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Léo Azambuja - The Garden Island | 8 comments

• *Editor's note. This is part one in a two-part series*

ANAHOLA — Born with good looks and an athletic disposition, Tony Viscosi had always been "part of the gang."

Active with friends, the Southern Californian first moved to Kauai when he was 18 where he surfed and played sports.

The island was the perfect spot for the recreationalist.

But today he no longer surfs, he no longer play sports and has a diffucult time enjoying the island's outdoor wonders.

It's because, according to the 45-year-old Anahola resident, a clinical trial gone-wrong nearly six years ago changed everything. Now Viscosi is even considering assisted suicide.

He said a clinical trial in 2007 for a then-experimental psoriasis drug went terribly wrong almost immediately after he dropped out of the program early due to a heart complication.

"All it does, it takes you on a spiral downhill," Viscosi said of Stelara, the drug since approved by the Federal Drug Administration. "It gives you about five good years until you're finished. Unless they come up with something between now and then, you're going to end up like me, on a bed waiting to die."

On Sept. 25, 2009, the FDA approved ustekinumab, marketed as Stelara, to treat plaque psoriasis. Stelara is produced by Janssen Biotech (formerly Centocor Ortho Biotech), a subsidiary of Johnson & Johnson. To date, it has been approved in 74 countries to treat plaque psoriasis.

But a year before the FDA approved Stelara — and just less than one year after he took it — Viscosi was laying on a hospital bed, with 90 percent of his

body covered in sores. Towels wet with sterile saline solution wrapped around Viscosi's nearly skinless body kept him from dying. Even now, nearly six years after dropping out of the clinical trial, Viscosi's psoriasis flares up regularly. Walking or sitting is extremely difficult — and impossible at times — due to the sores on his feet and buttocks. He spends most of his time laying on his bed, in pain and bleeding.

Psoriasis is a noncontagious auto-immune condition caused by molecular mimicry. Mild cases look like skin rashes, or peeling sunburns. But in Viscosi's case, it has disfigured his body.

He said he has been kicked out of several stores, from a restaurant, and has been placed on an isolated seat on an airplane. In August, Pat Kittler, a friend of Viscosi helping him through the ordeal, and Viscosi paid to move into a Kalaheo home, but when the landlord saw Viscosi he called the deal off. Viscosi called it "a loss of dignity."

"I had never in my life been discriminated against until I had this, and I was blown away," Viscosi said. "All of a sudden, I was different."

And he said he is sure that the drug is responsible.

He said more than 20 doctors told him it was Stelara that caused his psoriasis to come back five-fold, nearly killing him.

Yet, his plea for help has been ignored by just about everyone, from researchers to drugmakers to lawmakers, he said.

And without help, Viscosi said his body will give out before his mind does. It's pushed him to contact Oregon state to ask about death with dignity — assisted suicide — which is legal there.

"I don't want to be laying in some room just waiting (to die)," he said.

From diagnosis to experiment

At 32 years old, Viscosi was diagnosed with psoriatic arthritis, and two years later he developed plaque psoriasis.

He said he likely inherited plaque psoriasis from his father, who was diagnosed at 35 years old and has lived with it for 30 years. His father's case stabilized at 10 to 15 percent body coverage, the same degree of Viscosi's psoriasis prior to the clinical trial. But Viscosi's father never developed psoriatic arthritis.

Though there is no cure for psoriasis, there are treatments available, including a controlled diet, nutritional supplements, oils and drugs.

In the first three years after being diagnosed, Viscosi took an immunosupressant and chemotherapy drugs, but they caused more side-effects than results, so he switched to less aggressive treatments. Viscosi said his psoriasis was mild, but the arthritis — and the drugs he took for it — caused him to go onto disability in 2001.

