UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CRIMINAL NO.: SA-14-CR-926-FB
	)	**UNDER SEAL**
VASCULAR SOLUTIONS, INC., (1) and	)	
	)	
HOWARD ROOT, (2)	)	
	)	
Defendants.	)	

UNITED STATES' RESPONSE TO DEFENDANTS' MOTION TO DISMISS THE INDICTMENT BASED ON ALLEGED MISCONDUCT

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INTRODUCTION

Defendants' allegations of prosecutorial misconduct are either inaccurate or omit relevant context showing that prosecutors acted appropriately. The evidence detailed below shows that prosecutors gave four immunized subjects an opportunity to correct materially false statements after considering contemporaneous documents and information that contradicted their statements. The prosecutors gave the same immunized subjects truthful disclosures about their criminal exposure and accurate warnings about the potential consequences for giving false testimony. The lead case agent gave truthful testimony, prosecutors did not shield any exculpatory evidence from grand jurors, and the grand jury was correctly instructed. Defendants were not prejudiced. The way in which prosecutors conducted the investigation before the grand jury does not merit dismissal of the indictment.

BACKGROUND

I. THE CHARGES

The indictment charges Defendants with intentionally distributing Vari-Lase devices for unapproved use and conspiring to commit those offenses. Docket No. 1 at ¶ 25 (Indictment). It also charges that one object of the conspiracy was to defraud the United States by concealing their conduct from the FDA and misleading investigators. *Id.* ¶¶ 33(c), 35, 58-63. These conspiracy-to-defraud allegations are particularly relevant here because Defendants' motion attempts to refute them.

As set forth in the indictment, Defendants began selling their "Vari-Lase" laser devices for use in perforator vein ablations in 2007, despite having failed to

obtain FDA approval and despite receiving a warning from FDA not to sell the product for that use. The devices were only FDA-cleared for ablating (*i.e.* burning) superficial veins, which run along the surface of the skin. Perforator veins connect the superficial vein system to the deep vein system. Because perforator veins connect directly to the deep vein system, treating such veins is riskier and more difficult than treating superficial veins. *Id.* ¶ 13.

Aware that VSI could not openly sell the product for unauthorized use, Defendant Root decided to market the product for "short vein segments" or "short veins." *Id.* ¶ 58. Defendants instructed the sales force to tell doctors that there was "no definition" of "'short vein segment'" because the "physician decides." *Id.* ¶ 27. However, internal company documents approved by Root taught the sales force that the term "short vein" included perforator veins and urged them to suggest to health care providers that Vari-Lase devices could be used to treat perforator veins. *Id.* ¶ 58. Consistent with this guidance, members of the sales force used the terms "short vein segments" and "short veins" in their field trip reports to conceal that they were selling the devices for unapproved perforator use. *Id.* ¶ 35(b).

In August 2009, a former employee, DeSalle Bui, sent Root a letter accusing the company of promoting Vari-Lase products for unapproved perforator use and attached sales meeting presentations supporting the allegation. *Id.* ¶ 59. Aware that VSI had engaged in such conduct, Root presided over an internal investigation that found no evidence of any illegal activity. *Id.* Bui would later bring the *qui tam*

suit that ultimately led to the United States' parallel civil and criminal investigations of VSI and Root.

Two of the numerous overt acts in furtherance of the conspiracy to defraud are relevant to the instant motion. The first occurred in August 2012, when VSI's Southwest Regional Sales Manager, Shane Carlson, misled Special Agent George Scavdis during an interview. *Id.* ¶ 62. Carlson falsely stated that he had instructed Salesperson Daniel McIff to stop promoting the treatment of perforator veins. In fact, Carlson was aware that McIff had promoted the unapproved use, but did not instruct him to stop. Carlson's false statement thus concealed the role of company management in the perforator sales activity. *Id.* Defendants' motion attempts to refute these allegations and claims that prosecutors forced Carlson to lie in his second interview, during which he admitted that he had never instructed McIff to stop promoting perforator use. Docket No. 84 at 15-17. Defendants omit the specific evidence disproving this claim, detailed below.

The second overt act relevant to the present motion occurred in July 2013, when salesperson Glen Holden misled the grand jury in order to conceal his and VSI's ongoing sales of devices for unapproved perforator use. Docket No. 1 ¶ 63. Defendants dispute this allegation by claiming that Holden told the truth and was later indicted for perjury and obstruction of justice because he did not accede to prosecutors' demands to convert his truthful testimony into false testimony. Defendants' motion omits the specific facts refuting that claim, as shown below.

II. THE INVESTIGATION

The indictment arose out of a parallel civil and criminal investigation that began with the filing of a *qui tam* action by relator DeSalle Bui in 2010. Since then, four AUSAs from the Western District of Texas and three trial attorneys from the Department of Justice have worked on the parallel investigations. From the summer of 2013 until the filing of the indictment, the co-leads of the criminal investigation were AUSA Bud Paulissen and Timothy Finley, a criminal prosecutor with the Consumer Protection Branch. They, along with Special Agent George Scavdis from the FDA Office of Criminal Investigations, are the focus of Defendants' allegations of criminal misconduct. Paulissen has practiced law for 35 years, Finley for 20, and Scavdis has worked as a law enforcement agent for 14 years.

