Patients shocked, burned by device touted to treat pain

November 25 2018, by Mitch Weiss And Holbrook Mohr

In this Friday, Nov. 16, 2018 photo, Jim Taft watches The History Channel from the confines of his bed at his home in West Columbia, S.C. Taft has experienced debilitating health issues after a neurosurgeon implanted Boston Scientific's Precision spinal cord stimulator in his back in 2014. (AP Photo/Sean Rayford)

Desperate for relief after years of agony, Jim Taft listened intently as his pain management doctor described a medical device that could change his life.

It wouldn't fix the nerve damage in his mangled right arm, Taft and his wife recalled the doctor saying, but a spinal-cord stimulator would cloak his pain, making him "good as new."

Taft's stimulator failed soon after it was surgically implanted. After an operation to repair it, he said, the device shocked him so many times that he couldn't sleep and even fell down a flight of stairs. Today, the 45-year-old Taft is virtually paralyzed, a prisoner in his own bed, barely able to get to the bathroom by himself.

"I thought I would have a wonderful life," Taft said. "But look at me."

For years, medical device companies and doctors have touted spinal-cord stimulators as a panacea for millions of patients suffering from a wide range of pain disorders, making them one of the fastest-growing products in the $400 billion medical device industry. Companies and doctors aggressively push them as a safe antidote to the deadly opioid crisis in the U.S. and as a treatment for an aging population in need of chronic pain relief.

But the stimulators—devices that use electrical currents to block pain signals before they reach the brain—are more dangerous than many patients know, an Associated Press investigation found. They account for the third-highest number of medical device injury reports to the U.S. Food and Drug Administration, with more than 80,000 incidents flagged since 2008.

Patients report that they have been shocked or burned or have suffered spinal-cord nerve damage ranging from muscle weakness to paraplegia, FDA data shows. Among the 4,000 types of devices tracked by the FDA, only metal hip replacements and insulin pumps have logged more injury reports.

The FDA data contains more than 500 reports of people with spinal-cord stimulators who died, but details are scant, making it difficult to determine if the deaths were related to the stimulator or implant surgery.

Medical device manufacturers insist spinal-cord stimulators are safe—some 60,000 are implanted annually—and doctors who specialize in these surgeries say they have helped reduce pain for many of their patients.

Most of these devices have been approved by the FDA with little clinical testing, however, and the agency's data shows that spinal-cord stimulators have a disproportionately higher number of injuries compared to hip implants, which are far more plentiful.

The AP reported on spinal stimulators as part of a nearly yearlong joint investigation of the global medical devices industry that included NBC, the International Consortium of Investigative Journalists and more than 50 other media partners around the world. Reporters collected and analyzed millions of medical records, recall notices and other product safety warnings, in addition to interviewing doctors, patients, researchers and company whistleblowers.

The media partners found that, across all types of medical devices, more than 1.7 million injuries and nearly 83,000 deaths were reported to the FDA over the last decade.

The investigation also found that the FDA—considered by other countries to be the gold standard in medical device oversight—puts people at risk by pushing devices through an abbreviated approval process, then responds slowly when it comes to forcing companies to correct sometimes life-threatening products.

Devices are rarely pulled from the market, even when major problems

emerge. And the FDA does not disclose how many devices are implanted in the U.S. each year—critical information that could be used to calculate success and failure rates.

The FDA acknowledges its data has limitations, including mistakes, omissions and under-reporting that can make it difficult to determine whether a device directly caused an injury or death. But it rejects any suggestion of failed oversight.

"There are over 190,000 different devices on the U.S. market. We approve or clear about a dozen new or modified devices every single business day," Dr. Jeffrey Shuren, the FDA's medical device director said at an industry conference in May. "The few devices that get attention at any time in the press is fewer than the devices we may put on the market in a single business day. That to me doesn't say that the system is failing. It's remarkable that the system is working as it does."

In response to reporters' questions, the FDA said last week that it was taking new action to create "a more robust medical device safety net for patients through better data." "Unfortunately, the FDA cannot always know the full extent of the benefits and risks of a device before it reaches the market," the agency said. In the last 50 years, the medical device industry has revolutionized treatment for some of the deadliest scourges of modern medicine, introducing devices to treat or diagnose heart disease, cancer and diabetes.

