GAGGED:

FEDS USE CRIMINAL CHARGES, THREATS TO SILENCE DRUGMAKERS

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SEMANTIC SHAKEDOWN

Semantics and a quarter of an inch nearly ruined Howard Root's life and destroyed the billion-dollar medical device company he created.

Only a jury saved him.

Root had spent five years under federal investigation, indictment or in trial by the time he and his company, Vascular Solutions Inc. (VSI), were acquitted of all criminal charges by the jury in February 2016.

A conviction would have shuttered the company and sent Root to prison for three years.

By the time of the acquittal, $25 million had been spent on lawyers defending Root, his employees, and VSI's very existence.

The value of the company's stock plummeted.

Medical devices that might have saved countless lives went undeveloped.

Company employees were threatened with decades in prison, indictments, and financial ruin if they did not "fix" their testimony to comport with the prosecution's theory of the case.

All because of the pitches of a few rogue salespeople, which even the government prosecutors acknowledged were, in themselves, legal and protected by the First Amendment.

All over a financially insignificant and FDA-approved product in the company's inventory that constituted less than 0.1 percent of VSI's overall sales.

All over the definition of what constitutes a "varicose vein."

And all despite the fact that prosecutors conceded they made no claims that any patients were harmed.

Root is one of several pharmaceutical and medical device company executives who got entangled in the U.S. Food and Drug Administration's attempts to preserve its power to regulate what they can say about their products and how they are used.

Federal regulators have long maintained that drug and device companies are breaking the law if they make any claims about their products that have not been approved by the FDA, even if they are true. This includes providing accurate information about what are termed "off-label uses."

When a new drug or device is approved by the FDA, it is typically for a single condition and only after a long and expensive review process involving years of clinical studies. But once a product is approved for a single condition, it can usually be used by doctors to treat patients with other ailments. For instance, a drug approved to treat sinus infections might prove to be effective in treating ear infections. Doctors are free to use it for that purpose even though it is technically "off-label." They can also discuss the off-label benefits of a new drug, and even advocate its use. That's because the federal government does not regulate medical practitioners. States do.

However, the FDA has historically taken the position that it is illegal for a drug company to make claims

> The FDA "does not like this idea that free speech protects free speech."
>
> - Howard Root
> Former CEO of Vascular Solutions Inc.

about a product's off-label uses, regardless of whether the information is true and not misleading.

It's not just a technical distinction. Drug companies have paid billions of dollars to settle both civil and criminal allegations brought by the federal government claiming illegal marketing of off-label uses. A company convicted of a criminal violation related to off-label promotion of any of its products faces financial ruin and could be banned from doing business with any medical provider that accepts Medicare, a death knell for a pharmaceutical business.

Beyond that, corporate executives have been criminally prosecuted on felony charges such as fraud and conspiracy because of off-label claims made by sales representatives, even if the executives did not encourage or even know about those pitches.

As a result, most companies quickly strike settlement agreements or plea bargains whenever allegations of violating the FDA's interpretation of the law are raised.

Root was a rare exception.

FREE SPEECH

The FDA's view of its power to regulate off-label promotional claims began to crumble in 2011, about the same time federal prosecutors in Texas started investigating Root and VSI.

The U.S. Supreme Court explicitly recognized in *Sorrell v. IMS Health* that drug companies have constitutionally protected free-speech rights under the First Amendment.

The FDA's power was further eroded in subsequent court cases, most notably a 2012 ruling from the Second U.S. Circuit Court of Appeals, *United States v. Caronia*, which found a company sales consultant engaged in constitutionally protected speech when he discussed the legal off-label uses of a drug made by the company he represented.

FDA regulators and Justice Department prosecutors discounted the importance of those decisions. They argue that when they bring a case for off-label promotion, they are not prosecuting constitutionally protected free speech. Rather, they are using that lawful speech as evidence of the crime of misbranding, which is essentially misrepresenting the lawful uses of an FDA-approved product.

In the case of Root and VSI, prosecutors acknowledged it was legal for VSI salespeople to speak honestly about the off-label uses of its product. It was legal for doctors to use it off-label. And it was legal for the company to ship the product to those doctors.

However, when those three legal acts are taken together, they become a criminal conspiracy, according to the government's case as laid out in court documents. The constitutionally protected speech is proof that the off-label use of the product was its intended use all along, according to the government's theory of the case.

Prosecutors made the same argument in the 2012 *Caronia* case, but it was rejected by the appeals court.

To help clear this legal morass, the Goldwater Institute is advocating what it calls Free Speech in Medicine at the state level. The proposed law would protect drug and medical device companies from prosecution or other regulatory punishment, at least at the state level, for engaging in truthful and non-misleading communications about the off-label uses of their products. So far, two states have adopted Free Speech in Medicine: Arizona and Tennessee.

BEATEN UP

It was during this time of legal and regulatory turmoil that Root became a target of the FDA and federal prosecutors.

"They were getting beat up on this off-label promotion pretty badly, and they wanted to get a victory

because the FDA thought this was usurping their authority of regulating medical devices by people talking about things that hadn't been approved," Root said in an interview with the Goldwater Institute. "The Department of Justice was a willing accomplice by saying we can use the prosecution arm to go after these people."

Root added that the FDA "does not like this idea that free speech protects free speech."

