and geographically. For example, CBR has targeted parents in certain regions with ads that emphasize the “Keeping Up with the Joneses” theme:

A. New York:⁴⁸



B. The Bay Area and Southern California:^{49, 50}

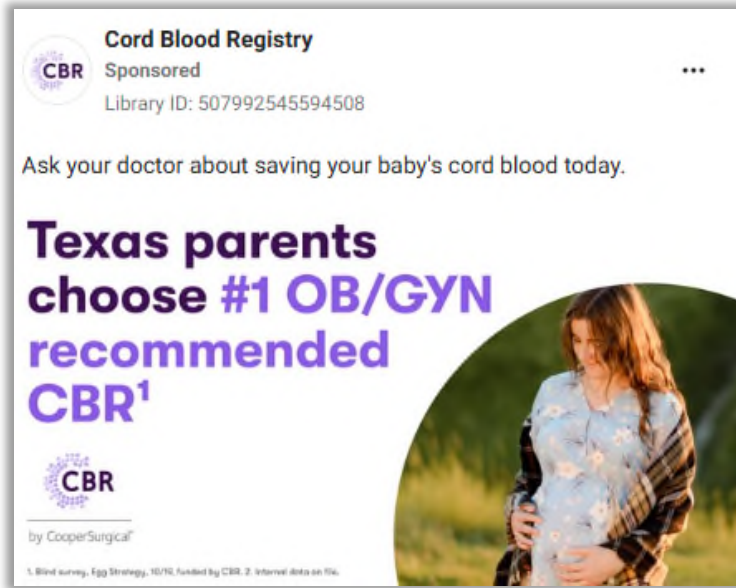


⁴⁸ Cord Blood Registry, Meta Ads Libr. (Nov. 13, 2024),
<https://www.facebook.com/ads/library/?id=1774306466667002>.

⁴⁹ Cord Blood Registry, Meta Ads Libr. (Nov. 13, 2024),
<https://www.facebook.com/ads/library/?id=1260624068398670>.

⁵⁰ Cord Blood Registry, Meta Ads Libr. (Nov. 13, 2024),
<https://www.facebook.com/ads/library/?id=914789780586044>.

C. Texas:⁵¹



D. Miami:⁵²



These ads all link to the CBR website promoting shipment to and storage in Arizona.

⁵¹ Cord Blood Registry, Meta Ads Libr. (Nov. 13, 2024),
<https://www.facebook.com/ads/library/?id=507992545594508>.

⁵² Cord Blood Registry, Meta Ad Libr. (Nov. 13, 2024),
<https://www.facebook.com/ads/library/?id=1595944617718915>.

54. The “CBR Parent Circle Rewards” program also provides benefits for people who refer other parents to CBR with the messaging “Someone’s looking out for you.”⁵³ For the third referral, a parent can receive a year of free cord blood storage plus a \$200 gift card.⁵⁴ CBR lets parents invite their friends and family to contribute toward their cord blood storage through the CBR gift registry.⁵⁵

55. At the same time as CBR uses emotionally-targeted advertising, it couples that appeal with deceptive scientific claims that are highly misleading, omit material information, and are at times outright false.

56. Research demonstrates that parent knowledge about cord blood banking is lacking:

Parent knowledge of cord blood banking options and cord blood use has been identified as poor. . . . parents have a lack of knowledge about the options of cord blood banking and donation, and the uses of cord blood. There is lack of clarity and consistency in the information provided for parents on cord blood banking, donation and cord blood use.⁵⁶

57. CBR’s advertisements weave together emotional appeal and seemingly informative, scientific “education” in an attempt to portray the product as a way to give parents a sense of security and agency about the future of their child’s health. CBR directly preys on a new parent’s fear that their child *could* become catastrophically ill by touting the plethora of diseases that autologous cord blood could treat whilst making the collection

⁵³ “Someone’s looking out for you,” CBR Sys., Inc., <https://learn.cordblood.com/referral.html>? (last visited Feb. 6, 2025).

⁵⁴ “Family programs,” CBR Sys., Inc., <https://www.cordblood.com/family-programs> (last visited Feb. 6, 2025).

⁵⁵ “Set up or search for a gift registry,” CBR Sys., Inc., <https://www.cordblood.com/gift-registry> (last visited Feb. 6, 2025).

⁵⁶ Lisa Peberdy *et al.*, *Parents’ knowledge, awareness and attitudes of cord blood donation and banking options: an integrative review* at 19, BMC Pregnancy & Childbirth (Oct. 2018), <https://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-018-2024-6> [<https://perma.cc/DD56-59XG>].

1 and storage process seem routine and physician-endorsed. The swaths of information and
2 claims packed into CBR's advertisements and website appear convincing and informative.

3 58. The combination of pseudoscience and fear mongering is as persuasive as it
4 is misleading. As one study remarked:

5 These private companies know the pressure future parents are under to do
6 what's best for their child and prey on those insecurities. It's not that private
7 cord blood banking is necessarily bad. It's that speculative uses are amplified
8 and the worth of this "bioinsurance" is greatly distorted. There is also an
9 attempt at normalizing the process that screams "keeping up with the
10 Joneses." . . . After all, it is a "once-in-a-lifetime opportunity."⁵⁷

11 59. The FDA previously issued warning letters to private cord blood banks that
12 have employed reckless marketing tactics to expecting parents. It stated that the FDA "is
13 aware that there are establishments who **prey upon vulnerable populations** by
14 commercially marketing stem cell products with false and misleading claims about their
15 effectiveness for treating serious diseases."⁵⁸

16 60. CBR has successfully convinced scores of parents that private stem cell
17 storage is not only a recommended procedure, but a necessary step to ensure the future
18 health of their child that will be lost forever.

19 61. In sum, CBR deliberately seeks to capitalize on a parent's natural desire to
20 safeguard their child. As shown in the subsequent sections, CBR combines both guilt and
21 fear into its marketing, while also concealing important information about its health claims
22 and supposed endorsements, misleading parents about the realistic applications of privately

23 ⁵⁷ Jonathan Jarry, *The "Once-in-a-Lifetime" Gamble of Private Cord Blood Banks*,
McGill (Apr. 29, 2021), <https://www.mcgill.ca/oss/article/health/once-lifetime-gamble-private-cord-blood-banks>.

24 ⁵⁸ *FDA sends warning to companies for offering unapproved umbilical cord blood*
25 *products that may put patients at risk*, U.S. Food & Drug Admin. (Dec. 6, 2019),
26 <https://www.fda.gov/news-events/press-announcements/fda-sends-warning-companies-offering-unapproved-umbilical-cord-blood-products-may-put-patients-risk> (emphasis added) (citation omitted).

banked cord blood, unfairly disparaging public cord blood banks, and misrepresenting the safety and security of its services in order to collect yearly storage fees.

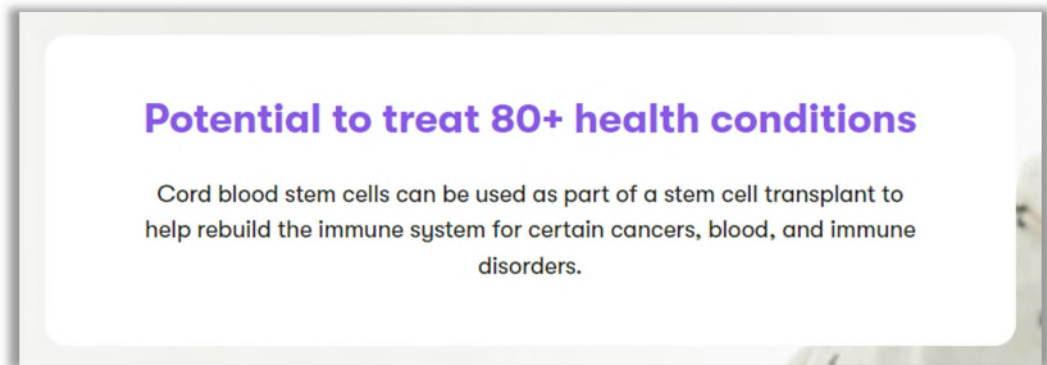
C. CBR Aggressively Pushed False, Deceptive, and Misleading Health Promises.

1. CBR Claims Stem Cells Might Treat a Broad Swath of Conditions, Blurring Approved and Experimental Uses

62. CBR engaged in deceptive acts and practices through use of deceptive advertisements and by routinely omitting the material facts from consumers with the intent that consumers rely thereon, including, but not limited to, failing to disclose in its advertisements and representations at the time of advertising to and contracting with consumers for private cord blood banking services.

63. For at least a decade, CBR has advertised on its webpage that cord blood stem cells might be used to treat 80+ health conditions.⁵⁹ This claim has been repeatedly made by CBR and expressed in consistent terms.

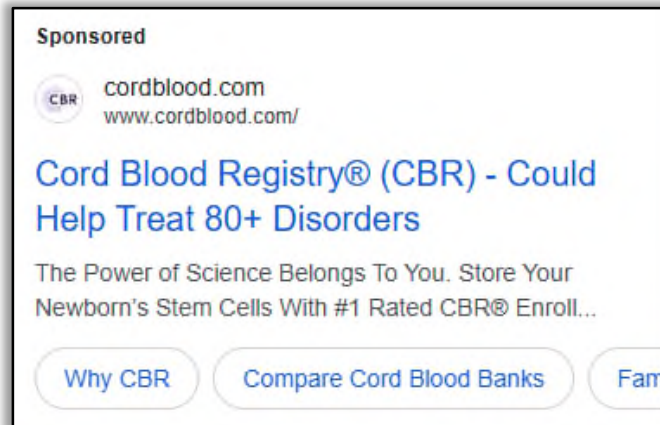
64. For example, CBR's current website advertises the "potential to treat 80+ health conditions"⁶⁰ and includes links to a list of conditions.



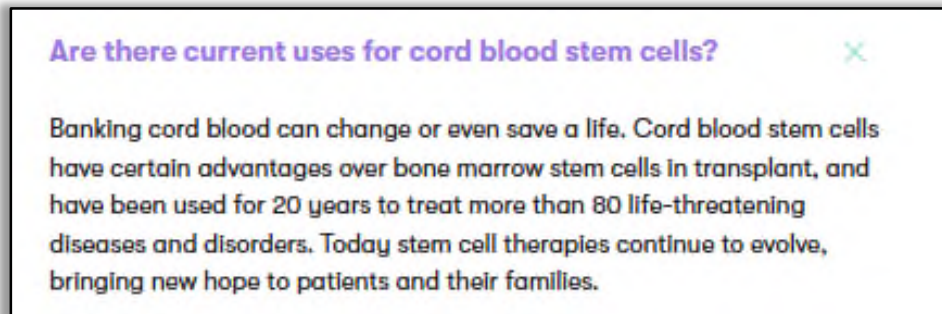
⁵⁹ *The science behind newborn stem cells, supra* note 5.

⁶⁰ *Id.*

65. A current CBR Google ad similarly claims:⁶¹



66. The prior iterations of CBR’s website made similar claims. For example, in or around November 2021 CBR’s website pointed again to the treatment of 80+ conditions and vaguely claimed that evolving science would offer “new hope to patients and their families.” Its language intentionally blurred approved existing uses for the cord blood with the potential of future research to possibly discover new applications:



67. Prior iterations of CBR’s website contained substantially similar claims about 80+ approved uses, while again confusing FDA-approved treatment with experimental applications and clinical trials. The CBR website from at least March 16, 2014 to around October 8, 2021 represented, for example:

⁶¹ *Cord Blood Registry (CBR) – Newborn Stem Cell Preservation*, Google Ads (Jan. 28, 2025), <https://adstransparency.google.com/advertiser/AR10270281379090530305/creative/CR13162615882108633089?region=US>.

