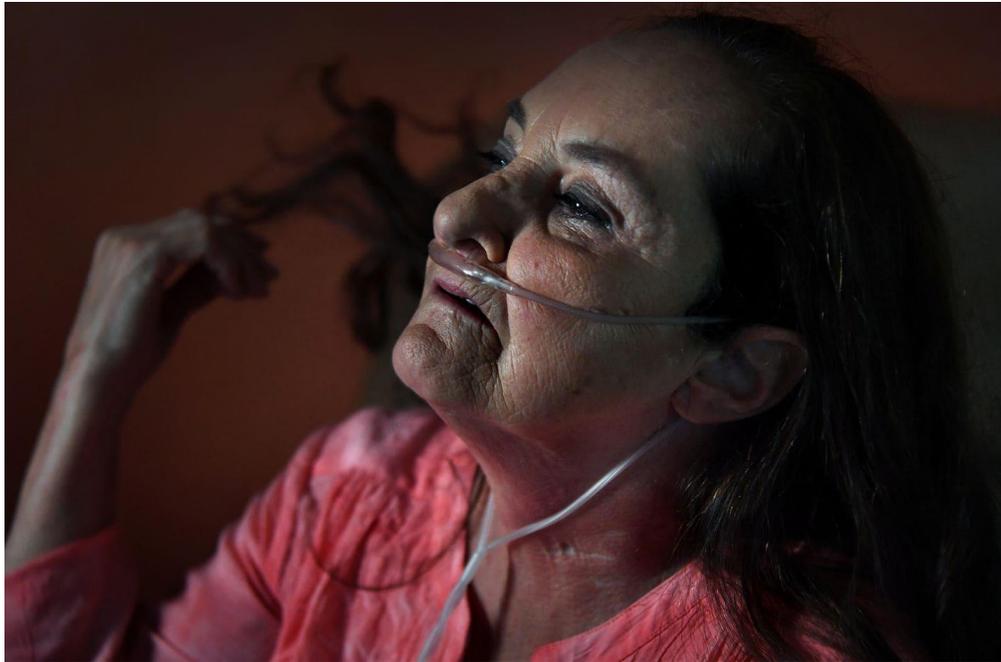


Clinic pitches unproven treatments to desperate patients, with tips on raising the cash



Tammy Rivero said a Lung Health Institute employee persuaded her to borrow against her home for her \$7,000 stem cell treatment. (Michael S. Williamson/The Washington Post)

By [William Wan](#) and [Laurie McGinley](#)

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By the time he called the Lung Health Institute, Ed Garbutt was desperate. The Dallas computer parts salesman could barely walk the length of his house without gasping for breath. Unable to work, Garbutt, 64, was going broke paying for trips to the emergency room.

Lung Health Institute staffers were reassuring, Garbutt recalled, telling him that more than 80 percent of their patients with lung disease said they found relief through their stem cell treatments — which would cost him \$5,500, thanks to a summer sale. He said they told him that if he didn't have the money, he could get it other ways, like fundraising on GoFundMe.

So Garbutt raised \$1,500 in donations, tapped the last of his savings and charged the rest on his credit card. “I spent every dime I had,” he said, “hoping it would make a difference.”

Over the past decade, [hundreds of clinics](#) have sprouted across the United States selling stem cell therapies for incurable conditions like Garbutt’s lung disease, Parkinson’s disease and [macular degeneration](#). But often, patients say, the only thing affected is their finances.

Former patients of the Tampa-based Lung Health Institute said they were encouraged to take out bank loans or borrow money from family members. Some withdrew from their retirement accounts and took up church offerings. Others borrowed against their homes.

“What they’re doing is taking a predatory approach to people with progressive, fatal diseases,” said Gregory Cosgrove, chief medical officer for the Pulmonary Fibrosis Foundation. His foundation issued [a warning](#) this year against such stem cell therapies, noting that desperate patients continue to “succumb to an onslaught of marketing and branding.”

