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‘Miraculous’ stem cell therapy has sickened people in five states

Liveyon, a company in Yorba Linda, Calif., sells tiny vials of a solution it says is derived from umbilical cord blood, which it claims is an especially potent source of healing stem cells. (Loren Elliott for The Washington Post)

By **William Wan** and **Laurie McGinley**

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After years of back pain, Timothy Lunceford decided in July to try an injection of umbilical cord blood, an unproven treatment increasingly touted by chiropractors and pain doctors as a cure for achy joints. A day after he got the shots, Lunceford’s back began throbbing. After two days, he was feverish and could hardly move.

“It felt like someone stuck a knife into the middle of my back and just left it there,” said Lunceford, a 52-year-old wildlife biologist from Athens, Tex.

Lunceford said his wife rushed him to a hospital, where doctors found E. coli and a second type of bacteria in his blood. Nurses gave him antibiotics to fight life-threatening sepsis, and a neurosurgeon scraped infected tissue from his spine. For 58 days, Lunceford remained hospitalized, wracked by intense pain.

Over the past year, at least 17 people have been hospitalized after being injected with products made from umbilical cord blood, a little-known but fast-growing segment of the booming stem cell industry, according to state and federal health officials and patient reports. Sold as a miracle cure for

a variety of intractable conditions, the injections have sickened people in five states, prompting new warnings from health officials about the risks of unproven stem cell treatments.

All but two of the illnesses have been linked to a single company: Liveyon of Yorba Linda, Calif. The Centers for Disease Control and Prevention issued a report in December tying 12 cases in multiple states to treatments sold by the company. Three additional patients in Texas and Maine have filed lawsuits against Liveyon claiming the company's product infected them with bacteria.

Liveyon, founded in 2016, sells tiny vials of a solution it says is derived from umbilical cord blood, which it claims is an especially potent source of healing stem cells. In ads and on its website, Liveyon says its product is "as miraculous as the birth of a child itself" and "stimulates regenerative healing."

Such products are not approved by federal regulators or supported by clinical research, but businesses selling them say they provide relief to many patients. Many scientists say the injections — like most stem cell therapies — violate Food and Drug Administration rules against marketing unapproved drugs and are potentially dangerous.

The CDC report revealed a specific risk: bacterial infection. The CDC said it had documented a dozen patients who had developed a variety of maladies from the injections, including swollen spinal discs, infected bones and joints, and abscesses in their backs. Three of the 12 patients were hospitalized for a month or more, the report said.

The CDC did not name the patients, but the date of Lunceford's injection and the length of his hospital stay match those of a patient listed in the CDC report.

On Sept. 28, after the FDA and other health officials inquired about the infected patients, the company issued a recall for all treatment vials marketed under the name "Liveyon ReGen." Blaming the California company that manufactured the vials, Liveyon executives said they hired a new manufacturer in Florida and changed the name of their product to "Liveyon Premier MAXCB."

"We're a victim as much as the patients who were infected," Liveyon's founder and chief executive, John Kosolcharoen, said in one of several interviews with The Post. "I feel like we tried to do everything right."

Internal company records obtained by The Post show that Liveyon received reports of patients falling ill and testing positive for E. coli as early as June 5, 2018 — nearly four months before the recall. Liveyon executives did not dispute that finding but said they did not act sooner because they believed the infections were caused by doctors who inadvertently contaminated their product while injecting patients.

However, the CDC found that the bacterial contamination probably "occurred before distribution" to doctors. After obtaining 10 unopened vials of Liveyon treatments from clinics in Texas and Florida where patients had fallen ill, the CDC report said, investigators found bacteria in eight of them. In the weeks since then, CDC officials said, they have obtained many more ReGen vials directly from Liveyon and found bacteria in a large proportion of them.

Kosolcharoen said he continues to believe that doctor error contributed to the rash of infections. He added that Liveyon has spent a lot of time and money trying to establish and follow best practices in a field rife with bad actors.

"We're just the tip of the iceberg, and we're the cleanest in the iceberg," Kosolcharoen said. "If anyone else knew what's going on in this industry, they would roll over in their grave."

Stem cells can divide and renew themselves over long periods, and some can grow into any kind of cell in the body. Eventually, researchers say, stem cells could be used to treat many diseases, including macular degeneration, diabetes and Parkinson's.