In this Oct. 31 2018 photo, George and Brenda Davis look at his nerve stimulator and medical documents at their home in Milton, Fla. George Davis had three Medtronic spinal-cord implants between 2003 and 2007 after a car accident mangled his back. They temporarily reduced some of his pain, but he said the non-rechargeable batteries that were supposed to last for years never did and he tired of multiple surgical removals. In 2015, he decided to try a Boston Scientific device. But he said he soon started feeling pain shooting down his back and legs and a burning sensation at the implant site. Brenda Davis said Boston Scientific disregarded her complaints after her husband suffered a life-threatening infection following implant surgery. (AP Photo/Holbrook Mohr)

Pete Corby, who injured his back working as a movie stuntman, said a spinal-cord stimulator helped him deal with his constant pain and stop using the opioids he'd become dependent on.

"This is the greatest thing that saved my life, literally saved my life," said Corby, estimating that up to three-quarters of his original pain was alleviated by the stimulator.

Medical device companies have "invested countless resources—both capital and human—in developing leading-edge compliance programs," said Janet Trunzo, head of technology and regulatory affairs for AdvaMed, the industry's main trade association.

At the same time, medical device makers also have spent billions to try to influence regulators, hospitals and doctors.

In the U.S., where drug and device manufacturers are required to disclose payments to physicians, the 10 largest medical device companies paid nearly $600 million to doctors or their hospitals last year to cover consulting fees, research and travel and entertainment expenses, according to an AP and ICIJ analysis of data from the Centers for Medicare & Medicaid Services. This figure doesn't include payments from device manufacturers like Johnson & Johnson and Allergan, which also sell other products.

On top of that, lobbying records show that the top four spinal-cord stimulator manufacturers have spent more than $22 million combined since 2017 to try to influence legislation benefiting their overall business, which includes other devices.

Some companies have been fined for bribing physicians, illegally promoting products for unapproved uses and paying for studies that proclaim the safety and effectiveness of their products, according to the joint investigation.

In a 2016 case, Olympus Corp. of the Americas, the largest U.S. distributor of endoscopes and related medical equipment, agreed to pay

$623.2 million "to resolve criminal charges and civil claims relating to a scheme to pay kickbacks to doctors and hospitals," according to the U.S. Justice Department. Olympus said that it "agreed to make various improvements to its compliance program."

In a case the previous year involving spinal-cord stimulators, Medtronic Inc. agreed to pay $2.8 million to settle Justice Department claims that the company had harmed patients and defrauded federal health care programs by providing physicians "powerful" financial inducements that turned them into "salesmen" for costly procedures. Medtronic denied wrongdoing. "As a matter of policy, Medtronic does not comment on specific litigation," the company said in a statement. "We do stand behind the safety and efficacy of our Spinal Cord Stimulators and the strong benefits this technology provides to patients, many of whom have tried all other therapy options to no benefit."

Some doctors enthusiastically promote spinal-cord stimulators without disclosing to patients they've received money from medical device manufacturers. Some experts say doctors are not legally required to disclose such payments, but they have an ethical obligation to do so. Sometimes the money goes to the doctors' hospitals, and not directly to them.

As for Taft, he said he just wanted to get better, but he has lost hope.

"This is my death sentence," Taft said, stretched out beneath his bed's wooden headboard on which he's carved the words "death row."

"I'll die here," he said.

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A generation ago, tens of thousands of women were injured by the

Dalkon Shield, an intrauterine device that caused life-threatening infections. Consumer advocates demanded testing and pre-market approval of medical devices to prevent deaths and injuries associated with defective products.

So in 1976, Congress passed the Medical Device Amendments, a law meant to assure Americans that devices recommended by their doctors would do good and not harm.

"Until today, the American consumer could not be sure that a medical device used by his physician, his hospital or himself was as safe and effective as it could or should be," President Gerald Ford said when he signed the bill into law.

