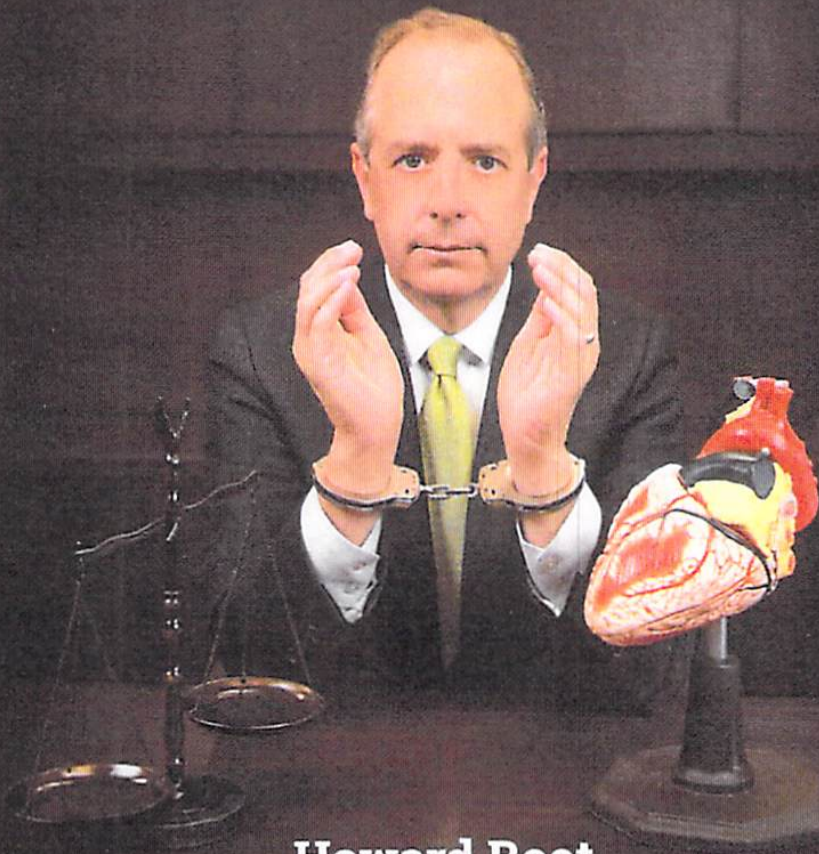


CARDIAC ARREST

Five Heart-Stopping Years
as a CEO on the Feds' Hit-List

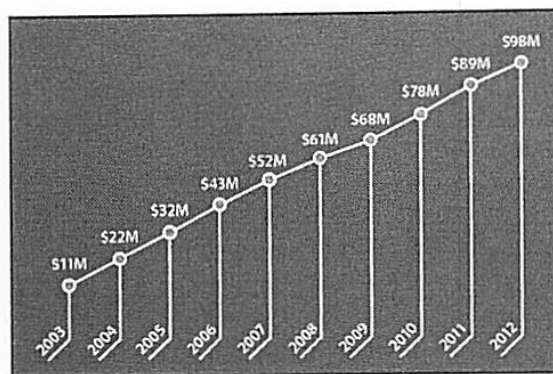


Howard Root
with Stephen Saltarelli

CHAPTER 4

DOJ BLIND DATE

FEBRUARY 5, 2013



While I was being served up by DeSalle and Eddie, Vascular Solutions was serving up another banner year. That was the conclusion of our glossy 2012 annual report, which showed double-digit sales growth for the ninth straight year, a feat none of our competitors could match. This year's success owed largely to a breakout year for what was becoming our first true blockbuster product – the GuideLiner catheter.

Three years since its launch, the GuideLiner had become the premier tool for interventional cardiologists working in hard-to-reach areas in the heart. It rose to prominence in September 2010, when a top cardiologist went before a packed crowd at the world's biggest cardiology conference and gushed, unprompted, that "the GuideLiner makes impossible cases possible and difficult cases easier."

He was right; the GuideLiner was revolutionary. Where the strategy before was "push as hard as you can and see if you can force the stent into the

artery,” GuideLiner now allowed doctors to easily deploy stents like a Push Pop into areas they couldn’t before access. Today, I’d say that 99% of interventional cardiologists know how to use GuideLiner to deliver a stent, and you wouldn’t want to be treated by the other 1%.

But when I invented the GuideLiner in 2006, doodling in the audience of a boring medical meeting, I never imagined it would be used how it is today. I thought I had a \$10 million product that would help doctors position their guide catheter into the opening of the coronary artery. But shortly after we released the product in 2009, I watched it go viral. One doctor used it to place a stent, then told another, who told his colleagues, then the big conference speech, and all of a sudden it was 2012 and I had a \$20 million monster, well on its way to \$50 million a year.

As I drove downtown on February 5, 2013, I was thinking about that annual report. But not about the GuideLiner or our sales growth. No, I was thinking about a single paragraph in the “Legal Proceedings” section.