But those therapies are still being developed; the only FDA-approved stem cell treatment is for blood disorders like leukemia. Many leading researchers compare the products being sold now to snake oil, saying there is little oversight, little scientific rationale for the procedures and little proof they have any effect.

Meanwhile, doctors have found evidence of harm: Several people have gone blind after receiving stem cell treatments, according to reports in the New England Journal of Medicine and elsewhere. And two people died shortly after being injected with stem cell treatments in Florida, most recently in 2012.

The for-profit stem cell business is nonetheless booming. After cropping up overseas in countries such as Thailand and China, the industry has flourished in the United States — without much resistance, until recently, from the FDA or other federal regulators. Academic experts have identified at least 716 U.S. stem cell clinics and say the true number probably exceeds 1,000. Many clinics use patients' own tissue — belly fat, blood or bone marrow — to fashion treatments. More recently, practitioners have begun offering treatments manufactured from birth-related products, including discarded placentas, amniotic tissue, umbilical cords and cord blood.

Such materials have a long history in commercial marketing, said Jeanne Loring, a neurobiologist and stem cell researcher at California-based Scripps Research.

"People have been putting things like that in creams and shampoo for ages," she said. "But there's nothing inherently magical about placental tissue or the amniotic sac."

Lisa Fortier, a Cornell University regenerative medicine researcher, said such products may not even contain stem cells. In a test of nine products — none of them from Liveyon — Fortier found that none contained stem cells, or a single live cell of any kind. She said they also contained very few "growth factors" — substances that many companies often claim stimulate healing.

If these products have any effect on patients, Fortier said, "it's not through live cells or growth factors."

Dorothy O'Connell was hospitalized with a dangerous infection following a Liveyon treatment and has had to learn how to walk again. (Loren Elliott/For The Washington Post)

In interviews with The Post, Kosolcharoen, 47, defended his company and its treatments. Whatever testing on other products may show, tests paid for by Liveyon have indicated that its vials contain live cells and stem cells, according to a self-published company report.

Kosolcharoen said he benefited from stem cell therapies in 2012, after falling off a balcony and shattering his knee.

“Liveyon was my way to share the success I had,” he said.

Kosolcharoen said he started Liveyon in 2016, after years of working as an entrepreneur in the insurance, real estate and telemedicine industries. To launch the company, he brought on Alan Gaveck, 59, a podiatrist who serves as Liveyon’s top medical expert.

Gaveck has had no formal training in stem cells, but he said he has spent the past nine years immersed in the industry. Comparing himself to other stem cell experts, he said: “I’ll stand up to any of them as far as knowledge of stem cells is concerned.”

Before Liveyon, both men experienced professional setbacks, according to court documents and other records.

Two months after filing Liveyon’s incorporation documents, Kosolcharoen pleaded guilty to defrauding the military health-care system.

According to an FBI affidavit, Kosolcharoen ran a sales team that persuaded soldiers to request prescriptions for a topical cream sold for “pain, scarring, stretch marks, erectile dysfunction, or for ‘general wellness.’ ” In return, Kosolcharoen received more than $600,000 from a compounding pharmacy that supplied the cream, the affidavit said.

In an interview, Kosolcharoen said he didn’t deliberately defraud anyone. He said federal officials charged him because he wasn’t directly employed by the pharmacy and therefore was receiving payment for his work under an improper tax status.

He said he pleaded guilty because federal officials threatened to charge his relatives involved in the business. His sentencing in the case has been repeatedly delayed; Kosolcharoen said federal officials are waiting to use his testimony against the compounding pharmacy. Federal prosecutors declined to comment because the case remains open.

Before that, Kosolcharoen ran into trouble with the Securities and Exchange Commission. The SEC barred him in 2014 from the securities industry after he made “material misstatements” and committed “fraud and deceit,” according to a settlement agreement between the SEC and Kosolcharoen.

In an administrative hearing on the case, the SEC said Kosolcharoen worked for a Dallas-based medical insurance company, Global Corporate Alliance, which SEC officials described as “a $10 million Ponzi scheme that victimized at least 80 investors.”

In an interview, Kosolcharoen said that he was duped by the company and that he and his relatives lost money when authorities exposed the scheme.