This combination of Saturday, Aug. 25, 2018 photos shows demonstration models of implantable neurostimulators, top row from left, the Medtronic Intellis and the Boston Scientific Spectra WaveWriter SCS. Bottom row from left are

the Abbott/St. Jude's Proclaim 7 Implantable Pulse Generator and Proclaim DRG Implantable Pulse Generator. For years, medical device companies and doctors have touted spinal cord stimulators as a panacea for millions of patients suffering from a wide range of intractable pain disorders. But the devices, surgically placed inside the back, that use electrical currents to block pain signals before they reach the brain—are more dangerous than many patients understand, according to an Associated Press investigation. (AP Photo/Mary Altaffer)

Charged with carrying out the law, the FDA created three classes of medical devices. High-risk products like spinal-cord stimulators are designated to be held to the most rigorous clinical testing standards. But the vast majority of devices go through a less stringent review process that provides an easy path to market for devices deemed "substantially equivalent" to products already approved for use.

As designed by Congress, that process should have been phased out. Instead, it became the standard path to market for thousands of devices, including hip replacements implanted in tens of thousands of patients that would later be recalled because metal shavings from the devices made some people sick.

The AP found that the FDA has allowed some spinal-cord stimulators to reach the market without new clinical studies, approving them largely based on results from studies of earlier spinal stimulators.

Spinal stimulators are complex devices that send electrical currents through wires placed along the spine, using a battery implanted under the skin. An external remote controls the device.

The four biggest makers of spinal-cord stimulators are Boston Scientific Corp., based in Marlborough, Massachusetts; Medtronic, with headquarters in Ireland and the U.S.; Nevro, in Redwood City,

California; and Illinois-based Abbott, which entered the market after its $23.6 billion purchase of St Jude Medical Inc.

St. Jude's application to go to market with its first spinal stimulator contained no original patient data and was based on clinical results from other studies, while Boston Scientific's application for its Precision spinal-cord stimulator was based largely on older data, though it did include a small, original study of 26 patients who were tracked for as little as two weeks.

Once approved, medical device companies can use countless supplementary requests to alter their products, even when the changes are substantial.

For example, there have been only six new spinal-cord stimulator devices approved since 1984, with 835 supplemental changes to those devices given the go-ahead through the middle of this year, the AP found. Medtronic alone has been granted 394 supplemental changes to its stimulator since 1984, covering everything from altering the sterilization process to updating the design.

"It's kind of the story of FDA's regulation of devices, where they're just putting stuff on the market," said Diana Zuckerman, president of the National Center for Health Research, who has studied medical devices for nearly 30 years.

Medical device manufacturers have cited multiple industry-funded studies showing the effectiveness of spinal-cord stimulation in the treatment of chronic pain. Experts say treatment is considered successful if pain is reduced by at least half, but not every patient experiences that much pain reduction.

A 2016 study looking at different stimulation systems found "significant

evidence" that they were "a safe, clinical and cost-effective treatment for many chronic pain conditions."

But Zuckerman noted that the more extensive studies came after the devices were being widely used on people.

"These patients are guinea pigs," she said.

FDA said in a statement that it approves, clears or grants marketing authorization to an average of 12 devices per business day and its decisions are "based on valid scientific evidence" that the devices are safe and effective.

Dr. Walter J. Koroshetz, director at the neurological disorders and stroke division at the National Institutes of Health, said trials for medical devices like spinal-cord stimulators are generally small and industry-sponsored, with a "substantial" placebo effect.

"I don't know of anyone who is happy with spinal-cord technology as it stands," Koroshetz said. "I think everybody thinks it can be better."

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In this Saturday, Aug. 25, 2018 photo, sales representatives for Medtronic and Boston Scientific work their booths at the NYC Neuromodulation Conference in New York. For years, medical device companies and doctors have touted spinal cord stimulators as a panacea for millions of patients suffering from a wide range of intractable pain disorders. But the devices, surgically placed inside the back, that use electrical currents to block pain signals before they reach the brain—are more dangerous than many patients understand, according to an Associated Press investigation. (AP Photo/Mary Altaffer)

Every time Jim Taft walked into his pain management doctor's office, he would glance at the brochures touting spinal-cord stimulators—the ones with pictures of people swimming, biking and fishing.

Inside the exam room, Taft said, his doctor told him the device had been successful for his other patients and would improve his quality of life.

On lifetime worker's compensation after his right arm was crushed as he

was hauling materials for an architectural engineering company, Taft had been seeing the doctor for five years before he decided to get a stimulator in 2014. What finally swayed him, he said, was the doctor's plan to wean him off painkillers.

