IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

SAN ANTONIO DIVISION

UNITED STATES OF AMERICA	§	
	§	
v.	§	
	§	
VASCULAR SOLUTIONS, INC.,	§	CRIMINAL NO. 5:14-CR-00926
	§	
and	§	
	§	
HOWARD C. ROOT	§	
	§	
Defendants.	§	

DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO DISMISS THE INDICTMENT BASED ON GOVERNMENT MISCONDUCT

INTRODUCTION

Defendants Vascular Solutions, Inc. ("Vascular Solutions," "VSI," or "the Company") and Howard C. Root file this Memorandum in Support of Motion to Dismiss the Indictment Based on Government Misconduct. Eighty years ago the Supreme Court made clear that a prosecutor's duty is to do justice, and not merely to obtain a conviction; to that end, while a prosecutor "may strike hard blows, he is not at liberty to strike foul ones." *Berger v. United States*, 295 U.S. 78, 88 (1935). Despite this admonition, some government attorneys continue to ignore their constitutional, legal and ethical obligations, instead seeking a conviction at any cost. Unfortunately, this is one of those rare cases. The prosecutorial misconduct detailed below has been so pervasive that it fundamentally undermined the reliability of the grand jury's determination and the defendants' Sixth Amendment

right to present testimony at trial. Rather than properly elicit facts in the search for truth, the government, led by an attorney from the Civil Division[1], first fashioned a theory and then endeavored to distort the evidence and the law to support that theory. 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. When witnesses contradicted the prosecution theory, the Civil Division attorney went so far as to recite lengthy secret grand jury excerpts and his own version of the facts, and to demand that the witnesses recant their prior testimony. This government attorney even resorted to threats of ruinous personal repercussions, including the loss of not only the witness's employment, but their entire career in the healthcare industry. As discussed more fully below, the government's strategy has been as multifaceted as it is astonishing.

The Government Endeavored to Distort the Evidence. First, when witnesses provided information that contradicted the prosecution theory, the government presented them with a stark choice: "fix" their testimony or face devastating personal consequences. For example, as demonstrated by the attached affidavits:

- The government characterized a group of witnesses' testimony as the "same line of sh**" given by others who refused to admit "the obvious truth," and warned that the witnesses must "fix" their testimony or face criminal prosecution.

- The government told one witness that if he wants to "be safe from prosecution," his testimony needs to be "consistent with" the testimony of others.

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[1] This prosecution is being led by the Consumer Protection Branch ("CPB") of the Civil Division of the Department of Justice. While CPB attorneys typically handle civil cases, they also have jurisdiction to initiate regulatory-based criminal cases. *See generally* Department of Justice, Consumer Protection Branch, *available at* http://www.justice.gov/civil/consumer-protection-branch (last visited Aug. 13, 2015).

- The government told another witness that her testimony was "pissing them off," and that the employment consequences could be severe, as the government could seek to have her fired.

- The government warned another witness that if she did not "fix" her testimony to be consistent with the others, she would face criminal charges, loss of employment, and referral for exclusion from participation in federal health care programs, effectively ending her career.

- The government warned another witness that he was a "coat of paint away from perjury," explained that the "poor f***er just on principle may be indicted," and demanded that the witness return "on bended knee" to admit that he misled the government.

The intimidating and long-lasting effect of these threats—especially when delivered by United States prosecutors backed by the full force of the government itself—cannot be overstated.

Second, the government endeavored to influence testimony by reading statements of certain witnesses to other witnesses, including secret grand jury testimony in deliberate violation of Federal Rule of Criminal Procedure 6(e). The Civil Division attorney purposefully read snippets of testimony from certain witnesses, which the government believed was helpful to their case, to other witnesses, whose statements had contradicted their case. The government itself acknowledged in this case that the rule against disclosing grand jury transcripts in this way exists to prevent "tampering with the witnesses who may testify before grand jury and later appear at the trial." *See* Gov't Motion for Authorization to Release Grand Jury Testimony to Witnesses, ECF No. 57 at 2. Yet they did precisely what the rule prohibits. This witness taint concern is also memorialized in Fed.R.Evid. 615, which requires the court upon the request of a party to prevent witnesses from observing a trial "so that they cannot hear other witnesses' testimony." Ironically, the government's standard instructions for witnesses admonish witnesses "not [to] discuss your testimony with others until the trial is over." Yet time and again the government itself read grand jury testimony and statements of one witness to another.

Third, perhaps worse than endeavoring to influence witness testimony, the government provided the grand jury with false and misleading testimony to support the linchpin of their case. During the presentation of the proposed indictment, the Civil Division attorney elicited testimony from the case agent that the agent knew from "interviews" with Food and Drug Administration ("FDA") officials that the Vari-Lase device "did not have any form of FDA marketing authorization for treatment of perforator veins." Indictment ¶13; *see* Exhibit 1, Grand Jury Transcript of George Scavdis ("Scavdis Tr.") at 10840-1.[2] But during a prior interview with that same agent and government attorney, an FDA medical officer admitted that "in some sense VSI may be right that the [FDA] indication would include" certain treatment of perforator veins. *See* Exhibit 2 at 16643. FDA authorization of any laser treatment of perforator veins is highly damaging to the government's theory. Moreover, this is not just any FDA witness: It is the government's expert witness on the issue. Yet the grand jurors never heard this startling admission.

Fourth, the government misused the grand jury's process to screen evidence that contradicted its theory. The Civil Division attorney improperly used grand jury subpoenas—issued pursuant to Rule 17—to induce witnesses to submit to sworn private examinations *outside the presence of the grand jury*. He further used the powerful leverage of a grand jury subpoena to exclude counsel from these private examinations. Compounding this violation, having heard testimony during these private examinations that contradicted its theory, the Civil Division attorney deprived the grand jurors of a meaningful opportunity to consider this evidence. The government did not read this

[2] Please note that certain exhibits supporting this memorandum are filed separately under seal.

testimony to the grand jurors or even summarize it for them, even though it was procured under the auspices of their authority. Instead, in a hollow gesture, on the morning of the indictment, the government piled 876 pages of these transcripts on a table in the grand jury room, among the hundreds of pages of real grand jury transcripts. At that point, it was impossible for the grand jurors to read them—much less consider and deliberate as to how the contradictory evidence weakened the government's case—before voting on the proposed indictment. By our estimate, it would have taken the grand jurors over 14 hours to read the transcripts of these private examinations.

Fifth, the government further discouraged testimony that contradicted their theory by interfering with witnesses' attorney-client relationship. During several grand jury sessions, when confronted with testimony that contradicted his theory, the Civil Division attorney blamed counsel's advice, pressing witnesses to reveal that privileged advice. The government attorney asked one witness, "are those things that your lawyer told you to volunteer?" and asked another, "has [your lawyer] told you to say that . . . ?" *See* Exhibit 14, Grand Jury Transcript of Witness A, at 26520; Exhibit 3, Grand Jury Transcript of Witnesses F, at 8932.[3] Astonishingly, when a flustered witness sought her lawyer's advice on how to answer this question, the Civil Division attorney refused to allow her to leave the room to consult with counsel, in violation of Department of Justice policy: "*No*. The options are, you can answer my questions, you can refuse to answer my question and if you refuse to answer my question *I* might have to bring you back." *See* Exhibit 3, Witness F, Tr. at

[3] To protect the privacy of grand jury and other witnesses, this Memorandum refers to each witness with a unique letter. The key will be provided to the government and this Court *in camera*.

8931-3 (emphasis supplied). There simply is no plausible legitimate reason for interfering with the confidential relationship between lawyer and client in this way.

The Government Endeavored to Distort the Law. To further support the prosecution theory, the government also misinstructed the grand jurors on the law. For example, the government instructed the grand jury that "[i]t was unlawful to use the Vari-Lase equipment on perforators, period." *See* Exhibit 4 at 8471-2. In fact, the law is clear that doctors can use the Vari-Lase products to treat perforator veins, on- or off-label. *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51, 351 n.5 (2001) (off-label use of medical devices "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."). The government also instructed the grand jury that Medicare did not cover laser ablation of perforator veins; in fact, in many (if not all) states—including Texas—Medicare *did* cover this treatment, regardless of the scope of its FDA authorization. Also, despite eliciting extensive testimony regarding marketing and sales of the Vari-Lase products in New York and Connecticut, the government never informed the grand jury that truthful and non-misleading promotion of off-label use is unquestionably legal in the Second Circuit (if not nationally, as we contend). *See United States v. Caronia*, 703 F.3d 149 (2nd Cir. 2012); *Amarin Pharma, Inc. v. FDA*, No. 15-cv-03588, 2015 WL 4720039 (S.D.N.Y. Aug. 7, 2015). These misstatements of the law, along with the government's practice of impermissibly asking lay witnesses to offer legal conclusions, misled the grand jury regarding the legal standard by which the defendants were to be judged, and thereby undermined the reliability of the their determination. While the government has refused to provide the defendants with the full record of its legal instructions to the jury (which the defendants are seeking by separate motion), the transcripts disclosed to the defendants reveal that they misled the grand jury in key respects. In light of the erroneous legal instructions in the transcripts that were

disclosed, a full review of these instructions is necessary to determine the full extent of the misleading instructions.