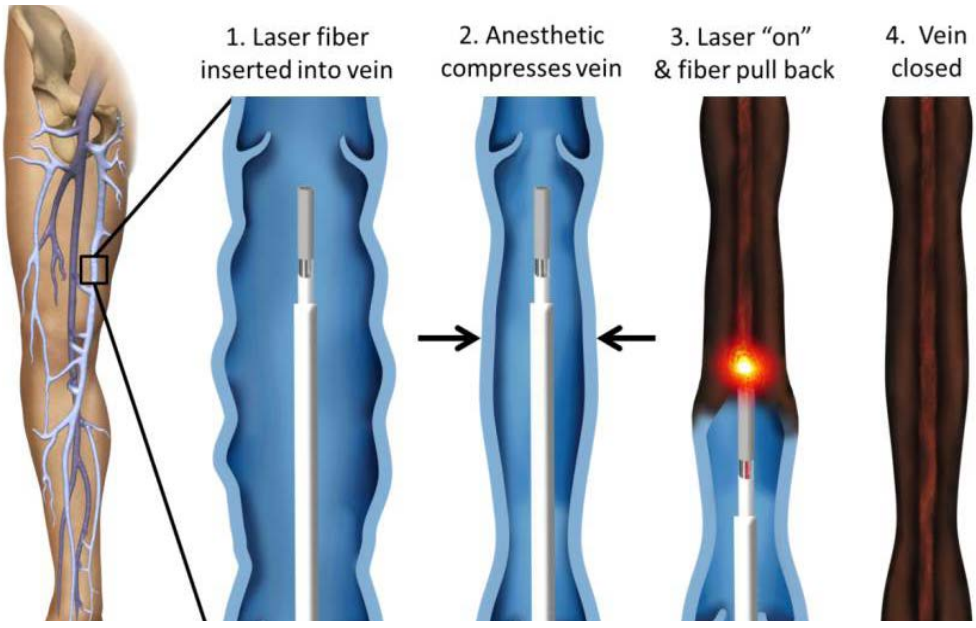
Root started his career as a corporate lawyer but got involved in the medical device industry and cofounded the Minnesota-based VSI in 1997. Prior to the federal investigation launched in 2011, neither he nor the company had ever had any problems with the FDA or the Department of Justice.

Root built VSI from a start-up medical device company with a single product to one that had more than 100 distinct products with 950 variations, and employed about 550 people. Throughout his tenure, Root and his company developed several lifesaving devices, which became the financial drivers of the company. One seals the arterial puncture made during the placement of stents in heart surgeries. Another allows doctors to place arterial stents more accurately. VSI was working with the U.S. Army to develop a freeze-dried blood plasma product that could be stored and used simply by adding water to treat the wounded on the battlefield.

Far down the list of VSI's product inventory was a device to treat varicose veins that it called the Vari-Lase. The Vari-Lase system is basically a laser device attached to a glass fiber that is inserted into the damaged vein. As the fiber is heated and withdrawn, it seals the vein and allows healthier veins to move the blood.

The procedure is minimally invasive, is performed in a doctor's office, takes about an hour, and allows the patient to quickly return to normal activity.

Federal prosecutors acknowledged they made no claims that any patients were ever harmed by the uses of the device they found objectionable.



The Vari-Lase device that was the subject of the indictments against Howard Root and Vascular Solutions uses laser technology to seal varicose veins. Federal prosecutors conceded they did not claim any patients were harmed through the uses of the device that they found objectionable.

WAR OF WORDS

The first semantical issue that eventually entangled Root and VSI was what constitutes a "varicose vein." There would be many others as his case progressed.

When the FDA gave its first approval for the Vari-Lase system in 2005, it specified the product could be used for the treatment of "varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein and for treatment of incompetence and reflux of superficial veins in the lower extremity."

The great saphenous vein runs through the legs relatively close to the skin, as do the superficial veins. There is a larger vein that runs deeper in the limb. Connecting the two like the rungs of a ladder are what are called perforator veins.

The quarter of an inch that nearly killed VSI and sent Root to prison is the junction where the perforator vein connects to the saphenous vein. Throughout the trial, VSI lawyers maintained that point of connection, which can become varicose, was covered in the FDA's initial approval for the Vari-Lase. Even the FDA's witnesses for the prosecution conceded that was a valid interpretation and the agency's approval could cover varicose perforator veins in some circumstances.

However, the government's case hinged on treating the perforator veins as unique and excluded from the FDA's authorization. While prosecutors conceded it was legal for doctors to use the Vari-Lase to treat varicose perforator veins, they argued VSI, under Root's direction, illegally promoted that use through its sales pitches.

"We are talking about a quarter of an inch on the difference between being a free person and being in prison for years," Root said. "We are talking about freedom and prison based on a quarter of an inch of using a lawful product for a lawful use."

Over the next several years, VSI produced the Vari-Lase in eight different lengths so that doctors could use the one most suitable for different veins in different locations. It also submitted eight prior notifications to the FDA describing intended uses for the products. Each one was approved without any difficulty.

Such pre-clearances from the FDA are not required so long as the new variations on a particular device are not substantial and the new uses are consistent with the prior approval. However, most companies, fearful of the consequences if FDA regulators disagree with their assessments, routinely submit the applications to clarify the FDA's position and avoid the potential of future enforcement actions, Root said.

About 2007, VSI developed what it called its "short kit," a shorter version of its standard kit, to use for short vein segments. It filed its ninth pre-clearance application with the FDA, saying the device would be appropriate for use on perforator veins.

This time the FDA balked. It rejected the pre-approval and insisted VSI conduct clinical tests to prove the short kit was appropriate and safe for treating varicose perforator veins. VSI did not submit additional data, and in March 2008, the FDA deemed the application withdrawn.

Root said he decided not to pursue the application because the short kit was such an insignificant product. In the seven years it was in production, the short kit generated only about a half-million dollars in total sales, roughly 0.1 percent of the company's total revenues in that period. Two-thirds of the company's sales representatives had never sold a single unit, and those that did only made a few hundred dollars, at most, in annual commissions from those sales.

It simply made no financial sense for the company to spend the money to pursue the FDA's approval for a product that generated so little revenue.

"We are talking about a quarter of an inch on the difference between being a free person and being in prison for years."

- Howard Root
Former CEO of Vascular Solutions Inc.

Root issued a directive that company sales representatives could not make any claims that the Vari-Lase short kit could be used on perforator veins. Although doctors could use it for that purpose, Root said his policy was that sales representatives could not discuss off-label uses of VSI products.

Perforator veins were arguably covered under the FDA's initial approval, Root said. However, no thought was given to trying to make that argument after the FDA demanded more testing.

"My rule is always stay far away from anything that can cause us any problems," he said. "So you don't even get close to the edge. You don't analyze it that way. And trying to say that this was covered was closer to the edge than I would ever want to be with a product that was so insignificant that it didn't matter to me. I wasn't going to waste any time on it."