"I felt backed into a corner," said, Taft, who lives in West Columbia, South Carolina.

Taft said his pain management doctor praised the technology, saying stimulators had improved the quality of life for his patients. But four years later, Taft is unable to walk more than a few steps.

Taft is one of 40 patients interviewed by the AP who said they had problems with spinal-cord stimulators. The AP found them through online forums for people with medical devices. Twenty-eight of them said their spinal-cord stimulators not only failed to alleviate pain but left them worse off than before their surgeries.

Zuckerman, who has worked at the U.S. Department of Health and Human Services and as a senior policy adviser to then-first lady Hillary Rodham Clinton, said no doctor wants to think they're harming patients.

"But there's a tremendous financial incentive to downplay, ignore or forget bad patient experiences and just focus on how happy patients are," she said.

More than half the patients interviewed by the AP said they felt pressured to get stimulators because they feared their doctors would cut off their pain medications—the only thing helping them.

Stimulators are considered a treatment of "last resort" by insurance companies, as well as Medicare and Medicaid. That means doctors must follow a protocol before insurance will pay for the device and

implantation.

Physicians must show that conservative treatments failed to help, and patients also undergo psychological assessments to evaluate the likelihood of success. They then typically undergo a trial period lasting three days to a week with thin electrodes inserted under the skin. If patients say they got relief from the external transmitter sending electrical pulses to the contacts near their spines, they have surgery to implant a permanent stimulator.

Taft said his three-day trial helped reduce his pain so, a few days before his surgery, he began preparing for a new life. He ordered lumber to refurbish a patio and deck for his wife, Renee, as thanks for her years of support.

In April 2014, Boston Scientific's Precision stimulator was implanted in Taft by Jason Highsmith, a Charleston, South Carolina, neurosurgeon who has received $181,000 from the company over the past five years in the form of consulting fees and payments for travel and entertainment. A Boston Scientific sales representative was in the operating room—a common practice, the AP found.

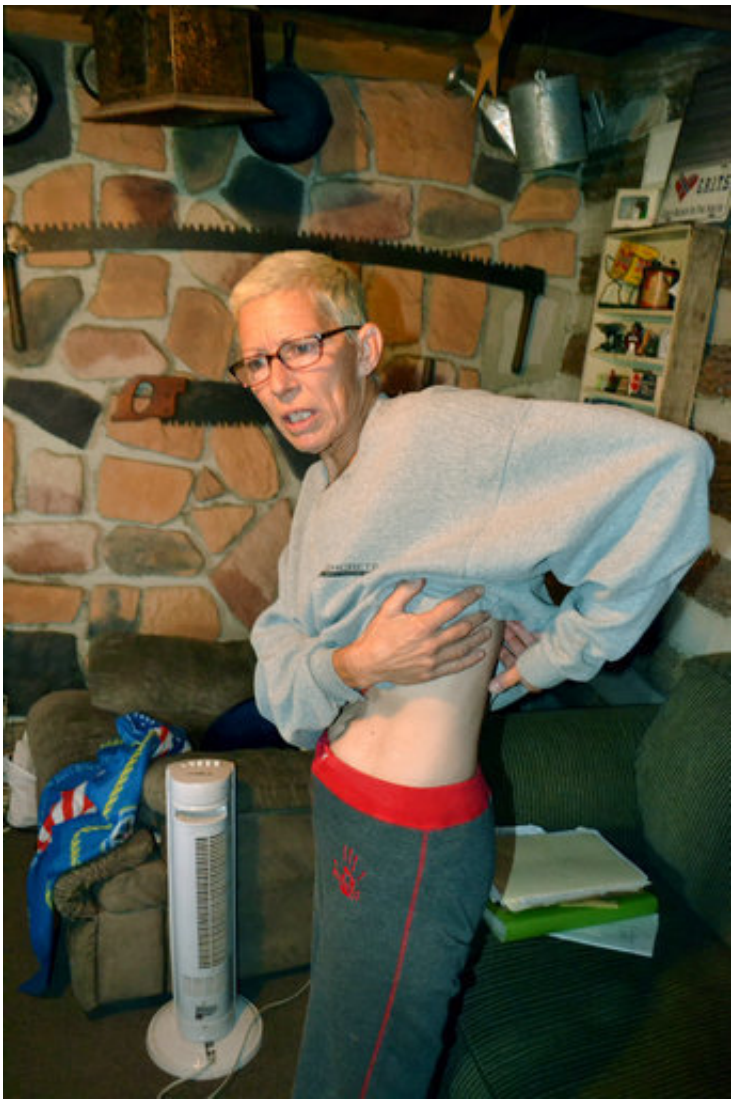
Highsmith would not comment on the payments. Other doctors have defended the practice, saying they do important work that helps the companies—and ultimately patients—and deserve to be compensated for their time.