The Damage Cannot be Undone. Taken together, the government's conduct so misshaped the evidence and misstated the law as presented to the grand jury that it undermined the fundamental fairness of the process, and casts grave doubt on the grand jury's decision to indict. Dismissal of the indictment therefore is appropriate. Further, the dismissal should be with prejudice, as the effects of the government's actions continue today. The Sixth Amendment to the Constitution guarantees the accused the right to present testimony in its defense. Yet many defense witnesses have been improperly threatened for providing testimony that does not support the government's theory. Many have been exposed to the testimony of other witnesses, including grand jury testimony. These witnesses cannot unlearn the government's version of the evidence, nor can they forget the threats of personal economic ruin if they fail to testify as directed. Further , the government's actions influenced the substance of testimony that witnesses will ultimately provide under oath. Should a witness now desire to testify in a manner inconsistent with the government's theory (but consistent with the witness's initial statements), that witness faces a perjury prosecution by the same government that threatened them in the first instance. For these reasons, the government's actions have irreparably impaired the defendants' right to present to the jury (and this Court) untainted testimony to support their case. A constitutional right to present testimony is a hollow one indeed if the testimony has been irreparably altered by the government.

Defendants "are entitled to be treated fairly throughout the process. In everyday language, they are entitled to a fair shake." *United States v. Stein,* 435 F. Supp. 2d 330, 357 (S.D.N.Y. 2006). Due to the government's misconduct, Vascular Solutions and Mr. Root have not gotten that fair shake. Given the pervasive effects of the government's actions—brushing aside as inconveniences

safeguard after safeguard—they never will. Accordingly, the defendants request that this Court dismiss the indictment with prejudice.

BACKGROUND

Vascular Solutions, Inc. is a medical device company located in Minneapolis, Minnesota that was founded in 1997 by Mr. Root, its Chief Executive Officer. Over the past 17 years, Mr. Root has led VSI in inventing, developing and launching over 100 new medical devices that diagnose and treat a variety of vascular medical diseases. The company specializes in developing new medical devices that meet clinical niche opportunities that the larger medical device companies in its market often ignore. Examples of VSI's products include the Pronto catheter (which removes blood clots from arteries in cases of heart attack), Langston catheter (the only catheter in the U.S. to simultaneously measure pressure in the aorta and heart to assess aortic valve stenosis), and the GuideLiner catheter (which facilitates distal delivery of coronary stents and has been described by physicians as an indispensable tool, without which certain critical medical procedures would be impossible). One of the company's newest products in development is RePlas freeze-dried plasma, developed in partnership with the U.S. Army to be used on the battlefield to save the lives of our wounded soldiers. As of July 2015, the company has 550 full-time U.S. employees, including 100 sales representatives located throughout the U.S. who sell VSI's medical devices directly to hospitals. VSI and Mr. Root have no prior history of regulatory or enforcement actions; prior to this case, neither has been the subject of any government investigation.

A. Doctors Use VSI's Vari-Lase Products to Treat Varicose Veins.

One of the 100 medical devices that the company has developed and sells is the Vari-Lase procedure kit, which is a set of components used to treat varicose veins. The company has developed 80 different configurations of the Vari-Lase procedure kit, one of which is called the

Vari-Lase Short Kit ("Short Kit"). Although FDA never took any regulatory action with respect to the Short Kit, the company voluntarily withdrew the product from the market in July 2014. During the seven years it was on the U.S. market, sales of the Short Kit constituted only 0.1% of VSI's total sales of all its products. Over two-thirds of VSI's salespeople never sold even a single Short Kit, and there have been no allegations of any harm to any patient due to the use of a Short Kit.

Varicose veins are enlarged leg veins caused by incompetent valves that cause blood to pool in the legs. Legs have two networks of vein systems: the deep and superficial venous systems. The deep veins are closer to the bones, while the superficial veins, including the Great Saphenous Vein, are closer to the skin. The two systems run parallel to each other and are linked by connecting associated veins called perforator veins. *See* Exhibit 5 (diagram of venous anatomy). Incompetent veins can cause varicosities, leading to itching, aching, swelling and, in severe cases, inflamed skin and open sores. The Vari-Lase products use laser heat to close varicose veins permanently, allowing the body to recruit healthier veins to move the blood. This is a minimally invasive, one-hour procedure performed in a physician's office where the patient walks in for treatment and walks out afterwards.

In 2005, the FDA authorized VSI to market the Vari-Lase products. Indictment ¶12. The authorization states that the Vari-Lase laser and procedure kits are "indicated 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." *Id.* Interpreting that authorization, the government takes the position that the Vari-Lase products were not authorized for the treatment of perforator veins. *Id.* The defendants' experts disagree.

B. The Government's Investigation of the Vari-Lase "Short Kit" Device.

In 2011, the government began investigating the Company for allegedly promoting the use of the Vari-Lase products to treat perforator veins. Specifically, the investigation focused on the Short Kit, which was designed for the treatment of short vein segments. *Id.* ¶ 17. The government theorized (and now alleges) that the Company developed and marketed the Short Kit for use on perforator veins. The government also claims that the Company: (1) directed employees to train and assist doctors on using the Short Kit to treat perforators; (2) falsely stated that Medicare would pay for the treatment of perforators; and (3) used the terms "short vein segments" and "short veins" as code for perforators to hide their intent to sell the Short Kit for that use. *Id.* ¶¶ 34, 35.

During the course of the investigation, witnesses provided information that flatly contradicted the government's theory. For example, witnesses told the government that the Short Kit was used for treating short vein segments in the superficial venous system; that the company did not instruct salespeople to promote the Short Kit to treat perforator veins; and that Medicare frequently covered this perforator treatment. *See* Exhibit 2, Compilation of Exculpatory Evidence, at 16647-8; 16684; 16697; 16687; 9463-4; 14670; 11016-7, 11026, 11030; 16695; 16749; 16921; 8862, 8903. Independent physicians confirmed their use of the Short Kit on short vein segments of the superficial veins and indicated that use of the device on perforators could fall within FDA's marketing authorization because the perforators extend into and may be treated at the superficial vein level. *See, e.g.,* Exhibit 9, Witness X Tr., at 9506. Even the government's own FDA expert acknowledged that "in some sense VSI may be right that the [FDA] indication would include" certain treatments of perforator veins. *See* Exhibit 2, at 16643. The government failed to present this and other exculpatory evidence to the grand jury.

Relying solely on the government's distorted presentations, the grand jury returned an indictment that contains eight misdemeanor adulteration and misbranding counts and a single felony conspiracy count. The adulteration and misbranding charges (Counts 2-9) allege that the company made four shipments of Vari-Lase devices to Austin, Texas. *See* Indictment ¶¶64-67. The conspiracy charge (Count 1) alleges that the company and Mr. Root conspired to commit the underlying misbranding and adulteration offenses, and agreed to conceal this conduct from law enforcement. *See* Indictment ¶33.

ARGUMENT

The Supreme Court recognized long ago that a government attorney is the "representative not of an ordinary party" to a controversy, but of "a sovereignty whose obligation to govern impartially is as compelling as its obligation to govern at all." *Berger v. United States*, 295 U.S. 78, 88 (1935). A government attorney's interest must not be "that it shall win a case, but that justice shall be done;" he must proceed with a "twofold goal" that "guilt . . . not escape or innocence suffer." *Id.* For a government attorney, it is "as much his duty to refrain from improper methods calculated to produce a wrongful conviction, as it is to use every legitimate means to bring about a just one." *Id.* The limitations on prosecutorial conduct must be strictly observed in the grand jury context, especially given a government attorney's largely autonomous role. *See United States v. Hogan*, 712 F.2d 757, 759 (2d Cir. 1983) (noting that the grand jury "convenes as a body of lay persons acting in secret, unfettered by technical rules of procedure or evidence," thereby requiring that "limitations [upon prosecutorial conduct] be observed strictly"). Unfortunately, the government's conduct in this case has fallen far short of these fundamental standards.