A. Root's Company-Wide Messages Denying the Conduct

Defendants learned about the parallel civil and criminal investigation concerning their sales of devices for unapproved use in June 2011, when the United States served VSI with a HIPAA subpoena. In an August 16, 2012 email informing the sales force that that "the U.S. Attorney's investigation . . . has been unsealed," Root denied the allegations of off-label promotion set forth in the civil qui tam complaint that the United States had joined: "Such is the world we live in today that a disgruntled ex-employee can make stuff up in an attempt to be the whistleblower 'hero' and try to make 30% of whatever the government [can] shake out of us . . . ." Ex. 1. He added, "I don't pay extortion, even to the U.S. government." *Id.*

Root echoed the same sentiment in the VSI quarterly newsletter: "And make no mistake about it – legal extortion is what the U.S. Attorney is trying to do." Ex. 2 at 1. He added that VSI "is being attacked by a group of government lawyers and disgruntled former employees who want to make a quick buck. That's not a group I'm inclined to apologize to or reward . . . ." *Id.* at 3.[1]

The audience for Root's company-wide messages included VSI executives and employees who, at his direction, had engaged in the illegal conduct under investigation. *Infra* at 28-30. These subjects of the investigation received the above messages from Root just as prosecutors were beginning to interview them. Root's statements created a situation where these subjects effectively had to choose between telling the truth – thus contradicting and incriminating the CEO on whom their livelihoods depended – or falsely denying the conduct consistent with his messages to them.

Five members of this group would falsely deny their own or the company's criminal conduct – Southwest Region Manager Shane Carlson, salesperson Glen Holden, Midwest Region Manager Elizabeth Matthews, Vice President of Marketing Carrie Powers, and Vice President of Sales Operations Susan Christian. These five witnesses are the focus of Defendants' allegation that prosecutors "threatened" witnesses who contradicted their "theory," in order to "distort" or "misshape" the evidence. Docket No. 84 at 2, 12, 19, 21. A reading of the full exchange between these witnesses and prosecutors shows that in each instance, prosecutors (1) asked

[1] VSI ultimately settled the parallel civil lawsuit in July 2014, for $520,000.

these witnesses to correct specific, materially false statements and (2) used accepted methods to seek truthful testimony and cooperation from these witnesses.

The five sections that follow (B-F) document the specific false statements that each of these witnesses gave, the evidence establishing the falsity of the statements in question, and the methods that prosecutors used to try to correct the false statements.

B. Efforts to Correct Shane Carlson's False Statement

Southwest Region Manager Shane Carlson gave a voluntary interview to investigators on August 1, 2012 (just prior to the Root statements described above). Ex. 3 (Carlson Memorandum of Interview ("Carlson 1st MOI")). VSI's lead criminal counsel at that time, William Michael, attended the interview. *Id.* at 1. Prosecutors informed Michael that Carlson was a "subject" in that his conduct was within the scope of the criminal investigation.

1. The False Statement

Prior to the interview, VSI had fired a salesperson under Carlson's supervision, Daniel McIff, for deleting documents responsive to the United States' June 2011 subpoena. Ex. 5 (McIff MOI). The deleted documents were presentations that McIff wrote entitled "Tips for Treating Perforator Veins" and "Treating Perforator Veins." Docket No. 1 ¶¶ 43, 45, 60. VSI witnesses have consistently described these presentations as encouraging salespeople to sell

Vari-Lase devices for unapproved use.[2] Ex. 6 at 17-21 (Powers Tr.); Ex. 7 at 147, 155-66 (Schmalz-Kern Tr.). The same documents had been attached to relator DeSalle Bui's August 2009 letter to Howard Root and were the subject of the subsequent cover-up investigation described in the indictment. Docket No. 1 ¶ 59. After McIff's termination, VSI offered to cooperate against him.

During the August 2012 interview, Carlson committed an overt act in furtherance of the conspiracy to defraud the United States (*supra* at 3) by giving a materially false statement concerning his supervision of McIff. Docket No. 1 ¶ 62. When confronted with company documents evidencing that Carlson knew about McIff's illegal sales, Carlson explained that he had warned McIff about off-label marketing at least five times and had told him to stop, all to no avail. Ex. 3 at 6.

This statement – Carlson 's claim that he told McIff to stop – was the specific false statement that prosecutors asked him to correct. Docket No. 84 at 16, 20. Prosecutors did not, as Defendants inaccurately claim, threaten Carlson because he contradicted their "theory" by stating that the Short Kit was designed for short vein segments. In fact, prosecutors did not take issue with that statement because it was true, provided that "short vein segment" is defined to include perforator veins. Defendants' inaccurate description of the statement that prosecutors asked Carlson to correct is at the heart of their claim that witnesses were threatened for contradicting a mere "theory." *Id.* at 20.

[2]As explained in full in the government's First Amendment brief, although some VSI witnesses believed that off-label marketing was itself illegal because of the training they had received from the company, the law does not treat wholly truthful off-label promotion as a crime, and neither does the indictment. Witnesses also testified that the McIff presentations were false and misleading.

2. Evidence of Falsity

The following evidence (omitted from Defendants' motion) demonstrates that prosecutors had a reasonable basis to believe that Carlson made a false statement at his August 2012 interview, when he said that he instructed McIff to stop promoting perforator use:

- Carlson had asked McIff (before becoming McIff's manager) for a copy of his "Tips for Treating Perforator Veins" presentation, and then emailed it to a doctor. Ex. 8 (Carlson Statement).

- Carlson wrote an email to another salesperson, Chris Harrelson, instructing him to promote perforator use to a doctor. Ex. 9 (Carlson-Harrelson email).

- There is no written evidence of any warning to McIff or Harrelson, who together sent Carlson dozens of field trip reports describing their perforator sales activities. *See e.g.,* Ex. 10 (sample McIff trip reports); Ex. 11 (sample Harrelson trip reports).

- McIff denied receiving any such instruction from Carlson, and Harrelson was not even aware that VSI did not have approval to sell Vari-Lase equipment for perforator treatment. Ex. 5 at 9 (McIff MOI); Ex. 12 at 8 (Harrelson Tr.).

