Two Families Fought Hospitals to Allow Alternative COVID Treatments, Now Their Loved Ones Have Died

By Nanette Holt

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Figure 1(L–R) Linda and Stephen Judge with Stephen's daughter, Caitlin, and her husband, Jeff, at their 2016 wedding. (Courtesy of Caitlin Judge Treister)

Two men on ventilators—one in Florida and one in Arizona—died within 24 hours of each other, even as their families were still fighting with hospitals for the chance to try alternative treatments.

After all other treatments offered by the hospitals failed, both families had begged to try ivermectin and other alternative treatments for <u>COVID-19</u>, as outlined in a <u>protocol</u> by the Front Line COVID-19 Critical Care Alliance.

Daniel Pisano, 70, had been fighting for his life in <u>Mayo Clinic</u> Florida since Dec. 11. His battle ended late Jan. 19.

Stephen Judge, 69, had struggled to overcome his illness in Banner Ironwood Medical Center in Queen Creek, Arizona, since Nov. 27. He died on Jan. 20.

Pisano had been on a ventilator for 36 days; Judge had been on a ventilator for 44 days.

Both hospitals repeatedly refused the families' requests for alternative treatments, and have not responded to repeated requests for comment by The Epoch Times.

Mayo Clinic vigorously fought the Pisano family's efforts in court and won, then won again when the family appealed the first judge's decision. The family had filed a lawsuit requesting an emergency injunction ordering Mayo Clinic to allow treatment prescribed by an outside doctor they trusted.

In court filings the company had asked to have sealed, attorneys and a doctor for the hospital said it wasn't clear what would happen to Daniel Pisano if the treatment requested by the family was used. The family had offered to sign a waiver releasing the hospital from all liability related to Pisano's treatment.

Daniel and Claudia Pisano. (Courtesy of Chris Pisano)

The Judge family consulted with an attorney, but didn't file a lawsuit because Arizona does not have a provision for expedited emergency hearing, and the family felt Stephen Judge didn't have time to wait, said his daughter, Caitlin Judge Treister. Even on the last day of his life, Treister was fighting to try a new drug for serious COVID-19 cases like her father's. The drug, ZYESAMI, now is in Phase 3 <u>clinical</u> <u>trials</u> and is more widely available under the federal <u>Right to Try Act</u>, the company announced Jan. 18.

The 2018 legislation "is another way for patients who have been diagnosed with life-threatening diseases or conditions who have tried all approved treatment options and who are unable to participate in a clinical trial to access certain unapproved treatments," according to the U.S. Food and Drug Administration (FDA) informational page about the law.

But Banner Ironwood refused the family's requests to initiate the process to obtain the drug for Stephen Judge.

Banner Ironwood Medical Center in Queen Creek, Arizona. (Bannerhealth.com) Under Right to Try, NRx Pharmaceuticals, the company that makes ZYESAMI, now will provide the drug for just the cost to overnight it to the patient. Requests can be made through the <u>form</u> on the company's website. The only catch is that the request must be made by the patient's doctor, said NRx spokesman Jack Hirschfield.

"A family member or friend cannot make the official request to a Right to Try Program," he said.

In case the company is flooded with requests," we're ready for that," Hirschfield said. "The goal is to save lives."

Upon their initial request to try the drug, the family of Stephen Judge was first told by a hospital representative that Banner Ironwood Medical Center "does not participate in <u>clinical trials</u>," his daughter said. But using a drug under Right to Try is an option for patients who don't qualify for clinical trials.

Treister submitted an urgent request in writing, formally asking for the hospital's cooperation in initiating the Right to Try process.

"We are immediately requesting this treatment for my father and expect an expedited response as my father's death without further treatment is imminent," she wrote.

Hours later, the hospital responded with a letter stating, "We are unable to meet your request."

The letter, signed by the hospital's chief medical officer, George Figueroa, M.D., described Stephen Judge's condition as "extremely critical" and stated, "Avidptadil (sic) is not FDA approved and there is no emergency use authorization for Aviptadil in a patient with this clinical condition at this time."