I. THE GOVERNMENT THREATENED WITNESSES WHO CONTRADICTED THE PROSECUTION THEORY.

When witnesses made statements and gave testimony that contradicted the prosecution theory, the government insisted that they "fix" that testimony or face criminal prosecution, loss of employment, and exclusion from participation in federal healthcare programs (thereby barring them from employment at any healthcare company). In addition to tainting the grand jury proceedings, these threats undermined the defendants' fundamental right to present evidence in future proceedings, including at trial.

A. The Government May Not Misshape Testimony with Threats of Criminal Prosecution and Loss of Livelihood.

The Sixth Amendment to the Constitution affords a defendant the right to call witnesses and present testimony in his defense. "The right to offer the testimony of witnesses, and to compel their attendance, if necessary, is in plain terms the right to present a defense, the right to present the defendant's version of the facts as well as the prosecution's to the jury so it may decide where the truth lies." *Washington v. Texas*, 388 U.S. 14, 19 (1967). "Just as an accused has the right to confront the prosecution's witnesses for the purpose of challenging their testimony, he has the right to present his own witnesses to establish a defense. This right is a fundamental element of due process of law." *Id.; United States v. Linder*, No. 12-CR-22, 2013 WL 812382, at *50-52 (N.D. Ill. March 5, 2013) (unpublished) (stating that a "defendant's right to present his own witnesses in establishing a defense is a fundamental aspect of due process of law and is strictly protected by the Fifth and Sixth Amendments to the United States Constitution").

Recognizing the fundamental nature of this right, courts do not permit the government to discourage and influence testimony with threats. "Substantial government interference with a

defense witness's free and unhampered choice to testify violates due process rights of the defendant." *United States v. Hammond*, 598 F.2d 1008, 1012 (5th Cir. 1979) (collecting cases and citing *United States v. Hendricksen*, 564 F.2d 197 (5th Cir. 1977)); *see also United States v. Goodwin*, 625 F.2d 693, 703 (5th Cir. 1980) (noting that threats by warden to prisoner witness that his time "would be made harder" "if he did any type of testifying" warranted remand); *United States v. Weddell,* 800 F.2d 1404, 1411 (5th Cir. 1986) (holding that threats of prosecution to a defense witness that prevented the witness from testifying violated the defendant's constitutional rights). The court in *United States v. Linder* concluded that threats to witnesses to misshape their testimony justified dismissal of the indictment. The court explained that:

> it is within the Executive Branch's power and authority to candidly warn a target of a prosecution that he can be charged with criminal offenses of which the prosecutor is aware and has evidence to support. This aggressive questioning can even include the candid threat of various sentences that a target could receive based on the evidence. But there is a difference between candidly and aggressively threatening a target with prosecution for offenses for which the target can be charged and the flippant threat that a target will be prosecuted for lying simply because that witness is not answering the investigator's questions in the way that the investigator believes they should be answered. Without support for such an accusation, the threat of prosecution for perjury or for conspiring with the defendant crosses the line [and becomes a] threat from an overbearing investigator used to bully the witness into compliance.

Linder, No. 12-CR-22, 2013 WL 812382, at *50-52. Courts have also held threats of loss of employment to be coercive. *See Lefkowitz v. Turley*, 414 U.S. 70, 85 (1973) (holding that in the context of the questioning of a state contractor, "answers elicited upon the threat of the loss of employment [by a state actor] are compelled and inadmissible in evidence"). The "imposition of economic punishment by prosecutors, before anyone has been found guilty of anything, is not a legitimate governmental interest—it is an abuse of power." *Stein*, 435 F. Supp. 2d at 363.

B. The Government Threatened Witnesses Who Refused to Adopt its Theory.

Time and again, the government threatened witnesses who provided information that contradicted the prosecution theory. When two Company employees—Witnesses D and N—testified that management was not aware of and did not condone off-label promotion, the government insisted that they change their testimony. *See* Exhibit 12, Affidavit of R.J. Zayed ("Zayed Affidavit"), ¶ 4. In a May 2014 conversation with the Company's counsel, the government attorneys asserted that they did not believe the testimony, which they characterized as the "same line of s***" provided by other witnesses who refused to admit "the obvious truth." *Id.* The government insisted that these employees "fix" their testimony, which flatly contradicted their prosecution theory. *Id.* The government went so far as to script the testimony that would satisfy them: "Fixing" their testimony meant "admitting that it was VSI's plan to market Vari-Lase for off-label use to treat perforators." *Id.* If they did not "fix" their testimony—that is, admit to the government's theory—the government warned that the witnesses would receive letters indicating that they were targets of a criminal prosecution. *Id.* The government's explicit threat—to provide testimony to the government's liking, or else—is a breathtaking abuse of authority.

The government continued its pattern of threatening witnesses to influence testimony of two VSI managers. During interviews with the government in August 2012 and June 2014, Witnesses N and O told the government that the Short Kit was designed for short vein segments in the superficial vein system, and that the company neither instructed sales representatives to promote for perforator use. *See* Exhibit 2, at 16910, 16921, 8862, 8903. These statements, among others, directly contradicted the government's theory of the case. On September 29, 2014, the government again met with these witnesses and their counsel (separately) at the U.S. Attorney's Office in San Antonio. *See* Exhibit 16, Affidavit of Jon Hopeman ("Hopeman Affidavit"), ¶¶16, 24. The

government informed Witness N that if she did not change her testimony, she may be criminally prosecuted, terminated from her employment, and barred from working in the industry.[4] Id. ¶¶20-21. The government attorneys first articulated to Witness N—at great length—their theory of the case, including claiming that a certain number of witnesses have provided specific testimony about the company's promotion of the Short Kit and management's involvement, which the Civil Division attorney described. *Id.* ¶¶16, 25-29. The Civil Division attorney even read one-sided, verbatim excerpts from grand jury transcripts of two other VSI employees, and excerpts from a statement of another VSI employee. *Id.* ¶¶17-18, 26-28. The government urged Witnesses N and O to conform their testimony accordingly. The government attorney told Witness N that they wanted to give her "a chance to fix her testimony:"

> Mr. Finley then stated to [Witness N] that he wanted to "give [her] a chance to fix the testimony and be at least as truthful as the other fifteen cooperators." He said that she could "cooperate and join the people who are telling the truth and walk away from scary consequences." He stated that if she did not "fix" her testimony, he would: (1) seek to charge her for perjury (he claimed that her testimony was comparable to that of another witness who they were going to charge with perjury and obstruction of justice); (2) refer her to the U.S. Department of Health and Human Services, Office of the Inspector General ("HHS-OIG") for possible exclusion from the medical device business; and (3) ask VSI to fire her.

Id. ¶20. As noted in the above quotation, the Civil Division attorney also threatened to refer her to the Department of Health and Human Services for exclusion from participating in federal Medicare and Medicaid programs. *Id.* ¶21. Exclusion would preclude her from working in the healthcare industry, thereby ending her career:

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[4]"Client Number 1," as referenced in the Hopeman Affidavit, is Witness C; "Client Number 2" is Witness D; "Client Number 3" is Witness N; and "Client Number 4" is Witness O.

> Mr. Finley then told her that he also intended to make a referral to HHS which has the power to exclude her from the medical device business. He said that he could not control what they do, but that HHS would want to hear what he has to say.

Id. The Civil Division attorney also warned Witness N that he would request that the Company fire her. *Id.* He even told her that "a lot of people failed to admit it out of the box," that the government "worked with them," and that "they are fine now." *Id.* ¶19. At the conclusion of the questioning, the government stated that they were glad she had "changed her story," and that they did not intend to prosecute her or recommend that HHS-OIG exclude her. *Id.* ¶23. After having "worked with" Witness N, the government now has issued a subpoena to her to appear at trial.

The government took the same heavy-handed approach with Witness O. The government informed this witness that they wanted to "clarify" information from his prior interview, because they had "suspicions that he did not tell the truth." *Id.* ¶25. The government claimed (inaccurately) that they had "talked to many VSI employees and that every one of them, to varying degrees, acknowledged that the company marketed the Vari-Lase system and the short kit for perforators but called it a short vein kit." *Id.* The government further told the witness that he was not trying to tell him what to say, but that the "cat is out of the bag," and that if he lied, he reserved the right to prosecute him. *Id.* The Civil Division attorney further warned that he will be "practically alone" if he denies the conduct. *Id.* The Civil Division attorney then "said that he wanted to read from testimony and statements of various employees," and read a statement from one executive, and the grand jury testimony from another. *Id.* ¶26-27. Finally, the Civil Division attorney claimed that "there is a group of witnesses that all agree it was clearly illegal, inappropriate and blatantly illegal," and that if the witness "wants to be consistent with them, he will be safe from prosecution." *Id.* ¶29. As outlined in counsel's affidavit, "[u]p to this point in the interview, the prosecutors had not asked [Witness O] to provide any information regarding the facts of the case, they simply stated what they

believed 'the truth' to be." *Id.* ¶29. After having "worked with" Witness O, the government also has issued a subpoena to him requiring him to appear at trial.