3. Efforts to Correct the False Statement

In September 2013, prosecutors served Carlson with a grand jury subpoena. On approximately October 21, 2013, VSI counsel Michael found separate counsel for Carlson and VSI's other current employees and executives, attorneys Jon Hopeman and Marnie Fearon ("pool counsel").[3] Ex. 13 (email from VSI counsel Michael).[4] Carlson asserted his Fifth Amendment privilege against self-incrimination in

[3] The term "pool counsel" refers to a lawyer representing a group of current or former employees of a corporate target. The fees of such pool counsel are typically paid by the corporate target (or its insurance carrier) and not by the employees themselves.

[4] The circumstances surrounding Michael's withdrawal due to conflicts of interest are set forth below. *Infra* at 16.

response to the grand jury subpoena, as did every other current executive or employee who received a subpoena from that date forward.

After prosecutors obtained a court order granting Carlson immunity and compelling his testimony, he gave a second interview on September 29, 2014. Before the interview began, prosecutors reviewed evidence with Mr. Carlson in order to ease his anxiety about cooperating against his boss and employer. The prosecutors encouraged him to correct his earlier false statement, and truthfully admit his role in the conduct.[5] Prosecutors also refreshed his memory by reviewing the documents he would be asked about at the subsequent interview. Ex. 14 at 3 (May 27 Finley letter). The prosecutors told him that many at VSI, including current executives, managers, and employees, had admitted illegal conduct. *Id.*

Defendant's portrayal of this evidentiary presentation (and the one preceding Elizabeth Matthews's interview, *infra* at 20-21), as an act of prosecutorial misconduct depends upon two inaccurate assertions of fact. First, Defendants claim without support that its purpose was to construct false testimony. Docket No. 84 at 14-17. That inaccurate claim is contrary to the specific evidence demonstrating the falsity of Carlson's initial statement set forth above. *Supra* at 8.

Second, Defendants accuse prosecutors of intentionally violating Rule 6(e) so that witnesses could get their stories straight. This was not what happened. As

[5] Defendants' motion is vague about this, but prosecutors did not warn Carlson that they were considering perjury charges. Docket No. 84 at 2 (unspecified number of witnesses "threatened" with perjury charges). The prosecutors gave such warnings to only two subjects, salesperson Glen Holden and regional manager Elizabeth Matthews, based on the evidence set forth below. *Infra* at 16-18 (Holden) and 20-22 (Matthews).

part of a larger evidentiary presentation that included numerous witness admissions and VSI documents obtained without grand jury process, prosecutors quoted from the admissions of one VSI witness who testified before the grand jury, Eastern Region Sales Manager Richard Steitzer. Although the Department's Grand Jury Manual recommends that prosecutors obtain a court order before disclosing grand jury testimony, and prosecutors did not do that here (*infra* at 47), they took precautions to preserve secrecy, disclosed a limited amount of information that Carlson likely knew about already, and read the testimony for a proper purpose.

Prosecutors did not use Steitzer's name and identified him only as a "regional manager" (VSI had at least eight). Prosecutors read three brief exchanges and omitted specific factual details. The exchanges consisted of the manager's ultimate admissions that (1) all of his salespeople sold devices for unapproved perforator use, (2) management encouraged this conduct, and (3) the conduct was illegal according to the company's training on appropriate sales practices. Ex. 69 (full exchanges quoted to Carlson). The quotations were part of a larger evidentiary review and revealed only that an unidentified manager, along with many others, was admitting the conduct under investigation and had implicated senior management. *Id.* This was already well known to pool counsel (Hopeman and Fearon) at that point because (1) they had represented six witnesses who made similar admissions during their grand jury testimony and (2) prosecutors had told them, in an effort to overcome Carlson's reluctance to cooperate against his boss, that many former VSI employees had made

similar admissions outside of the grand jury proceedings.[6] Presumably, pool counsel shared this important information with their client. Disclosing the exact wording of certain admissions by an unnamed witness demonstrated only that prosecutors had not exaggerated when they had described these and other admissions to pool counsel as unequivocal.

Contrary to Defendants' motion, there was no "shaping" of testimony, not only because Steitzer was not identified to Carlson and his admissions lacked specific detail, but also because his conduct did not overlap with Carlson's. Steitzer was Sales Manager for the Eastern Region; Carlson held the same position in the Southwest Region. Steitzer's admissions were based on emails and trip reports that did not involve Carlson, and Carlson's admissions (and the documents supporting those admissions) did not involve Steitzer. *Compare* Ex. 69 (Steitzer testimony quoted to Carlson) and Ex. 4, Ex. 15A (documents corroborating Steitzer admissions), *with* Ex. 8 (Carlson signed statement).[7] The point was not to "shape" Carlson's testimony to fit Steitzer's. The point was to let Carlson know that an unnamed manager (Steitzer) and many others (based on non-grand jury interviews) had

[6] *See United States v. Kouba*, 632 F. Supp. 937, 941-42 (D.N.D. 1986) (disclosing facts about the grand jury's investigation to witnesses who likely already knew them was not a Rule 6(e) violation) (discussed *infra* at 48).

[7] Although their conduct did not overlap, Carlson and Steitzer received the same company-wide marketing and training materials. Both gave similar testimony about such documents, as did nearly every witness, not because of any "misshaping" but because the testimony simply repeated what the documents themselves said.

admitted to their own, separate conduct, and Carlson should not be afraid to tell the truth when he explained the specific documents that he himself authored and read.[8]

After prosecutors described the evidence that contradicted his August 2012 statement, Carlson gave a second interview.[9] He provided a signed statement, under penalty of perjury, correcting his earlier false statement. In this October 2014 statement, he admitted:

> I was aware that one of the salespeople I supervised, Danny McIff, actively sold Vari-Lase devices to health care providers for perforator use. This was inappropriate. I told McIff that Vari-Lase devices were not approved for perforator use, but I did not instruct him to stop. McIff continued selling Vari-Lase devices for perforator use throughout the time that I supervised him.