From the time Taft was cut open and the device placed inside his body, he had nothing but problems, according to hundreds of pages of medical records reviewed by the AP. The device began randomly shocking him, and the battery burned his skin.

Taft and his wife complained repeatedly, but said his doctors and a

Boston Scientific representative told them that spinal-cord stimulators don't cause the kind of problems he had.

That runs counter to Boston Scientific's own literature, which acknowledges that spinal stimulators and the procedures to implant them carry risks, such as the leads moving, overstimulation, paralysis and infections.



In this Oct. 4, 2018 photo, Lisa Snyder, of Kempton, Pa., shows where a malfunctioning spinal cord stimulator was removed. After a March 29 implant

by Dr. Steven Falowski, she had problems, similar to others interviewed by AP. "I complained about this battery right away. I knew it was positioned funny. It burned," she said. (AP Photo/Peter Banda)

That also is not reflected in the AP's analysis of FDA injury reports, which found shocking and burning had been reported for all major models of spinal-cord stimulators. For Boston Scientific devices, infection was the most common complaint over the past decade, mentioned in more than 4,000 injury reports.

In response to questions, the company called infection "unfortunately a risk in any surgical procedure" that the company works hard to avoid. It added that the FDA's data "shouldn't be interpreted as a causal sign of a challenge with our device. In fact, many examples of reportable infections include those that were caused by the surgical procedure or post-operative care."

"In our internal quality assessments, over 95 percent of the injury reports were temporary or reversible in nature," the company added.

Taft said had he known the devices hurt so many people, he would have reconsidered getting one. A Boston Scientific sales representative tried reprogramming the device, he said, but nothing worked.

"I told them that it feels like the lead is moving up and down my spine," Taft said. "They said, 'It can't move.'" But in July 2014, X-rays revealed the lead indeed had moved—two inches on one side.

Highsmith told the AP the electrode broke from "vigorous activity," though Taft said that would not have been possible due to his condition. Taft said he was in such bad shape after his surgery that he was never

able to redo the patio and deck for his wife or do anything else vigorous.

That October, Highsmith said, he operated on Taft to install a new lead, tested the battery and reinserted it.

Still, Taft's medical records show that he continued to report numbness, tingling and pain. During a January 2015 appointment, a physician assistant wrote that the device "seemed to make his pain worse."

The stimulator was surgically removed in August 2015. The following June, Taft got a second opinion from a clinic that specializes in spinal injuries, which said he had "significant axial and low back pain due to implantation and explantation" of the stimulator.

Highsmith said other doctors have documented severe arthritis in Taft and that, while he has not examined Taft in more than three years, it's "likely his current condition is the result of disease progression and other factors."

He did not answer questions about whether he informed Taft of the risks associated with stimulators.

The doctor said the overwhelming majority of his spinal-cord stimulator patients gain significant pain relief.

"Unfortunately, in spite of the major medical breakthroughs with devices like these, some patients still suffer from intractable pain," he said.

Renee Taft, a paralegal, reached out to Boston Scientific in 2017, but said the company refused to help because her husband's stimulator had been removed and blamed Taft for his problems, also saying he had engaged in "rigorous physical activity" after surgery.

In the letter from the company's legal department, Boston Scientific also noted that federal law shielded manufacturers from personal liability claims involving medical devices approved by the FDA.

In response to questions from the AP, Boston Scientific again blamed Taft's "activity level" but didn't elaborate. The company also said other factors could contribute to his problems such as "hyperalgesia, a phenomenon associated with long-term opioid use which results in patients becoming increasingly sensitive to some stimuli."