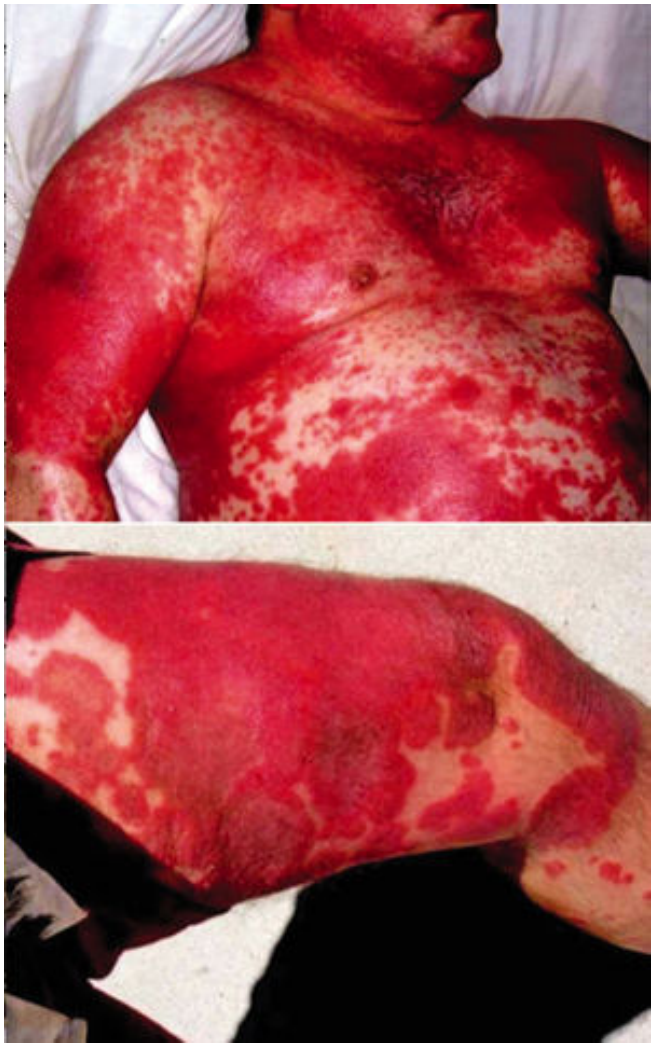
In early 2007, Viscosi entered into a five-year clinical trial of Stelara for plaque psoriasis, hoping it would also address the arthritis, since both conditions are linked by a high amount of a certain blood factor.

The trial was conducted in California by Therapeutics Clinical Research (TCR). In a matter of a few months, Stelara cleared Viscosi's skin, but didn't reduce his psoriatic arthritis.

Then in late 2007, Viscosi dropped out of the trial under his doctor's recommendation, because an electrocardiogram detected something wrong with Viscosi's heart.

In February 2008, tiny red spots, guttate psoriasis, appeared all over Viscosi's body. By March 2008, the spots had grown much larger.

By May 1, 2008, Viscosi said he had called TCR several times and had sent letters with pictures showing his condition, but received no replies.



On May 15, 2008, he was admitted to a hospital for the first time. He had developed infections all over his body, caused by cracked skin, which bled constantly.

By August 2008, Viscosi was clinging to life, with about 90 percent of his body covered in sores and with nearly no skin left. He had to lay in bed for 20 hours a day, covered in towels wet with sterile saline to keep his fever down and avoid shock and kidney failure due to dehydration.

Around that time, three TCR doctors — research coordinator Barbara Doyle, staff physician Sandra Adsit and the company's owner — examined Viscosi and told him his condition had nothing to do with Stelara, though they never took skin tissue or blood samples, he said.

The Garden Island contacted TCR over the phone and sent them questions via email, which were never answered despite several requests.

Stelara FDA approved

Since its first approval, Stelara went through several label revisions by the FDA.

Recently, it was approved to treat an additional condition, arthritis.

On Sept. 20 the FDA approved the drug to treat psoriatic arthritis, a joint inflammation that attacks about 30 percent of people with psoriasis, and the main reason Viscosi entered the clinical trial.

The drug's producer is Janssen Biotech.

Janssen Medical Affairs Vice President Cindy Guzzo, in press release Sept. 23, praised the safety and efficacy of Stelara, calling it "a meaningful new option" for psoriatic arthritis patients.

Brian Kenney, director of public affairs at Janssen Global Services, told The Garden Island that Stelara demonstrated efficacy and safety in one of the largest clinical development programs ever conducted for a "biologic therapy" in the treatment of moderate to severe plaque psoriasis.

A biological therapy is a treatment with substances made from living organisms, according to the National Cancer Institute. Some biological therapies stimulate or suppress the immune system to help the body fight cancer, infection and other diseases.

Kenney said it would be "inappropriate" for the company to comment on Viscosi's medical condition, but said that the drug has a track record of testing success.

"We have accumulated five years of efficacy and safety data," Kenney said. "Stelara continues to demonstrate a positive safety profile, as demonstrated in the clinical trials."