Ex. 8 at 1. Carlson stated that the "Tips for Treating Perforator Veins" presentations that he had obtained from McIff and sent to a doctor contained what he believed to be "incorrect and inappropriate" billing advice that "could cause doctors to submit improper claims to Medicare or other insurers." *Id.* Carlson further admitted sending an email to salesperson Chris Harrelson asking him to help "[a doctor] 'add value to his practice' by starting to treat perforators in certain cases," the

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[8] Defendants assert that prosecutors told Carlson he needed to conform his testimony to that of others to be "safe from prosecution." Docket No. 84 at 2. This did not happen. Prosecutors were explaining that under the terms of the Court's immunity order, Carlson would be safe from prosecution, even if he admitted illegal conduct, as long as he told the truth. Prosecutors also pointed out that other witnesses, many of whom also were immunized, had done so without being prosecuted. It was not improper to explain to Carlson the terms of his immunity or to allude to prosecutors' past compliance with immunity orders and non-prosecution agreements.

[9] Defendants also seem to suggest that the evidentiary presentation was itself an inappropriate tactic, but a review of the evidence is a common occurrence in plea and proffer negotiations with co-conspirators and potential cooperators like Carlson. *See* Stephanos Bibas, *Plea Bargaining Outside the Shadow of Trial*, 117 Harv. L. Rev. 2463, 2525 (2004) (noting that in plea negotiations "defendants are often impressed" when "prosecutors are willing to show many of their cards during reverse proffers," and recommending the practice as "effective").

effect of which "was to encourage [him] to sell Vari-Lase devices for unapproved perforator use." *Id.* at 2.

Prosecutors did not provide Carlson's sworn statement to the grand jury, but Special Agent George Scavdis did testify that Carlson, during his second interview, corrected his initial false statement that he instructed Daniel McIff to stop selling devices for unapproved use. Nevertheless, even assuming Carlson's testimony had been "misshaped" as Defendants' allege, Carlson's initial false statement was only one of several overt acts independently supporting the conspiracy-to-defraud charge. Docket No. 1 ¶¶ 36-63 (Indictment).

C. Efforts to Correct Glen Holden's False Testimony

Prior to salesperson Glen Holden's grand jury testimony in July 2013, prosecutors told VSI counsel Michael that Holden was a subject of the investigation. Prosecutors informed VSI counsel of their view that it would pose a conflict of interest for company counsel to represent Holden, a fact that was evident from his emails (described below). Ex. 17 (5/28/2013 Finley email); *see Wood v. Georgia*, 450 U.S. 261, 269 n.15 (1981) (it is "inherently wrong for an attorney who represents only the employee to accept a promise to pay from one whose criminal liability may turn on the employee's testimony") (quoting another source). VSI counsel declined to obtain independent counsel for Holden. Ex. 17 at 1 (Finley email to Michael).

1. The False Testimony

During his grand jury testimony, Holden gave materially false and evasive testimony that formed the basis for his indictment charging him with five counts of

perjury and one count of obstruction of justice. Ex. 18 (Holden indictment). Holden denied that he had ever tried to "increase business" by selling devices for perforator use or offered any doctors "perforator specific" devices. *Id.* ¶¶ 17-18, 26. He also denied knowledge of Medicare's practice generally barring reimbursement for procedures involving unapproved devices. *Id.* ¶¶ 28-29. Based on the evidence listed below, prosecutors had a reasonable basis for believing Holden's denials to be false.

2. Evidence of Falsity

Some of the evidence of the falsity of these statements includes:

- Holden's field trip report in which he described a joint presentation he made with a sales representative from another company showing that "[t]he combination of *laser on perforators* and [the other salesperson's product] on the non-healing ulcers works fantastic. I have been working with the rep to *increase business* in laser centers and wound care centers." *Id.* ¶ 17 (emphasis added).
- A report from Holden's manager, Richard Steitzer, describing how Holden "got into a good discussion [with an account] on *treating perfs*," "presented our short kit," "offered to bring in his [Vari-Lase] demo console and do cases with them," "and stressed that another of his big accounts" was "*very happy with our perf kit*." *Id.* ¶ 24.
- Richard Steitzer's testimony, based on the above report, that Holden was "clearly selling" Vari-Lase for perforators, and that Holden's actions were "illegal" and "wrong." Ex. 15 at 20-21 (05/06/2014 Steitzer Tr.)
- Holden's email to a health care provider that VSI sold a "short perforator specific" kit. Ex. 18 ¶ 26.
- Interviews from Holden's customers that he promoted devices for perforator use without any solicitation by the doctor. Ex. 19 at 2 (Dr. De Natale MOI); Ex. 20 at 2 (Dr. Belcher MOI).
- Holden's e-mail to Salesperson John DeVito, in response to his question about whether doctors could bill for laser perforator ablations, stating, "Can't bill for perfs. Not approved." Ex. 21 (Holden-DeVito email) (contradicting testimony that he did not know about this rule).

3. Potential Coaching

During his testimony, prosecutors asked questions aimed at determining whether Holden had been improperly coached. The evidence, though not necessarily conclusive, supported the need to inquire about this subject. This included: (1) Holden's representation by company counsel in spite of the conflict of interest between him and VSI (a conflict eventually conceded when company counsel later withdrew), (2) his false and evasive testimony, and (3) his non-responsive answers volunteering company arguments. *Supra* at 13 (conflict) and 14 (false and evasive testimony); Ex. 18 ¶ 26 (Holden Indictment) (setting forth non-responsive testimony in italics). Before asking these questions, and again during the questioning, prosecutor Finley instructed Holden not to reveal actual attorney-client communications, a fact omitted from Defendants' claim that he intentionally sought to violate the privilege. Ex. 22 at 26, 66 (Holden Tr.).