HIDDEN MOTIVES

Root's warning wasn't enough to either curb pushy salespeople or to insulate him from blame. In fact, prosecutors later used Root's directive not to pitch the short kit for perforator veins as proof he was covering up his crime. Root's real motive, they maintained, was to prohibit discussion of perforator treatment publicly, while encouraging his sales staff to tout off-label uses in private conversations with doctors.

Shortly after the FDA's rejection in 2008, a series of seemingly minor and unrelated events would lead to Root's legal troubles.

Danny McIff, western regional sales manager for VSI, gave a presentation to a dozen company sales representatives in which he used two documents he'd created, one titled "Tips for Treating Perforator Veins" and the other, a PowerPoint presentation, called "Treating Perforator Veins."

About 2009, another salesman, DeSalle Bui, quit VSI and went to work for a competitor. Root sent a cease-and-desist letter claiming that was a violation of a non-compete clause in his contract.

In August 2009, Bui responded to Root with a letter claiming the company was promoting the off-label use of Vari-Lase to treat perforator veins. He attached the sales presentations given by McIff as proof.

Root directed an internal investigation but found no evidence of illegal activity.

The following year, Bui filed what's called a qui tam action in Texas, invoking a Civil War-era law that allows private parties to essentially sue their current or former employers to reveal criminal or fraudulent activities against the federal government. The purpose of the law is to encourage employees of government contractors to expose illegal activities that would otherwise go undetected. Their incentive is that the whistleblower who brings the claim can collect up to 25 percent of the damages recovered by the government as a result.

Bui claimed VSI had defrauded the government of $20 million with false claims about the Vari-Lase. If that amount was collected, Bui would be entitled to around $5 million.

Federal prosecutors in San Antonio soon took up the allegations raised by Bui, and in June 2011 issued a subpoena demanding the company turn over documents related to the Vari-Lase short kit.

Root said he was dumbfounded when he learned of the investigation. The Vari-Lase short kit was such a minor product in the company's inventory, and there were no reports a patient was ever harmed as a result of its use, he said.

His first instinct was not to overreact.

Over the years, he came to realize the case was never about patient safety or false claims. It was about putting a medical company's chief executive officer in prison as a warning to others not to test the power of the FDA to limit what they could say about their products, despite court rulings to the contrary, he said.

"It didn't matter about how big the sales were. It wasn't the patient harm they were after," he said. "It was the defendant. They wanted to go after me. They wanted to put me in prison as a test case.

"They were mad at what's going on with *Caronia*, and they found Vascular Solutions; and they chose that case, and they went on the offensive to try to get a CEO behind bars. In my world, that's criminalization, that's not criminal enforcement … So they just want to find a couple of people to put the industry on notice that 'You've got to stay away from that. You can't do that, even if the Second Circuit (Court of Appeals in *Caronia*) says you can. We beat up Vascular Solutions and put its CEO in prison, because we can.'"

RAILROAD TRACKS

The investigation lasted more than three years. The most damning evidence the government turned up was the two sales presentations on perforator veins, written by McIff. Making matters worse, after a subpoena was issued for documents related to marketing of the Vari-Lase, McIff attempted to delete the files from his computer and then lied about doing so. They were later discovered by company officials during an internal investigation and turned over to federal prosecutors, who already had copies.

The government made three plea offers to the company and Root to settle the case, each more onerous than the last, he said. Initially, prosecutors said they might allow VSI to plead guilty to misdemeanor misbranding charges and recommend to the U.S. Department of Health and Human Services that the company not be excluded from the medical industry. In return, VSI would pay a civil settlement of $20 million—the exact figure cited by Bui in his qui tam action—and cooperate with the investigation of Root and other company executives. It also would pay a $2.3 million fine.

The second plea offer, which came in June 2014, would have both VSI and Root plead guilty to a misdemeanor, and VSI would pay a "seven-figure fine." That offer also required the company to fire several of its employees whom prosecutors claimed had engaged in off-label promotion.

The final offer would have required Root to plead guilty to a felony charge of conspiracy to defraud the government. Though Root would not have to serve any prison time, he would be on probation for four years and automatically banned from working in the healthcare industry.

As CEO of the company, Root answered to the board of directors responsible for protecting the interests of shareholders. The board refused the offers and allowed Root to remain in charge of VSI.

It would have been easy for the board to accept the plea agreements, and it would have done so if prosecutors had not insisted on criminal convictions against Root and punitive actions against other employees, he said. It would have been a cost of doing business, especially since any felony conviction would have resulted in exclusion from the healthcare industry and the collapse of the company.

"We would have caved if there was an opportunity to do it," Root said. "If it was just about the money, I would have given them the $20 million. I didn't fight for the money. But all the way along, somebody had to admit they did something wrong that they didn't do, and it would have left a permanent mark on them, whether it was pleading guilty to a crime or being excluded from healthcare.

"If it's just an argument about money and compliance agreements, nobody is going to risk the entire company just because they say 'I didn't do it.' They're just never going to do it. But if you add that someone is going to go to prison, then the board can have a backbone and say, 'Nope. I don't care about that. We're not going to put someone on the railroad tracks.'"

VSI did reach a settlement in the civil case, agreeing to pay $520,000 in July 2014. Root said that was an easy decision because he did not have to admit any wrongdoing and the company was already paying lawyers $1 million per year to deal with the investigation.

Four months later, a grand jury in San Antonio issued a nine-count indictment against Root and VSI. Both faced charges that included eight misdemeanor counts alleging misbranding and adulteration, all based on the notion that the Vari-Lase system was marketed for off-label use in treating perforators without having received pre-clearance from the FDA. Specific counts in the indictment referred to individual shipments of the Vari-Lase short kit to medical providers in Texas, all of which were legal absent any claims about their potential off-label uses.

But the most serious charge leveled against Root and VSI was the felony count of conspiracy, both to commit the misdemeanor misbranding and adulteration offenses, and to conceal it from the FDA.

