

# When Medicine Meets Marketing

**The business of storing umbilical-cord blood is growing. Is salesmanship outpacing science?**

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Dallas Hextell was just a baby when his parents bought him a walker—not because he was late reaching a milestone, but because they worried he might never toddle on his own. At 9 months he had been diagnosed with cerebral palsy, a form of brain injury caused by oxygen deprivation in utero or at birth. A neurologist had told Derak and Cynthia Hextell there was no cure, that it was best to wait and see if their son improved. But Cynthia, after months of research, enrolled Dallas in a highly experimental trial at Duke University, where a pediatric-transplant surgeon infused him with a sample of his own stem cells harvested from his umbilical-cord blood. A few days later, Derak and Cynthia went home with their son, who was 18 months old and still not crawling, much less walking or talking. They "stared at him" for a week, says Cynthia. "One day he just started saying, 'Mama, mama, mama.' And I started crying." The Hextells ended up donating the walker to another child. By 2, Dallas was not only walking unaided, he was chasing the family dogs.

If the Hextells' names sound familiar to some readers, it is because, in the wake of their son's remarkable recovery, they have become minor celebrities. Their story has appeared on the "Today" show and in advertisements in almost every pregnancy magazine in the country. The ads are not for the trial at Duke, which remains a small, academic endeavor. They are for a company called Cord Blood Registry, which charges parents \$2,000-plus to freeze and store samples of their children's umbilical-cord blood, a fluid rich in stem cells. Cynthia Hextell paid the company to freeze Dallas's cord blood at his birth. That sample was the source of the stem cells used in the Duke trial—and as the ads remind parents, it was available only because the Hextells had paid for it to be.

The Hextells' story has become the centerpiece of CBR's marketing efforts. Recently the company invited about 30 obstetricians and midwives to the Westin La Paloma resort in Tucson, Ariz., for a weekend of sun, golf and medical briefings, including dinner in a ballroom with the Hextells as guest speakers. Since these doctors had collected cord blood for CBR clients in the past, the company hoped to turn them into evangelists. The next day, the group went for a tour of CBR's glittering 60,000-square-foot lab. The agenda also included more time at the La Paloma, home to a Jack Nicklaus golf course, a spa, five restaurants and a swim-up bar. CBR can easily afford to put on this kind of show. Ten years ago it was a fledgling business with 10,000 clients. Today it is the country's largest private cord-blood bank, with 250,000 samples in storage, 300 employees and \$100 million in annual revenue.

In medicine, money often comes with controversy—and right now, CBR has plenty of both. The company says it is providing precious biological insurance, that to freeze a child's cord-blood stem cells is to provide him a medical option for the future, perhaps a lifesaving treatment for childhood cancer or brain injuries. But critics, including the American Academy of Pediatrics, accuse private cord-blood banks like CBR of making exaggerated medical promises and exploiting vulnerable new parents. Cord blood's uses are limited at best, they say. The blood does not provide enough cells to cure an adult of a disease or injury; it is not appropriate for treating genetic conditions; and thus far there have been few trials to determine how effectively the cells can repair damaged tissue. Even Joanne Kurtzberg, the Duke transplant specialist who treated Dallas Hextell, is skeptical. She says it's difficult to know if his improvement is related to the cells or would have occurred without them—he probably would have gotten better on his own; some cerebral-palsy patients do—and she points out that her trial is small and yet to be analyzed and published. But CBR has a response for this. It says more uses for cord-blood stem cells will surely be discovered in the future. It also knows the power of a good story. David Zitlow, the company's senior vice president of public affairs, says doctors "haven't made a big enough deal about anecdotes" like

the Hextells'.

So what are other parents, faced with the choice of banking their children's cord blood or brushing off the idea as a luxury—the medical equivalent of an \$800 stroller—supposed to make of Dallas Hextell's case? Is it a breakthrough, a harbinger? Or is it ultimately just an anecdote, a moving tale with a happy outcome that may or may not have anything to do with cord blood and stem cells?

Doctors have been wondering if cord blood is something of a miracle cure for the past 15 years. The blood—which is usually thrown away in delivery rooms—contains a distinct type of stem cell that may act as a biochemical foreman, helping to build healthy tissues and repair damaged ones. In the early 1990s—before embryonic stem cells took over the spotlight—researchers began to explore whether cord-blood cells might be of practical medical use. At Duke, Kurtzberg performed a few cord-blood transplants on patients with leukemia and rare types of bone-marrow failure, sending them into remission. Meanwhile, the National Institutes of Health started funding public banks of frozen, donated cord-blood samples, modeled on adult blood banks. A cord-blood stem-cell transplant at that point was a long shot, an experiment to see if stem cells could either become new tissue or trick the body into fixing itself. But the idea behind the public banks was to make the option available to all families who might want to try it as a last resort.