Cord blood has been used for 20 years to treat more than 80 serious diseases.³⁴ Successful treatments have paved the way for further research and today, FDA-regulated clinical trials are exploring the use of a child's own stem cells for conditions that currently have no cure.

Several of these groundbreaking trials only use cord blood stem cells processed by Cord Blood Registry as a way of ensuring consistent quality. That means, saving with Cord Blood Registry gives families access to more uses and treatments.

Cord blood stem cells are currently being evaluated as potential treatment for:

- Acquired Hearing Loss
- Autism
- Cerebral Palsy
- Pediatric Stroke
- Traumatic Brain Injury

68. xCBR's advertisements have consistently made broad, vague claims about the medical power of cord blood stem cells. CBR's medical claims have been consistent for at least a decade if not more.

69. For example, CBR's website in 2014 broadly advertised stem cells as "smart," "powerful" and "unique," and stressed the genetic "match" of a baby with his or her own cells. In these claims, CBR did not differentiate between approved and experimental uses:

What are newborn stem cells?

Stem cells can be found in places like bone marrow and fat tissue, but the younger, more flexible stem cells in the body come from a newborn's umbilical cord blood and tissue. There are many advantages of newborn stem cells over other sources of stem cells.

Newborn stem cells are:



Unique: Your baby will be a perfect match for their own stem cells and may be a match for a sibling or other family member.³⁵

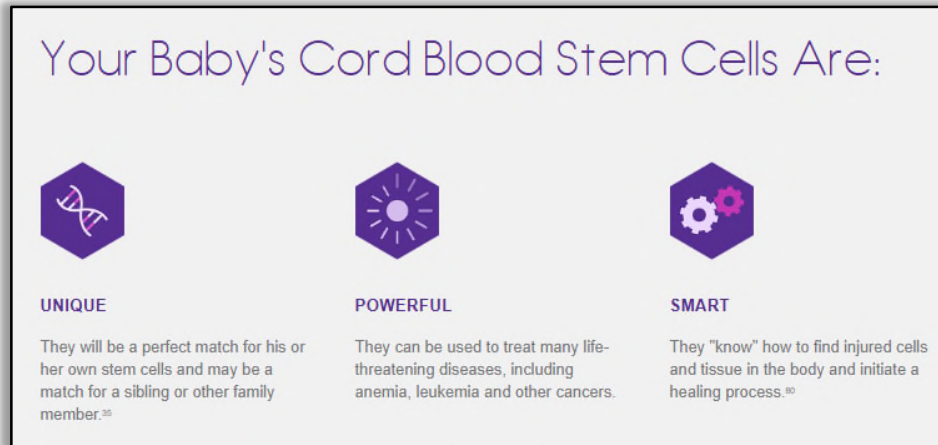


Powerful: They're used to treat many life-threatening diseases, including anemia, leukemia and certain other cancers, primarily for a family member or genetic match. They've also shown in laboratory studies the potential to heal serious conditions like brain damage for the child's own use.

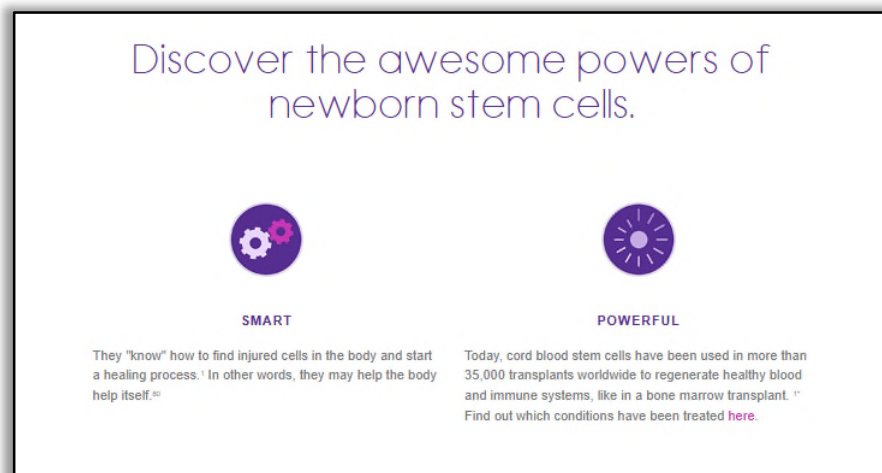


Smart: They "know" how to find injured cells and tissue in the body and initiate a healing process.

70. In 2015 and 2016, CBR's website made similar representations. Again, CBR stressed the "match" for a baby's own cells, while failing to differentiate approved from experimental uses in extolling the "power" of newborn stem cells. In this timeframe, CBR's website contained claims in the same or substantially in the same form as the following:



71. Sometime in late 2016, CBR's website was updated with a slightly revised claim, but kept the core message. This version or a substantial equivalent appeared until sometime in or around November 2021. Again, CBR stressed that newborn stem cells are powerful and claimed that they were frequently used, without differentiating approved and experimental uses:



72. In or around November 2021, the appearance of the claims changed slightly, with the same substantive gist, stressing the healing potential of newborn stem cells while implying that uses in the testing/experimental stage were in fact approved uses:

The advertisement is a rectangular box with a light purple background. At the top, the text "Newborn stem cells are a powerful resource." is written in a bold, purple font. Below this, there are three columns of text, each with a heading in bold purple font. The first column is titled "Healing potential" and contains the text: "Your baby's umbilical cord contains both cord blood and cord tissue, which are rich sources of unique stem cells that have potential for healing." The second column is titled "Transplant options" and contains the text: "Cord blood stem cells have been used in more than 40,000 transplants around the world to regenerate healthy blood and immune systems.¹⁰⁶" The third column is titled "Clinical trials" and contains the text: "Over 200 clinical trials have studied using cord tissue stem cells as a treatment for conditions like Parkinson's, heart disease, and Alzheimer's.¹³⁴"

Healing potential	Transplant options	Clinical trials
Your baby's umbilical cord contains both cord blood and cord tissue, which are rich sources of unique stem cells that have potential for healing.	Cord blood stem cells have been used in more than 40,000 transplants around the world to regenerate healthy blood and immune systems. ¹⁰⁶	Over 200 clinical trials have studied using cord tissue stem cells as a treatment for conditions like Parkinson's, heart disease, and Alzheimer's. ¹³⁴

73. CBR's direct and targeted social media advertisements likewise combined emotional appeal with vague health claims that did not distinguish between approved uses or experimental claims. For example, one "influencer" who contracted with CBR implied a treatment for Alzheimer's. Upon information and belief, CBR compensated influencers to make posts promoting its products and services, such as the following:⁶²

The image shows a screenshot of a Facebook advertisement. At the top, it says "Lissette Calveiro with Cord Blood Registry" in bold, followed by "Sponsored" and "Library ID: 590438486746995". Below this, the ad text reads: "[ad] The first and most important investment I made for our family was enrolling with and preserving our baby's newborn stem cells with @CordBloodRegistry 🙌". At the bottom, it says: "My grandparents meant the world to me, and after their battles with diseases like non-Hodgkin's lymphoma and Alzheimer's, I knew this was an investment I didn't want to pass up on — that it could be a ...".

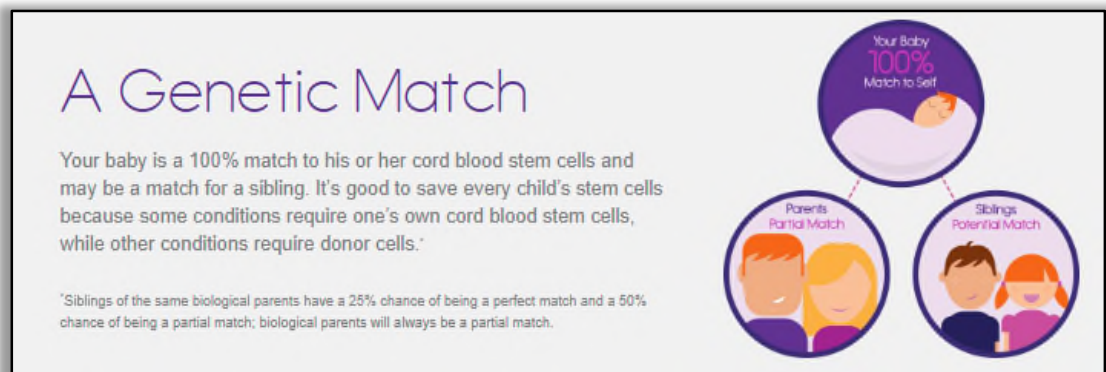
⁶² Cord Blood Registry, Meta Ads Libr. (Nov. 1, 2024), <https://www.facebook.com/ads/library/?id=590438486746995>.



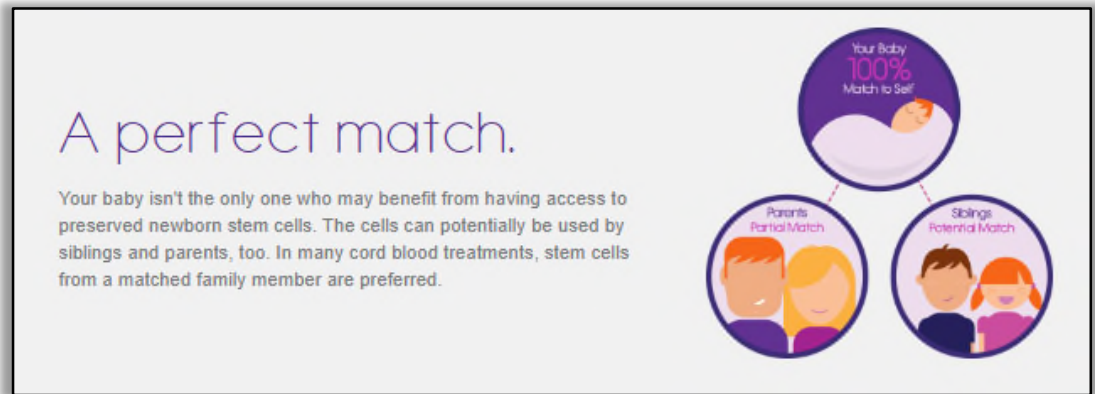
2. CBR's Advertising Consistently Stressed the "Match" of a Newborn's Stem Cells

74. CBR consistently engaged in unfair and deceptive business acts and practices in connection with the sale and advertisement of private cord blood banking services in violation of the CFA by, among other things, consistently stressing the importance of a "genetic match" of a baby to his or her own cord blood stem cells on its company website. In addition to the claims outlined elsewhere in this Complaint, over the preceding decade CBR has made the following claims about generic matching.