But to Viscosi, the drug is neither safe nor efficient.

The clinical trial Viscosi entered was to treat plaque psoriasis, which used to cover 10 to 15 percent of his body. He'd hoped Stelara would target psoriatic arthritis, a condition which made him go on disability.

He said Stelara had no effect on his arthritis, and once he dropped the trial, five other types of psoriasis developed all over his body. *Part two tomorrow: Seeking help*

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Editor's note: This is part two in a two-part series.

An Anahola resident who underwent a clinical trial in 2007 for a then-experimental psoriasis drug is saying things went terribly wrong almost immediately after dropping out of the program early due to a heart complication.

Tony Viscosi said more than 20 doctors told him it was Stelara — now federally approved — that caused his psoriasis to come back five-fold, nearly killing him.

ANAHOLA — Nearly six years after dropping out of the clinical trial, Viscosi's psoriasis flares up regularly.

Walking or sitting is extremely difficult — and impossible at times — due to the sores on his feet and buttocks. He spends most of his time laying on his bed, in pain and bleeding.

His body has been back at 90 percent coverage on three flare-ups, he said. Usually he remains at 50 to 80 percent body-coverage. Lately, the psoriasis has been creeping inside his body.

In 2011, a grapefruit-sized growth developed on muscle tissue on Viscosi's left leg.

That same year, an immune reaction required surgical removal of all but four of his teeth. Nerves grew throughout his mouth, causing severe pain, something his dentist had never seen in 30 years of practice.

Nerves and blood vessels grow into Viscosi's nails, turning a simple task of clipping nails extremely painful.

Last year, a spot developed in his right lung.

Doctor after doctor denied treatment to Viscosi due to lack of information. He said each doctor told him Johnson & Johnson has the information and resources to investigate and treat his immune system breakdown.

Johnson & Johnson's case manager who contacted Viscosi requested his medical records — the same records that Viscosi had sent the company prior to the clinical trial, he said.

Pat Kittler, a friend of Viscosi helping him through the ordeal, said it would cost thousands of dollars and countless hours to order Viscosi's medical records. But Johnson & Johnson could have it for free, he said.

In the last few years, Viscosi and Kittler have spent at least $250,000 in medical expenses related to Stelara's alleged adverse reactions. They were only able to pay for it because they liquidated all their assets, including homes, properties, a business and cars. They even cashed in their entire 401K retirement fund.

"I live on $700 a month that I get for supplemental Social Security," Viscosi said. "I can't even get my full Social Security because they don't have a name for the disease that I have. I should be getting $1,800 a month, that's what I paid into."

Viscosi said he gets federal Medicaid, which pays for medical bills, but doesn't approve everything. He said he has been waiting for two years for a wheelchair to help him get around.

Viscosi said Stelara costs at least $30,000 a year. The drug is projected to bring the company $1.47 billion in 2013, and gradually increase profits, reaching $2.74 billion by 2016.

The drug's producer is Janssen Biotech.

Brian Kenney, director of public affairs at Janssen Global Services, said without having complete information of Viscosi's situation and history, it would be inappropriate for the company to speculate who should pay for Viscosi's medical bills. But Johnson & Johnson wants to reconnect with Viscosi to understand his health situation and assess how they may be able to help him, he said.

Tony Viscosi and his grandmother, Fran Tripol in 2002

'No big deal'

In 2008, when things first started to go wrong, Viscosi said he wasn't scared.

"All I could think of was, 'Oh, thank God, Johnson & Johnson is the biggest company in the world, as long as they're with me I'm sure that this will be no big deal, they will know what's wrong, they'll fix it,'" he said.

After repeated attempts to seek help, he said he slowly found out the company didn't seem to care.

"If you call, you better bring your lawyer," he said.

But the company said that isn't true.

"Patient safety is of the utmost importance to us and we take individual accounts of adverse events potentially related to our products very seriously," Kenney said.

The company, Kenney said, strives to improve the quality of life of people living with plaque psoriasis and psoriatic arthritis, and to ensure the continued safe and effective use of Stelara as a treatment.

Viscosi also sent letters to Johnson & Johnson CEO Alex Gorsky, seeking medical help. He said the only response he got was from a company lawyer. But he is not interested in lawsuits, he just wants to receive treatment, which he says was in the clinical trial agreement he signed.