The government likewise threatened Witness C when her testimony before the grand jury contradicted the prosecution theory. After the witness was in the grand jury for approximately one hour and 44 minutes, she came out of the grand jury room, and counsel met with the government attorneys. The government stated she was on the verge of "pissing us off," and the Civil Division attorney was "not buying the company line that no one else at the top knew and that it was just a bunch of rogue salespeople who committed the crime." *Id.* ¶¶7-8. Counsel related the government's comments to his client, but she declined to change her testimony in any respect. *Id.* ¶10. Later, both government attorneys said the employment consequences to the witness could be "severe." *Id.* ¶¶11,12. While the Civil Division attorney claimed that he wanted the witness to tell the truth, he made clear what he thought the "truth" was—he "wanted the people responsible at the top of the company, including Howard Root, to be brought to account." *Id.* ¶11. After having "worked with" Witness C, the government has issued a subpoena requiring her to appear at trial.

And in early 2014, the government asked company counsel to "encourage" three company employees (Witnesses A, L and O) to change their testimony. *See* Exhibit 13, Letter dated May 29, 2015, from Timothy Finley to John Richter, et al. ("Finley Letter"), at 3. When the witnesses did not change their testimony, the government asked the company "to consider" terminating two of those employees, and three others who had provided information that contradicted the prosecution theory. *See id.* (Witnesses A, C, D, N).

The government demonstrated that its threats were not idle ones by actually carrying them out with respect to VSI sales representative Glen Holden, who sold devices in Connecticut. In June 2014, after Holden testified in a manner inconsistent with the government's theory, the government

informed counsel that he was a "coat of paint away from perjury," that the "poor f***er just on principle may be indicted," and demanded that the witness come in "on bended knee" and admit that he misled the government. *See* Exhibit 12, Zayed Affidavit, ¶¶3,5. Holden declined, and was indicted on November 13, 2014. The government's tactics with these witnesses were essentially the same: put forth the prosecution's theory, then demand the witness agree or face disastrous personal consequences.

These improper threats are a far cry from the government's description in their discovery letter that they merely advised the witnesses of possible consequences of being untruthful. *See* Exhibit 13, Finley Letter at 1, n.1 (stating that it is "standard practice" to inform witnesses of the consequences of knowingly testifying falsely). A more accurate description would be that 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. The government no doubt would view as criminal a threat by the company to terminate the employment of witnesses unless they testified consistently with the company's position. *See* 18 U.S.C. § 1512(b)(1) (proscribing "knowingly . . . threatening . . . another person . . . with intent to . . . influence . . . the testimony of any person in an official proceeding . . .") The government should be held to no lesser standard.

These improper threats have deprived the Company and Mr. Root of their due process and Sixth Amendment rights to "present . . . witnesses to establish a defense," and "present the defendant's version of the facts as well as the prosecution's to the jury so it may decide where the truth lies." *Washington*, 388 U.S. at 19. To address similar threatening conduct by the prosecution team, the court in *United States v. Linder* dismissed the indictment. *See Linder*, No. 12-CR-22, 2013 WL 812382, at *50-52. The threats of prosecution in the present case are even more abusive than

those in *Linder* because here they were coupled with threats of job loss and healthcare exclusion, and were made by the prosecutors who controlled the prosecution decision, not simply the investigators. Threats of criminal prosecution and economic ruin directly coupled with express entreaties to alter testimony to the government's liking violates the defendants' right to present testimony in a fair trial.

II. THE GOVERNMENT VIOLATED THE STRICT PROHIBITION AGAINST DIVULGING GRAND JURY TESTIMONY.

To further its effort to misshape witness testimony to conform to its theory, the government on at least four occasions divulged secret grand jury testimony of selected witnesses to other witnesses. The Supreme Court has "consistently . . . recognized that the proper functioning of our grand jury system depends upon the secrecy of grand jury proceedings." *United States v. Sells Engineering, Inc.*, 463 U.S. 418, 424 (1983). To that end, Federal Rule of Criminal Procedure 6(e) strictly prohibits a government attorney from disclosing "a matter occurring before the grand jury." *See* Fed. R. Crim. P. 6(e)(2)(B)(vi). Any disclosure of grand jury matters must be specifically authorized by rule or court order: "[i]n the absence of a clear indication in a statute or Rule, [courts] must always be reluctant to conclude that a breach of this secrecy has been authorized." *Id.* at 425.

The disclosure of grand jury testimony of one witness to another violates this fundamental rule. *See, e.g.*, *United States v. Bazzano*, 570 F.2d 1120, 1124-6 (3d Cir. 1977) (holding that disclosure to one witness of grand jury testimony of another witness violated Rule 6(e)). As the *Bazzano* court explained, the government may not read one witness's "testimony verbatim to [another witness] in an attempt to 'shape' [the witness'] trial testimony to coincide with" the other witness' testimony. *Id.* at 1127. Reading the transcript of one witness's testimony to another squarely presents the risk of improperly influencing testimony. *Cf. Miller v. Universal City Studios, Inc.*, 650 F.2d 1365, 1373 (5th Cir. 1981) (holding that reading transcripts of one witness to another violates the Rule on Witnesses, which is designed "to prevent the shaping of testimony by one witness to match that of another, and

to discourage fabrication and collusion"); *see also Perry v. Leeke*, 488 U.S. 272, 281 (1989) (the rule operates "to lessen the danger that [one witness'] testimony will be influenced by hearing what other witnesses have to say, and to increase the likelihood that they will confine themselves to truthful statements based on their own recollections"). Indeed, the government itself recognized this prohibition, correctly explaining that disclosure of grand jury testimony creates the danger of "'subornation of perjury or tampering with the witnesses who may testify before grand jury and later appear at the trial . . . .'" Gov't Motion for Authorization to Release Grand Jury Testimony to Witnesses, ECF No. 57 at 2 (citation and quotations omitted).

Despite this recognition, and without permission, the government intentionally and on multiple occasions divulged secret grand jury testimony to advance its case.[5] As discussed above, during government interviews in August 2012 and June 2014, Witnesses N and O provided information that directly contradicted the prosecution theory. *See* Exhibit 2 at 16910, 16914; 16725. When the government again met with these witnesses and their counsel in September 2014, the Civil Division attorney read each witness one-sided excerpts from two grand jury transcripts that they had deliberately brought to the interviews. *See* Hopeman Affidavit, ¶¶17, 27. The government attorneys even identified the grand jury witnesses by their position at the company. *Id.* The transcripts that the government read were of the grand jury testimony provided by two VSI employees, Witnesses C and R. Troublingly, however, the case agent's memorandum that purports to summarize these meetings fails to mention that the government read excerpts from any grand jury transcripts to these

[5] In recently seeking permission to disclose to witnesses transcripts of their own grand jury testimony, the government failed to inform the Court that, months before, it had unilaterally disclosed grand jury testimony of certain witnesses to other witnesses without any permission.

witnesses. Nor does the government's discovery letter disclose these exchanges with the witnesses. *See* Exhibit 13, Finley Letter. To the contrary, in the letter, the Civil Division attorney stated only that they "showed [the witnesses] documents" and "told [them] that many VSI employees had admitted" to the conduct (Finley Letter at 3, 6); nowhere did the Civil Division attorney reveal in this discovery correspondence that he deliberately read grand jury transcripts. Only after undersigned counsel asked the government attorneys directly did they reveal the violations.

The government also violated Rule 6(e) in attempting to influence the testimony of VSI employee Witness C. During a grand jury session on May 6, 2014, the government asked this witness about the Company's use of the term "short kit" to describe the product—apparently attempting to adduce evidence to support one of the government's key allegations: that the company referred to the treatment of "short veins" or "short vein segments" as code for the allegedly off-label treatment of perforator veins. *See* Indictment ¶35. During this line of questioning, the government attorney stated that "witnesses . . . very recently have told the Grand Jury that the terms 'perf kit, perforator kit, short kit, and shorty' were all used interchangeably in the company." *See* Exhibit 17, Witness C, Tr. at 8582. The government was referring to grand jury testimony from a session held on February 18, 2014. *See* Exhibit 15, Witness S, Tr. at 8265. The government attempted a similar tactic on numerous other occasions with other witnesses to misshape their testimony.[6] The government since has subpoenaed each witness to appear at trial.