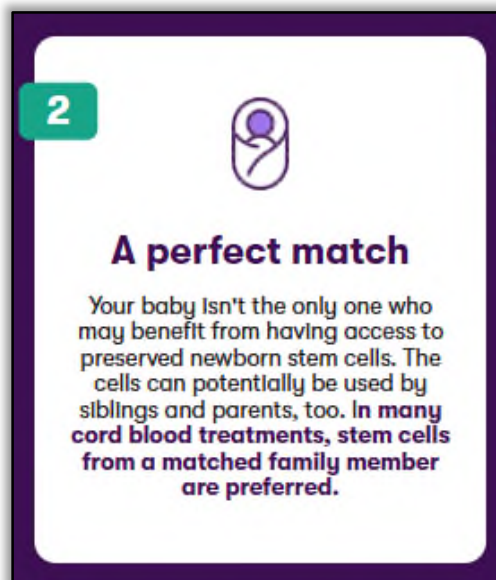
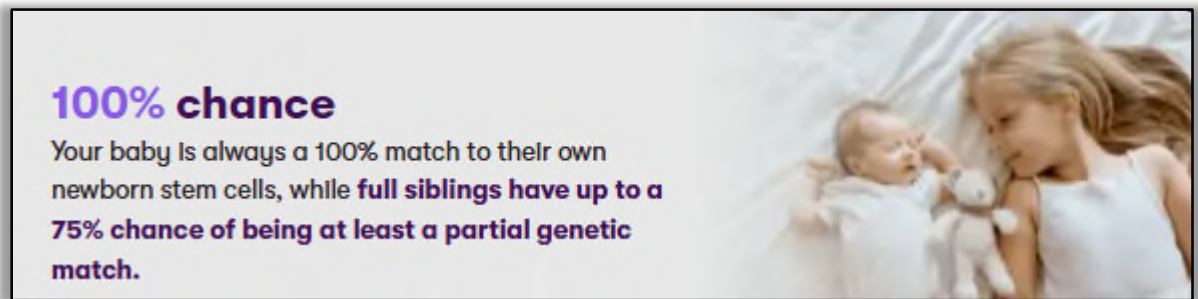
75. From at least January 2015 through 2016 the following or the substantial equivalent of the following appeared on its website, for example:



76. Sometime in late 2016, CBR's website was slightly modified to say the following, which remained until in or around November 2021:



77. CBR's current website represents, in a substantially similar fashion, the importance of the "perfect match."⁶³



⁶³ *The science behind newborn stem cells, supra* note 5.

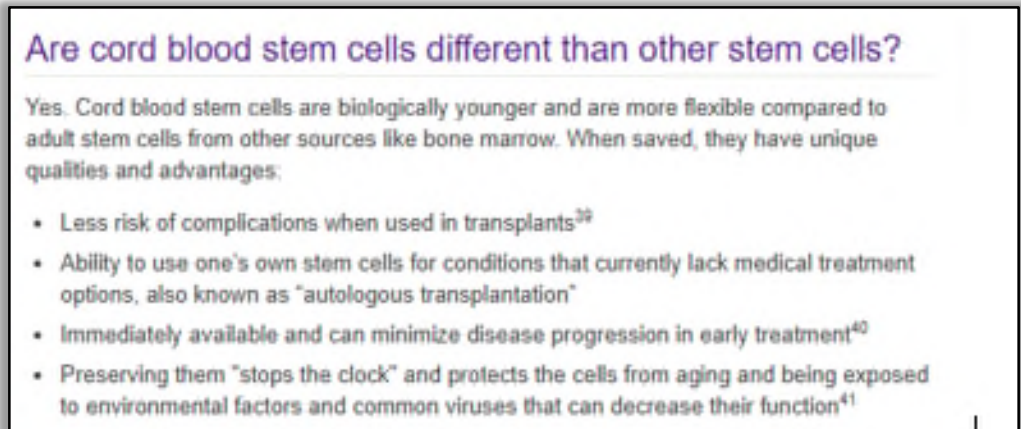
1 **3. CBR's Health Claims Are Deceptive, False and Misleading**

2 78. CBR's website has touted, for at least a decade, health claims that are at best
3 misleading and deceptive, and at worst intentionally false. CBR's health claims are
4 deceptive for several independent reasons.

5 **a. CBR Misleads Regarding the Potential That Cells Will Ever Be**
6 **Used, Including by Concealing and Failing to Disclose Critical**
7 **Information About Autologous Transplants**

8 79. As shown above, CBR's advertisements have consistently and misleadingly
9 touted that a baby's cord blood stem cells can treat a host of conditions and will be a match
10 for their own transplantation.

11 80. What CBR deceptively omits in violation of the CFA is the rarity of
12 successful autologous transplants. This omission is particularly confusing and misleading
13 when coupled with CBR's other broad claims about the healing powers of preserved cord
14 blood cells.



25 81. CBR gives a grossly misleading impression about the likelihood that a family
26 will be able to use a donor's own (autologous) cord blood for therapeutic purposes. The
27 potential for autologous (for donor) or allogeneic (for others) use of privately banked cord

1 blood is extremely low—a point confirmed by usage data.⁶⁴ Private banking is also costly
2 and can elude regulatory oversight, in turn impacting overall blood quality.⁶⁵

3 82. The chance of using a unit of privately stored cord blood for future
4 autologous transplant is, at best, “from a 1:400 to a 1:200,000 chance over the child’s
5 lifetime.”⁶⁶ Some studies put the likelihood of use *even lower*. For example, the Canadian
6 Blood Services quote even slimmer odds: a range from a 1 in 20,000 chance to a 1 in
7 250,000 chance.⁶⁷

8 83. In fact, despite widespread collection, privately banked cord blood has been
9 successfully transplanted into the donor *only* 19 times since 2010.⁶⁸

10 84. CBR’s statements are misleading for additional reasons: Indicators of disease
11 are often found in a patient’s blood, meaning that an autologous transfusion could be
12 damaging to the donor’s health if transplanted. Although CBR has advertised the benefits
13 of an exact match of cells, such as by statements that “your baby is always a 100% match
14 to their own newborn cells,” it has consistently neglected to specify that most stem cell
15 treatments and therapies require different donor matches from a public bank⁶⁹ due to the
16 genetic traits that can be present in a donor’s own cord blood.

17 85. Should a child develop certain types of blood diseases, such as leukemias or
18 myelomas, or genetic immunological conditions, the ill child’s blood cannot be
19

20 ⁶⁴ William T. Shearer *et al.*, *Cord Blood Banking for Potential Future Transplantation*,
21 140 Am. Acad. Pediatrics 5 (2017), https://pmc.ncbi.nlm.nih.gov/articles/PMC6091883/pdf/PEDS_20172695.pdf.

22 ⁶⁵ *Id.*

23 ⁶⁶ Renece Waller-Wise, *Umbilical Cord Blood: Information for Childbirth Educators*, 20
24 J. Perinatal Educ. 54–60, 57 (2011), https://pmc.ncbi.nlm.nih.gov/articles/PMC3209739/pdf/JPE20-1_PTR_A8_054-060.pdf.

25 ⁶⁷ Jarry, *supra* note 57.

26 ⁶⁸ Kliff & Ghorayshi, *supra* note 2.

⁶⁹ *CBR families’ top 5 FAQs after storing newborn stem cells*, CBR Sys., Inc. (Dec. 31,
2021), <https://www.cordblood.com/blog/cbr-families-top-5-faqs-after-storing-newborn-stem-cells>.

therapeutically used for transplantation due to the blood's genetic predisposition for malignancy.⁷⁰ "[W]hen a child needs a stem-cell transplant to treat metabolic or blood disorders, doctors are unlikely to use that child's own cells—donor cells can spark the necessary immune response to keep disease at bay[.]"⁷¹

86. In addition, it is rare that the sample size from a private cord blood collection will be sufficient. "[I]n many cases, not enough cord blood can be captured to make a unit viable—even the best collections have only enough stem cells to treat a child, not an adult."⁷² CBR does not disclose this, however.

87. Despite CBR's claims about the unique power of cord blood stem cells, moreover, umbilical cord blood is not the preferred source of stem cells for nearly any procedure or disease.⁷³ Many clinical trials and available treatments rely upon adult stem cells from whole blood and bone marrow, not cord blood stem cells.⁷⁴ For example, in 2008, it was found that patients in need of a stem cell donation could receive cells from a partial match from a preferred source of stem cells, like bone marrow, in combination with immunosuppressive medications.⁷⁵ A more recent *Blood and Marrow Transplant Clinical Trials Network* report supports this practice, writing that "if a fully matched donor is not available, a halfmatched donor is better than umbilical cord blood."⁷⁶ Since the discovery of the partially-matched stem cells and immunosuppressants regime, the already low

⁷⁰ Shearer, *supra* note 64.

⁷¹ Carly Weeks, *Why banking on cord blood isn't necessarily a good idea*, Globe & Mail (May 26, 2012), <https://www.theglobeandmail.com/life/health-and-fitness/why-banking-on-cord-blood-isnt-necessarily-a-good-idea/article4209835/> [<https://perma.cc/B4BJ-W759>].

⁷² *Id.*

⁷³ Kliff & Ghorayshi, *supra* note 2.

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Half-matched BMT better than cord blood in some cases*, Nat'l Marrow Donor Program, <https://www.ctsearchsupport.org/research-studies/half-matched-bmt-better-than-cord-blood-in-some-cases> (last visited Jan. 30, 2025).

1 amount of cord blood transplants has dropped even lower. In 2018, only about 500 cord
2 blood transplants were recorded,⁷⁷ and that number dropped to 346 transplants in 2023.⁷⁸

3 88. Umbilical cord blood cells are typically not the preferred form of stem cells
4 in the United States.⁷⁹ This is because those cells are twice as expensive to access; can be
5 harvested in only small amounts; and are highly likely to become contaminated.⁸⁰

6 89. CBR's advertising practices are both deceptive, and unfair, causing harm to
7 consumers by misleading as to the nature, value, and benefit of its services.

8 **b. CBR Confusingly Blurs Experimental and Accepted Uses, Giving**
9 **a Misleading Impression About the Uses for Banked Cord Blood**
10 **Cells**

11 90. As shown above, *supra* paragraphs 64-67, CBR has consistently advertised
12 the existence of 80+ approved uses for stem cells. CBR's deceptive advertisements have
13 never disclosed, however, that the majority of these 80+ referenced conditions are
14 extremely rare blood and immunological conditions.

15 91. Instead of providing concise and factual information about the uses of banked
16 cord blood cells, CBR's advertisements often blur FDA-approved treatment with
17 experimental applications and clinical trials, making promises of speculative future health
18 benefits. *See supra* paragraphs 68–73.

19 92. Seeking to bolster the perceived benefit of its services, CBR's advertisements
20 have leaned on the possibility of clinical trials and future research—for conditions as
21 disparate as autism, COVID-19, hearing loss, and cerebral palsy. These advertisements
22 indiscriminately conflate recognized treatments with research, incomplete clinical trials,
23 and pure hypothesis. For example, CBR's current website represents as follows:

24 ⁷⁷ Anita D'Souza *et al.*, *Current Use of and Trends in Hematopoietic Cell*
25 *Transplantation in the U.S.*, 26 Am. Soc'y Transplantation & Cellular Therapy 8, 177–
26 82 (2020), [https://www.astctjournal.org/article/S1083-8791\(20\)30225-1/fulltext](https://www.astctjournal.org/article/S1083-8791(20)30225-1/fulltext).

⁷⁸ Kliff & Ghorayshi, *supra* note 2.