“I was the middle person, transferring paperwork,” he said. Kosolcharoen said authorities told him, “We won’t charge you with anything, but you have to agree to never get a security license.” The SEC declined to comment on the agreement.

Gaveck, meanwhile, no longer holds a medical license. He was reprimanded by the Arizona podiatry board in 2007, when the board voted unanimously to censure him for his treatment of a patient who came to him for a dislocated toe and — two surgeries later — had to have the toe amputated. The patient sued Gaveck for malpractice, he said; he later decided not to renew his medical license.

"I had a very busy surgical practice and, yes, I had a malpractice suit," Gaveck said in a telephone interview. Such lawsuits, he said, are a common occurrence for "anyone who has been in medicine long enough."

Gaveck said he does not need a medical license because Liveyon does not treat patients directly in the United States. Instead, the company sells its treatments to chiropractors and other practitioners. Over the past two years, Kosolcharoen said the company has sold 25,000 vials at $1,500 for a single-injection dose or $1,800 for a multiple-injection dose.

Those sales have brought in tens of millions of dollars in revenue, Kosolcharoen said, but he said the company's profits so far have been modest because of start-up and overhead costs.

Until recently, Liveyon also did not engage directly in manufacturing. Kosolcharoen and Gaveck said it would have taken too long to set up their own manufacturing operation, so they turned to Exeligen Scientific in San Diego.

Liveyon officials said executives at Exeligen set up a third company in San Diego, called Genetech, to produce Liveyon's vials. In June — about the time Liveyon first started hearing from providers about infected patients — an FDA inspection of Genetech's facility found numerous sterility and safety lapses, according to FDA records.

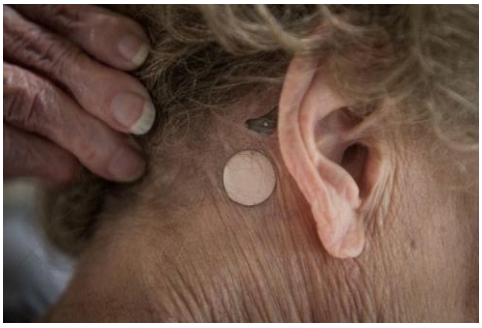
At the time, inspectors reprimanded Genetech for not following safe manufacturing practices — such as consistently screening donor cells for communicable diseases, FDA records show. The agency issued a formal warning to the company in November and told Genetech it was selling an unapproved product. It copied Liveyon's Kosolcharoen on the letter.

Neither Genetech nor Exeligen could be reached for comment. The websites and phone numbers for the companies no longer work, and top executives did not respond to multiple emails or repeated calls and texts to their cellphones.

Kosolcharoen said he knew nothing about the FDA's findings at Genetech until several months after the June inspection.

"I gotta be a little mad at FDA," he said. "Had we been notified that they had done an inspection of Genetech and found these deviations, we would have stopped buying from them immediately."

O’Connell organizes her kitchen with her daughter, Elaine Dilley, who said her mother’s pain was so intense “you couldn’t touch her.” (Loren Elliott For The Washington Post)



O’Connell displays a patch used to counteract her vertigo. Dilley said O’Connell has been left with damaged vision, hearing and balance. (Loren Elliott For The Washington Post)

Liveyon continued to distribute vials of “Liveyon ReGen” through the summer and into the fall. The first reports of infected patients reached the CDC in September.

After investigating cases reported by health departments in Texas and Florida, CDC officials issued a call to other health departments nationwide. By mid-December, the CDC had found 12 patients, its report said: seven in Texas, four in Florida and one in Arizona. This week, CDC officials said they confirmed a 13th case of infection.

Dorothy O’Connell, 90, of Brazoria, Tex., said she is among those patients, and details of her case match one investigated by the CDC.

O’Connell received Liveyon injections for her arthritic back and neck on Sept. 12, according to her daughter, Elaine Dilley. Within days, “she started throwing up, and I had to call an ambulance,” Dilley said, adding that her mother’s pain was so intense, “you couldn’t touch her.”

O’Connell was airlifted 50 miles north to a hospital in Houston. “Her kidneys were shutting down, and they were worried she was going to have a heart attack,” Dilley said. “The doctors didn’t think she was going to make it.”