Even in a booming industry long denounced by medical experts, the Lung Health Institute has been singled out for its aggressive marketing and unproven claims. In 2015, for example, pulmonologists at Johns Hopkins wrote to the Food and Drug Administration urging it to take action against the Lung Health Institute. “We would ask that the FDA take necessary action to prevent the further advertising of this unproven treatment,” their letter read.

Since 2013, the company has conducted a multimillion-dollar campaign to lure patients with targeted online ads, hyped claims and high-pressure seminars, according to internal documents and former staff.

In interviews, former employees responsible for fielding patients’ calls said they were given monthly sales quotas. Former company doctors and nurses described working as “closers,” using their medical credentials to persuade wavering patients to put money down.

In two lengthy interviews, the company’s chief operating officer, Ann Sells Miller, defended the company, saying its treatments have helped many patients who have no other options. Miller and other executives dismissed complaints about their marketing strategies and treatments, saying that their critics are often people who don’t understand their stem cell procedures or lawyers looking to make money by filing lawsuits against them.

“Our patients come to us. We don’t call them. They come to us because their current standard of care is not working for them,” Miller said. She said the company’s marketing is intended to “educate people with the disease.”

The reason the company offers financial tips, Miller said, “is to make sure that patients understand what their treatment options are and to discuss the associated finances with it.”

The FDA has not approved most stem cell treatments and has said it considers many of them illegal. Miller and other officials at Lung Health Institute said they believe their treatment doesn’t require FDA approval. Nevertheless, the company now plans to apply to the FDA for approval, said Marc Scheineson, the company’s lawyer, “even though this is a long, expensive and arduous process ... This action distinguishes LHI from the bulk of the other providers of stem cell and related blood-based therapies.”

This article is based on documents obtained by The Washington Post, including internal memos, telephone scripts, emails and financial records. The Post also interviewed 14 former employees of the Lung Health Institute, including marketers, doctors, nurses and patient coordinators, whose job is to talk to potential customers. All were approached separately and spoke on the condition of anonymity; most said they were required to sign nondisclosure agreements and feared that the company would sue them for speaking out.

Their assertions were corroborated by The Post using documents and accounts from patients such as Garbutt and in some cases confirmed by the company itself.

A year and a half after receiving treatments at the Lung Health Institute, Garbutt’s health has only gotten worse. He can no longer shop or cook. He uses his monthly Social Security disability check to pay someone to make his meals.

Meanwhile, he is [still struggling](#) to pay off a \$3,000 credit card bill from the procedure.

“I maxed out my credit card to pay for the stem cells. I don’t know how I’ll pay it back,” he said. “I’m just trying to take it one day at a time.”



A typical treatment room at the Lung Health Institute in Tampa. (Michael S. Williamson/The Washington Post)

Origins

The Lung Health Institute — which operates clinics in Florida, Arizona, Texas, Tennessee and Pennsylvania and has treated, by [its own count](#), more than 5,800 people — began in many ways as the offspring of another company: the Laser Spine Institute.

Laser Spine was co-founded in 2005 by James St. Louis, an osteopath and orthopedic surgeon who offered a minimally invasive alternative to traditional neck and back surgery. As Laser Spine grew into a nationwide chain, with ubiquitous cable TV ads, it claimed to have a 98 percent patient satisfaction rate.

But the company was also the subject of [dozens of malpractice](#) lawsuits. In 2011, nine surgeons interviewed by Bloomberg Businessweek said many surgeries by Laser Spine were unnecessary or inappropriate. In response, Laser Spine officials at the time cited in-house surveys showing patient satisfaction. In 2014, a competitor sued Laser Spine, accusing it of using [illegal marketing practices](#) such as offering free airfare and hotels to persuade Medicare patients to sign up for procedures. Laser Spine officials denied the allegations in court, and the case has not yet been resolved.

This year, Laser Spine [abruptly](#) shuttered its business after banks froze its assets [amid multiple lawsuits](#).