That seemed to contradict NRx 's Jan. 18 announcement that ZYESAMI now could be used by any COVID-19 patient with respiratory failure for whom all other treatments have failed.

The drug's clinical trials, being conducted by the National Institutes of Health (NIH), are testing it as an intravenous treatment for "Critical COVID-19 with Respiratory Failure" and an inhaled treatment for "Severe COVID-19," according to a January <u>corporate document</u>. The Radnor, Pennsylvania-based drugmaker's report gives a comprehensive description of how the new drug works, and gives details on the development timeline.

Before her father died, Treister told The Epoch Times she was "questioning whether we did everything we could. It's hard navigating a system that's stacked against us."

"This drug sounds like something that could really benefit him, if it's not too late. I wish we would have known about it earlier, but that won't stop me from fighting until the bitter end. Only my dad and God decide when it's his time. Not this hospital."

About five hours later, she told The Epoch Times, "My dad has officially gone to Heaven. Heaven just got a lot more fun."

The drug she'd begged to try already has been used to cure critically ill COVID-19 patients.

In December 2020, a 47-year-old Florida physician told his story of recovery using the new drug to WSVN-TV Channel 7 News.

Early in the pandemic, Jacobo Elgozy, D.O., was caring for COVID-19 patients at Mount Sinai Medical Center in Miami Beach, he told the news station. But then, he became infected with the virus, developing one of the worst cases his doctor had seen, and eventually landing him on the schedule for a double-lung transplant, the news station reported.

Jacobo was granted access to the drug through a clinical trial on the drug, NRx confirmed.

"In a matter of two weeks plus, I recovered like this," Elgozy was reported as saying as he snapped his fingers to indicate the speed of his recovery. "My lungs started responding like there was no tomorrow. Everybody thinks it was related to the RLF-100 [now known as ZYESAMI] that was given to me, that protected my lungs from any injury or scarring."

He no longer needed a lung transplant and has gone back to work as a doctor, NRx founder, chairman, and CEO Jonathan C. Javitt, MD, MPH told The Epoch Times.

For now, ideally, a patient would take ZYESAMI as soon as remdesivir and other therapies approved for use against COVID-19 proved ineffective, Hirschfield said.

The company is working hard to gain approval for emergency use from the U.S. Food and Drug Administration (FDA) as quickly as possible that would allow the drug to be used sooner, he said.

Pisano did not improve after the use of remdesivir, their family said. Judge refused remdesivir.

A vial of the drug remdesivir held by a researcher at a facility in Hamburg, Germany, on April 8, 2020. (Ulrich Perey/Pool/AFP via Getty Images) Developed to help patients with advanced COVID-19, ZYESAMI is the brand name of aviptadil, a synthetic version of a natural chemical made in the human body, called human vasoactive intestinal polypeptide.

"We didn't invent it—nature invented it," Javitt said. "With 28 amino acids, you can make it in a factory."

What results from the manufacturing process is a bio-identical chemical, Javitt said, meaning it's exactly the same as what's made naturally in the human body.

The company has shared a <u>document explaining the technicalities</u> of how the drug works on its website.

Javitt shared a simplified explanation with The Epoch Times:

"Air goes into your lungs, and that's how oxygen gets into your bloodstream.

"People hear about COVID respiratory failure or respiratory distress, and they think it has something to do with not being able to breathe. And that's just not true.

"What it means is that the lungs have started to malfunction, such that they're no longer able to transmit the oxygen from the air to the blood. That's how COVID kills people. "So the way the lungs work—it's really just a collection of hundreds of thousands of air sacs called alveoli, where you have air on the inside and blood vessels on the outside. That's where the oxygen is exchanged.

"The alveoli stay open, because they're lined with a fluid called surfactant. It's kind of like soap in a soap bubble. Without the soap, you've just got a drop of water, and without the surfactant in the lungs, the lungs collapse.