It was around this time, in 1992, that Tom Moore, a technology and pharmaceutical executive with passion for startups, hatched a plan to found a cord-blood bank of his own. Unlike the NIH banks, this one would operate for profit. Its clients would retain exclusive access to their own genetically identical samples, for a fee of \$1,500 up front plus \$125 for each year of storage. One problem: Moore "didn't really know anything about stem cells except the name," he admits. So he sought out David Harris, a University of Arizona immunologist and cord-blood researcher, to serve as CBR's scientific director; meanwhile, as the CEO, he took care of the business side. Now it takes care of him. CBR is the largest of 30-some private cord-blood banks in the United States, with a 45 percent share of the \$250 million market. It's probably not done growing yet. Moore's "big, hairy, audacious goal" is a million clients, quadruple the company's current size.

A number of trends have likely contributed to CBR's growth, including the enormous boom in the baby-products market and the hype around stem cells in general. But one thing that has not been a factor is a rapid rise in medical uses for cord blood—because there hasn't been one yet. Just as it was in the '90s, a cord-blood stem-cell transplant is still an experimental procedure. This hasn't deterred CBR from publicizing the results of a few positive studies, including a small, preliminary trial in kids with type 1 diabetes from last year.

In Dallas Hextell, CBR has another case to promote. In ads, the Hextells call the cord-blood treatment "a miracle." But nobody really knows what has happened in Dallas's brain. The story sounds less clear-cut coming from Kurtzberg, the doctor who performed the transfusion and who examined Dallas again in November. "He has made progress, there's no question," she says. "But he still has a global developmental delay of about a year. He looks like where we would have expected him to be without cells." When she saw him at his follow-up visit, she adds, "I thought, wow, he doesn't look as good as I was expecting based on what's been in the press." (The Hextells find Kurtzberg's assessment frustrating and note that Dallas's therapists at home—who knew him before the transfusion—are impressed and surprised at his improvement.) Kurtzberg also has not completed the follow-up and analysis of the study or published the results from 50 other kids with cerebral palsy who have enrolled in her trial thus far.

Kurtzberg, it turns out, is not a big booster for private cord-blood banks; although she uses samples from CBR, she does not receive funding from the company, and also uses cells from public banks and other companies. In fact, she's one of the authors of a statement the American Academy of Pediatrics put out last year discouraging parents from using private banks on the grounds that the science isn't solid enough yet to justify a multi-thousand-dollar gamble. (The AAP does support public, nonprofit banks, which patients can use for free.) The American College of Obstetricians and Gynecologists released its own statement in February, noting that "there is no reliable estimate of a child's likelihood of actually using his or her own saved cord blood later." Then it made a guess anyway: 1 in 2,700, which Kurtzberg calls "generous."

Why is this number so small? There are reasons to think cord-blood treatment will never be a widespread medical procedure. The blood contains only enough stem cells to treat a small child; unlike embryonic stem cells, cord-blood cells cannot be multiplied into self-rejuvenating "lines" in a petri dish. The cells are limited in other ways, too. There's little point in treating a genetic condition with a patient's own cord-blood cells, which have the same DNA and thus the same deleterious mutations. Scientists could someday overcome these hurdles; they could develop new ways of cultivating and genetically tweaking cord-blood cells in the lab. But by then, the same scientists will probably know much more about all stem cells, especially once restrictions on embryonic research are lifted—and there may be better ways of getting safe, usable cells from other sources, ways that won't require a lot of technological wizardry.

These difficulties don't deter everyone, of course. The pediatrician Robert Sears, a talk-show regular and the coauthor of popular parenting books, supports private cord-blood banking; he froze his own kids' samples with CBR. It's also possible that 1 in 2,700 is too conservative. CBR's executives toss around much more dramatic odds. Harris, the scientific director, puts them at a breathtaking 1 in 3. His calculations, unlike the professional groups', include injuries to the brain. There is, he notes, "no genetic predisposition to falling out of a crib"—so as he sees it, every child, technically, is at risk.

Until widespread trials of cord-blood treatment take place, both sides will be able to use arbitrary calculations. Those trials, alas, are probably far off: rare conditions are difficult to study on a large scale, since by definition there aren't many patients to enroll. Three years ago, Congress tried to put cord-blood trials on a faster track by expanding funds for the NIH's public banks—more donations to the banks could mean more studies—but the law hasn't made much of an impact. Public banks have collected cord blood from just 105,000 babies, and fewer than 200 hospitals in the U.S. are able to draw and ship the blood to public centers. The private banks, of course, have larger stores. But they are not huge contributors to research either: only 100 of CBR's 250,000 clients have enrolled in trials thus far.

For now, parents are left to make the same speculative wager at the heart of CBR's business model: how much should you invest in science that's promising but not proven? Back in the ballroom in Tucson, the OBs and midwives on the CBR junket were considering that question too. They pressed Cynthia Hextell for more details. How were the other kids in the Kurtzberg trial doing? Cynthia said the few other families she had talked to had seen improvements like Dallas's. And what risks were they warned about? "The only risk was that it wouldn't work and we would be out the money," she said. "But we just knew in our hearts that it was going to work." Other parents will have to decide whether they have that kind of faith.

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