Laser Spine's chief operating officer for some years was St. Louis's son, Jimmy St. Louis III. In 2011, the son left his father's company and founded what would become the Lung Health Institute, using capital raised from some of his father's investors, according to an early email to investors. Jimmy St. Louis also enlisted his dad as the Lung Health Institute's chief medical officer.

In an interview last year at its Tampa headquarters, the younger St. Louis said he started the Lung Health Institute not to make money, but because he lost grandparents to lung disease.

“There hasn’t been any movement in this space really in 30 years,” he said. “It’s an area of medicine that’s been largely neglected.”

A former employee — who worked at Laser Spine and followed St. Louis to the Lung Health Institute before leaving the company for another job — said, “He took the Laser Spine business and marketing and made an exact carbon copy. The only thing we did different was swap out the product — stem cells instead of spine surgery.”



The porch at Rivero’s house with a supply of oxygen tanks. (Michael S. Williamson/The Washington Post)

Marketing hope

The Lung Health Institute developed a marketing profile of its typical customer: elderly patients suffering from incurable lung diseases who need supplemental oxygen and are not able to leave home easily — and therefore spend hours online, said former employees.

Early on, the company’s marketers bought ads on search engines such as Google and Bing so its website would appear prominently whenever anyone searched for “cure” and “treatment” for illnesses such as chronic obstructive pulmonary disease, said three former marketing team members.

They bought ads on solitaire and blackjack sites popular among older patients, the former marketers said, and if a city was hit by a snowstorm, they would quickly buy more search ads in that location, knowing patients on oxygen tanks would be

homebound. And they targeted cities with direct flights to their clinic locations, knowing that patients on oxygen often struggled to travel with their equipment, former marketers said.

Patients who attended [seminars](#) held by the company said they were offered discounts if they put down a deposit on the spot.

In a statement, the company said its marketing strategy “focuses on patient education and advocacy . . . through several platforms, such as our website, online seminars.”

The ads generated hundreds of “leads” each month as patients called, emailed or clicked for more information, internal budget documents show. Those in charge of converting the leads into sales were called patient coordinators.

Former coordinators said they were given a minimum quota of 10 sales each month. And as recently as last year, coordinators got paid only if they made a sale, working purely on commission, according to Miller, the company’s COO. In recent months, the company has returned to the practice of giving coordinators a base salary in addition to their commission, Miller said. She disputed former coordinators’ assertions that they were given firm quotas, saying that, “like any healthy organization, we have to have projections.”

According to a 2013 marketing script, if patients asked whether the treatments were approved by the Food and Drug Administration, coordinators were taught to respond: Although “the treatments are not FDA approved . . . all of the drugs and equipment we use are FDA-approved.”

If patients asked why insurance wouldn’t cover the procedure, the script told coordinators to answer: “I am sure that one day it will, however, right now we want to provide treatment to those who want it.”

If patients asked whether the treatments would work on them, coordinators were taught to point to a handful of [patient testimonials](#).

Several patient coordinators said they were troubled by these calls. “Some people wouldn’t have that much money, and you’re doing everything you can to convince them to use it on something you’re not sure even works,” said a woman who worked at the Lung Health Institute for two years and left for another company after she said she became uncomfortable with the job. “People would call afterward and say, ‘I trusted you, but I don’t feel any better.’ Some would call just to yell: ‘I spent all this money, and you guys said this and that. You sold me fake medicine.’ Often I’d need a drink by the end of the day.”



Rivero talks to a friend on her phone who is helping her manage a fundraising account. She and other former patients are suing the Lung Health Institute, accusing it of deceptive business practices. (Michael S. Williamson/The Washington Post)

Encouraging debt

When patients couldn't afford the procedure, the company frequently urged them to find other sources of money, according to its own website.

A November 2017 company [blog post](#) explained that some patients “have turned to relatives for a loan or a gift,” while others have held “bake sales, garage/yard sales, walkathons, potlucks and raffles.” The blog also suggested obtaining “a fixed-term loan with monthly payments.”