On June 28, 2011, we received a subpoena from the U.S. Attorney’s Office for the Western District of Texas requesting documents related to the use of the Vari-Lase® Short Kit for the treatment of perforator veins. The Short Kit has been sold under [FDA] clearance since 2007 with total U.S. sales through December 31, 2011 of approximately \$410,000 (0.1% of the Company’s total U.S. sales) and has not been the subject of any reported serious adverse clinical event. We are fully complying with this inquiry.

I wanted that paragraph gone. And I was headed to the Minneapolis U.S. Attorney’s Office to see what it would take to make that happen.

Although no federal prosecutors from Minnesota would be attending, the Minneapolis federal courthouse was chosen for our convenience. An early sign of good will and cooperation, perhaps. With my Dorsey legal team of Bill Michael and Tom Vitt at my side, we arrived at the obsidian courthouse and made our way up to the U.S. Attorney’s Office, whose quarters were even nicer than Dorsey’s. After waiting 18 months and getting stood up on my offer to meet to explain this matter, I was finally getting my first date with the suits behind the government’s investigation, even if it was only to hear what they wanted from us.

Waiting for us in the conference room was Charles Biro, a dour-faced junior lawyer with DOJ's Civil Frauds Section. Kimberly Johnson, his Texas partner who'd sent us the subpoena, joined in by videoconference.

Biro led things off with his theory of what happened. VSI's indications didn't cover perforators, he said, but our competitor – VNUS Medical – had the word “perforator” right there in their indications. Because VNUS had it, Biro nervously argued, we needed it. We asked FDA to add the word, but when FDA said we needed a study before putting “perforator” on our label, and we didn't have one with good enough data, he claimed that high-ranking executives (read: me) hatched this secret plot: keep the label the same, but tell the sales force, through coded instructions, to illegally market the new Short Kit for perforators anyway.

Biro proudly announced that he'd personally combed through the sales records and sales reps' weekly activity reports and determined that there were hundreds of potentially fraudulent Medicare claims. Biro had a habit of pausing when he got to a number, seemingly impressed with himself for wielding power over a case in which literally *hundreds of thousands of dollars* were at stake. And then he got to his final number – the one he said represented Vascular Solutions' total civil liability in this case ...

Twenty million dollars.

There it was again. *The number*. I looked over at Bill Michael, whose face wrinkled in disbelief. “How'd you get that?” he asked, knowing the answer was that they'd ripped it from DeSalle's “information and belief.” Biro fumbled through his spreadsheets, before Kimberly Johnson piped up to assist him. In contrast to Biro, Johnson seemed confident in her grip on both the process and the facts. “That's not our resolution offer,” she clarified. “That's what we believe a verdict could bring at trial, worst-case scenario.” Bill Michael's brow remained furrowed.

Next up was a 30-something government attorney with a prematurely receding hairline, seated at the end of the table. He'd introduced himself when we walked in but hadn't said a word since then. Frankly, I'd forgotten he was there. “I'm Tim Finley,” he said, re-introducing himself as a trial attorney from DOJ's Consumer Protection Branch. Bill Michael had explained to me that these guys usually handle things like fireworks safety and lottery fraud,

but a jurisdictional quirk also gives them power over criminal violations of FDA laws.

Finley didn't have much to say, admitting he'd just been assigned to the case because the hot-tempered Lauren Hash Bell was on maternity leave. He nevertheless agreed with Biro's analysis. After that borrowed conclusion, Finley speculated as to what it would take to resolve the criminal case. With a \$2.3 million fine and a criminal misdemeanor plea, he said, the case *might* go away. But he was at pains to say he was waiting for Hash Bell to return before making any real offer – those figures were just his personal impression.

I had the numbers written down on a pad in front of me. Twenty for the civil lawsuit, two-and-change for the criminal penalty, plus a federal criminal guilty plea. They added up to a shakedown.

It was our turn now to talk, and the plan was for Bill Michael to lead a charge of reason that would convince the government to back off. He began by saying that in his many years as a prosecutor and private attorney, he'd never seen a prosecution – civil or criminal – reach the terms described over half a million in sales and no patient harm. "As you'll see from the documents," he told them, "this is an insignificant product in every sense of the word."

But as I measured the faces across the table, they had the look of poker players who didn't care what their opponent's hand was, because they were holding aces. *What's going on here?* Sensing Bill Michael's failure to get traction, Tom Vitt chimed in to remind the prosecutors that they were meeting with a company that, in over 15 years, had no criminal history and never so much as received a warning letter from FDA, usually the first step in this sort of case. Again, they didn't care. Johnson checked her watch and announced through the slight lag of the videoconference that our time was up. We concluded the meeting with tepid handshakes, unmoved prosecutors, and no real settlement offers. Not good.

This was getting hairy. We'd given them the documents, plead our case in person, and we were still no closer to reaching a resolution or even building up good will with the other side.

On paper, Bill Michael was the perfect defense lawyer. He knew the process, knew the law, and commanded credibility. But he wasn't a charmer. In fact, in our meeting with the government, he was kind of a jerk. I was be-

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