The adulteration charges were later dropped in a superseding indictment. The conspiracy and misbranding counts remained against Root and the company.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TOP NEWS
SECRET SERVICE STUMBLES

Med-tech CEO accused of conspiracy

Vascular Solutions' Howard Root is charged in case involving sale of varicose-vein device.

A felony conviction would automatically ban VSI from the medical industry. A single misdemeanor conviction would allow the Department of Health and Human Services to impose the ban but would not make it mandatory.

VSI lost $117 million in stock value the day the indictment was announced.

LEGAL PERILS

At that point, the legal perils extended far beyond a dispute over how much the FDA could regulate a company's off-label promotions without violating the First Amendment's free speech protections. Other laws and Department of Justice policies were coming into play.

The most onerous for Root is what's called the Park Doctrine, so named because of a 1975 U.S. Supreme Court case that held a company executive could be criminally liable for corporate misbehavior. A CEO could be charged, and convicted, of misdemeanors even if he or she did not order the improper conduct or was not even aware of it. All that is required under the Park Doctrine is that the company executive had the authority to prevent or correct the improper conduct and failed to do so. Neither knowledge nor criminal intent is required.

Root acknowledged he was a "nano-manager" who personally oversaw all aspects of VSI, and so he would be criminally liable for illegal acts committed by company employees under the Park Doctrine.

The next complication came in September 2015—after the indictment but before the trial—in the form of what's known as the Yates Memo. Authored by then Deputy U.S. Attorney General Sally Yates, the directive to all U.S. attorneys required DOJ lawyers to gear cases involving corporate misconduct to get criminal convictions against individuals, not just the companies themselves. Financial settlements and even corporate pleas to criminal charges do not necessarily deter illegal conduct, Yates wrote.

So the DOJ policy as outlined by Yates was that, in cases involving corporate wrongdoing, it would not be enough to get financial settlements or corporate guilty pleas. Wherever possible, settlements and pleas should be structured with the goal of bringing criminal charges against top corporate executives.

Root did get one break in the fluid legal climate surrounding off-label speech. In 2012, Aramin Pharma received FDA approval for one of its drugs, Vascepa, to treat people with severely high levels of triglycerides. It subsequently sought approval to market the drug for those with high but less severe levels. That application was rejected.

The FDA took the same position in the *Amarin* case that it did in VSI's: Any claims as to medical benefits of Vascepa that had not been approved by the agency would constitute proof of the crime of misbranding.

But rather than risk the kind of enforcement action that entangled VSI and Root, Amarin proactively sued in 2015, seeking a declaratory judgment that discussions of off-label uses of the drug were protected under the First Amendment. The company argued that the FDA's lack of a clear standard for off-label promotion had a chilling effect on Amarin's free-speech rights.

The judge sided with Amarin in a sharply worded ruling that held the FDA could not bring a misbranding action based on the truthful promotion of off-label uses alone.

"Where the speech at issue consists of truthful and non-misleading speech promoting the off-label use of an FDA-approved drug, such speech, under Caronia, cannot be the act upon which an action for misbranding is based," the judge wrote.

The FDA and Amarin reached a settlement in the case that allowed the company to promote the triglyceride-reducing benefits of Vascepa.

The *Amarin* case was brought in New York, which is under the jurisdiction of the Second U.S. Court of Appeals that ruled in the *Caronia* case. Therefore, the precedent applied. Since Root's case was brought in Texas, which is not in the Second Circuit, courts there were not bound by *Caronia*.

LINGUISTIC LABELS

In pretrial motions and during the trial, three main issues emerged.

The first was whether treating perforator veins with the Vari-Lase short kit was an off-label use at all. Perforator veins can become varicose, the defense argued. The FDA approved the Vari-Lase to treat varicose veins *and* the superficial veins that run closer to the skin. That meant the prior FDA approvals covered perforator veins.

Two high-ranking FDA officials admitted that treatment of perforator veins might be covered by the prior FDA approvals.

"In some sense, VSI may be right" that the indication would include perforator veins, said Dr. Pablo Morales, FDA medical officer.

Prosecutors countered in written arguments that the statements of the two FDA witnesses does not bind the agency or change the fact that the Vari-Lase was never cleared for use specifically on perforator veins.

The second issue was whether off-label promotion of the Vari-Lase was constitutionally protected speech, if indeed it was not deemed an on-label use.

Here again, the argument turned on semantics.

Defense lawyers invoked both *Caronia* and *Amarin* in arguing that the prosecution's whole case hinged on the truthful and non-misleading statements of VSI salespeople as to potential uses of the Vari-Lase, speech that is clearly protected. Aside from that speech, no other evidence of illegal activity had been raised.

Prosecutors claimed the speech itself was not being prosecuted, to the degree it was truthful. Rather, the promotion of off-label uses, which itself was constitutionally protected, was being used as evidence that VSI and Root designed and developed the short kit specifically to treat perforator veins. After the FDA rejected the application for that use, company officials began using terms like "short veins" as code words for perforators to hide their real intentions, the government claimed.

Since the sales promotions suggested the Vari-Lase was appropriate for a use that had not been cleared by the FDA, it was therefore not truthful speech and therefore not protected by the First Amendment.

The judge left the issue up to the jury. At the close of testimony, he did include jury instructions that made it clear neither Root nor VSI could be convicted on the basis of legal speech alone.

"If you find that VSI's promotional speech to doctors was solely truthful and not misleading, then you must find the Defendants not guilty of the misbranding offense," the jury instructions stated.

Prosecutors objected, but the judge reminded them that they'd agreed to similar language in responding to pretrial motions.