Crowdfunding was a frequent suggestion. A 2018 [study](#) found that more than 13,000 people had made donations for stem cell treatment campaigns listed on two crowdfunding platforms as of December 2017.

Almost a third of all of those campaigns were related to the Lung Health Institute. “No one goes as far as they do in actively and explicitly pushing their patients to crowdfund and fundraise,” said Leigh Turner, the study's co-author and a bioethicist at the University of Minnesota, who is serving as a pro bono expert witness in a lawsuit against the company.

Lung Health Institute COO Miller said, “We don't track information as far as how many patients use fundraising efforts or financing efforts in order to come here.”

GoFundMe has policies that [prohibit fundraising](#) for therapies considered illegal by a regulatory body. But last year, GoFundMe's company blog included an upbeat post touting stem cell treatments offered by for-profit clinics.

“Patients can find a number of clinics that promise to relieve pain or help regain declining motor skills, all with a single stem cell injection,” the blog said. “Hundreds of conditions fall under this umbrella, with promises of curing blood disorders like sickle cell anemia, to autoimmune diseases like multiple sclerosis.”

After The Post asked about the blog post, GoFundMe took it down. The company said it also launched an audit of content on its website. But months later, the site continues to host thousands of campaigns raising money for stem cell treatments, including [more than a hundred](#) that mention the Lung Health Institute [by name](#).

Former patient Tammy Rivero, who is 62 and lives on an \$800 monthly disability check, said in court testimony that a patient coordinator persuaded her to borrow against her home at the end of a dirt road in Hildebran, N.C.

Since receiving the treatment in 2015, however, Rivero’s illness has gotten much worse. Doctors say she now [needs a double lung transplant](#) to survive, which would be covered by Medicare and Medicaid. But Rivero doesn’t have the money to rent an apartment near the transplant center for months of mandatory pre- and post-surgery rehabilitation. That would cost about \$7,000, Rivero said — the same amount she paid the Lung Health Institute.

“I’m going to pass away for \$7,000,” she said.

Rivero and 34 other former patients have [filed a lawsuit](#) accusing the Lung Health Institute of deceptive marketing practices. The patients are seeking class-action status, said their [lawyer](#), Ben Vinson. Among them is Tom Johnston, a Michigan man who recalls the excitement of his wife, Judy, upon seeing one of the company’s online ads.

Johnston, a retired pipe welder, said that clinic staff told his wife she would no longer need her oxygen tank after the procedure.

His wife died a year later, Johnston said, still haunted by the cost. “She kept apologizing to me for spending our money. I said, ‘We spent it together.’ ”

In court filings, the Lung Health Institute has denied the allegations of deceptive and unfair practices. In a statement the company pointed out that all patients sign an informed-consent form, which warns that the treatment might not improve their conditions.

“As with any medicine, there are no guarantees,” the company said.

'Borderline propaganda'

The company’s [descriptions](#) of its procedure have [evolved](#) over the years, but [the basic premise](#) has remained the same: extract blood from patients, spin it in a centrifuge to isolate “stem cells” or “platelet-rich plasma platelet-concentrate,” then reintroduce

those using an IV into the patient's bloodstream, where they "naturally" find their way to damaged parts of the lung and heal them.

Lung disease experts say there is no evidence such treatments work.

National medical groups including the [American Lung Association](#) and [COPD Foundation](#) have warned against such stem cell treatments.

Miller said the Lung Health Institute has never been contacted by the FDA. She noted that its clinics have never had to report a serious adverse event. And she said that out of the 5,800 patients the company has treated in total, very few have filed lawsuits.

In 2016, the company self-published a white paper on its website that said almost 85 percent of patients say they experienced improvements in "quality of life." Since then, the company has presented similar data in academic conference presentations and articles.

But unlike many medical studies, the Lung Health Institute's do not include a control group of patients who received a placebo. And all of its data, except for a one-page conference presentation, relied on follow-up phone surveys with patients rather than physical measurements, such as pulmonary function tests. The company's own researchers acknowledged the limitations of the data, concluding in one report: "There is a very real possibility that response may simply be a placebo effect."