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[6] On June 20, 2014, the government questioned whether Witness D would disagree with another witness who purportedly said she would have stopped this conduct, and another witness who (in the government's words) "characterized [conduct of another] as a blatant example of off-label marketing." Exhibit 18, Witness D, Tr. at 8417. On another occasion, the government told a

Once a witness has been exposed to the testimony of another witness, the witness's future testimony has been tainted; the effect can never be undone. In this case, the government exacerbated the contaminating effect by reading only certain segments of the testimony and not divulging to the witness the substantial statements and testimony that tended to undermine the government's theory. There is no means to make the witnesses forget the disclosure of secret grand jury testimony, and there is no way to restore the defendants' right to present at trial the untainted recollections of these witnesses. As a result, the government's unauthorized disclosure of grand jury testimony in violation of Rule 6(e) violated defendants' right to a fair trial.[7]

III. THE GOVERNMENT KNOWINGLY PROVIDED FALSE AND MISLEADING TESTIMONY TO THE GRAND JURY.

As discussed below, the government not only influenced witness testimony, it affirmatively presented false information to the grand jury. To secure the integrity of the grand jury process, the government is under a duty not to mislead the grand jurors. *United States v. Smith*, 552 F.2d 257, 261 (8th Cir. 1977) (citing *United States v. Estepa*, 471 F.2d 1132, 1136 (2nd Cir. 1971)); *see United States v. Hogan*, 712 F.2d 757, 762 (2d Cir. 1983) (noting that the government was "duty bound not to

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witness that other witnesses had said that they: "were promoting the kit for this off-label use. They have told us they were. Do you deny it? . . . In other words, those salesmen who told us that you were well aware of this practice that they're promoting for the off-label use, you don't deny that? And you knew it is what they tell us." Exhibit 19, Witness R, Tr. at 8371-72.

[7] Only hours before this motion was filed, the government attorneys admitted that they read grand jury testimony in this case not only to each of these witnesses, but also to another individual, with whom they reportedly are negotiating a disposition. The defendants have requested more information regarding this additional Rule 6(e) violation.

introduce false and misleading testimony" and concluding that the grand jury was likely misled by extensive hearsay and double hearsay speculation).

In perhaps most direct example of the government's endeavor to distort evidence before the grand jury, the Civil Division attorney elicited—and the case agent provided—false and misleading testimony on a critical point before the grand jury. The government attorney asked the case agent whether it was true that the Vari-Lase device "did not have *any* form of FDA marketing authorization for treatment of perforator veins." Indictment ¶13 (emphasis supplied). After the agent answered that it was true, the government attorney asked the agent how he knew that it was true. The agent answered, among other things, that he knew it was true "from the interviews we've done of the FDA reviewers . . . ." *See* Exhibit 1, Scavids Tr. at 10840-1. Yet during one of those interviews, Dr. Pablo Morales, an FDA medical officer, admitted that "in some sense VSI may be right that the [FDA] indication would include" certain perforator vein ablation treatment. *See* Exhibit 2 at 16643. Specifically, Dr. Morales said it is possible for a patient to have a certain varicose vein condition, and that "in some sense VSI may be right that the indication would include" the treatment of perforator veins under those circumstances. *Id.* He conceded further that although this situation is not very common, it is possible. *Id.* The testifying case agent and interrogating government attorney knew that the FDA official had made this admission: The same agent and attorney had interviewed the FDA official, and the same agent recorded the official's critical concession in a memorandum. Therefore, both the government attorney who asked the question and the agent who answered it knew that "the interviews [they]'ve done of the FDA reviewers" revealed a concession that "in some sense VSI may be right that the [FDA] indication would include" certain perforator vein ablation. Moreover, this was not just any witness: The government has identified him as their expert witness on this same topic. *See* Exhibit 11, Government's Notice

of Expert Witnesses, at 5. To be sure, at other points during the interview, Dr. Morales opined that the indication does not include perforator ablation. But the scope of the indication goes to the heart of the government's case. That this tactic was no accident is further supported by the fact that the government likewise never informed the grand jury that another medical doctor, an independent vascular surgeon, told the same FDA agent that in his view, the FDA's authorization covered the treatment of perforator veins. *See* Exhibit 2, at 16947. Given this testimony, the grand jury no doubt would have been stunned to learn that a key FDA medical officer conceded that the company "may be right" that the cornerstone of the government's theory is wrong.

IV. THE GOVERNMENT MISUSED GRAND JURY PROCESS TO INDUCE EXAMINATIONS OUTSIDE THE GRAND JURY.

As discussed below, the Civil Division attorney used grand jury process to leverage witnesses into private examinations, under oath, without the presence of the grand jury or counsel. Taking testimony outside the presence of the grand jury enabled the government to screen from the jurors testimony that contradicted its theory.

A. The Government Cannot Use Grand Jury Subpoenas to Leverage Private Examinations.

The "Constitution of the United States, the statutes, the traditions of our law, [and] the deep rooted preferences of our people . . . recognize the primary and nearly exclusive role of the Grand Jury as the agency of compulsory disclosure . . . ." *See Durbin v. United States*, 221 F.2d 520, 522 (D.C. Cir. 1954). The law "do[es] not recognize the United States Attorney's office as a proper substitute for the grand jury room." *Id.* Courts have made clear that the government may not use grand jury subpoenas to compel witnesses to attend private examinations or interviews with government attorneys or agents. *See, e.g.*, *United States v. Wadlington*, 233 F.3d 1067, 1075, 1083 (8th Cir. 2000) (reasoning that Rule 17(a) "does not authorize the Government to use grand jury

subpoenas to compel prospective grand jury witnesses to attend private interviews with government agents"); *United States v. DiGilio*, 538 F.2d 972, 985 (3d Cir. 1976) (holding that grand jury subpoenas could not be used "as a ploy for the facilitation of office interrogation").

B. The Government Used Grand Jury Subpoenas to Induce Examinations Outside the Presence of the Grand Jurors and Counsel.

The government issued grand jury subpoenas under the seal of this Court and pursuant to Rule 17 requiring witnesses to appear on a particular day before the grand jury in the Western District of Texas. *See* Exhibit 6 (grand jury subpoenas). These witnesses resided hundreds of miles outside this District. The government then offered certain witnesses a coercive choice: submit to a sworn examination at the witness's location outside the presence of the grand jury, or travel to appear before the grand jury in Texas. Facing the leverage of the subpoena, the witnesses agreed to answer the government's questions, under oath, outside the presence of the grand jury and counsel.[8]

Early in this investigation, the government requested that counsel for several witnesses, including Witness I, agree to an interview of a client outside of counsel's presence. *See* Exhibit 7, Affidavit of Daniel M. Scott ("Scott Affidavit"), ¶3. Having "never encountered this practice in all of [his more than 40] years of experience," counsel declined the government's request. *Id.* Undeterred, in or about September 2013, the government issued grand jury subpoenas to three of counsel's witnesses, requiring their appearance before the grand jury in San Antonio in October

[8] The government used grand jury subpoenas in this way to examine at least four witnesses outside the grand jury: two former VSI employees (Witnesses F and J), and two physicians (Witnesses W and X). They also took testimony outside the grand jury from two other witnesses, although it is unclear whether the government issued grand jury subpoenas or raised the specter of doing so.

2014; the date later was rescheduled to February 2015. *Id.* ¶4. Counsel immediately informed the government that one witness (Witness F) was unavailable on that date, due to a previously scheduled vacation; the government offered the witness a choice: forgo her vacation, or submit to sworn testimony, outside the presence of the grand jury and her counsel. *Id.* ¶¶5-6. Counsel objected to his exclusion from the examination, but the government persisted. *Id.* ¶¶6-7. As recorded in an e-mail dated February 7, 2014, counsel and the witness agreed to submit to the extrajudicial examination because they were "between a rock and a hard place." *Id.* The government likewise used grand jury subpoenas and offered similar "choices" to Witnesses J, W, and X to secure extrajudicial examinations outside the presence of the grand jury and counsel. *Id.* ¶8; *see also* Exhibit 8 at 10969; *see also* Exhibit 9 at 9417-8. Pursuant to a grand jury subpoena, each witness appeared before the Civil Division attorney in a conference room, was sworn, and was examined by government counsel, while the witness's counsel waited outside of the conference room. A court reporter recorded the testimony. The Civil Division attorney continued to hold the leverage of the grand jury process over the heads of these witnesses, admonishing one witness that "[y]ou have to answer the question or you'll come to Texas and answer it." Scott Affidavit, ¶13.

