



TechTonics: Medical Device Startup CEO Eyes Regulatory OK After Years-Long Wait

Gabi Niederauer has medical innovation in her blood.

The CEO of San Antonio's Bluegrass Vascular Technologies took after her father, a German engineer who developed one of Europe's first ceramic hip implants. A trained biomedical engineer, Niederauer took over Bluegrass in 2014, as the Kentucky-based medical device firm moved its headquarters to San Antonio.

After five years navigating the often-difficult terrain that is federal regulation, she expects, in the first half of this year, to finally receive Food and Drug Administration approval for Bluegrass' novel catheter system for kidney dialysis patients.

Sometimes patients' veins collapse, so typical hemodialysis access points, such as the neck, become unavailable. Bluegrass' system allows medical professionals to reach large veins for hemodialysis through the femoral artery in the thigh. Niederauer said the catheter device has saved lives in Europe and Canada, where it's already in use.

Entering the U.S. market will be a boon to the company, but Niederauer called it a shame that it will have taken four years longer to get approval in the U.S.

"You wish you could provide a life-saving product like ours as quickly as you could," she said.

In particular, the product would benefit Bexar County residents, who suffer from a high rate of diabetes – a risk factor for kidney disease. About 14 percent of adults in the county have diabetes compared to 7 percent nationally, according to data from the U.S. Census Bureau.

The catheter method was developed by Dr. John Gurley, a researcher at the University of Kentucky, who founded Bluegrass in 2011.

Now that the technology is nearly commercialized in the U.S., Niederauer has been seeking funding from venture capital investors in the San Francisco area. The funds will help launch the product in the U.S. David Spencer, a fellow medical device entrepreneur, believes Bluegrass will likely sell the company after the device enters the market.

Spencer, as someone who has felt the frustration of slow regulatory processes, said he knows the difficult road Niederauer has had to navigate. Prior to founding Prytime Medical, Spencer spent years in the tech industry building a software company from the ground up.

"Coming out of the techie world, the concept that you are going to let the market decide is such an important part of the free market system," he said. "[In the medical device field] you have to spend millions of dollars to convince the FDA to allow you go into the market and then see if it works.

"Convincing the FDA can be very challenging because they are the judge, jury, and executioner. They set the rules. They get to decide, and you have literally almost no recourse."

Spencer said Niederauer has been unflappable in the face of regulatory burdens. Because the Bluegrass catheter system is novel – there isn't a U.S. market analogue that exists – it takes more clinical studies and a generally more rigorous process to satisfy all of the FDA's questions and concerns, Niederauer said.

Niederauer has been part of the San Antonio biomedical community for decades and credits the city, its medical facilities, and array of talent for providing fertile ground to grow Bluegrass. She expects that once the product hits the market it will be heavily utilized by local physicians.

“San Antonio’s biomedical ecosystem has the kind of business-friendly infrastructure and workforce talent needed to foster ongoing innovation in collaboration with our academic and military medicine partners,” said Ann Stevens, president of BioMed SA, a nonprofit that supports the growth of the local biomedical industry. As a result, the pipeline of promising medical device companies and innovations based here in San Antonio – including Bluegrass Vascular – shows great promise for the future.”

Niederauer has known she wanted to become an engineer for a long time.

One of her earliest memories is sitting on her father’s lap when she was about 3 years old and helping him draw schematics. But Niederauer credits her career in engineering and biomedical entrepreneurship to her family’s move stateside. Niederauer and her family arrived in South Carolina from Stuttgart, Germany, when she was 11.

Traditional roles for women remain fairly entrenched in her native country, Niederauer said, and she feels she would not have had as many avenues to pursue a career in engineering there.

Many women step out of the workforce during their child-rearing years in part because the government provides monetary support during maternity leave, she said.

“Had I stayed in Germany, I’m not sure I would have been encouraged or had the role models to [pursue a career in engineering],” she said.

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The representation of women in leadership positions in the U.S. private sector remains dismally low, however. According to [Fortune](#), women made up less than 7 percent of Fortune 500 CEOs in 2019, an increase from less than 5 percent the year prior.

As a female CEO with an engineering background leading a company in the STEM field, Niederauer is an even rarer sight. Women represent just [14 percent](#) of the workforce in architecture and engineering occupations, according to the U.S. Bureau of Labor Statistics.

Niederauer said women represent about 8 percent of CEOs in the medical device field. She said she remembers more than a few times when she has been one of the only women in a room of 30 people. In meetings with funders, it’s rare that the person holding the purse strings is a woman, she added.

Despite the hurdles, Niederauer found many female role models at Clemson University in South Carolina, where she earned her undergraduate degree.

Despite the inherent biases that remain, Niederauer has found a way to skate past some people’s preconceived notions of women in leadership positions, said Spencer.

“Gabi has an innate ability to seek out competence,” he said. “And she knows that people that disdain women because they’re women, are not particularly competent.”

Source: <https://therivardreport.com/techtionics-gabi-niederauer-preps-novel-device-for-u-s-market-after-years-long-wait/>

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