A stem cell researcher, Arnold Caplan — hired by the Lung Health Institute to testify in court as its expert — said he found the data convincing.

"The truth is, I don't exactly know how [the treatments] work," said [Caplan](#), a biologist at Case Western Reserve University. But after seeing the phone surveys conducted by the company, he said, "The important point for me is, there are clearly statistically relevant and positive outcomes from these treatments."

But three leading pulmonologists with no connection to the company or to any legal action said they found the data unconvincing and flawed, given its lack of comparative groups and placebo controls and other methodological problems.

"It's borderline propaganda to suggest this information is evidence of efficacy," said Cosgrove, a pulmonologist at National Jewish Health in Denver, which runs one of the world's largest interstitial lung disease programs.

The company's claims are "a nothing, a come on," said Michael Matthay, a pulmonologist and stem cell researcher at the University of California at San Francisco. "Those statements are not supported by any medical data or medical studies."

"There has never been a randomized trial" for this treatment's effect on lung diseases, said Marilyn K. Glassberg Csete, a leading expert in lung diseases and stem cell therapies at the University of Miami. "There's no data."

Some patients said they felt better after the cellular procedures.

During a reporter's visit to the Lung Health Institute's Tampa offices, company executives arranged interviews with two patients — Larry Wood, 71, and Marie Hilton, 74 — who said the treatment improved their breathing.

Before the infusion, Hilton said, "I couldn't go grocery shopping. . . . I couldn't clean my house or vacuum without oxygen." She said she was able to stop using an oxygen tank after her \$12,000 treatment last year.

Wood said he paid \$6,500 for the procedure in 2014 after being offered a discount at a company seminar. "I found within about three weeks I had improved lung function," he said. But the improvements only lasted about 10 months, he said, and he now pays \$1,500 every three to four months for booster treatments.

Researchers said anecdotes like that are what make clinical trials so important. "You want to rule out things like placebo effects," Cosgrove said. "If you as a patient paid \$10,000 for treatment, you're going to want it to work. You may even start taking care of yourself better to try to make it work. There are all sorts of factors that you need to control for."



Jack Coleman, senior medical director at the Lung Health Institute, enters a patient waiting area. On the wall are featured clients who have said they are happy with the treatments they've received at the clinic. (Michael S. Williamson/The Washington Post)

Adapting to new rules

The FDA has made clear that selling unapproved stem cell therapies is illegal and [won a recent lawsuit](#) barring a [prominent clinic](#) from offering a treatment based on fat cells.

After the FDA started cracking down on fat-based stem cell treatments, the Lung Health Institute stopped selling them and focused on selling its blood-based treatments.

Company executives said they made the change not to avoid regulation, but because they felt the blood-based treatment was less invasive.

In the summer of 2017, Google suddenly stopped permitting the Lung Health Institute to buy search engine ads, a crucial source of sales leads, according to five former employees.

When asked by The Post about its actions related to Lung Health Institute's ads, Google declined to comment. In a statement, the company said: "If we find ads that violate our policies, we take immediate action, which can include taking down violating ads or suspending an account altogether."

Lung Health Institute officials denied they did anything wrong and said that "Google began to update its internal policy and rules for advertising related to regenerative medicine." Company officials said, "[We] hold ourselves to the highest standards and will continue to evolve to stay within guidelines."

The result was a sharp drop in sales leads. "They told us to start calling back every one of our old leads, to hand out discounts and offer booster treatments to past patients," one former coordinator said. "We didn't know if we were going to survive."

Around the same time, the company changed its name. For years, it had been called the Lung Institute, but in 2017, the company inserted the word "Health" and moved to a new main website — thelunghealthinstitute.com. Former employees said the rebranding solved some of the search engine and ad problems. Company officials said it was done to reflect "expanded services."

In September this year, Google [announced](#) a policy barring ads for "unproven or experimental medical techniques such as most stem cell therapy." Google [said it](#) was taking the step after seeing "a rise in bad actors attempting to take advantage of individuals by offering untested, deceptive treatments."