Brenda Simpson-Davis of Milton, Florida, said Boston Scientific also disregarded her complaints after her husband suffered a life-threatening infection following implant surgery.

NY713: In this Oct. 4, 2018 photo, Dr. Steven Falowski holds an electrode for a spinal cord stimulator in Bethlehem, Pa. The AP found that a number of high-profile doctors, including Falowski, who promote stimulators, co-authored

manufacturer-funded studies and have implanted spinal cord stimulators, have received money for themselves or their hospitals from the industry or belong to trade associations that promote them. (AP Photo/Peter Banda)

George Davis, 57, had three Medtronic spinal-cord implants between 2003 and 2007 after a car accident mangled his back. They temporarily reduced some of his pain, but he said the non-rechargeable batteries that were supposed to last for years never did and he tired of multiple surgical removals.

In 2015, his pain management doctor urged him to try Boston Scientific's Precision Spectra, which he called the best on the market. Unlike Davis's old models, it had a rechargeable battery.

Within weeks of his surgery, Davis said, he started feeling pain shooting down his back and legs and a burning sensation at the implant site. After his skin started turning black, the doctor performed emergency surgery to remove the device.

Months later, Davis reluctantly agreed when his doctor urged him to try another Boston Scientific model but found that device even worse.

Over the next year, he spent more than 100 days in and out of hospitals battling a life-threatening infection. Today, Davis says he has trouble getting out of bed.

Boston Scientific said it never received the stimulators that were implanted in Taft and Davis so could not "conclusively identify" the causes of their problems. "Numerous factors can contribute to a patient's ongoing symptoms, from increased physical activity to the onset of pain in other areas," the company said.

Simpson-Davis said she spoke with attorneys around the country, who warned her about the high bar set for a lawsuit . Finally, she found a Texas lawyer who said he will consider taking the case if she can find another two dozen potential plaintiffs.

"To me, it's not about the money, It's about the people. It's about them knowing what they're getting themselves into," she said.

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For years, Valerie McJunkin had been seeking relief from a rare neurological disorder that made her legs and feet feel like they were on fire. So when a medical device company sales representative and her West Virginia pain management doctor recommended what sounded to her like a "miracle device," she was all in.

They said a new kind of stimulator—one that targeted a bundle of sensory nerve cells in the lower back—was better than a spinal-cord device. She just needed to undergo a weeklong trial.

When McJunkin showed up at the pain clinic this January for the trial, the Abbott sales representative was there, along with her doctor and his staff. They explained every detail. This device wasn't for everyone, but she was the perfect candidate, she recalled them saying.

Over the next week, they called or texted her nearly every day to see if the stimulator was easing her torment. And since the trial did seem to help, she went ahead with the implant.

Within days, though, the device began randomly shocking her—a sharp pain that felt like a lightning bolt.

When McJunkin called her doctor and the Abbott representative, she

said they suggested that she was at fault because "stimulators don't do that." It wasn't until she received a certified letter from Abbott in March that she learned it wasn't all in her head: The company said her device was being recalled due to a glitch that could cause patients some "discomfort."

Since 2005, there have been 50 recalls involving spinal stimulators, averaging about four per year in the last five years. Roughly half the recalls involved stimulators made by Medtronic, the world's largest device manufacturer, though none warned of a risk of serious injury or death.

In early September, McJunkin invited an AP reporter to accompany her when she met with her doctor and the company sales representative to request the device be removed.

In this Oct. 4, 2018 photo, Dr. Steven Falowski holds a display of spinal cord

stimulation equipment in Bethlehem, Pa. The neurosurgeon and his hospital have received $863,000 from medical device companies since 2013, including $611,000 from St. Jude or its new parent company, Abbott. The payments range from consulting fees to travel reimbursements and food and beverage costs. (AP Photo/Peter Banda)

The Abbott salesman and her doctor both suggested she get another stimulator, saying she had run out of options, especially since her doctor couldn't write prescriptions for opioids because of a government crackdown. If she didn't get another stimulator, he said, she faced a lifetime of pain. He did not suggest other options, such as steroid shots or continued physical therapy.