The circumstances of these examinations stand in sharp contrast to a permissible witness interview in lieu of a grand jury appearance, which are attended by the witness's counsel, without the presence of a court reporter, and without the administration of any oath. In fact, one witness stated that "I understand this is [] grand jury testimony." *See* Exhibit 10, Witness Y Tr. at 9517. The government responded: "well, we are doing a grand jury investigation, but this isn't grand jury testimony . . . This is just testimony outside the grand jury." *Id.* After undersigned counsel raised the impropriety of this process (pre-indictment) with senior management at the Department of

Justice (to no effect), the government attorneys elicited from the case agent in the grand jury the following explanation for the practice:

> It was for the convenience of the witness. I think one witness in particular had a vacation planned for the time that she was supposed to come to the grand jury. So it was to, you know, help them avoid having to travel down here. So it was purely for the witnesses' convenience.

See Exhibit 1, Scavdis Tr. at 10837; *see* Exhibit 22, Witness J Tr. at 9178-80 (government stated that it "felt badly about the hardship and the inconvenience" caused by a canceled trip to the grand jury and "that was the reason why we extended the opportunity for you to testify under oath outside the Grand Jury"); Exhibit 3, Witness F, Tr. at 8832-33 (government stated that it requested this private examination because the witness had a pre-planned vacation that conflicted with the February 2015 date). But this explanation is belied by the fact that the government made no such "accommodation" for a dozen other witnesses who traveled to testify in the grand jury from across the country, including Connecticut, Minnesota, New Hampshire, New York, and Virginia. For example, the government insisted that Glen Holden travel from Connecticut to San Antonio to testify before the grand jury, while "accommodating" a private examination of another witness "because [he was] all the way over here in Connecticut." Exhibit 9, Witness X Tr. at 9417-18; *see also* Exhibit 8, Witness W Tr. at 10969 (witness in Connecticut agreed that he was giving a statement under oath "in lieu of going down to San Antonio and appearing before the grand jury"). And the government embarked on this series of private examinations only after counsel for several witnesses denied the government's request for interviews outside of counsel's presence.

Perhaps the best evidence of the powerful leverage created by the grand jury subpoena was the witness's concession to answer questions without the presence of counsel. Counsel for Witnesses E, F and J "would not have agreed to such an examination but for the leverage of the grand jury subpoena." Scott Affidavit, ¶7. Of course, counsel plays a key role in representing the

client in government interviews, especially where the examination might elicit incriminating evidence. *See United States v. Ash*, 413 U.S. 300, 312 (1973) (right to counsel applies to "trial-like confrontations" and instances in which individuals face prosecuting authorities); *United States v. Ming He*, 94 F.3d 782, 785 (2d Cir. 1996) (holding that the government's standard practice of conducting debriefing interviews outside the presence of counsel was inconsistent with the fair administration of criminal justice); *Thomas-Bey v. Nuth*, 67 F.3d 296 (4th Cir. 1995) (unpublished) (finding ineffective assistance of counsel where lawyer consented to and failed to attend a presentencing interview by a government psychiatrist); *United States v. Koerber*, 966 F. Supp. 2d 1207, 1227 (D. Utah 2013) (finding that inquiring into certain matters of a represented person outside the presence of counsel "significantly weakens the protection a party has by being represented by counsel"). The government sought to interfere with counsel's role—a purpose of which involves ensuring a fair examination— in first requesting an interview outside counsel's presence, and when counsel refused, inducing such an interview without counsel's presence.

The potential for abuse inherent in the government's practice is substantial. The notion that Department of Justice attorneys may use subpoenas in the name of a grand jury in this or any other district as leverage to induce sworn examination outside the presence of the grand jury and outside the presence of counsel is anathema to the grand jury process and Rule 17. The institution of the grand jury does not exist to enable government attorneys to leverage private examinations under conditions they prescribe, most notably the exclusion of the witness's counsel. Nor does any law afford government attorneys the power to compel witnesses to appear at a location of the government's choosing and provide testimony outside the presence of a grand jury. Yet that is precisely how the government used the grand jury subpoenas in this case: If the witness balked at these conditions—by seeking the presence of counsel, for example—the government invoked the

leverage of the grand jury subpoena. As the Civil Division attorney explained to counsel: "I understand that you take exception to [testimony outside counsel's presence], but this is how we have done it historically . . . *If [the witness] prefers the grand jury, that's fine too.*" *See* Exhibit 7, Scott Affidavit, ¶6 (emphasis supplied). This case sharply illustrates one of the dangers of such an extrajudicial process, as the government subsequently deprived the grand jury of a meaningful opportunity to consider the testimony from these examinations, which in many respects materially contradicted their theory.

C. The Government Did Not Read or Summarize Exculpatory Testimony from its Extrajudicial Examinations and Other Interviews.

Despite having issued subpoenas on behalf of the grand jury to elicit testimony, the government chose not to read the transcripts of the extrajudicial examinations to the grand jury, to our knowledge. Nor did they summarize that testimony. Instead, the government waited until the day of the proposed indictment to provide the grand jury with the six lengthy transcripts. Offering no reference to the content, the government left these transcripts, along with transcripts from every grand jury witness in the case—"about 20" in all, on a table in the grand jury room while the jury deliberated. *See* Exhibit 1, Scavdis Tr. at 10906 (government informed the jury, immediately before deliberations on the indictment, that they placed "statements under oath" and grand jury transcripts "in that stack" on a table in the grand jury room). The gesture was an empty one. It would have taken each juror more than 14 hours to review the transcripts, to say nothing of the further time required to consider and deliberate as to how the contradictory evidence weakened the government's case.

The extrajudicial testimony contradicted its prosecution theory in key respects. For example, a central allegation of the indictment is that the FDA's authorization to market the Vari-Lase devices

did not encompass the treatment of perforator veins. *See* Indictment ¶13. Yet the government elected neither to read nor reference testimony suggesting that perforator veins were part of the superficial system that was covered by the indication. *See* Exhibit 9, Witness X Tr. at 95-6 ("We always treat perforators at the superficial level, above the fascia."). Testimony classifying perforator veins as part of the superficial vein system—and thus encompassed within the FDA's authorization—would be highly damaging to the government's case.

Similarly, the government elected to neither read nor refer to extrajudicial testimony that rebutted two other key allegations of the indictment: that the company's clinical study produced "disappointing" results, and that the physician who conducted it had portrayed it in a misleading fashion. *See* Indictment ¶¶23, 49. The independent physician who conducted the study testified that it was far from a failure, and that to characterize the results in the fashion suggested by the government would not be giving doctors good information. *See* Exhibit 10, Witness Y Tr. at 9625 (study showed the device to be "modestly effective . . . and pretty safe"); *id.* at 9619 ("in the end, I don't think they took a dangerous product and hid the danger from doctors who were going to use it."), *id.* at 9620 ("if I ended a presentation and said don't use this because 14 percent of people will get major adverse events, I'm not really giving good information to doctors . . . I don't believe this is misleading an audience of doctors to use something that is going to be bad for their patients").

Nor did the government elect to read or reference for the grand jurors extrajudicial testimony that undermined its allegation that the company "used the terms 'short vein segments' and 'short veins' to hide their intent to sell Vari-Lase devices for perforator use." *See* Indictment ¶35. An independent vascular surgeon testified that he uses the device on both greater saphenous veins and short saphenous veins. *See* Exhibit 9, Witness X Tr. at 9463-4 (testimony that the surgeon uses the Short Kit on veins other than perforator veins, such as greater saphenous veins, on short

saphenous veins, and "all the veins that I use laser, because I prefer it"). A former VSI employee corroborated the same point during an extrajudicial examination that the grand jurors never heard. Exhibit 22, Witness J, Tr. at 9352 (stating that the terms "short vein segments" and "perforators" "are two different things").

The government also withheld from the grand jury numerous other statements from physicians that contradicted its theory that the Short Kit was designed to be used only on perforators. *See* Exhibit 2, 16647-8; 16684; 16697; 16687; 9463-4; 14670; 11016-7, 11026, 11030; 16695; 16749 (quoting portions of memoranda of interviews of numerous physicians). Multiple independent physicians made statements that undermined the government's theory, including that: (a) physicians use the Short Kit to treat short segments of the saphenous vein on-label; (b) physicians do not regard the term "short vein" as code for perforators, *id.* at 31479, 16865, 16699, 16684, 16885, 16697, 16903, 16689, 14668, 16976, 16645, 16868, 16892, 16879, 16821; and (c) reimbursement codes for endovenous laser ablation cover perforator ablation, according to the physician who chaired The Society for Vascular Surgery which drafts the national Medicare reimbursement codes. *Id.* at 16947.