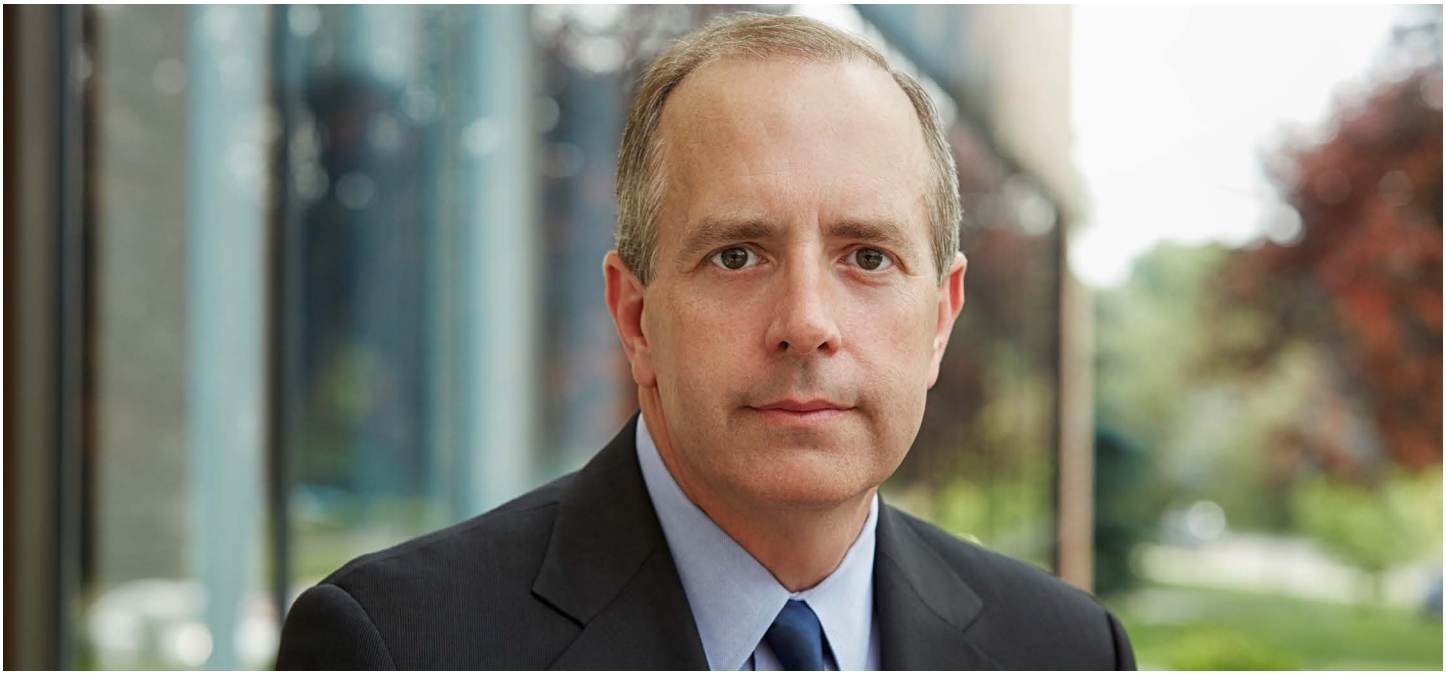
MALICIOUS 'MISCONDUCT'

The third and most disturbing issue that dominated the trial was defense claims of government misconduct, yet another instance in which semantics came into play. Many VSI employees denied any misconduct in their initial interviews with federal investigators. As the case progressed, some of them changed their stories to align with the government's theory of the case after they were threatened with jail time, criminal charges, and exclusion from the medical industry.

A favored tactic, as outlined by several witnesses, was that a witness would be questioned under the guise of a secret grand jury investigation, meaning their lawyers were not allowed to accompany them. Prosecutors spent the first couple of hours explaining their theory of the case. Sometimes they would read transcribed grand jury testimony from other witnesses who admitted off-label promotions of the Vari-Lase—a tactic that violated DOJ policies and laws governing grand jury secrecy, the defense argued. At that point, the witness would be told to "fix" their testimony by admitting criminal conduct both individually and by the company. If they did not, they would be charged with perjury, obstruction of justice, or a variety of other crimes, the prosecutors warned.

One sales executive initially said he'd done nothing wrong. During later questioning, government lawyers waved a draft indictment with his name printed on it in front of him and warned that if he did not correct his testimony and admit wrongdoing, they would charge him. Prosecutors made clear that if he gave testimony supporting the government's case, the indictment would go away, according to defense filings and trial testimony. The man signed a confession that had been written by prosecutors.

McIff, who had authored then deleted the presentations on treating perforator veins, was told he would be charged with perjury and obstruction of justice,



and would face 20 years in prison, if he did not sign a plea agreement admitting the Vari-Lase was illegally marketed and cooperate in the prosecution of Root and VSI. He signed.

A regional sales manager was told that if she continued to claim she'd done nothing wrong, she would be charged with perjury and obstruction of justice, and that the government would seek to have her banned from working in the healthcare industry. After the trial, the woman informed Root through an email that she'd also been warned by prosecutors that "If you do not deliver us with the answers we want to hear … we have the power to withhold rights/privileges provided to your natural born son." They did not explain.

Another salesperson, Glen Holden, refused to change his testimony that he'd not attempted to increase business by marketing the short kit specifically for perforator use. He was indicted by federal prosecutors on five counts of perjury and one of obstruction of justice in November 2014.

Even a doctor who used the Vari-Lase successfully was told that if he did not cooperate with the prosecution, he could be investigated for Medicare fraud for billing the government for any off-label procedures he'd performed.

"In this backwards approach, the government resorted to vulgarity and threats to get witnesses not to recall facts, but to construct them, consistent with the prosecution theory," defense lawyers argued in a pretrial motion to dismiss the case against Root and VSI. "The government directly coupled threats of criminal prosecution and career destruction to the requirement that the witnesses make statements consistent with the government's theory."

Federal prosecutors countered that they never threatened or pressured anyone to "fix" their testimony by lying. Instead, what they did was make clear to the witnesses the consequences of failing to testify truthfully. Outlining the government's theory of the case, and reading secret grand jury testimony, was simply the prosecution's way of letting reluctant witnesses know they would not be alone if they told the truth by implicating the company and Root in criminal activity, they said in court filings.

As with the First Amendment claims, the judge left the issue for the jury to decide. He did say the defense had failed to prove government misconduct because prosecutors had a reasonable basis to believe testimony that was inconsistent with their theory of the case was untrue.

ZBD

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TOP NEWS

Device CEO acquitted in off-label case

In berating prosecutors, Minn. executive calls legal attack "obscene."