"There's one cell in the lung called the Type II cell that makes all the surfactant, and that's exactly the cell that's attacked by the COVID virus. The virus targets that cell, because" of the chemical makeup of its surface, Javitt explained.

"The virus enters that cell. It knocks out the surfactant production, and it also liberates some very inflammatory toxic molecules called cytokines. In fact, the reason COVID kills people and doesn't kill other air-breathing animals is because the virus specifically binds" to those cells in human lungs, but not in the lungs of animals, he said.

His company's drug binds to that important cell in the human lung "and when it when it enters the cell, it increases surfactant production, it prevents cytokine production, and it actually keeps the virus from replicating," Javitt said.

The Epoch Times has filed a Freedom of Information Act (FOIA) request with the FDA for details about when drugs in clinical trial for the treatment of COVID-19—including ivermectin and ZYESAMI—might be approved for emergency use. The FDA has not indicated when that information will be provided.

The FDA maintains an <u>informational page</u> about why not to use ivermectin as a treatment for COVID-19, citing "multiple reports" of injuries from people self-medicating with a formulation of the drug used in animal care. The page says there are ongoing <u>clinical trials</u> testing the safety and efficacy of the human formulation of ivermectin in the treatment of COVID-19.

A spokeswoman for the FDA told The Epoch Times that a FOIA request would need to be filed in order to receive information about the injuries mentioned on the agency's page. That request also has been filed.

After fighting so hard to obtain alternative treatments for Daniel Pisano, attorneys representing his family said they were stunned by his death.

"After nearly a week of improvement to the point he was being weaned off life support, Dan Pisano experienced a sudden, devastating setback and all hope for his recovery blew away," wrote Jeff Childers, of Childers Law, in his <u>coffeeandcovid.com</u> blog on Jan. 20.

"My reaction on hearing the news was, mostly, a white-hot righteous anger. These hospitals really have no idea at all how their bad short-term decisions WILL have long-term consequences. There are systemic problems in our corporate hospital system that must be addressed."

He later told The Epoch Times, "We are analyzing the deficiencies in the law that prevented us from saving Dan, and we will be pursuing a legislative strategy, including activists, thought-leaders, influencers, and lawmakers from around the state.

The Mayo Clinic logo at Mayo Clinic Square, Minneapolis, Minn., on June 24, 2018. (Tony Webster via Wikimedia Commons) "The problem is he was trapped [in Mayo Clinic Florida]. They wouldn't let him leave. They wouldn't let them bring in a doctor to treat him, the only doctor who expressed hope he could be saved. Madness."

The family's other attorney, Nick Whitney, of the AndersonGlenn law firm, said, "Mr. Pisano and his family never suspected that they would lose all control over medical decisions when they went to the Mayo Clinic. No one should find themselves facing that brutal reality." He continued, "If the courts got it right here, the law is sadly undeveloped and woefully behind. If there is a bright side to this tragedy, it is that many more people now know what they are up against."

Chris Pisano said he doesn't regret sharing the details of the battle surrounding his father's final days.

"I take great comfort in knowing people all around this world have read my father's story and have chosen an alternate path in care that has saved their lives," he told The Epoch Times, just hours after his father's death.

"As of today I know of three [patients'] stories that will continue because my father's has ended. What a great legacy this is."

Correction: a previous version of this article incorrectly described the treatment administered to Judge and the date on which he was admitted to the hospital. The Epoch Times regrets the errors.

Nanette Holt

Follow

Nanette covers a wide range of issues, mostly in Georgia and her home state of Florida. She started as a journalist in a competitive, daily-newspaper market, and later launched a community newspaper in a geographic area ignored by other media. She spent many years writing and editing for a variety of national and international magazines, and has been hired to coach best-selling authors for book publishers. When she's not chasing news, Nanette enjoys cattle ranch life with her husband, three children, and far too many horses, goats, cats, and dogs.