By failing to give the jurors any real opportunity to consider this and other exculpatory evidence, the government compounded their misuse of the grand jury's process by further violating its own policies regarding the disclosure of exculpatory evidence, not to mention the Rules of Professional Conduct. *See* U.S.A.M. 9-11.233 (Department of Justice policy requires that the government present to the grand jury all "substantial evidence" that directly negates the guilt of the subject of the investigation); TEX. DISCIPLINARY R. PROF'L CONDUCT 3.03(a)(3), cmt. 4, reprinted in TEX. GOV'T CODE, Tit. 2, Subtit. G app A (Vernon Supp. 2000) (TEX. STATE BAR R. art. X § 9) (providing that criminal prosecutors have a duty "to make disclosures of unprivileged material facts

known to the lawyer if the lawyer reasonably believes the tribunal will not reach a just decision unless informed of those facts"); D.C. RULES OF PROF'L CONDUCT R. 3.8(g) (2007) ("shall not . . . fail to bring to the attention of the grand jury material facts tending substantially to negate the existence of probable cause"); *see also* 28 U.S.C. § 530B (applying state ethical rules to government attorneys). While the failure to present material exculpatory evidence alone generally does not warrant dismissal of an indictment, *see United States v. Williams*, 504 U.S. 36, 46 (1992), the government compounded the impropriety of inducing these extrajudicial examinations, further casting doubt on the reliability of the grand jury's decision. All of the government's misconduct relating to the grand jury—from improperly leveraging its authority to burying exculpatory evidence from its attention—evidenced an approach contrary to the pursuit of justice.

V. THE GOVERNMENT ATTEMPTED TO INVADE THE ATTORNEY-CLIENT PRIVILEGE.

Another tactic that the government took when witnesses offered unfavorable testimony was to invade the attorney-client privilege by asking witnesses to reveal attorney-client communications and preventing the witnesses from consulting counsel. On multiple occasions during grand jury questioning, the government suggested that the witness's counsel had advised the witness to testify in a particular manner, and then pressed the witness to reveal the advice of his lawyer, who was not present to object. In this way, the government impermissibly attempted to undermine "the sacrosanct confidential relationship between lawyer and client." *United States v. Neill*, 952 F. Supp. 834, 839 (D.D.C. 1997); *see also Upjohn Co. v. United States*, 449 U.S. 383, 389 (1981) (the privilege exists "to encourage full and frank communications between attorneys and their clients," and its protection is essential in "promot[ing] broader public interests in the observance of law and administration of justice").

On one occasion, when a grand jury witness attempted to provide context for his testimony, the Civil Division attorney squarely asked: "[A]re these things that your lawyer told you to volunteer?" Exhibit 14, Witness A, Tr. at 26520. On another occasion, this government attorney asked a different grand jury witness: "[I]n your preparation to come here and testify, did the lawyers urge you to stress that doctors are coming to you . . . and asking about this?" Exhibit 15, Witness S, Tr. at 8248. With a third witness, the same government attorney took a similar approach after receiving an answer not to his liking:

> Q: I noticed there's been several times today when I've asked a question, and while the question was pending, you've went to consult with your attorney and then come back, objected to my question as being hypothetical or speculative. Has [your lawyer] told you to say that my questions are hypothetical? . . .
>
> A: I can – I don't have to tell you what my attorney and I have … talked about.
>
> Q: Well, when your attorney tells you what to say and then you say it, you do have to answer the question.

Exhibit 3, Witness F, Tr. at 8932. After that astonishing exchange, the witness requested to consult with her lawyer. The government refused that request and instead demanded that the witness answer the question or be forced to return for another grand jury session:

> A: I need to go ask [my lawyer] how to respond to that. That's not – that's not –
>
> Q: *No.* The options are, you can answer my question, you can refuse to answer my question and if you refuse to answer my question I might have to bring you back.

Id. at 8932-3 (emphasis added).

There is simply no plausible legitimate reason to refuse to permit a witness to consult with counsel during a grand jury appearance. *See* U.S. Attorney's Manual, § 9-11.151 (stating that a witness's grand jury rights include "a reasonable opportunity to step outside the grand jury room to

consult with counsel if [the witness] so desire[s]"); *see also United States v. Mandujano*, 425 U.S. 564, 606 (1976) (Brennan, J., concurring) (grand jury witnesses may consult with attorney at will); *United States v. George*, 444 F.2d 310, 315 (6th Cir. 1971) (right to consult with attorney "after every question"). Nor is it permissible to ask a witness about his or her counsel's legal advice, especially in the grand jury, outside the presence of counsel. In spite of these unambiguous rules, the government repeatedly attempted to invade the attorney-client privilege.

VI. THE GOVERNMENT MISSTATED THE LAW AND IMPROPERLY ELICITED LEGAL OPINIONS FROM LAY WITNESSES BEFORE THE GRAND JURY.

The government also distorted the law to support its theory. Courts have dismissed indictments when the government gives the grand jury erroneous legal instructions that lead to "grave doubt that the decision to indict was free from the substantial influence of such violations." *See, e.g.*, *United States v. Stevens,* 771 F. Supp. 2d 556, 567, 569 (D. Md. 2011) (dismissing indictment where prosecutor gave erroneous advice to grand jury on advice-of-counsel defense that negated wrongful intent); *United States v. Peralta*, 763 F. Supp. 14, 19–20, 21 (S.D.N.Y. 1991) (dismissing indictment where prosecutor's instructions to the grand jury did not "merely fail to instruct the grand jury on a question of applicable law," but rather "seriously misstated the applicable law" on constructive possession).

Although the government has refused to disclose its legal instructions to the grand jury (which defendants are seeking by separate motion), the grand jury transcripts that have been disclosed make clear that the government mischaracterized the law in ways that went to the heart of the case. For example, the government instructed the jury unequivocally that "[i]t was unlawful to use the Vari-Lase equipment on perforators, period." *See* Exhibit 4, Witness T, Tr. at 8471-2. This

is simply wrong. Doctors may use lawfully marketed medical devices for any purpose consistent with their medical judgment, whether on-label or off-label. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51, 351 n. 5 (2001) (off-label use of medical devices "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine. . . . [and] is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize").

It also appears that the government mischaracterized the misbranding statute to the grand jury. The government elicited substantial testimony concerning Vari-Lase sales in New York and Connecticut. *See* Exhibit 19, Witness R, Tr. at 8339-40 (regional manager in charge of New York, Connecticut and Vermont); Exhibit 20, Witness Q, Tr. at 8190-7 (account representative for New York State); Exhibit 14, Witness A, Tr. at 26527-33 (account representative for Connecticut). As the Second Circuit has squarely held, the misbranding statute does not criminalize the truthful off-label promotion of medical devices. *United States v. Caronia*, 703 F.3d 149, 162 (2d Cir. 2012) (reversing conviction of sales representative for off-label promotion of drugs, reasoning that "criminaliz[ing] the simple promotion of a drug's off-label use by pharmaceutical manufacturers and their representatives . . . would run afoul of the First Amendment"). Consequently, in New York and Connecticut, where these Vari-Lase sales occurred, the misbranding criminal statute did not proscribe the truthful promotion of Vari-Lase, on-label or otherwise. The grand jury was entitled to know that such marketing was legal where it took place, regardless of the government's view of the law in this Circuit (which will be determined by this Court). Yet, during questioning in front of the grand jury, the government repeatedly made suggestions to the contrary. *See*, *e.g.*, Witness R, Tr. at 8371-2; Exhibit 20, Witness Q, Tr. at 8190-7; Exhibit 14, Witness A, Tr. at 26527-33.

The government also misinstructed the grand jury regarding the law to support the indictment's allegation that the company "repeatedly misinformed doctors that Medicare and private insurers would pay for laser perforator procedures." *See* Indictment ¶32. When asked for the basis for this claim, the case agent testified unequivocally that the "true answer is that Medicare does not – doesn't matter what you name it. If you're accurately describing the vein that's being treated as a perforator, Medicare does not reimburse for it." *See* Exhibit 1, Scavdis Tr. at 10860-1. The case agent agreed with the government attorney that "because [VSI] didn't have approval, they couldn't get reimbursement from Medicare." *See id.* at 10858. This is simply false, as made clear by the attached affidavit of Dr. Thomas R. Barker, a former Acting General Counsel of the U.S. Department of Health and Human Services. He explains that:

> Between 2007 and 2014, there were more than 60 unique [Medicare coverage policies] in effect across all 50 states with regard to the treatment of varicose veins of the lower extremities (which includes treatment of the greater saphenous vein and perforator veins) [and] there were hundreds of different policies impacting coverage for laser ablation of varicose veins in the lower extremities.