By JOE CARLSON
joe.carlson@startribune.com

Maple Grove medical-device maker Vascular Solutions and its CEO Howard Root have been acquitted on all counts in a criminal case that had alleged a conspiracy to illegally promote sales of a device to treat varicose veins.

The case, unusual because it featured a CEO who opted to wage a vigorous counterattack against prosecutors, became a closely watched battle that could reshape the FDA's power to regulate medical device sales.

"I feel vindicated, but outraged by the obscene legal process that I had to endure and the public trashing that my reputation and my company had to take," Root said in a phone interview Friday afternoon, shortly after a San Antonio jury returned not-guilty verdicts on nine counts in the indictment.

The case turned on a somewhat arcane legal question about the Food and Drug Administration's approved label for Vascular Solutions' now-discontinued Vari-Lase

CEO Howard Root decried "the public trashing" that his firm had to endure.

Short Kit device. The jury deliberated for a day and a half, following weeks of testimony from prosecution witnesses.

Vascular Solutions said it spent $25 million building its defense, but ultimately chose not to call any of the 20 witnesses it had lined up.

The case is likely to draw industry scrutiny in part because of the trial judge's instruction to the jury that declared unequivocally that it is not a crime for a device company to provide doctors with truthful, non-misleading information about unapproved product uses. That's contrary

See ACQUITTED on A6 ▸

BUDGET SURPLUS SHRINKS

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Pollinators

"Detroit is not this bad. Washington, D.C., is not this bad. I would hate to see what it was like before it was efficient if this is efficient."

Traveler Stephanie Declercq, on the lines at MSP

St. Paul looking at

'NOTHING SHORT OF CRIMINAL'

All three of the key issues were hashed out in testimony during the four-week trial at which the prosecution laid out its case. The defense did not call any witnesses, relying instead on admissions by the government's own witnesses that the use of the Vari-Lase short kit might be covered on its FDA-approved label, and that several company employees changed their testimony after threats from the government.

The jury acquitted both Root and VSI on all counts.

One juror later emailed Root, stating: "What the federal government did to you, your company and your employees is nothing short of criminal."

Within about an hour after the jury verdict was announced, the VSI stock price increased 7 percent.

About a month after the verdict, the Justice Department dropped all charges against Holden, the salesman who refused to alter his testimony, "in the interest of justice." It also did not pursue the plea agreement it secured against McIff, according to Root.

Even though he was acquitted, Root said the government still won in the end by sending a message to the industry that it would not tolerate any discussions of off-label product uses, despite what the courts said. VSI spent $25 million for lawyers to represent Root, the company, and all of its employees who were caught up in the case. Federal law prohibits the company from recouping those costs.

Victims of malicious prosecution can sue the government for their costs incurred defending themselves. However, under a 1997 law, that recourse is not available to any individual with a net worth of more than $2 million, or a corporation with a net worth of more than $7 million.

The law is well-intentioned but worthless, Root said. The only companies financially able to defend themselves against a malicious federal prosecution are those with a net worth of more than $7 million. So companies with values below that cap have no choice but to strike a deal with prosecutors rather than face financial ruin. The same is true for individuals.

"The first punishment that every defendant gets is punishment by the process," Root said. "Everyone in the industry sees that punishment by process. Five years. $25 million. People say 'I don't want that to happen to me. Let's not develop that product. Let's not try to do too much.' It's a big chill on the industry.

"It's not just a chilling effect. It's a frozen effect. It freezes everyone out of communicating information about your medical devices. They just can't have that risk."

DRIP, DRIP, DRIP

Another medical device executive who ran afoul of the FDA's interpretation of its power was William Facteau, chief executive officer of a medical device company called Acclarent Inc., which specialized in products used primarily in the ear, nose and throat.

One of those products was called the Stratus Microflow Spacer, essentially a small balloon with tiny holes that was implanted in the sinuses to hold them open.

All of the same laws and federal policies that entangled Root came into play when federal prosecutors brought criminal charges against Facteau and a fellow Acclarent executive, Patrick Fabian. So did the government's semantical argument that protected speech was evidence of a crime, not the crime itself.

When the FDA approved the Stratus device in 2006, it did so based on the use of saline solution—salt water – that would slowly drip out of the holes to moisten the tissues. However, promotional materials and training slides depicted a thicker solution dripping out of the holes in the Stratus spacer, a liquid that looked suspiciously like an FDA-approved steroid commonly used to treat recurring sinus problems.

While that would be a legal off-label use, the government maintained those slides were proof that the Stratus was designed to release the steroid all along, not saline as had been represented to the FDA when it granted approval.

The federal investigation began in 2011, about the same time Root fell under scrutiny from the Department of Justice. And like Root, the investigation was opened after a former company employee filed a whistleblower action under the False Claims Act, and therefore stood to gain a percentage of any financial settlement reached with the company.

In April 2015, a federal grand jury in Massachusetts issued an indictment charging Facteau and Fabian with multiple felonies, including conspiracy, securities fraud, and wire fraud, as well as misdemeanors that included misbranding and distribution of an adulterated device. Four of the felony counts were later dropped without explanation.

The gist of the government's case was that Acclarent fraudulently obtained the FDA's approval for the Stratus device by claiming it would dispense saline, when the real intent was to market it for steroid delivery off-label, a use the agency never approved.

THOUGHT POLICE

The prosecution conceded no patients were harmed, that it was legal for doctors to use the steroid in the Stratus device, and that it was legal for Acclarent to sell it for off-label treatment. It was even legal for company employees to discuss off-label uses, so long as their representations were true and not misleading.

The way the defense characterized the case was that the government prosecuted Facteau and Fabian based on what prosecutors believed the two were thinking, not for anything they did.

In her instructions to the jury, the judge explained the principle under *Caronia* that the defendants could not be convicted of the crime of misbranding, on which the felony conspiracy and fraud charges hinged, simply for making true and non-misleading statements about the off-label use of their product. However, she also embraced the prosecution's claims that the protected speech itself could be used as evidence of other crimes, including the felonies.

The judge explained that under the Park Doctrine, top executives could be convicted of misdemeanor crimes even if they did not intend, participate in, or know about any illegal activity.