Questioning of Holden uncovered additional evidence supporting an inference of coaching. When asked if he had received "talking points" to give in response to certain questions, he said, "A little bit, yeah." *Id.* at 27. Later, after Holden had denied selling any kit specifically for perforators, prosecutors showed Holden his email advising a customer that she could buy "short perforator specific" kits from VSI. *Id.* at 52. In response to the question – "So is this an example of you telling an account that you've got a perforator specific kit for them to use?" – Holden asked to leave the room to consult with counsel. *Id.* at 52-53. His request was granted. His ultimate answer stood by his false denials and evaded the pending question:

"Oh, yeah. Exhibit 12? Yeah, you asked me about a statement I had made. And you know what? Poor choice of words." *Id.* at 65.

During the break, Finley discovered that Holden had left the grand jury room with grand jury exhibits. Finley found Holden in the foyer area of the same floor, reviewing the grand jury documents with VSI counsel. *Id.* at 53-55. When questioned about it, Holden testified, "I showed him the [pending] question that was asked of me" and "he discussed possible responses." *Id.* at 53-54. Holden testified that he did not know he was not supposed to leave the grand jury room with the grand jury exhibits. *Id.* at 55.

4. Efforts to Correct the False Testimony

After Holden's testimony, AUSA Paulissen wrote VSI counsel Michael that Holden had criminal exposure arising out of his grand jury appearance and that his exposure might be reduced if he cooperated against the company. Ex. 23 (Oct. 8, 2013 Paulissen letter). In response to that letter, Michael withdrew from his conflicted representation of VSI and Holden and informed prosecutors that Holden would be represented by Hopeman and Fearon – the same pool counsel who would represent Carlson (*supra* at 8) and all other current VSI executives and employees involved in the investigation.

In a January 2014 letter to Hopeman and Fearon, AUSA Paulissen cited the portions of Holden's testimony that were false[10] and described specific documents evidencing falsity. Paulissen requested that Hopeman and Fearon "contact us as

[10] The letter included Holden's transcript and a protective order limiting the use of that transcript.

soon as possible to discuss whether Mr. Holden is willing to correct his misstatements and provide truthful testimony in this investigation." Ex. 24 (Paulissen letter). Hopeman and Fearon responded by telling the prosecutors that Holden was unwilling to change his testimony. Later, prosecutors disclosed their view that it would pose a conflict of interest for pool counsel to simultaneously represent Holden and all current VSI employees, because the evidence made it likely that they would incriminate one another and VSI, the source for pool counsel's fees. Hopeman and Fearon declined to withdraw.

Shortly thereafter, one of their clients, Holden's supervisor Richard Steitzer, gave testimony incriminating Holden, who himself had previously incriminated Steitzer. Ex. 15 at 20-21 (Steitzer Tr.) (agreeing that Holden was "clearly selling" the short kit for perforators, describing conduct as "illegal" and "wrong"); Ex. 22 at 49-51 (Holden Tr.) (Steitzer praised him for selling "perf kit"). After that, Vice Presidents Susan Christian and Carrie Powers, while represented by the same pool counsel, also incriminated Holden. Ex. 6 at 29 (Powers Tr.) (agreeing that Holden's promotional activities described in Ex. 25 (Holden Field Trip Report) were illegal according to company policy); Ex. 26 at 30-32 (Christian Tr.) (Holden's sales activities described in a weekly report Steitzer had sent her were "not acceptable"). A fourth witness, salesperson John DeVito, represented by the same pool counsel, incriminated Holden by contradicting his false denial of any knowledge that doctors generally could not get reimbursed for performing procedures with unapproved

devices. Ex. 27 at 34-36 (DeVito Tr.) (discussing email exchange in which Holden told him that doctors "Can't bill for perfs. Not approved.").[11]

In July 2014, prosecutors informed pool counsel that if Holden did not cure his perjury he would receive a target letter. Holden declined the offer, and prosecutors sent pool counsel the target letter. Ex. 28 (Holden target letter). After receiving it, pool counsel withdrew from their representation of Holden. The grand jury indicted Holden on November 13, 2014.

D. Efforts to Correct Elizabeth Matthews's False Testimony

After first refusing to testify because she might incriminate herself, Midwest Region Manager Elizabeth Matthews received immunity from the Court and testified before the grand jury on June 26, 2014.

1. The False Testimony and the Evidence of Its Falsity

Defendants inaccurately describe the testimony that prosecutors asked Matthews to correct. Docket No. 84 at 14. They did not ask her to correct her testimony that the Short Kit was designed for "short vein segments," which would have been a true statement if that term is defined to include perforator veins. Rather, they asked her to correct false statements about a weekly report she wrote to senior management, a related email to a doctor, and trip reports that she received from subordinates, as discussed below.

[11] In response to DeVito's statement in an email, "Text me what they call them then," DeVito testified that Holden called him and told him to use the term "short vein segments" and the same billing code used for superficial veins." Ex. 27 at 37, 40-41 (DeVito Tr.). DeVito passed this information along to a doctor. *Id.* at 41.

Matthews denied that she or her subordinates had sold Vari-Lase devices for perforator use. Ex. 29 at 29-30 (Matthews Tr.). She persisted in these denials even after reviewing her weekly report in which she wrote to Root and other executives that she had visited an account and "uncovered potential business lost to [a competitor's] perf. [b]usiness" but had an opportunity because the competing "perf kits" were overpriced. Ex. 30 (Matthews weekly report); Ex. 29 at 32-36, 45-47 (Matthews Tr.). According to her email to the same account from the following week, she followed up by delivering "our VSI Perforator kit for free trail [*sic*]" and offered a lower price than the competitor. Ex. 31 (Matthews free trial email). Matthews denied that her use of the term "our VSI perforator kit" indicated to the doctor that it was meant for perforator veins, claiming instead that her words meant that it was for "short vein segments." Ex. 29 at 49-50 (Matthews Tr.). She claimed further that she had only used the term "perforator kit" because that was what the doctor had called it. *Id.* at 35-36, 49.