But Kenney said it wasn't the company who stopped contact between the parties.

Kenney said a "case manager" was appointed in June 2012 — following Viscosi's outreach to Gorsky — to work in collaboration with physicians to review all the available information.

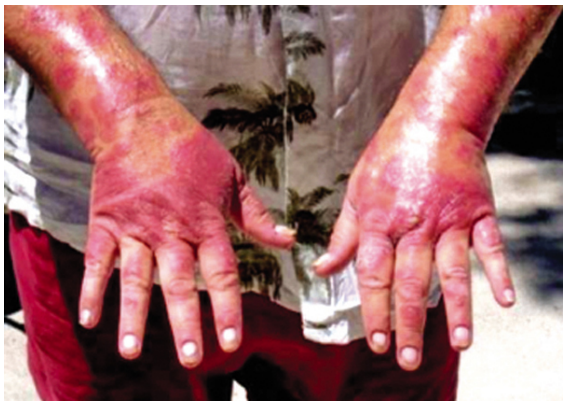
"Unfortunately, we never received further information as requested in July 2012 of Mr. Viscosi through Mr. Kittler, which would have allowed us to more thoroughly review the situation and the reasons for his current health status," said Kenney, adding he never heard from Kittler again until August 2013.

Kenney said Janssen remains interested in obtaining the information requested in 2012 to fully understand Viscosi's current health situation and to assess how they may be able to assist him.

But Kittler disputes that.

He said he sent medical release forms to the pharmaceutical company, as requested, and informed them of the two hospitals which treated Viscosi. After two months of trying to get answers from Johnson & Johnson, Kittler said he gave up seeking their help.

So in August, Kittler put together a petition at www.change.org and sent copies to Gorsky, he said.



Viscosi hands and body was almost completely covered by psoriasis by August 2008

"We're not trying to hide anything here, we need Tony to get treatment," Kittler said.

Seeking help

Viscosi said he, his mother and Kittler filed at least 10 adverse reaction reports with the FDA in the last five years, but never heard back.

Stephanie Yao, of the FDA Office of Media Affairs, told The Garden Island when adverse event reports

are submitted directly to the FDA via MedWatch, an acknowledgment of receipt is sent to the reporter.

“This acknowledgment does not include a response to specific questions regarding the adverse event,” she said. “When an adverse event report is submitted to the FDA by a manufacturer, the FDA does not acknowledge receipt of the report.”

Viscosi and Kittler said they also sought help from four U.S. senators, including Sen. Brian Schatz from Hawaii. Despite an interest from Schatz’s staff in January — immediately after Schatz was sworn in — they never followed up, and ignored 10 emails and follow up calls, Kittler said.

Julie McClain, Schatz’s press secretary said after Kittler contacted Schatz’s office, they filed an inquiry with the FDA to better understand Viscosi’s situation and what options or resources might be available to him.

“Our inquiry is still ongoing, and we hope that the FDA will provide additional information that will be helpful to the Viscosi family,” she said.

Without Viscosi’s violent reaction on the record with the FDA or Johnson & Johnson, the potential devastating side effects that Stelara could have on others have been muted, Viscosi said.

Kenney said any potential adverse reaction related to Stelara is documented by the company.

“We regularly communicate information and data from clinical trials and post-marketing registries to inform health care professionals and patients about the efficacy and safety of Stelara and the benefits and risks of treatment,” he said.

Yao said information from all sources contribute to the evaluation of all clinically relevant cases that can provide further understanding on safety and may also result in recommendation of regulatory actions. Those actions include a label update, a Risk Evaluation and Mitigation Strategy or restricting use pending further studies, or even market withdrawal.

“The FDA regularly publishes any emerging safety issues to inform the public and prevent or minimize the risk of harm,” Yao said.

But without help, Viscosi said his body will give out before his mind does. And that has pushed him to contact Oregon state to ask for death with dignity — assisted suicide — which is legal there.

Meanwhile, friends and families posted a petition at www.change.org asking President Barack Obama and the Congress for a “tiny speck” of Stelara’s profit to be put toward a solution for Viscosi.

Kittler said he may go to Washington D.C. later this year to protest before Congress.

Viscosi said whatever Johnson & Johnson can do to help him is going to help many others down the road. It’s not just him, he said.

“I don’t think this is isolated, as me being the one in a million,” he said.

Visit www.helpfortony.org to see a progression of Viscosi’s condition.

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