At an earlier hearing, the judge expressed misgivings about how all of the laws and legal precedents could ultimately play out, particularly if the jury convicted the defendants of the misdemeanor misbranding charges but acquitted them of all of the felonies, a result that would indicate the split verdict was based on legal speech absent other crimes.

That is exactly the result the jury delivered in July 2016. It acquitted both defendants of all 14 felony charges, but convicted them of 10 misdemeanor misbranding and adulteration counts based on the Park Doctrine.

Defense lawyers filed a motion in August 2016 asking the judge to issue a directed verdict of acquittal on the misdemeanor counts or, short of that, order a new trial. They argued the acquittals on the felony charges showed the jury did not believe that any crimes unrelated to protected speech had been committed. And absent representations in sales and training presentations, neither of the defendants could have been charged. Therefore, the only basis for the misdemeanor convictions was the legal and constitutionally protected speech.

Prosecutors reiterated their claims that the speech was used only as evidence of the crimes of misbranding and adulteration, and the Park Doctrine justified the misdemeanor convictions.

Since then, nothing.

For more than two years, the judge has neither ruled on the motion for a directed verdict nor moved ahead with the sentencing of Facteau and Fabian. There is no explanation in court files.

Facteau could not be reached for an interview, despite attempts to contact him through his lawyer and the company for which he now works.

"The DOJ systematically treats people like criminals when all they've done is develop products that help people, and this approach sends a chilling message to the healthcare industry."

- Christina Sandefur
Executive Vice President, Goldwater Institute

Justice Department officials also would not comment on their prosecutions of Facteau or Root.

A week after the trial ended with a split verdict, Acclarent reached a settlement agreement with the Department of Justice in which it agreed to pay about $18 million. The company also withdrew the Stratus device from the U.S. market.

Acclarent was sold to the pharmaceutical giant Johnson & Johnson in 2010, about a year before the federal investigation began, for $785 million.

PROMOTIONS AND PAYOUTS

Other companies, big and small, have paid billions of dollars to the federal government to settle misbranding claims and other related charges rather than face the wrath of the FDA and federal prosecutors.

In 2007, Jazz Pharmaceuticals, which acquired the firm that the defendant in the *Caronia* case worked for, agreed to pay $20 million to settle civil and criminal claims associated with the off-label marketing that later led to the precedent-setting decision.

In 2012, GlaxoSmithKline and Abbott Laboratories reached unrelated settlement agreements totaling nearly $5 billion to settle charges related, at least in part, to marketing practices and off-label promotions of their products. Also in 2012, Amgen, the world's largest biotechnology firm, pleaded guilty to criminal misbranding charges related to off-label promotion and agreed to pay $762 million in criminal fines and civil settlements.

A year later, Johnson & Johnson and its subsidiaries agreed to pay more than $2.2 billion to resolve criminal and civil claims arising in large part from its off-label promotion of its drugs.

For most companies, admitting to any charges the government brings and paying whatever amount it demands is just good business, Root said.

Small companies could never afford to fight the kind of legal battle he waged against the government, especially when the value of their stock tanks because of the bad publicity and threat of exclusion from the medical industry, Root said.

Big pharmaceutical giants—like Johnson & Johnson, GlaxoSmithKline, Abbott, and Amgen—have enough layers of upper management that responsibility for policing salespeople is diffused. So their top executives face little risk of being charged under the Park Doctrine. That makes it easy for them to quickly reach settlement deals as a cost of doing business, even if it means sacrificing a mid-level manager or two.

Only midsized companies like VSI are apt to challenge the FDA and Justice Department, Root said. They are financially stable enough to sustain a prolonged legal battle. And their chief executives have clear control over all aspects of their business, including the sales force, making them vulnerable to being charged under Park.

"It's only that middle school, those CEOs like me and Bill Facteau, who actually have the ability to get indicted, plus we have the money to have the ability to fight and can actually push back," Root said.

The Justice Department in November slightly revised the guidelines set out in the Yates Memo. Under the new policy, announced by Deputy Attorney General Rod Rosenstein, local prosecutors will have more leeway in crediting corporations that cooperate in the prosecution of individuals who were "substantially" involved in misconduct. The Yates guidelines required a company to identify any individual involved, which Rosenstein said was sometimes impractical.

'BREATHTAKING ABUSE'

The aggressive prosecutions of pharmaceutical and medical device executives in a manner contrary to the clear court rulings are stifling innovation in the industry, which ultimately harms patients, said Christina Sandefur, executive vice president at the Goldwater Institute. Even though it is settled that drug companies have free speech rights protected by the Constitution, the ruinous cases brought by the Department of Justice and Food and Drug Administration have chilled the free exchange of information that doctors need to make treatment decisions, she said.

As a result, drug companies can neither communicate about the benefits nor the risks of the off-label uses of their products without risking the wrath of federal prosecutors.

"The aggressive tactics employed and encouraged by the Department of Justice are breathtaking abuses of government power," Sandefur said. "The DOJ systematically treats people like criminals when all they've done is develop products that help people, and this approach sends a chilling message to the healthcare industry. The cost and uncertainty of these never-ending prosecutions ultimately harms patients, as companies are discouraged from sharing valuable information with doctors and insurance companies."

Free Speech in Medicine is an attempt to offer some protection. The legislation, already passed in Arizona and Tennessee, would protect the ability of drug and device companies to share accurate and non-misleading information about their products with medical providers in a manner consistent with the rulings in the Caronia and Amarin cases.

Typically, it is the manufacturers that have the most complete and up-to-date information about the off-label uses of their products, as well as the risks involved in using them off label. However, because of the fear of running afoul of federal regulators and even being criminally prosecuted, they avoid communicating any of that information. As a result, doctors may end up not using the most effective treatments available, or they may use them in ways that are inappropriate and even dangerous, Sandefur said.