⁷⁹ *Id.*

⁸⁰ *Id.*

Newborn stem cells: the building blocks of the body

Your baby's umbilical cord is made up of tissue and contains blood. Both cord blood and cord tissue are rich sources of powerful stem cells being researched for their ability to act like our body's own personal repair kit and may be able to help our bodies heal in new ways. Plus, cord blood stem cells are currently used in transplant medicine to regenerate healthy blood and immune systems.

Your family's healthier tomorrow starts today.

Preserving your baby's newborn stem cells gives you access to the most cutting-edge science that medicine has to offer.

CBR CLINICAL TRIALS AND STEM CELL RESEARCH



Cord blood has been used for 20 years to treat more than 80 serious diseases.³⁴ Successful treatments have paved the way for further research and today, FDA-regulated clinical trials are exploring the use of a child's own stem cells for conditions that currently have no cure.

Several of these groundbreaking trials only use cord blood stem cells processed by Cord Blood Registry as a way of ensuring consistent quality. That means, saving with Cord Blood Registry gives families access to more uses and treatments.

Cord blood stem cells are currently being evaluated as potential treatment for:

- Acquired Hearing Loss
- Autism
- Cerebral Palsy
- Pediatric Stroke
- Traumatic Brain Injury

93. Misleadingly, from at least 2015 through sometime in 2021, CBR's website did not appear to disclose that the referenced clinical testing was only in very preliminary stages, with no guarantee that treatments will be available for future use. Until relatively recently, CBR's website lacked clarification regarding the claims of potential transplant

options and did not explain that these investigatory treatments were not guaranteed.⁸¹ Even now, this clarification is not consistently made on CBR's website or across advertisements.

94. CBR's misleading promotion of potential regenerative medicine applications is another example of a violation of the CFA. CBR's websites—current and past—are replete with claims about regenerative medicine such as the following:

Access to a valuable regenerative resource

Advancements in newborn stem cell research are happening every day. Stem cells found in cord blood and cord tissue are helping to change the science of regenerative medicine, which involves repairing or establishing normal tissue function in the body, replacing organs, and curing life-threatening diseases.

What are stem cells?

Stem cells are the body's "master cells" because they are the building blocks of organ tissues, blood, and the immune system. Stem cells from bone marrow were first used to regenerate blood and immune cells for patients who had received chemotherapy for cancer. In the late 1980s, doctors started using cord blood stem cells to treat diseases that had previously been treated with bone marrow transplantation.

Today, cord blood stem cells are successfully being used to save lives. They also are being researched in an exciting new area of medicine called regenerative medicine, where scientists are studying the use of cord blood stem cells in experimental treatments for conditions like brain injury and acquired hearing loss.

95. Despite CBR's prominent advertisement of regenerative medicine, the ACOG says that "there is no current evidence to support the use of an autologous umbilical cord blood sample in regenerative medicine."⁸² While small clinical studies have tested

⁸¹ *Compare Family Programs*, CBR Sys., Inc. (Aug. 11, 2024), <https://web.archive.org/web/20240811121126/https://www.cordblood.com/family-programs> with *Family Programs*, CBR Sys., Inc., <https://www.cordblood.com/family-programs> (last visited Jan. 30, 2025).

⁸² *Umbilical Cord Blood Banking*, 133 Am. Coll. Obstetrics & Gynecologists 249–52, 251 (2019), <https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2019/03/umbilical-cord-blood-banking.pdf>.

1 umbilical cord blood for non-blood diseases, most testing has not advanced beyond very
2 preliminary stages.⁸³

3 96. The advertising tactics of private cord blood banks—of which CBR is typical
4 and most prominent—are highly misleading to prospective parents. Studies concluded that
5 these marketing tactics are likely deceptive: “Private cord blood bank marketing that
6 advertises hypothetical future treatments can be misleading and may influence consumer
7 behaviour.”⁸⁴ Furthermore, the studies have shown: “Statements about potential future
8 health benefits from banking blood that do not currently exist, if they form part of the
9 general impression of a private bank’s representation, could easily mislead a ‘credulous’
10 and inexperienced consumer – especially in the emotional context of pregnancy or birth.”⁸⁵

11 97. Researchers have noted, in particular, the misleading nature of
12 advertisements like CBR’s that tout the “enormous potential” of stem cells, intended to
13 leverage “hype surrounding stem cell research, a rhetorical strategy that is frequently used
14 to market unproven therapies. The marketing testimonials in particular, portraying positive
15 and emotionally-charged anecdotes, might play a key role in hyping the benefits and in
16 turn influencing customers’ decisions.”⁸⁶ Accordingly, they concluded:

17 [W]e can certainly say that unsupported claims that misrepresent or
18 exaggerate the present or future potential of cord blood-related treatments are
19 materially misleading and likely to affect consumer behaviour. The noted
20 statistical claims on private bank websites about likelihood of usage are also
21 potentially misleading, as they seem to diverge from the more widely

22 ⁸³ *Id.*

23 ⁸⁴ Blake Murdoch *et al.*, *The law and problematic marketing by private umbilical cord*
24 *blood banks*, 21 BMC Med. Ethics 52 (2020), <https://bmcmethics.biomedcentral.com/counter/pdf/10.1186/s12910-020-00494-2.pdf>.

25 ⁸⁵ *Id.*

26 ⁸⁶ Alessandro R. Marcon *et al.*, *Peddling promise? An analysis of private umbilical cord*
blood banking company websites in Canada, 22 Cell Tissue Bank 609–22, 619 (2021),
https://pmc.ncbi.nlm.nih.gov/articles/PMC8558271/pdf/10561_2021_Article_9919.pdf.

1 accepted and much lower probabilities found in public sources and
2 elsewhere.⁸⁷

3 98. CBR's advertisements thus lead its customers – expectant parents – to
4 believe that the preserved stem cells will be of use if their child one day becomes ill. Its
5 customers are led to mistakenly believe that current treatments make use of privately
6 banked cells, that future treatments are just on the horizon, and that stem cells can or will
7 soon be used regularly and successfully in the treatment of deadly and/or debilitating
8 diseases. These parents pay more for CBR's service than they otherwise would (if they
9 would purchase CBR's services at all) if they properly understood the chances that the stem
10 cells would ever become useful to the baby or its family.

11 **D. CBR Falsely Touted Endorsement by the Medical Community and**
12 **Accreditations While Wrongly Disparaging Public Cord Blood Banks.**

13 **1. For At Least 10 Years, CBR Has Falsely Claimed or Implied Physician**
14 **Endorsement of Its Services**

15 99. For at least a decade, CBR has consistently advertised medical endorsement
16 of its services.

17 100. For example, from at least 2015 through sometime in 2021, CBR's website
18 had a page entitled "Doctors Recommend Cord Blood Banking" (submenu "What is Cord
19 Blood"), stating:

20 
21
22

23 101. CBR's website was later modified, but continued to declare it was endorsed
24 by doctors.

25
26

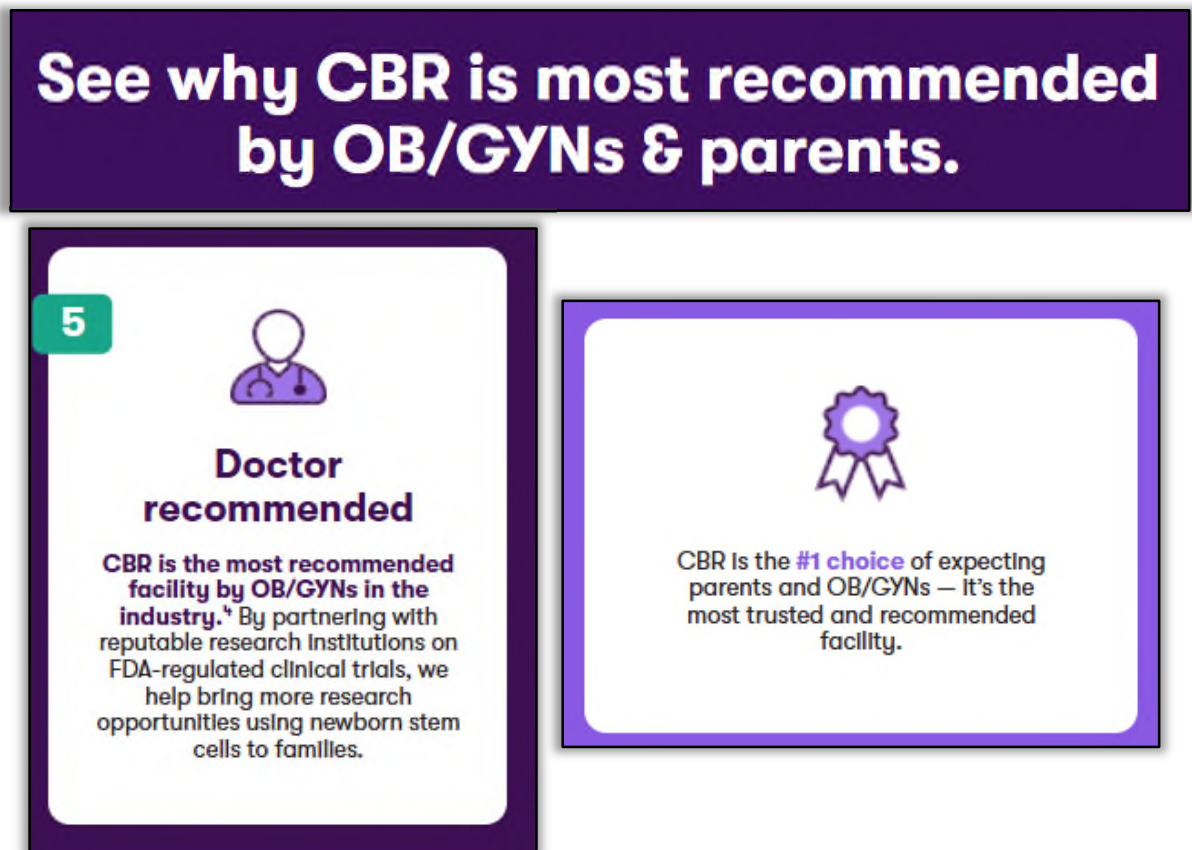
⁸⁷ *Id.* at 62.

102. A current CBR Google ad similarly touts its #1 ranking with OB/GYNs:⁸⁸



⁸⁸*Cord Blood Registry (CBR) – 40% Savings With CBR*, Google Ads (Feb. 6, 2025), <https://adstransparency.google.com/advertiser/AR10270281379090530305/creative/CR12278373237888385025?region=US>.

103. From sometime in or around November 2021 through the present, CBR's website continues to misleadingly represent supposed medical endorsement as a reason to engage CBR's services:



2. **Contrary to CBR's Claims of Physician Endorsement, Private Cord Blood Banking Is Discouraged by the AAP, the ACOG, and the AMA**

104. Although CBR has advertised its services as physician-endorsed, the AAP, the ACOG, and the AMA all actively discourage private cord blood banking. The advertisements regarding physician endorsement are misleading to consumers as it provides false medical support for CBR's services.

105. The AAP was founded in 1930 and is the largest association of pediatric physicians in the United States, hosting more than 67,000 pediatricians within its

1 organization.⁸⁹ The AAP has published hundreds of policy and advocacy statements
2 regarding a variety of topics in pediatric healthcare, including umbilical cord blood
3 banking.