Matthews denied that her subordinates engaged in similar conduct. *Id.* at 29-30. These denials were contradicted by the field trip reports she received from them. Ex. 32 (sales rep reporting to Matthews that he showed a doctor "what we have to offer him in regards to perfs and some training options"); Ex. 33 (another salesperson reporting to Matthews that "[a]nother patient needed perforator help and I made [the doctor] aware that they have the short kits").

2. Efforts to Correct the False Testimony

Matthews gave a follow-up interview on September 29, 2014, subject to the immunity protection granted by the Court's prior order. Before the interview, prosecutors showed her documents evidencing the intentional sale of Vari-Lase devices for perforator use, and told her that many VSI employees had admitted engaging in this conduct. Prosecutors quoted from the admissions of numerous VSI witnesses. This included six exchanges from the grand jury testimony of two witnesses, Eastern Region Sales Manager Richard Steitzer (same three exchanges discussed above) and Vice President of Marketing Carrie Powers (three exchanges). The Powers exchanges established that an unnamed vice president admitted that (1) a company presentation instructed the sales force to "target perforator doctors," (2) she encouraged an unnamed salesperson to engage in "inappropriate off-label promotion," and (3) company documents encouraged the sales force to sell devices for unapproved use by teaching them that the term "short veins" includes perforator veins. Ex. 68 (exchanges quoted to Matthews).

Prosecutors used the same methods to preserve secrecy that they used with Carlson – they did not identify witness names, and they read quotes that did not reveal specific factual details. The conduct underlying Powers's and Steitzer's admissions did not overlap with that of Matthews, who worked in a separate region of the country (Indiana) from Powers (Minnesota) and Steitzer (New York). Although the three witnesses received the same official training and marketing materials and repeated some of their contents, the admissions that Matthews

ultimately made were based on her own documents and involved a separate set of events. *Compare* Ex. 34 (Matthews Sworn Statement) with Ex. 68 (exchanges quoted to Matthews). As with Carlson, the point was not to "shape" witness accounts so that they matched; rather, the prosecutors communicated to Matthews that she should not be afraid to truthfully admit her own, separate conduct, because many others had admitted their separate conduct.

At the September 29 meeting, prosecutors told Matthews that she had given false testimony to the grand jury, showed her the specific portions of her testimony that were false, and identified the evidence that established its falsity. Prosecutor Finley, with the concurrence of AUSA Paulissen, warned that if she did not correct her false testimony, he would (i) recommend to Department of Justice management that perjury and obstruction of justice charges be brought against her, (ii) refer her to HHS as a candidate for possible exclusion from participation in government healthcare programs, and (iii) ask VSI to terminate her employment. Ex. 14 at 6 (5/27/15 Finley letter). These warnings were supported by the evidence described above and were based on specific guidance from the United States Attorney's Manual. *Infra* at 44-45 (citing and quoting relevant sections).

Defendants suggest that prosecutors concealed the above warnings during discovery and only disclosed "that they merely advised the witnesses of possible consequences of being untruthful." Docket No. 84 at 18. This is inaccurate. The very same letter discloses the above warnings nearly verbatim. *Id.* at 6 (May 27 letter).

Following the interview, Matthews signed a sworn statement under penalty of perjury. Matthews admitted that "[i]t was inappropriate for me to refer to the Short Kit as a 'perforator kit' because it is not approved for use on perforator veins." Ex. 34 (Matthews Statement). She stated that "[m]anagement at VSI instructed us to promote the Short Kit for treating 'short veins.' In company training materials and presentations, the company repeatedly used the term 'short vein' as a term that included perforator veins." *Id.* She stated further that the trip report she had received from her subordinate could be read to describe perforator marketing efforts. *Id.* The United States did not present Matthews's revised testimony to the grand jury, nor did Special Agent Scavdis summarize it. From the grand jurors' perspective, her initial false denials stood uncorrected.

E. Efforts to Correct Carrie Powers's False Testimony

Vice President of Marketing Carrie Powers testified before the grand jury in May 2014, pursuant to the Court's order granting her immunity and compelling her to testify. Initially, Powers admitted that field trip reports that she received included examples of illegal conduct. Ex. 6 at 25 (05/06/2014 Powers Tr.) (field trip report described "an example of illegal conduct"); *id.* at 29 (same conclusion as to another report). She also agreed that company sales presentations "encourage[d] the sales force to sell the Short Kit for perforator use" and told them "to target perforator doctors." *Id.* at 37-38. Yet, she denied any management intent to sell devices for unapproved perforator use. She instead blamed VSI's sales representatives for misinterpreting these marketing messages. *Id.* at 51-52.

However, as she continued to review more documents, Powers eventually admitted that management participated in the conduct. For example, she admitted that she told a salesperson that the short kit was suitable for treating perforator veins, and that by doing so, she encouraged him to promote the short kit for unapproved use. *Id.* at 58-59. After a detailed study of VSI's training materials, she testified:

> Q. So, it took you two steps as a company to tell the sales force to promote this for perforators. First, you say, promote for short vein segments, and then, you teach them that short vein segments includes perforator?
>
> A. That's how it appears.

Id. at 73.