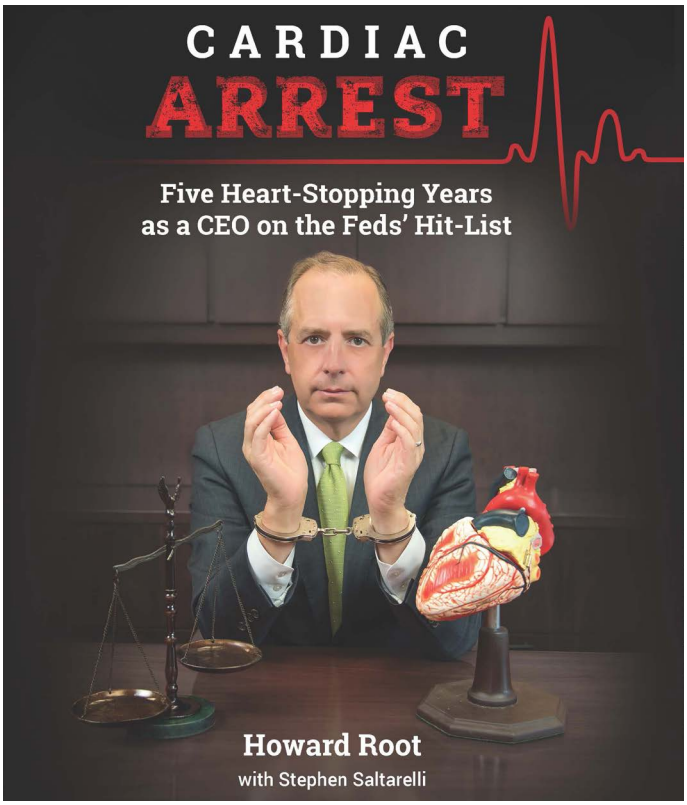
"The FDA's approach to off-label communications has effectively become a gag order," she said. "The resulting ignorance can be deadly because doctors, payers, and patients will not be presented with all the information they need to make medical decisions. At the end of the day, the patient is the one who suffers."

The Goldwater Institute is currently advocating Free Speech in Medicine at the state level. In states that adopt it, drug and device companies would be shielded from prosecution and regulatory enforcement actions by states if they communicate accurate information about off-label uses. The law would also bolster free speech arguments if the federal government takes punitive action, though the extent of that protection would have to be hashed out in federal courts, Sandefur said. She is confident the law would be effective, even though federal law generally takes precedence over conflicting state laws, because Free Speech in Medicine is consistent with federal court rulings, whereas recent enforcement actions by the Justice Department are not.

SUSTAINING THE SILENCE

As for Root, he's done with the medical business.

A year after his acquittal, Root quit VSI, and the company was sold for $1 billion.



He also left the medical device industry because he is unwilling to take the risks associated with a business that could make him the target of a malicious government prosecution at any time, particularly under the Park Doctrine.

But he's not done with federal prosecutors.

Root wrote a book about his experience, *Cardiac Arrest: Five Heart-Stopping Years as a CEO on the Feds' Hit-List*. He also continues to give lectures about the tactics used by federal prosecutors in their quest to get a conviction and shut down any constitutionally protected talk about off-label uses of medical products.

Today, he's involved in a small company developing electric-powered pontoon boats.

The government is not done with Root either.

In May 2017, Root was asked to participate in a panel discussion about his case at an American Bar Association summit on healthcare fraud. Prosecutors from the San Antonio U.S. Attorney's Office who brought the charges were also supposed to be on the panel.

The Department of Justice not only refused to participate in any discussion with Root or about his case, it warned the ABA that if Root appeared, the agency would bar its lawyers from ever participating in the future.

Root's invitation was rescinded.

The DOJ employed a similar tactic in 2018, when Root was invited to speak at a conference on the False Claims Act and qui tam enforcement actions. If Root participated in any way, DOJ officials warned, none of its attorneys would participate or attend.

Again, Root was disinvited.

Sen. Chuck Grassley, R-Iowa, at the time chairman of the Senate Judiciary Committee, sent two letters to DOJ regarding Root's case. The first, sent in May 2016, sought an internal investigation of the threats and other hardball tactics used by prosecutors to secure the testimony of company employees.

In its response to Grassley, DOJ said the issues of misconduct had been raised by the defense in pretrial motions but had been rejected by the judge. It also said the agency's Office of Professional Responsibility was looking into the allegations.

The second Grassley letter, dated March 2018, asked for the status of any internal investigation and an explanation as to why the DOJ apparently retaliated against Root by spiking his appearance at the two conferences.

In September 2018, DOJ replied that the internal investigation "found no evidence that Department attorneys engaged in professional misconduct" and closed the matter.

As to the conferences, the letter from Assistant Attorney General Stephen Boyd said DOJ lawyers get many invitations to speak, and they decide which to accept based on a variety of factors, including their workloads, the content of the conferences, and whether participation would be in the DOJ's interests.

Root characterized the department's refusals to participate in conferences as petty and an ironic attempt to further stifle his free-speech rights.

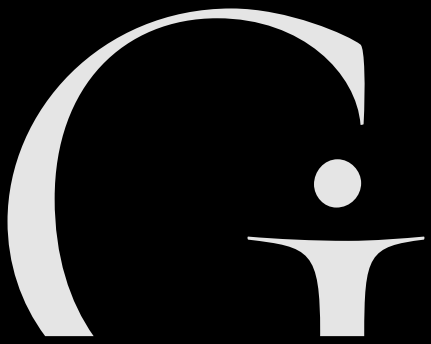
But that's not the greatest damage that was done in his case, he said.

Nor is the personal peril he and VSI faced as a result of what he deems a malicious prosecution, or the $25 million that it cost to defend himself and his company.

The real damage is the lives lost because the innovative medical devices he or others at VSI might have developed were never invented, he said.

"Over the five years Vascular Solutions fought the government, we grew slower, invested less in R&D (research and development), hired fewer employees, and were robbed of $25 million we would have otherwise spent on productive medical activities," Root said in his book.

"The interventional catheter I didn't invent because I was sitting in a San Antonio courtroom will never be seen by anyone, and when you need it, you won't even know it's not there. Multiply that by all the medical device and pharmaceutical companies that have come under criminal investigation, and imagine how many medical breakthroughs you'll never see."



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