4 106. The AAP has consistently maintained that private cord blood banking should
5 be avoided, primarily due to the lack of federal regulation of private banks and the lack of
6 “scientific data to support the claim that autologous cord blood is a tissue source proven to
7 be of value for regenerative medical purposes.”⁹⁰

8 107. The AAP further advocates that regulatory agencies, such as the FDA or the
9 Federal Trade Commission, should have a strong and active role in the regulation of the
10 cord blood industry. Because the private banking industry is not subject to the same
11 oversight as public banks, private banking often lacks the safeguards of public banks. By
12 this, the AAP continues to promote the usage of public banks given their substantial state
13 and federal or state oversight, compared to the oversight of private banks which often falls
14 through regulatory cracks.⁹¹

15 108. The ACOG, founded in 1951, is a professional organization for obstetrician–
16 gynecologists in the United States, with over 60,000 members over the course of the
17 ACOG’s lifespan. ACOG Fellows are board-certified OB/GYNs who maintain the highest
18 levels of professional and ethical standards.⁹² ACOG produces guidance materials for
19 practitioners and educational materials for patients.

20 109. The ACOG issued its opinion on umbilical cord blood banking in 2015. It
21 stated that collection of cord blood is not routine obstetric care and is not medically
22 necessary. Further, the ACOG opinion stated that if patients were interested in cord blood

23 ⁸⁹ *About the AAP*, Am. Acad. Pediatrics, <https://www.aap.org/en/about-the-aap/> (last
24 visited Jan. 30, 2025).

⁹⁰ Shearer, *supra* note 64 at 6.

⁹¹ Am. Acad. Pediatrics, *supra* note 89.

⁹² *About*, Am. Coll. Obstetricians & Gynecologists, <https://www.acog.org/about> (last
25 visited Jan. 30, 2025).
26

1 banking, “balanced and accurate information” regarding both private and public options
2 should be explored, but the “routine storage of umbilical cord blood as ‘biologic insurance’
3 against future disease is not recommended.” ACOG’s 2019 opinion superseded their 2015
4 opinion, and further reaffirmed the 2019 opinion in 2023⁹³ while stating that: “This
5 document is updated with a statement that the routine use of private cord blood banking is
6 not supported by available evidence and that public banking is the recommended method
7 of obtaining cord blood.”

8 110. ACOG’s recommendation states, inter alia:

9 A. Umbilical cord blood collected from a neonate cannot be used to treat
10 a genetic disease or malignancy in that same individual (autologous transplant)
11 because stored cord blood contains the same genetic variant or premalignant cells
12 that led to the condition being treated.

13 B. The routine collection and storage of umbilical cord blood with a
14 private cord blood bank is not supported by the available evidence.

15 111. In 2023, the Committee on Genetics and the Committee on Obstetrics at the
16 ACOG reaffirmed their 2015 opinion on umbilical cord blood banking. The ACOG
17 continues to maintain that public banking should be pursued by families in lieu of private
18 banking, for similar reasons as other institutions: autologous transplantations are not
19 possible when there are known precursors of disease, private banking is not supported by
20 any available evidence, and public banking dramatically increases public resource
21 availability for all patients in the United States.⁹⁴

22 112. Founded in 1847, the AMA is the largest medical lobbying association in the
23 United States, with physicians of all practice areas as members.

24
25 _____
⁹³ *Umbilical Cord Blood Banking*, *supra* note 82.

26 ⁹⁴ *Umbilical Cord Blood Banking*, *supra* note 82 at 250–51.

113. The AMA Principles of Medical Ethics maintains that parents who wish to donate their child's umbilical cord blood should donate to a public bank and encourages parents to consider the "limited likelihood of use" at a private bank.⁹⁵ It notes that public donation increases the availability of stem cells for all patients, including their own child.⁹⁶

114. CBR's claims of physician endorsement are highly misleading in light of the weight of medical recommendations by the preeminent United States organizations. Instead of disclosing the weight of medical opinion, CBR's website has presented a handful of purported endorsements by individual physicians for its services over the last decade. From 2014 or earlier, through in or around November 2021, the CBR website presented several of the same purported doctor endorsements in some format or another:

Potentially Lifesaving Purchase

"There's only two things that (you can) potentially buy your new baby that are lifesaving: One is a good car seat and the other is cord blood."

~ Dr. Marra Francis, Ob/Gyn, CBR medical consultant

More Uses Than We Know

"Just like we didn't envision the powers of PCs thirty years ago, we may not be seeing all the uses of cord blood yet."

~ Dr. LeeAnn Jensen, Immunologist National Institutes of Health

Potential to Heal the Body in New Ways

"A really exciting area that's just now in the basic science lab, is the area where stem cells...can be used for going over to muscle cells like your heart muscle if you had a heart attack...or brain cells if you had Parkinson's Disease...Hopefully, in 20 or 30 or 40 years...these might be potential applications for stem cells including umbilical cord blood stem cells."

~ Dr. Stanton Goldman, Pediatric Hematologist Oncologist and stem cell transplant Physician, Medical City, Dallas, Texas

⁹⁵ *AMA Code of Medical Ethics Opinion 6.1.5 Umbilical Cord Blood Banking*, Am. Med. Ass'n, <https://code-medical-ethics.ama-assn.org/sites/amacoedb/files/2022-08/6.1.5.pdf> (last visited Jan. 30, 2025).

⁹⁶ *Id.*

115. These are largely the same as those misleading or false endorsements still presented by CBR today:



"Just like we didn't envision the powers of computers thirty years ago, we may not be seeing all the uses of cord blood yet."

Dr. LeeAnn Jensen, Immunologist

National Institutes of Health



"A really exciting area that's just now in the basic science lab is the area where stem cells... can be used for going over to muscle cells like your heart muscle if you had a heart attack... Hopefully, in 20 or 30 or 40 years... these might be potential applications for stem cells, including umbilical cord blood stem cells."

Dr. Stanton Goldman, Pediatric Hematologist Oncologist and Stem Cell Transplant Physician

Medical City — Dallas, TX



"Stem cell technology is evolving rapidly, offering innovative treatments where none previously existed. We get one opportunity to bank a child's stem cells that could be lifesaving one day. Why would we choose to discard them?"

Tricia Shimer MD, PA, Comprehensive Women's Care

Dallas, TX



"There are only two things that (you can) potentially buy your new baby that are lifesaving: One is a good car seat, and the other is cord blood."

Dr. Marra Francis, OB/GYN

CBR Medical Consultant

116. These endorsements mislead parents into believing that the broader medical community recommends private cord blood banking. Just as parents would buy a new car seat or ensure a safe crib environment, they sign up for costly cord banking services thinking that they are following the doctors' recommendations.

3. CBR Has Disparaged the Medically-Preferred Alternative of Public Cord Blood Banking in False and Misleading Ways

117. CBR engaged in deceptive acts and practices in connection with the advertisement of its private cord blood banking services by knowingly representing the medical community supports such services. However, the preeminent medical organizations' discouragement of private cord blood banking highlights the superior alternative: public cord blood banking. Because public banking is inconsistent with CBR's profit motive, however, CBR actively disparages public banks for a myriad of unsubstantiated, unfair, and/or misleading reasons.⁹⁷

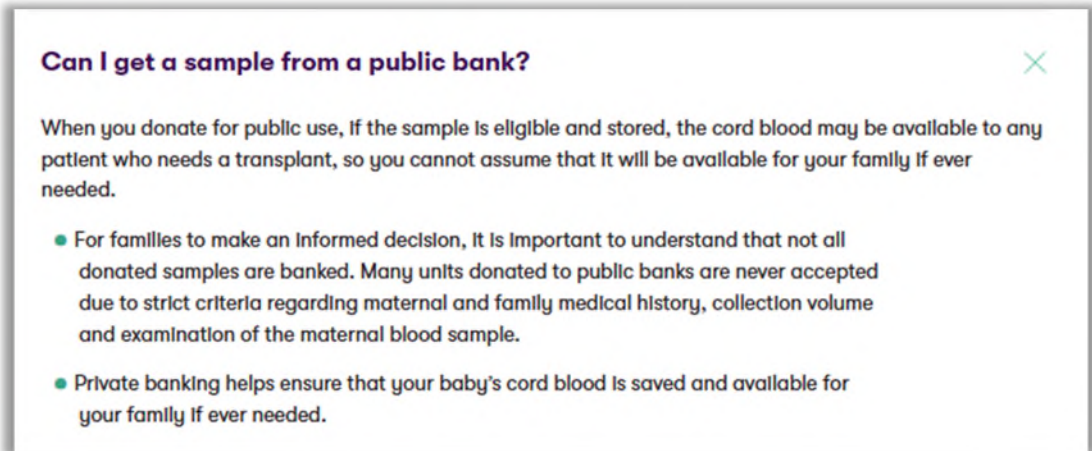
118. CBR, for example, discourages public banking by claiming that there are limited collection sites and low sample retention rates, and that donated samples cannot be retrieved.⁹⁸ In reality, there are 185 hospitals in the United States that actively partner with and accept umbilical cord donations to both local and national public registries.⁹⁹

⁹⁷ See *FAQs – Cord Blood Banking: Donating stem cells to the public – Can I donate to a public bank?*, CBR Sys., Inc., <https://www.cordblood.com/faqs> (last visited Jan. 30, 2025) (“[d]onating to a public bank may not be possible for several reasons”).

⁹⁸ *Id.*

⁹⁹ *Umbilical Cord Blood* at 1, Am. Acad. Fam. Physicians (Sept. 2011), <https://www.aafp.org/pubs/afp/issues/2011/0915/p667.pdf>.

119. To provide another example: CBR states that cord blood matches are not guaranteed in public banks and that fully genetic family members bear a greater potential to be matched with the donated child's cord blood.¹⁰⁰



120. CBR's premise is apparently that a child and his or her siblings are better off receiving their own blood or that of a sibling, rather than engaging with public cord blood registries and being "matched" with an anonymous donor. But, if cord blood is privately stored and determined to have precursors to disease, these parents would be forced to find an anonymous donor through a public registry.

121. Storing umbilical cord blood privately does not guarantee use for a donor's family either. CBRs failure to expressly state this fact is a material omission and violation of the CFA. Unlike bone marrow or peripheral stem cells, cord blood cells can be transfused into a recipient with only a partial human leukocyte antigen ("HLA") match,¹⁰¹ meaning that a donor and recipient need not share identical HLA markers in order for transplantation. The ideal donor and recipient combination will still be a perfect HLA match for each other, however, otherwise the recipient's immune system could create

¹⁰⁰ *FAQs – Cord blood banking: Donating stem cells to the public – Can I get a sample from a public bank?*, CBR Sys., Inc., <https://www.cordblood.com/faqs> (last visited Jan. 30, 2025).

¹⁰¹ Martin, *supra* note 9.

antibodies against the donor blood, leading to a dangerous and potentially fatal response.¹⁰² Fully genetic siblings have a 25% chance of being a full match; however, about 70% of individuals will not have a fully matched donor within their immediate family.¹⁰³ CBR, as shown above, emphasizes the potential for sibling matches. Yet while fully genetic siblings have the greatest *potential* to be full HLA matches, the chances of siblings being a recipient for private stored cord blood are small.