Amid [growing scrutiny and regulation](#) of stem cell clinics, the Lung Health Institute made another change last year, removing all mention of "stem cells" from its website. The company now calls its procedure "[cellular therapy](#)" and "platelet-rich plasma platelet-concentrate," or PRP-PC. Company officials said that their procedure hasn't changed, and that they still believe their treatment contains stem cells. They said their language change reflects how "regenerative medicine has evolved."

The move, however, came after the FDA issued tougher regulations making clear most stem cell therapies being sold are illegal and promising to crack down on bad actors.

Attorney Scheineson, a former top FDA official who now represents the Lung Health Institute, said in an interview that because the company's sole treatment now is PRP-

PC, it isn't subject to stem cell regulations and instead is governed by rules for blood banks.

FDA officials declined to talk about Lung Institute, but have said in recent months that their agency [has struggled](#) to regulate an industry that is rapidly expanding and morphing.

FDA officials said in general that PRP isn't covered by the same regulations as stem cells. But they also said that using a device such as a centrifuge to manufacture PRP for an unproven medical use — such as treating COPD — may still require review by the FDA. The FDA has never approved the use of a centrifuge for COPD, they said.

In addition, generally if a product is described as something that can “treat” a disease, then it is subject to much tougher regulation, according to FDA experts.

“When you start saying it will improve COPD, that's an intended use that, from FDA's perspective, would require a higher degree of regulation,” said Mark Schwartz, an attorney who served as deputy director in FDA's Office of Compliance and Biologics Quality between 2012 and 2015.

The company said it plans to begin the application process with the FDA for conducting a clinical trial and getting FDA approval needed for its stem cell treatment. At the same time, the company said, it will keep selling its treatment even as it makes its FDA application.

Meanwhile, Lung Health Institute executives have made plans to expand. Late last year, the Lung Health Institute was acquired by Medovex, a medical technology products company run by former Laser Spine executive William “Bill” Horne. In April, the company [raised \\$7.2 million](#) in new capital, and in recent weeks it [raised another](#) \$6 million. Horne has said he plans to open more Lung Health Institute clinics.

In July, Medovex announced it was changing its name to “H-CYTE” and had entered into a business partnership with a start-up called Rion LLC — run by two researchers from the prestigious Mayo Clinic — to develop a new “proprietary cellular platform” to treat COPD.

[In news releases](#), the company [said](#) the two researchers — Atta Behfar and Andre Terzic, who research regenerative medicine at Mayo — had joined its board of directors.

When reached by phone, Behfar said he was unaware that patients have accused the Lung Health Institute of deceptive marketing and sued the company he was partnering with. “To be perfectly frank, I don't have much awareness in regards to what Lung Health Institute has done,” he said.

Behfar said the goal of the partnership is to test a new cellular treatment for COPD — different from the one the Lung Health Institute currently sells — using FDA-sanctioned

clinical trials. The new treatment will not be sold to patients until it's proved effective by rigorous science, Behfar said.

Contrary to the news releases, however, the two Mayo researchers never agreed to serve on the board of directors, according to Behfar and Rion LLC's chief administrative officer, Mike Pfenning. "We've asked them to issue a retraction to correct that," Pfenning said. "They just agreed to serve in an unpaid advisory role."

In an interview this fall, Miller — chief operating officer for H-CYTE and the Lung Health Institute — insisted that Terzic and Behfar were indeed members of her company's [board of directors](#). But in a [news release](#) this month, the company said the two doctors had resigned from the board of directors and instead become scientific advisers.

Miller said that the company hopes to sell the new treatment it is developing initially to COPD patients. But they plan to expand that business model and sell it eventually to many more patients suffering from a whole range intractable diseases.



Rivero has to carry oxygen tank tubing, connected to a stationary unit, to get around her house. (Michael S. Williamson/The Washington Post)

Alice Crites contributed to this report.