"I'm not trying to force your mind," the doctor said. "But for me, would I want to live my life like this?... If I get that new battery and it totally helps, that changes my life 180 degrees, right? But if I don't I already know what's going to happen to me: I'll be suffering for the rest of my life."

On the drive home to Martinsburg, West Virginia, McJunkin gripped the steering wheel of her car, her tattoo reading "persevere" visible on her forearm.

"You trust your doctor. You think he's going to do the right thing," she said. She paused, fighting back tears. "I just wanted to live without pain. But now that hope is gone."

In late October, her doctor removed the device.

The experience of nearly all the 40 patients interviewed by the AP mirrored McJunkin's: Their pain was reduced during the trial but

returned once their stimulators were implanted.

Experts say the answer may be a placebo effect created when expectations are built up during the trial that only the stimulator can offer relief from pain, exacerbated by patients not wanting to disappoint family members, who often have been serving as their caregivers.

"If patients know this is a last resort, a last hope, of course they will respond well," said Dr. Michael Gofeld, a Toronto-based anesthesiologist and pain management specialist who has studied and implanted spinal-cord stimulators in both the U.S. and Canada.

By the time the trial ends, the patient is "flying high, the endorphin levels are high," Gofeld said.

Manufacturer representatives are heavily involved during the entire process. Along with often being in the operating room during surgery in case the physician has questions, they meet with patients to program the devices in the weeks following surgery.

Most of the patients interviewed by the AP said the adjustments to their devices were performed by sales representatives, often with no doctor or nurse present. That includes one patient who was billed for programming as if the doctor was in the room, though he was not.

"People who are selling the device should not be in charge of maintenance," Gofeld said. "It's totally unethical."

In a 2015 Texas case, a former Medtronic sales representative filed suit contending she was fired after complaining that the company trained employees to program neurostimulators without physicians present. She also claimed that a Medtronic supervisor snatched surgical gloves away from her when she refused to bandage a patient during a procedure,

pushed her aside and then cleaned and dressed the patient's wound. Medtronic denied the allegations, and the case was settled on undisclosed terms.

In the Justice Department case involving Medtronic, a salesman who said he earned as much as $600,000 a year selling spinal-cord stimulators claimed sales representatives encouraged physicians to perform unnecessary procedures that drove up the costs for Medicare and other federal health programs.

"While there have been a few instances where individuals or affiliates did not comply with Medtronic's policies, we acted to remedy the situation in each case once discovered and to correct any misconduct," the company said.

Gofeld said he believes stimulators do work, but that many of the problems usually arise when doctors don't choose appropriate candidates. And he thinks the stimulators are used too often in the U.S.

Nevro, one of the four big manufacturers, has cited estimates that there are as many as 4,400 facilities in the U.S where spinal-stimulation devices are implanted by a variety of physicians, including neurosurgeons, psychiatrists and pain specialists.

In this Oct. 4, 2018 photo, Dr. Steven Falowski stands for a portrait in Bethlehem, Pa. If spinal cord stimulators are used early enough for pain, they can prevent people from going on opium-based pain killers, said Falowski who speaks at conferences and teaches other doctors how to implant stimulators. (AP Photo/Peter Banda)

It's a lucrative business . Analysts say stimulators and the surgery to implant them costs between $32,000 and $50,000, with the device itself constituting $20,000 to $25,000 of that amount. If surgery is performed in a hospital, the patient usually stays overnight, and the hospital charges a facility fee for obtaining the device. Costs are typically covered by insurance.

The AP found that doctors can make more money if they perform the surgery at physician-owned outpatient surgery centers, since the doctor buys the device, marks it up and adds on the facility fee.

In Canada, where Gofeld now works, he said the surgeries are done only by those who specialize in the procedures. He said spinal-cord stimulators should be used when pain starts and not after failed back surgeries.

"By then," he said, "it's too late."

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While manufacturers and top FDA officials tout stimulators as a weapon in the battle against opioids, neurosurgeons like Steven Falowski are the front-line evangelists.

"Chronic pain is one of the largest health-care burdens we have in the U.S. It's more than heart disease, cancer and diabetes combined," Falowski said in an interview.

He referred AP to Corby, as one of his surgical patients who was helped by a spinal-cord stimulator.

Corby got the device more than two years ago and says that, after some initial adjustments, he hasn't had any further problems. He says he wouldn't trade the stimulator for opioids.