122. There is a public cost to this conduct by CBR: Private umbilical cord blood banks dramatically undercut the ability of cord blood to be effectively used for medical treatments and therapies by diverting samples into private laboratories, rather than allowing blood units to be readily accessible by the public blood registries and thereby accessed by more patients.¹⁰⁴ These privatized institutions emphasize that if a patient decides to use a public cord blood registry for transplantation, there is no guarantee that they will “match” with a public donor. Yet, the risk of not matching with a public donor is equivalent or less than the risk of a blood unit’s viability at a private cord blood bank.¹⁰⁵

123. A common concern in engaging with public banks is the ability for patients of diverse ethnic backgrounds to match with a public donor, as the resources and chances of matching are significantly lower than for white, European patients.¹⁰⁶ Private banks directly contribute to this devastating problem by convincing parents to safeguard their

¹⁰² *Blood Type and Crossmatch*, Univ. Rochester Med. Ctr., https://www.urmc.rochester.edu/encyclopedia/content.aspx?contenttypeid=167&contentid=blood_type_crossmatch (last visited Jan. 30, 2025).

¹⁰³ *What is HLA?*, Nat’l Marrow Donor Program, <https://www.nmdp.org/patients/understanding-transplant/finding-a-donor/hla-typing-matching> (last visited Jan. 30, 2025).

¹⁰⁴ Kliff & Ghorayshi, *supra* note 2.

¹⁰⁵ *See id.* (“private banks disclose in small print that the odds of using the cells are low, or that clinical trials may not pan out”).

¹⁰⁶ *Why ethnicity and diversity matter when matching*, Nat’l Marrow Donor Program, <https://www.nmdp.org/get-involved/join-the-registry/ethnicity-and-diversity-matter> (last visited Jan. 30, 2025).

1 child's blood for their own use, rather than donating to a national public bank which, in
2 turn, would directly counteract the lack of ethnically diverse cord blood samples available
3 for transplantation and therapeutic usage.¹⁰⁷

4 124. For comparison, while Caucasian recipients have a 70% chance of matching
5 with an unrelated donor, other individuals of differing ethnic backgrounds only have a 10%
6 chance of matching with an unrelated donor. Yet, private banks exploit this statistic and
7 continue to expand the ethnic disparity by arguing that the lack of diverse ethnic public
8 donors is a reason why families should *not* publicly bank their child's cord blood.¹⁰⁸

9 125. What is not disclosed in this narrative is that public banks pay for all fees
10 associated with collection, testing, and storage of umbilical cord blood.¹⁰⁹ While the cost
11 of retrieving blood from a public bank is typically significantly higher than the cumulative
12 costs of private banking, this cost is usually covered by one's health insurance.¹¹⁰

13 4. CBR Has Sought to Mislead Consumers About FDA Oversight

14 126. All cord blood banks—both public and private—must register with the
15 FDA.¹¹¹ Registration with the FDA does not indicate federal “endorse[ment]”; rather,
16 registration with the FDA only indicates that the entity has notified the FDA that it is

17 ¹⁰⁷ *Id.*

18 ¹⁰⁸ *FAQs – Cord Blood Banking: Donating stem cells to the public – If someone in my*
19 *family needs a transplant, could we find a donated sample at a public bank?*, CBR Sys.,
Inc., <https://www.cordblood.com/faqs> (last visited Jan. 30, 2025).

20 ¹⁰⁹ *Donating Umbilical Cord Blood to a Public Bank*, Health Res. & Servs. Admin.,
21 [https://bloodstemcell.hrsa.gov/donor-information/donate-cord-blood/options-umbilical-](https://bloodstemcell.hrsa.gov/donor-information/donate-cord-blood/options-umbilical-cord-blood-banking-donation/donating-umbilical-cord-blood-public-bank)
[cord-blood-banking-donation/donating-umbilical-cord-blood-public-bank](https://bloodstemcell.hrsa.gov/donor-information/donate-cord-blood/options-umbilical-cord-blood-banking-donation/donating-umbilical-cord-blood-public-bank) (last visited
Jan. 30, 2025).

22 ¹¹⁰ James Christmas, MD, *Umbilical Cord Blood Donation*, HCA Va. Physicians (Mar.
23 20, 2018), [https://hcavirginiaphysicians.com/about/newsroom/umbilical-cord-blood-](https://hcavirginiaphysicians.com/about/newsroom/umbilical-cord-blood-donation)
[donation](https://hcavirginiaphysicians.com/about/newsroom/umbilical-cord-blood-donation) (“Public banks do not charge for donating cord blood. It costs approximately
24 \$30,000 to obtain a cord blood collection from a public bank, but that cost typically is
charged to the patient's healthcare insurance.”).

25 ¹¹¹ *Blood Establishment Registration and Product Listing*, U.S. Food & Drug Admin.,
26 [https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/](https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/blood-establishment-registration-and-product-listing)
[blood-establishment-registration-and-product-listing](https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/blood-establishment-registration-and-product-listing) (last updated May 12, 2021).

performing one or more manufacturing steps.¹¹² Any FDA-registered cord blood agency is subject to public inspection by the Center for Biologics Evaluation and Research (“CBER”) Human Cell and Tissue Establishment.¹¹³

127. While public cord blood banks are subject to extensive federal regulation, private banks are not. Instead, umbilical cord blood intended for personal use or for use by first- or second-degree relatives is not subject to FDA regulation regarding use, material information that CBR routinely omits from its advertisements and solicitations to consumers.¹¹⁴

128. In 2011, the FDA issued a compliance document to help manufacturers of human cells, tissues, and cellular and tissue-based products (“HCT/Ps”) comply with Current Good Tissue Practice (“cGTP”) requirements.¹¹⁵

129. All FDA-registered establishments must have a self-devised quality program to ensure that their facility complies with the basic requirements that FDA-registration requires.¹¹⁶ The quality program is responsible for establishing notification procedures.¹¹⁷ In the case of possible contamination or spoilage discovered after the cord blood sample has been made available for distribution, shipped to the consignee, or transferred to the recipient, all entities to whom the sample was distributed must be notified.¹¹⁸

¹¹² *Cord Blood Banking – Information for Customers*, U.S. Food & Drug Admin., <https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/cord-blood-banking-information-consumers> (last updated Mar. 23, 2018).

¹¹³ 21 C.F.R. § 1271.37 (2023).

¹¹⁴ *Umbilical Cord Blood Banking*, *supra* note 82 at 250–51.

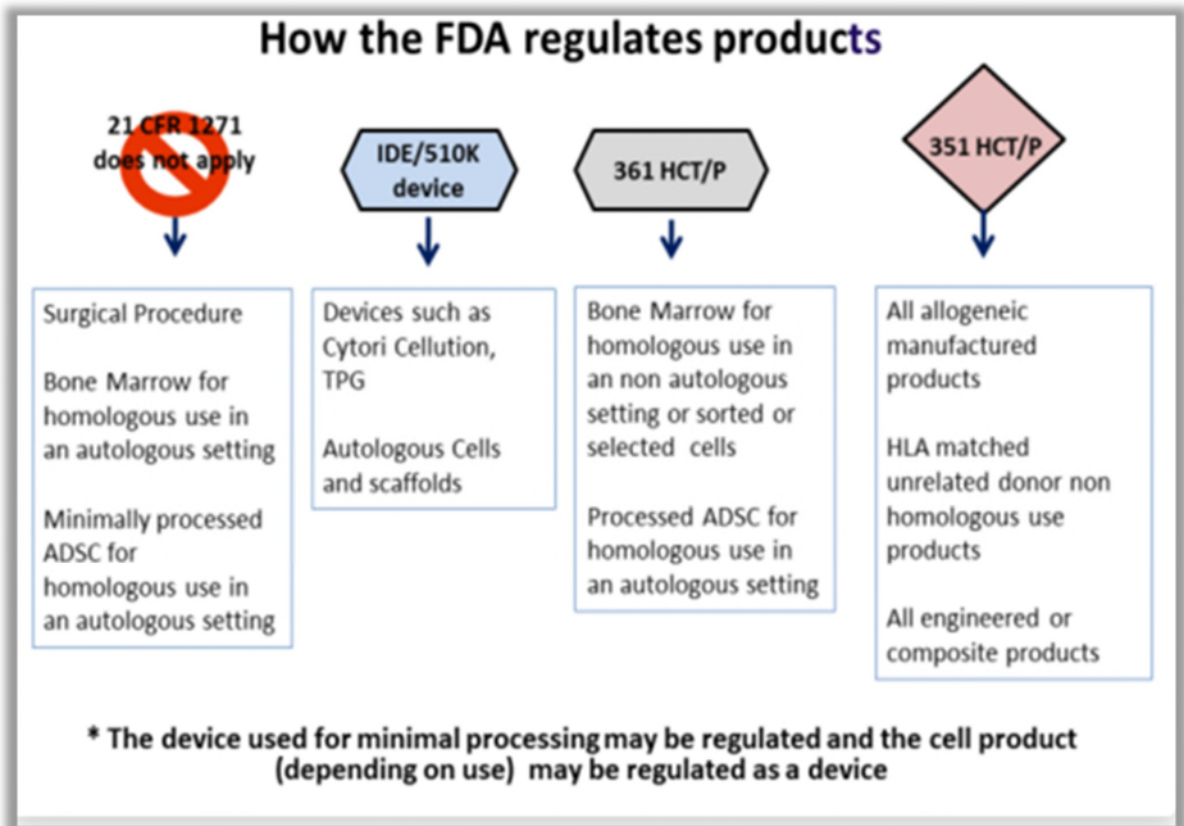
¹¹⁵ *Guidance for Industry Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*, U.S. Food & Drug Admin. (Dec. 2011), <https://www.fda.gov/media/82724/download>.

¹¹⁶ *Id.* at 11–16.

¹¹⁷ 21 C.F.R. § 1271.160(b)(2) (2025).

¹¹⁸ 21 C.F.R. § 1271.160(b)(2)(iii).

130. Many of the cGTP requirements are limited by the caveat that they apply only “where appropriate,” meaning that private entities have discretion to determine when a requirement is appropriate for their establishment.¹¹⁹ Thus, private cord blood banks have immense discretion over the functioning of their facility, from collection to storage outside of the regulatory framework that governs public cord banks.



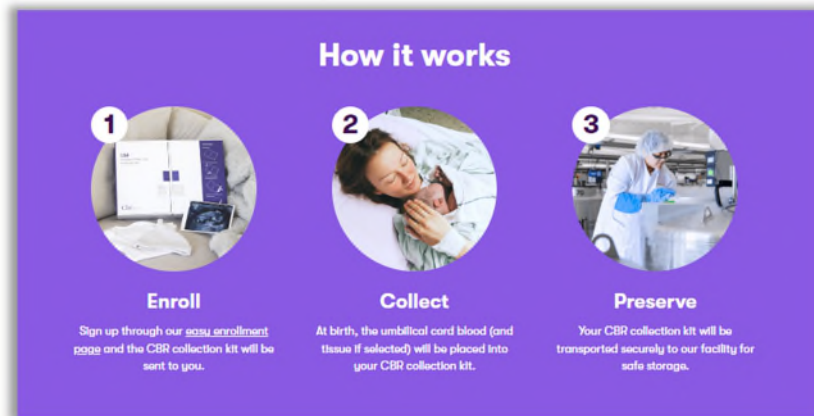
E. CBR’s Promises Concerning Safe Shipping, Testing, Storage and Communication Are False and Misleading.