After Powers testified, the prosecutors told her attorneys, Hopeman and Fearon, that they believed her testimony was less than fully candid. Contrary to Defendants' motion, prosecutors did not take issue with her testimony simply because she contradicted a "theory." Rather, her initial denial of management involvement contradicted her own documents (set forth above) and her subsequent admissions.[12] Prosecutor Finley cautioned pool counsel about the problems that Powers's lack of candor might create for her later. Finley advised that one such risk was exclusion from federal healthcare programs, because if VSI was convicted, Powers, as a corporate officer, would automatically be subjected to potential

[12] In the absence of specific documents demonstrating otherwise, other witnesses who denied management involvement were not asked to correct their testimony. *See, e.g.*, Ex. 35 at 1 (Thielen MOI). Such testimony by itself does not contradict prosecutors' "theory," as Defendants claim. Rather, it shows a lack of knowledge and participation in the conspiracy by that particular witness.

exclusion from federal programs (*e.g.*, Medicare). *See* 42 U.S.C. § 1320a-7(a)-(b). He also informed pool counsel that she was at risk of losing her job because the corporation, as part of any plea resolution, would have to demonstrate acceptance of responsibility by holding accountable those who participated in the illegal conduct. *See, e.g.*, U.S. Dep't of Justice, United States Attorneys' Manual § 9-28.300, Factors to be Considered (2015) (hereinafter "USAM") (in determining whether to charge a corporation, prosecutors should consider "the corporation's remedial actions, including any efforts . . . to replace responsible management [and] to discipline or terminate wrongdoers"). Finley pointed out that by cooperating with the investigation, Powers could reduce these risks. Contrary to Defendants' claim that Finley threatened her with "economic ruin" and "disastrous personal consequences" (Docket No. 84 at 7, 18, 19), he accurately disclosed to pool counsel *pre-existing risks* that Defendants had exposed her to and invited her to lessen those risks through cooperation.

Defendants' claim that "[t]he *government told another witness* [Powers] that her testimony was 'pissing them off'" (Docket No. 84 at 3) (emphasis added) is inaccurate. First, the alleged statement was made to Powers's counsel, not Powers herself. (Docket No. 86, Ex. 15A at 2-3) (Hopeman Aff.) (under seal). This is not the only time Defendants inaccurately suggest that a statement to counsel alone was made directly to a witness. *See infra* at 32-35 (listing three other examples). Second, Defendants omit that AUSA Paulissen immediately apologized to counsel for

expressing himself poorly and stressed that his point was Ms. Powers had been less than candid.

Notwithstanding the Court's grant of immunity, Powers declined an additional interview. In response, the prosecutors warned pool counsel that Powers's non-cooperation might lead them to consider charging her as a responsible corporate officer who had failed to prevent FDCA violations, a misdemeanor. *See United States v. Park,* 421 U.S. 658, 673-74 (1975).[13] The prosecutors told pool counsel that any such charge would be based solely upon evidence obtained prior to her grand jury appearance and therefore not subject to the Court's grant of use immunity.

In October 2014, pool counsel indicated that Powers was "open" to signing a proposed statement withdrawing her earlier denial of any corporate plan in favor of an admission that she actually *did not know* whether such a plan existed, subject to her review of her grand jury transcript. Ex. 36 (Fearon email). Powers's counsel asked for confirmation that the United States would regard Powers as a cooperating witness until she had an opportunity to review the transcript. The prosecutors agreed. Counsel for Powers stated on May 8, 2015, that Powers would prefer not to sign the statement, not because it was untrue but because it was unnecessary, given the admissions she had already made. In light of the difficult position a signed

[13] Defendants inaccurately allege that prosecutors concealed the above disclosures and warning during discovery. In fact, prosecutors disclosed this in discovery. *Supra* at 23-24.

statement might put her in as an executive reporting directly to Root, the prosecutors advised that they would not press for the statement.

Prosecutors did not inform the grand jurors about the above discussions, so any alleged attempt to "misshape" her testimony could not have affected the grand jury's decision.

F. Efforts to Correct Susan Christian's False Testimony

Vice President of Sales Operations Susan Christian testified on the same day as Carrie Powers and was also represented by Hopeman and Fearon. Like Powers, she had demanded and received immunity, and she gave somewhat similar testimony in that she acknowledged illegal conduct at the company but denied that it resulted from any corporate plan. For example, Christian reviewed a weekly report from Eastern Region Manager Richard Steitzer to her and Root praising salesperson Glen Holden's "persistent" effort to sell a doctor Vari-Lase equipment for perforator use. She agreed that the document described behavior that was against the law and prohibited by VSI's Code of Conduct. Ex. 26 at 30-32 (Christian Tr.). Yet despite this and another weekly report Christian had received, in which a VSI senior executive praised a regional manager for similar conduct (Ex. 30), she denied any "corporate plan" to make such sales. *Id.* at 38. Christian said this even though she admitted that this management encouragement was "consistent with actions that were taken to sell products off label." *Id.* at 39. She also agreed that the company's actions were inconsistent with a "no tolerance" policy for off-label sales. *Id.* But

she continued to insist that no corporate plan could exist because the Short Kit had poor sales. *Id.* at 39 ("it's just such an immaterial level of sales").

Prosecutors informed Christian's attorneys that her testimony was less than candid and asked for a follow-up interview. Like Powers, she declined an additional interview in spite of the Court's grant of immunity. Prosecutors gave the same warnings to Hopeman and Fearon with respect to Christian's exposure that they had given to Powers.[14]

In October 2014, pool counsel indicated that Christian was "open" to signing a proposed statement correcting her grand jury testimony denying a corporate plan to market off label, subject to her review of her grand jury transcript. Ex. 36 (Fearon email). Counsel requested confirmation that prosecutors would regard Christian as a cooperating witness until she had an opportunity to review the transcript. *Id.* Prosecutors agreed. Counsel for Christian stated on May 8, 2015, that Christian would prefer not to sign the statement, not because it was untrue but because it was unnecessary given the admissions she had already made during her testimony. As with Powers, the prosecutors withdrew their request for the statement.

The prosecutors did not inform the grand jurors about these discussions. Therefore, Christian's denials of a corporate plan stood uncorrected when the grand jury indicted.

