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OPINION | REVIEW & OUTLOOK

## No Justice for Business

A small Minnesota company fights a bad prosecution—and wins. But where's the redress?

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When governments try to criminalize honest businesses, the good guys lose even when they win. Take the ordeal of Vascular Solutions, a Minnesota-based medical-devices company that recently won in court but is wondering how to undo the damage to its business and reputation.

The tale began in 2014 when a disgruntled former employee filed a whistleblower's complaint with the U.S. Attorney's office in San Antonio. After a review by the DOJ's Civil Division, the company was accused of marketing a kit the FDA had authorized to treat one type of varicose veins to treat another type of varicose veins the FDA had not authorized. Rather than let the case drag out, Vascular Solutions agreed to settle the civil suit for \$520,000, while denying any wrongdoing.



Howard Root, co-founder of Vascular Solutions Inc., in 2007. PHOTO: ASSOCIATED PRESS

That should have ended it. But then the DOJ's Criminal Division took over. In November 2014, a San Antonio grand jury indicted the company on several counts related to the alleged promotion of a varicose vein kit for off-label uses. The lead prosecutors in this criminal case were Timothy Finley, a trial attorney from the Consumer Protection Branch in the Civil Division, and Walter Paulissen, an Assistant U.S. Attorney in the U.S. Attorney's Office for the Western District of Texas.

The company wasn't spreading false information—off-label uses often work as therapies—but this didn't matter to the feds. The

FDA has taken the position that companies cannot share information about products for uses it hasn't authorized. But as federal Judge Royce Lamberth rightly pointed out in his instruction to the jury, it is “not a crime for a device company or its representative to give doctors wholly truthful and non-misleading information about the unapproved use of a device.”

We count that as a victory for common sense and the First Amendment, given that the case will now force the FDA to reconsider the way it deals with how companies market their products. Still, the greater villain here is the Justice Department.

Justice pursued the Eliot Spitzer model of prosecution, named for the New York Attorney General who built a reputation as the “sheriff of Wall Street” largely by forcing companies into fines and settlements without ever going to trial. Threaten a CEO with trumped up criminal charges, then watch the company settle to avoid the expense and reputational damage of a long legal defense.

Unfortunately for Justice, Vascular Solutions CEO Howard Root refused to play this game. He hired a team of former DOJ lawyers, headed by John Richter, a former U.S. Attorney who was also an acting Assistant Attorney General for the Criminal Division.

In addition to rebutting the charges against Vascular Solutions, Mr. Richter also filed court papers accusing prosecutors of abuses. These included sharing secret grand jury testimony from some witnesses to get company employees to change their stories, interviewing witnesses outside the grand jury without their counsel present, and telling witnesses whose testimony did not fit the prosecutors’ narrative to “fix” their testimony or they would be fired from their jobs, banned from the health-care industry for life or prosecuted.

DOJ says “we respect the jury’s verdict,” and notes the trial judge declined to dismiss the case on grounds of prosecutorial misconduct. That’s not reassuring. For though the judge said he found no such misconduct, he held no evidentiary hearing and in the trial the defense made the prosecutors’ behavior part of its case. The acquittal on all counts suggests there are grounds for a closer look.

Mr. Richter says he did not make these accusations lightly, and business needs better avenues of redress from overreaching prosecutors. It cost Vascular Solutions \$25 million to clear its good name—no small amount for a firm that reported \$147 million in revenues for 2015.

There are any number of ways to proceed from here, but one idea would be for the Attorney General to transfer internal discipline cases from the Office of Professional Responsibility to the Office of Inspector General. Congress might also take a page out of civil law and provide a way for a defendant who prevails in criminal cases to recoup legal fees from the government. If Congress starts noticing a pattern of such cases, it can also show its displeasure through the budget process.

It’s a good day when an honest company succeeds against attempts to criminalize an honest business. Even sweeter would be if Congress and DOJ used the occasion to institute reforms to ensure accountability for prosecutions that never should have happened.

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