131. CBR engages in a variety of additional conduct constituting misleading, fraudulent, deceptive and unfair practices aimed at consumers nationwide, including Arizona consumers, to convince new parents to trust it with the storage of their newborn’s cord blood samples.

¹¹⁹ 21 C.F.R. § 1271.160(b)(3).

132. The process for private cord blood banking is simple, in theory: expectant parents enroll with a private cord blood bank such as CBR and pay an upfront collection fee. They are then sent a collection kit to be taken with them into the delivery room. After delivery, a physician extracts the blood from the baby's umbilical cord and deposits it into the kit. A courier from the bank then comes to collect the kit for shipment to the storage laboratory, where testing and cryo-preservation of the blood *should* occur. Parents continue to pay "rent" on their child's sample until the blood is needed, if ever.

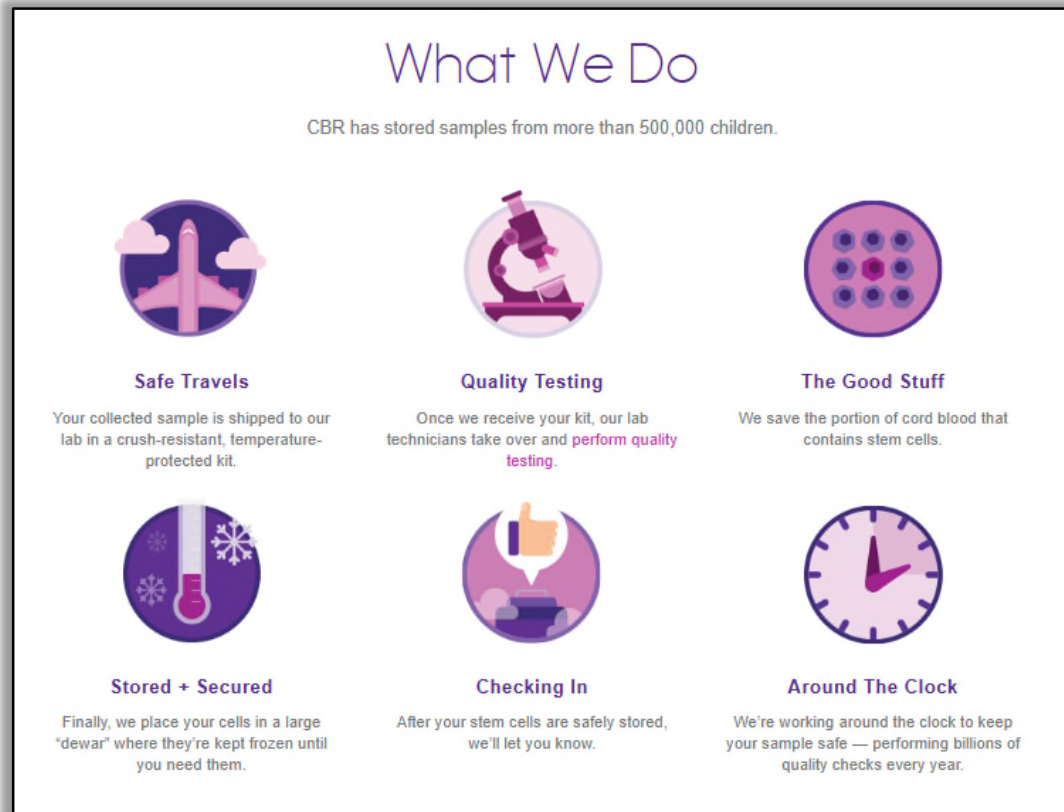
133. Cord blood samples must be sufficient in volume and cell count, and kept in pristine condition from collection to storage, in order for the cord blood sample to be viable for potential future use. Before a sample can be transplanted, autologous or otherwise, the blood must be tested for two main factors: contamination of cells and the quantity of cells collected.¹²⁰ Discrepancies or deficiencies in either test can render the cord blood useless and even dangerous to a child's health if used.¹²¹



¹²⁰ Kliff & Ghorayshi, *supra* note 2.

¹²¹ *Id.*

134. CBR advertises that it provides safe collection, shipping, testing, and preservation. It also says it will communicate with parents about the status and viability of their child's sample. For example:



135. As detailed below, however, CBR is falling short on its promises.

1. CBR Misleads and Conceals the Issues Relating to the Collection and the Quantity of Cells

136. A major factor that is considered in all stem cell therapies is cell dose. Cell dose correlates with the volume of blood collected and directly indicates the amount of satisfactory stem cells present.¹²² A single umbilical cord typically yields 50 to 200 ml of blood. Any cord that yields less than 50 ml is discarded as medical waste and deemed

¹²² Renece Waller-Wise, *Umbilical Cord Blood: Information for Childbirth Educators*, 20 J. Perinatal Educ. 54–60, 57 (2011), https://pmc.ncbi.nlm.nih.gov/articles/PMC3209739/pdf/JPE20-1_PTR_A8_054-060.pdf.

1 unsatisfactory, as the volume of blood would not be great enough for even a small child to
2 receive.¹²³

3 137. Unlike public banks, private banks have no minimum volume requirement
4 for a cord blood unit, and will accept any amount collected, despite the fact that over 50%
5 of all cord blood collections yield an insufficient volume for public storage.¹²⁴ This means
6 that a significant percentage of privately banked blood is almost guaranteed to not even
7 contain enough cells to be therapeutically useful. Yet, CBR ignores this issue and typically
8 omits any related information from consumers when advertising and soliciting their
9 services. CBR implies that its collections yield sufficient cell volumes and deceptively
10 claims that an autologous transplant is better than that utilizing a sample from a public
11 donor from a public cord blood bank.¹²⁵

12 **2. CBR Misleads Consumers with respect to Transport and Shipping**
13 **Safety and Related Concerns**

14 138. CBR has consistently represented, for at least the past 10 years, that it
15 provides safe and secure transportation of the collected samples to its Tucson storage
16 facility.¹²⁶

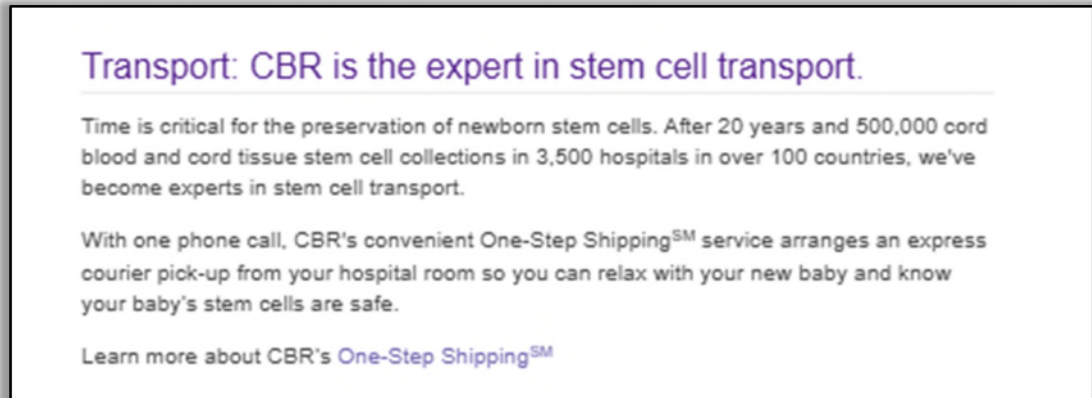
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24 ¹²³ *Id.*

25 ¹²⁴ *Id.*

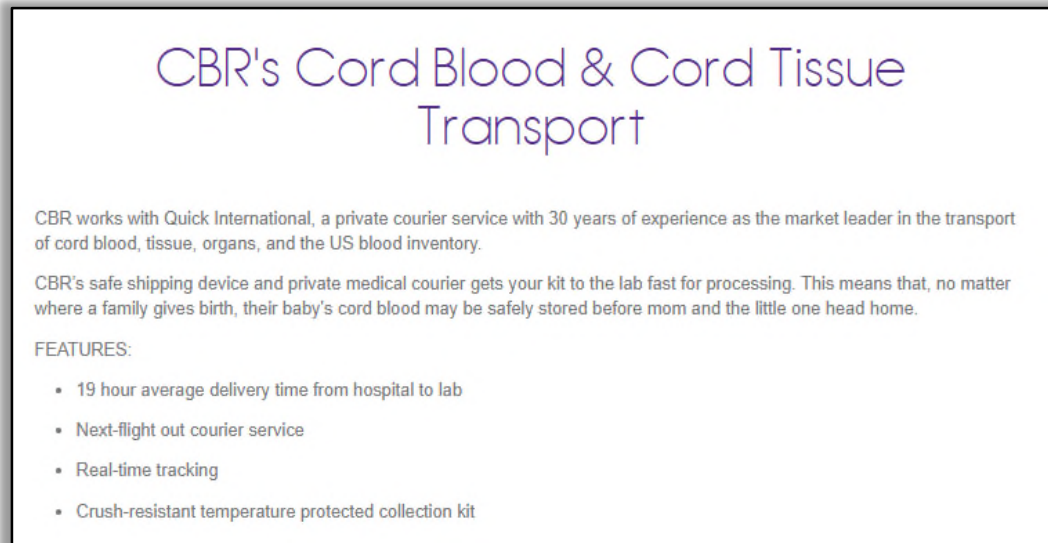
26 ¹²⁵ *FAQs – Cord blood banking: Donating stem cells to the public – Can I get a sample from a public bank?, supra note 97.*

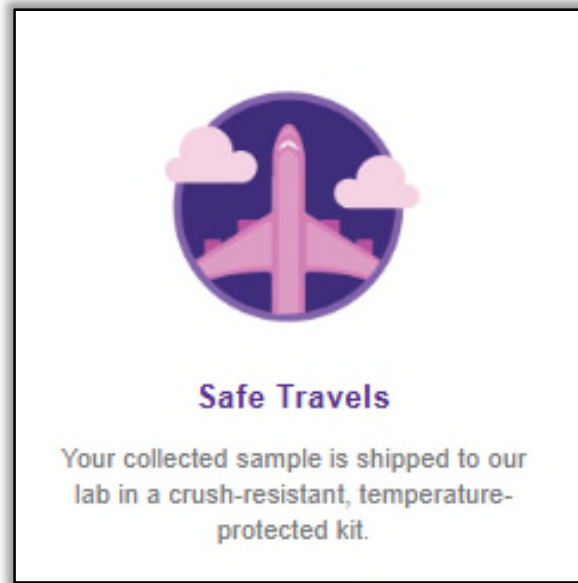
¹²⁶ *Why preserve with CBR?, supra note 10.*

139. For example, from at least July 2014 through May 2019, CBR's website advertised as follows:

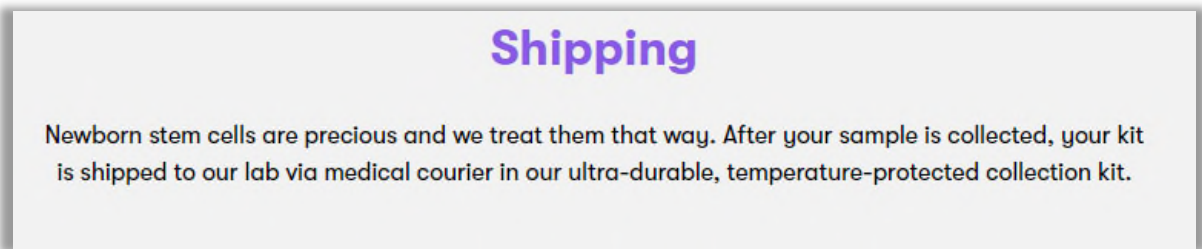


140. CBR similarly advertised its shipping services as follows, over time, consistently claiming that its transport was appropriately temperature controlled and safe:





141. Presently, CBR continues to advertise the safety of its shipping practices, including the temperature-controlled transport of samples:



142. This is another false and misleading representation to consumers in violation of the CFA. After a baby has been delivered and a cord blood sample collected, the onus is on the new parents to contact CBR for a courier to collect the sample. Once a courier has arrived, the blood unit is transported to the bank without strict temperature controls or any temperature monitors in transit to Tucson. Thus, once the sample is received by CBR's lab, there is no way to determine whether the sample became overheated en route.¹²⁷ CBR relies on its transfer containers as a fool proof way to ensure the proper temperature is maintained from collection to receipt at the Tucson facility.