"I was actually buying them on the street ... a little like a druggie because I couldn't get them anymore" from his pain doctor, Corby said.

Falowski said opioids are good for acute pain, but were never meant to treat long-term chronic pain. For him, that's where spinal-cord stimulators come in.

If they're used early enough for pain, they can prevent people from going on opium-based pain killers, said Falowski, who speaks at

neuromodulation conferences and teaches other doctors how to implant stimulators.

Since 2013, device manufacturers have paid Falowski—or St. Luke's University Health Network in Fountain Hill, Pennsylvania, where he works—nearly $863,000, including $611,000 from St. Jude or its new parent company, Abbott, according to the Centers for Medicare and Medicaid Services database. The payments range from consulting fees to travel and entertainment expenses.

Falowski said he has conducted research and done other work for manufacturers, adding, "The contracts with industry are with my hospital and not with me."

St. Luke's told the AP that it keeps the majority of the payments from device makers, but that Falowski "may receive a portion of these payments through his annual compensation."

Another of Falowski's patients was Lisa Snyder of Kempton, Pennsylvania, who was searching for relief from a painful nerve disorder. By the time she came to Falowski, she had cycled through three spinal-cord stimulators, which were removed for reasons ranging from infection to rejection.

"Not everybody could do it, but he was confident he could," she said.

In this Friday, Nov. 16, 20158 photo, Jim Taft watches The History Channel from the confines of his bed at his home in West Columbia, S.C. Taft has experienced debilitating health issues after a neurosurgeon implanted Boston Scientific's Precision spinal cord stimulator in his back in 2014. (AP Photo/Sean Rayford)

After her fourth implant this March, "I complained about this battery right away. I knew it was positioned funny. It burned," Snyder said.

AP's analysis showed Abbott products were more likely than other major models to include reports of a hot or burning sensation near the site of the battery, with about 5,600 injury reports since 2008 referring to the words "heat" or "burn."

Abbott said that many of the "adverse events" reports in the FDA's data stemmed from a device that was voluntarily recalled in 2011. The company added that feeling a temperature increase at the implant site "is

often a reality for rechargeable spinal-cord stimulation systems," which is why the company is now concentrating on devices that do not need to be recharged.

Snyder said she felt like Falowski's nurse and physician assistant downplayed the problems and that the reprogramming of her device was conducted by the Abbott sales representative, with no medical staff present. On at least one occasion, she was charged as if the medical staff was there, when she said they weren't, according to insurance bills reviewed by the AP.

Despite insisting nothing was wrong with the unit, Snyder said, Falowski called her one day out of the blue. "He said 'Under no circumstances are you to turn it on.' I asked him why and he wouldn't say," Snyder recalled.

Falowski then scheduled immediate surgery to remove the stimulator, she said.

Falowski called Snyder a difficult patient and said she was receiving "100 percent pain relief" when she had the stimulator removed, adding that she "remained very appreciative of her care." He added that programming is "performed under the direction of a physician."

"The physician is not present during the entire programming session, but provides oversight and direction....The only time programming sessions are billed is when the physician is actively seeing the patient during a visit which was the case with this patient," he said.

Snyder disputed the doctor's characterization of her and became angry after being told Falowski and his hospital received money from manufacturers.

"They need to be a little bit upfront," she said.

Falowski said doctors do important work for medical device companies, and he has been involved in device development, education, clinical trials and research.

"You're trying to help patients and you realize as a physician by yourself you're not going to generate $200 million to make the next best implant for a patient and it's going to take a company to do that," he said. "So I think the important part in that relationship is transparency and disclosures."

Experts interviewed by the AP said doctors are not legally required to tell their patients about financial relationships with medical device manufacturers, but that it would be the right thing to do.

"The patient should be fully informed before consenting to a procedure," said Genevieve P. Kanter, an assistant professor at the University of Pennsylvania who specializes in internal medicine, medical ethics and health policy.

All Snyder ever wanted was to feel better. Today, she often is immobilized by pain.

Before the latest stimulator, she could walk, stand and cook meals. Now, she finds it hard to get out of bed and rarely leaves her house. She says the device has ruined her life.

"My fear is I'll be like this forever," she said.