Exhibit 21, Affidavit of Thomas R. Barker ("Barker Affidavit"), ¶7. As a result, the "question of whether or not Medicare covered laser ablation for the treatment of perforator veins at any point in time, in a particular location, between 2007 and 2014, is a complex question with no single answer." *Id.* ¶8 (emphasis added). Rather, in order to determine what coverage looks like at any given pinpoint in time, one must ask several questions, such as who is the beneficiary; what is their diagnosis; where does the beneficiary live; and at what point in time was the beneficiary seeking treatment. *See id.* "[U]nless one knows specific answers to all of these questions, one cannot definitively answer the question as to whether or not Medicare covers laser ablation for perforator veins." *Id.* (emphasis added). Ironically, although a patchwork of policies were in place throughout the country, there was one state where the FDA approval was never a requirement for coverage of

laser ablation of perforator veins: Texas. In fact, "[f]rom May 2006 and October 2014, there was no coverage exclusion in place in Texas limiting laser ablation to only its FDA label [and] [t]herefore . . . a provider could have reasonably concluded that coverage was generally available under the Medicare programs for laser ablation of perforator veins in Texas." *Id.* ¶9.

Furthermore, the government improperly called on lay witnesses to agree with their legal conclusions regarding the company's alleged conduct. For example, the prosecutors repeatedly asked one witness to agree to the government's characterization of conduct as "not legal," "illegal," "clearly illegal," and "blatantly illegal." *See* Exhibit 17, Witness C, Tr. at 8544, 8546, and 8574. Soliciting lay opinions that certain conduct is illegal is without question improper. *See, e.g.*, *United States v. El-Mezain*, 664 F. 3d 467, 512 (5th Cir. 2011) ("It is . . . generally prohibited for a lay witness . . . to give legal opinions."); *United States v. Riddle*, 103 F.3d 467, 428-29 (5th Cir. 1997) (holding it was improper for bank examiner in bank fraud prosecution to explain provisions of banking regulations, to express opinion on "prudent" banking practices, and to express opinions about the defendant's actions). The mischaracterization of the law and solicitation of lay opinions on its application cast grave doubt on the grand jury's decision to indict. We believe that a review of the full record of the instructions will reveal significant additional shortcomings.

VII. THE PERVASIVE VIOLATIONS WARRANT DISMISSAL OF THE INDICTMENT WITH PREJUDICE.

Dismissal of an indictment is appropriate when government misconduct "substantially influenced the grand jury's decision to indict or if there is grave doubt that the decision to indict was free from the substantial influence of such violations." *Bank of Nova Scotia v. United States*, 487 U.S. 250, 256 (1980) (citations and quotations omitted). Such errors include violations of the "few, clear rules which were carefully drafted and approved by this Court and by Congress to ensure the integrity of the grand jury's functions." *United States v. Strouse*, 286 F.3d 767, 773 (5th Cir. 2002).

Dismissal also is appropriate when the errors are "fundamental," that is, where "the structural protections of the grand jury have been so compromised as to render the proceedings fundamentally unfair." *Bank of Nova Scotia*, 487 U.S. at 256-57.

Courts have dismissed indictments where the prosecutors' actions have unduly interfered with the grand jury's ability to independently and fairly exercise its duties. "The prosecutor's right to exercise some discretion and selectivity in the presentation of evidence to a grand jury does not entitle him to mislead it or to engage in fundamentally unfair tactics before it." *United States v. Ciambrone*, 601 F.2d 616, 623 (2d Cir. 1979). This includes misleading the jurors as to the relevant facts and law and interfering with the normal jury processes. *See, e.g.*, *United States v. Breslin*, 916 F. Supp. 438, 443-46 (E.D. Pa. 1996); *United States v. Peralta*, 763 F. Supp. 14, 21 (S.D.N.Y. 1991) (concluding that "defendants were seriously prejudiced by the cumulative effect of the government's misleading statements of law and its use of inaccurate hearsay testimony."); *United States v. Hill*, 1989 WL 47388, at * 6 (S.D.N.Y. March 22, 1989) ("The ATF agent quoted the defendant as stating that he was 'a repeated felony offender' . . . a fact of which the examining prosecutor knew" was false); *United States v. Hogan*, 712 F.2d 757, 757-8 (2d Cir. 1983) (noting that "the incidents . . . are flagrant and unconscionable. Taking advantage of his special position of trust, the [prosecutor] impaired the grand jury's integrity as an independent body.").

In making this inquiry, courts typically consider the cumulative effect of the misconduct. *Breslin*, 916 F. Supp. at 446 ("The cumulative effect of the many instances of misconduct can fairly be said to have 'substantially influenced the grand jury's decision to indict'"); *Peralta*, 763 F. Supp. at 21 (cumulative effect required dismissal). As discussed below, the cumulative effect of the government's misconduct casts grave doubt that the jury's indictment decision was free from the substantial influence of that misconduct.

The violation of Rule 6(e) through the improper disclosure of grand jury testimony as well as the misuse of Rule 17 through the extrajudicial examinations amount to violations of "clear rules which were carefully drafted and approved by" the Supreme Court. The Fifth Circuit has expressly stated that "Rule 6 of the Federal Rules of Criminal Procedure contains a number of such rules" contemplated by *Bank of Nova Scotia*, including Rule 6(e), which "plac[es] strict controls on disclosure of matters occurring before the grand jury." *Strouse*, 286 F.3d at 773. The improper disclosure of grand jury testimony in this case caused witnesses to modify their statements on substantive matters, which undoubtedly influenced the grand jury process. The improper disclosure of grand jury information to Witness O is particularly prejudicial because it, compounded by the improper threats of personal ruin, resulted in the creation of evidence that did not previously exist concerning an overt act alleged in the indictment. *See* Indictment ¶62; Exhibit 1, Scavdis Tr. at 10904-5. The violation of Rule 17 by the government's misuse of the grand jury subpoena process prevented the grand jury from hearing substantial testimony—including material exculpatory information—that would have been presented to it, but for the violation.

The Supreme Court in *United States v. Russell* recognized "a situation in which the conduct of law enforcement agents is so outrageous that due process principles would *absolutely bar* the government from invoking judicial processes to obtain a conviction." 411 U.S. 423, 432 (1973) (internal citation omitted, emphasis supplied). Prejudice may be presumed—and further prosecution barred—based on the government's violation of due process rights. *See United States v. Stein*, 435 F. Supp. 2d 330 (S.D.N.Y. 2006). In *Stein*, the court dismissed the indictment because the government coerced an employer to stop paying attorneys' fees to which defendants were legally entitled. *Id.* at 382. The court found that this violated due process and amounted to a structural defect that "threatened to contaminate this proceeding" and made it "impossible to restore a

criminal defendant to the position that he would have occupied but for the misconduct." *Id.* at 371, 374 (citations and quotations omitted). As in *Stein*, the "cumulative effect of the many instances of misconduct in this case can fairly be said to have substantially influenced the grand jury's decision to indict." *Breslin*, 916 F. Supp. at 446 (dismissing indictment due to "cumulative effect of the many instances of misconduct," at least some of which, standing alone, would not have justified dismissal). The government not only violated Rule 6(e); it did so knowingly, repeatedly, and for the purpose of polluting the recollections of witnesses who had previously provided exculpatory information. The government not only misused subpoenas to compel interviews, it used them as a wedge to separate witnesses from their counsel in an extrajudicial process that also effectively screened evidence from the grand jury. The government not only threatened witnesses with criminal prosecution, it bullied them with the specter of ruinous personal consequences if they did not change their testimony as instructed. The government not only misled the jury on the law, it claimed that clearly legal actions were illegal and elicited legal opinions from lay witnesses.

There is simply no way to correct for the cumulative effect of the sheer breadth and pervasiveness of these abuses and restore the defendants to the legal position they would have occupied had the government operated within the confines of the law. The Sixth Amendment to the Constitution guarantees the accused the right to compulsory process for witnesses in its defense. The witnesses the defendants intend to call at trial cannot now unlearn the tainted version of the evidence presented to them by the government. The witnesses cannot now forget the government's threats of prosecution and career destruction if they refuse to testify as directed—particularly because one VSI employee witness who refused to do so is scheduled to remain under indictment throughout this case. The defendants, who face destructive consequences if convicted, cannot now present to the jury the testimony they intended to produce because the government has intimidated

and improperly influenced the witnesses into changing that testimony such that reversion back to the uncoerced version could result in a perjury charge. In short, the government's misconduct not only casts grave doubt on the grand jury's decision to indict, it has enormous ramifications throughout the remainder of this case, deprives the Company and Mr. Root of their due process rights, and is starkly inconsistent with prosecutorial obligations and the best traditions of the Justice Department. The indictment therefore should be dismissed with prejudice.

CONCLUSION

For the foregoing reasons, Defendants Vascular Solutions, Inc. and Howard Root respectfully request that the Court dismiss the indictment with prejudice.

Dated: August 13, 2015

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I hereby certify that on August, 13, 2015, I electronically filed the foregoing document via the CM/ECF system, which will effectuate service on all counsel of record who are properly registered for CM/ECF service.

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