¹²⁷ Kliff & Ghorayshi, *supra* note 2.

1 143. As noted *supra*, the FDA issued a cGTP guidance document to help
2 establishments that handle human cells, tissue, and cellular products comply with cGTP
3 requirements.¹²⁸ The guidance document provides that many of the cGTP requirements are
4 qualified “where appropriate,” indicating that CBR is given the discretion to determine
5 when a “requirement” is appropriate for its business.¹²⁹

6 144. By proxy of being an FDA-registered establishment, CBR is subject to FDA
7 inspection to ensure the prevention and spread of infectious diseases.¹³⁰ As reported on by
8 the *New York Times*¹³¹ and confirmed in a FOIA request response from the FDA, in January
9 2024, the FDA observed multiple violations of quality control standards at CBR’s storage
10 lab in Tucson.

11 145. One violation observed by FDA concerned inappropriate shipping conditions
12 of umbilical cord blood and tissue. At CBR, both cord blood and tissue are transported in
13 the same vehicle, but upon arrival to the facility, only the umbilical cord blood collection
14 bag is recorded for arrival temperature. Yet, the arrival temperature is only used as a
15 “proxy” to determine whether the maternal blood draw tubes remained within “the
16 temperature specifications of the infectious disease assays package insert.”¹³² If a cord
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22 ¹²⁸ *Guidance for Industry Current Good Tissue Practice (CGTP) and Additional*
23 *Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-*
24 *Based Products (HCT/Ps), supra* note 115.

25 ¹²⁹ *Id.* at 9.

26 ¹³⁰ *Id.*

¹³¹ Kliff & Ghorayshi, *supra* note 2.

¹³² Letter from Donald R. Ball, Vice President, Stem Cell Operations, CBR Systems, Inc.
to Karlton Watson, Program Division Director, U.S. Food & Drug Admin. (Feb. 5, 2024)
(unpublished letter on file with FDA).

1 blood sample is proven to be too hot, a mere warning is applied to the infectious disease
2 results and the blood is still cryogenically stored.¹³³

3 **OBSERVATION 3**

4 Appropriate shipping conditions were not maintained and followed for each type of HCT/P.

5 Specifically,

6 At time of receipt, only umbilical cord blood temperature is recorded by your receiving department. You
7 have received (b) (4) umbilical cord blood units out of your temperature range since 01/01/2021. The
8 umbilical cord tissue temperature is not taken or recorded.

9 **3. CBR's Misleading Conduct with Respect to Contamination Issues**

10 146. CBR also misleadingly touts the safety of its storage facility and conceals
11 serious contamination concerns and risks from consumers in order to continue reaping
12 storage fees. Once again, CBR's advertisements of and assurances regarding the safety of
13 its storage conditions have been substantially consistent over the past 10 years.

14 **Storage**

15 Our safe and secure lab is located in Tucson, Arizona, which
16 historically is not impacted by hurricanes, tornadoes, and
17 earthquakes.

18 147. Private banks consistently struggle with bacterial contamination of cord
19 blood units, however.¹³⁴ Consumers of CBR, upon information and belief, have reported
20 their sample becoming infected with contaminants such as E. coli.¹³⁵

21 148. Sadly, much of this contamination happens shortly after birth. Parents have
22 learned that their children's samples were either unusable or ruined shortly after collection,
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25 ¹³³ *Id.*

26 ¹³⁴ Kliff & Ghorayshi, *supra* note 2.

¹³⁵ *Id.*

1 through improper transit or handling. Yet, upon information and belief, CBR does not
2 promptly inform its customers of deficiencies in their sample and continues to charge
3 parents an annual fee on blood that is irrevocably damaged, unfairly pocketing the fees its
4 customers pay for storing useless samples.¹³⁶ In some cases, parents have even been
5 pressured into paying for storage of contaminated samples with conjecture that science
6 might develop an avenue for ruined cord blood to be used.¹³⁷

7 149. CBR’s contracts indicate that if a blood sample is deemed questionable for
8 storage or the testing results are unavailable, an attempt will be made to reach the parents.
9 However, upon information and belief, many parents have learned that their children’s
10 samples were either unusable from the outset or irretrievably ruined shortly after being
11 collected, through improper transit or contamination, only when they have attempted to
12 extract the blood for therapeutic usage—after paying storage fees for any range of time to
13 have CBR hold the sample at its facility.

14 150. The FDA does not review or copy quality audit reports during their routine
15 inspections, in an attempt to encourage establishments to install “candid and meaningful”
16 quality assurance programs.¹³⁸ Instead, FDA-registered facilities are afforded their own
17 discretion in creating and implementing testing policies for umbilical cord blood
18 samples.¹³⁹ Unlike public banks, which must comply with federal requirements regarding
19 all HCT/Ps, private cord blood banks are free to decide their own testing policies.

20 ¹³⁶ *Id.*

21 ¹³⁷ *Id.*

22 ¹³⁸ *Compliance Policy Guide (CPG) - CPG Sec. 130.300 FDA Access to Results of*
23 *Quality Assurance Program Audits and Inspections*, U.S. Food & Drug Admin.,
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-130300-fda-access-results-quality-assurance-program-audits-and-inspections> (last
24 updated Nov. 8, 2024).

25 ¹³⁹ *Testing Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products*
(*HCT/P*): *Specific Requirements*, U.S. Food & Drug Admin.,
26 <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/testing->

1 151. Under these regulations, CBR is not required to notify the original donor of
2 potential contamination, resulting in parents paying thousands of dollars for storage of
3 unusable blood, without any notice from their bank.¹⁴⁰

4 **V. CLAIM FOR RELIEF**
5 **VIOLATIONS OF THE ARIZONA CONSUMER FRAUD ACT**

6 152. The State realleges and incorporates by reference herein each and every
7 allegation contained in the preceding paragraphs 1 through 151.

8 153. The conduct described in the preceding paragraphs of this Complaint
9 constitutes deception, deceptive or unfair acts or practices, fraud, false pretenses, false
10 promises, misrepresentations, or concealment, suppression or omission of material facts
11 with intent that others rely on such concealment, suppression or omission, in connection
12 with the sale or advertisement of merchandise in violation of CFA, A.R.S. §§ 44-1521 –
13 34, including but not limited to:

- 14 a. Engaging in a deceptive practice of misrepresenting the objective
15 endorsement of physicians and medical community support for CBR;
16 b. Engaging in a deceptive and unfair practice of omitting the existence
17 of de facto kickbacks paid to physicians who sold CBR's services;
18 c. Engaging in the deceptive practice of misrepresenting or deceptively
19 implying the number and scope of treatments that could reliably use
20 same-individual cord blood;
21 d. Engaging in the deceptive practice of misrepresenting the likelihood
22 of intra-familial use;

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25 [donors-human-cells-tissues-and-cellular-and-tissue-based-products-hctp-specific-](#)
26 [requirements](#) (last updated May 3, 2019).

¹⁴⁰ *Id.*

- e. Engaging in the deceptive and unfair practice of misrepresenting and wrongly disparaging public cord blood banking;
- f. Engaging in a deceptive practice of omitting material information regarding the viability of samples and sample sizes that could or would be collected from customers;
- g. Engaging in a deceptive practice of omitting material information about the lack of support in the medical community for private cord blood banking;
- h. Misrepresenting the quality and security of transport and storage; and
- i. Engaging in a deceptive practice of omitting or concealing material information about tainted and/or insufficient samples;
- j. Engaging in a deceptive and unfair practice of representing that no “initial payment” until after birth and deceptive and misleading advertising stating that “[w]e won’t charge you for processing or storage until your sample has been safely stored” and “[y]ou will be charged after your baby is born,” designed to mislead consumers to believe that no up-front payment is required; and
- k. Engaging in a deceptive and unfair practice of failing to notify customers, or failing to promptly and timely notify customers, that their samples are tainted or unusable samples, in order to collect or continue collecting recurring storage fees.

154. These representations and omissions occurred in online advertising and CBR’s website viewed by expecting parents over at least the last ten years.

155. While engaging in the acts and practices alleged in this Complaint, CBR knew or should have known that its conduct was of the nature prohibited by A.R.S. § 44-1522, subjecting CBR to enforcement and penalties as provided in A.R.S. § 44-1531(A).

1 with anyone described in (a) or (b) of this paragraph, directly or indirectly, from engaging
2 in deceptive, misleading, or unfair acts or practices, or concealments, suppressions, or
3 omissions, that violate the CFA, A.R.S. § 44-1522(A), including specific injunctive relief
4 requiring CBR to:

5 A. Disclose to the public any financial compensation and/or kickbacks to
6 hospitals and/or physicians who recommend or have recommended CBR;

7 B. Disclose to consumers, at the time of recommendation, any financial
8 compensation and/or kickbacks to hospitals and/or physicians who recommend
9 CBR;

10 C. Timely test samples and immediately disclose results to consumers;

11 D. Ensure that all of CBR's public-facing communications are truthful
12 and not misleading;

13 E. Disclose results fairly and accurately of all testing related to stem cell
14 and regenerative therapies applicable to cord blood banking;

15 F. Offer termination and refund procedures to consumers who are found
16 to not have a viable sample for future use;

17 G. Cease marketing and selling cord blood collection and storage
18 services; and

19 H. Improve transparency of communication surrounding contaminated
20 samples and use in treatments and clinical trials.

21 161. Pursuant to A.R.S. § 44-1528(A)(3), order CBR to disgorge all profits, gains,
22 gross receipts, or other benefits obtained as a result of its unlawful acts alleged herein;

23 162. Pursuant to A.R.S. § 44-1531, order CBR to pay to the State a civil penalty
24 of up to \$10,000 for each willful violation of the CFA;

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s/ Gary A. Gotto

s/ Alison E. Chase

Gary A. Gotto (007401)

Alison E. Chase (028987)

KELLER ROHRBACK L.L.P.

3101 N. Central Avenue, Suite 1400

Phoenix, AZ 85012

Tel.: (602) 248-0088

ggotto@kellerrohrback.com

achase@kellerrohrback.com

s/ Joseph C. Tann

Joseph C. Tann (029254)

LAW OFFICE OF JOSEPH C. TANN, PLLC

7735 N. 78th Street

Scottsdale, AZ 85258

Tel.: (602) 432-4241

josephtann@josephtann.com

Attorneys for Plaintiff