Despite her age, O’Connell had always been able to take care of herself, including mowing her own lawn, Dilley said. Now her mother has been left with damaged vision, hearing and balance, Dilley said, and has had to learn how to walk again.

Seven months after his July injections, Lunceford, the patient from Athens, Tex., said he still experiences persistent stabbing pains and has been unable to return to work. He, O’Connell and three other Texas patients have filed lawsuits against Liveyon, alleging negligence.

Liveyon has denied their claims and is fighting them in court.

In addition to Lunceford and O’Connell, The Post reviewed the medical claims of five other people who said they were hospitalized after receiving Liveyon treatments. Among them is John Herzog, 63, an osteopathic physician in Falmouth, Maine, whose case was not among the 12 investigated by the CDC.

Herzog said he injected himself in May after some of his patients asked for cord-blood injections. Regional chiropractors were “making a killing” on the shots, he said. But before charging his patients

“$1,800 a vial for something that wasn’t effective,” he said, he decided to try it himself on a painful knee.

When Herzog expressed concerns about the product’s safety, a Liveyon sales person arranged a phone call with Gaveck, the company’s top medical expert. Gaveck assured Herzog the product was sterile, he said.

“Everything was glowing, glowing,” Herzog said.

Within minutes of the injection, however, Herzog said, his knee ballooned, and he couldn’t straighten his leg. The pain was excruciating. In the hospital, doctors found two types of bacteria, and Herzog said he was later diagnosed with a bone infection and a related blood clot.

Once an enthusiastic biker and windsurfer, Herzog said he lost 30 pounds and now cannot walk up stairs without pain.

Last week, Herzog filed a lawsuit alleging negligence against Liveyon, Genetech — and Gaveck. Asked to comment on the case, Gaveck said the phone call occurred before Liveyon had gotten the first reports of bacterial infections in patients.

“I probably did have a conversation with him,” Gaveck said. “Sales reps refer folks to me all the time.”

But, he said, “I don’t talk glowingly about anything. I talk about what I know and the science of it.”

After years of minimal regulation of the stem cell industry, the FDA issued guidelines in 2017 making clear that many products are unapproved drugs being marketed illegally. The agency says it is giving many in the industry time to become compliant while targeting riskier treatments, such as injections into the eye and spinal cord, for enforcement. It has also gone to court to try to stop procedures at two clinics.

So far, Liveyon has not received a warning letter from the FDA, even though federal regulations say distributors are responsible for their products’ safety.

FDA officials declined to discuss the details of the Liveyon-Genetech case. In an interview, FDA Commissioner Scott Gottlieb said the agency “continues to investigate the circumstances surrounding the product, how it became contaminated and how patients became injured and may take additional action.”

Last month, Los Angeles health officials reported two patients had become seriously ill after being injected with a similar product sold by a different company.

Scott Gottlieb, commissioner of the Food and Drug Administration. (Astrid Riecken for The Washington Post)

FDA officials said the agency lacks the resources to pursue a comprehensive crackdown on the sprawling stem cell industry. It is difficult to impose a “regulatory architecture after an industry has sort of grown up,” Gottlieb said.

“There’s now a marketplace where arguably hundreds of millions of dollars are being made,” said Mark Schwartz, a former top official for the FDA’s Center for Biologics Evaluation and Research. Manufacturers, clinics and distributors like Liveyon “have a vested interest in keeping this going and are not so easily scared off.”

Kosolcharoen said the recent infections will not impede Liveyon’s success. He and Gaveck said the company recently set up its own laboratory, so it won’t have to rely on outside manufacturers. They are already aggressively marketing vials being produced by their new lab under the label “Liveyon Pure” and have increased their asking price by $200 a vial.

Meanwhile, the company is planning a rapid expansion. Liveyon hired 10 new employees, Kosolcharoen said, and plans to hold 36 seminars in the coming year to teach chiropractors and pain doctors about its treatments. The company aims to be selling in 13 countries by year’s end.

Liveyon also recently opened its own clinic in Cancun, Mexico, Kosolcharoen said, so that American patients can receive its treatments unfettered by FDA regulations.

So far, he said, the clinic has injected hundreds of patients, including people with spinal cord injuries, people with Parkinson’s disease and many children with autism.

“The future for Liveyon,” Kosolcharoen said, “is the brightest it’s ever been,”

Alice Crites contributed to this report.