[14] Defendants misrepresent that prosecutors sought to conceal in discovery that it had given such warnings. Docket No. 84 at 18. This is inaccurate. *See* Ex. 14 at 4 (May 27, 2015 letter describing specific disclosures and warnings given to Christian).

G. At Least 18 Witnesses Admitted the Charged Conduct

Carlson, Matthews, Powers, and Christian were only four out of at least 18 VSI witnesses who admitted facts establishing Defendants' guilt. This includes five current VSI sales personnel who received immunity and, without having any prior communication with prosecutors, testified as follows:

- **Eastern Region Manager Richard Steitzer.** He encouraged his ten or eleven salespeople to sell devices for perforator use, and "just about every one of them did." Ex. 15 at 32. Management wanted him to do it. *Id.* After the company learned of the investigation, he used the term "short veins" to conceal perforator sales efforts. Ex. 15A; Ex. 70 at 4, 7-10, 12-13.

- **Salesperson Anthony Paszkeicz.** He knew that actively selling perforator use was illegal. Management encouraged him to do it. Ex. 37 at 7, 10, 14 (07/17/2013 Paszkeicz Tr.); Ex. 37A.

- **Salesperson Robert Lehoullier.** He sold devices for perforator use. He agreed that it was "[p]retty well understood in the company . . . that it's not approved by the FDA for perforator use, but we're going to make money so sell it for perforator use . . . ." Ex. 39 at 40; (2/18/14 Lehoullier Tr.). After the company learned of the investigation, he used the term "short segment" to refer to ongoing perforator sales activity, agreeing that the term "perf kind of sends up . . . red flags." Ex. 40 at 11 (6/26/14 Lehoullier Tr.); Ex. 40A.

- **Salesperson Anthony Ramiro.** He knew it was illegal to sell devices for unapproved perforator use, but he did so anyway, agreeing that "that the people above you in the chain of command wanted you to . . . ." Ex. 41 at 7, 23, 37-38 (Ramiro Tr.).

- **Salesperson John DeVito.** He agreed that he "promot[ed] Vari-Lase equipment for use on perforators here with the knowledge of Fred Reuning, who is the director of marketing." Ex. 27 at 18-19. He admitted that his email with Glen Holden discussing how to coach doctors so they could still get reimbursed for ineligible perforator procedures "looks devious." Ex. 27 at 42. (DeVito Tr.); Ex. 27A (documents corroborating DeVito admissions).

- **Salesperson Chris Harrelson.** He made sales calls with the hope that doctors would use VSI's equipment on perforators. Ex. 12 at 27 (Harrelson Tr.); Ex. 12A (Harrelson Field Trip Report).

In addition to the current employees above, seven former VSI executives and employees made similar admissions:

- **Vice President of Marketing Fred Reuning.** "Management at the company, including the CEO Howard Root, knew about and encouraged the sales force's efforts to sell Vari-lase products for unapproved perforator use." Ex. 42 (Reuning Sworn Statement).[15]

- **National Sales Director Mark Valls.** Root and the marketing department instructed sales reps to promote the Short Kit for perforators, and they did as they were instructed. Ex. 43 (Valls MOI).

- **Western Region Sales Manager Kip Theno.** Based on direction from management, he encouraged his subordinates to sell the Short Kit for perforator use. Root was critical by nature, but he never criticized Theno for promoting perforator use. Ex. 44 (Theno MOI).[16]

- **Mid-Atlantic Region Sales Manager Tom Nowak.** Official training materials instructed the sales force to use the Short Kit to compete directly against a competitor's "perforator kit." Ex. 45 at 2 (Nowak MOI). His subordinate, Anthony Ramiro, was only "applying the strategy VSI wanted him to apply" when he sold devices for perforator use. *Id*. at 3 (Nowak MOI); Ex. 45A at 22-23.

- **Salesperson Eddie Pedregon.** VSI sales representatives were trained to sell Short Kits for perforator veins. Shane Carlson urged him to do this at regional teleconferences. Ex. 46 at 3-4 (Pedregon ROI).

- **Salesperson Danny McIff.** He sold devices for perforator use and was encouraged to do so by management. Ex. 5 at 6-8 (McIff MOI).

- **Salesperson DeSalle Bui.** He sold devices for perforator use and was encouraged to do so by management. Ex. 47 at 2-3 (Bui MOI).

- **Salesperson Earl Detrick.** He knew that selling Vari-Lase devices for unapproved perforator use was illegal. With the knowledge of management, he sold Vari-Lase devices for this use. Ex. 48 (Detrick MOI).

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[15] Reuning received a target letter prior to providing this statement. Ex. 14 at 8 (May 27 Finley letter).

[16] Theno is cooperating with the United States pursuant to a non-prosecution letter. Ex. 14 at 9 (May 27 Finley letter).

In most cases, the above admissions are corroborated by contemporaneous trip reports, emails, official presentations, and training materials. *See, e.g.*, Ex. 11 and Ex. 12A (Harrelson Field Trip Report); Ex. 15A (documents corroborating Steitzer admissions); Ex. 27A (documents corroborating DeVito admissions); Ex. 37A (Paszkeicz Field Trip Report); Ex. 45A (VSI "perfect pitch" document that Nowak, in his MOI, Ex. 45, confirmed was in VSI sales binders).

Finally, at least five doctors stated that VSI sales personnel, unsolicited by that doctor, marketed devices to them for perforator use. Ex. 19 at 2 (Dr. De Natale MOI); Ex. 20 at 2 (Dr. Belcher MOI); Ex. 49 at 2 at (Dr. Gensler MOI); Ex. 50 at 2 (Dr. McEnroe MOI); and Ex. 51 at 1 (Dr. Wolschleger MOI).

H. Prosecutors Did Not Make Improper Threats During Plea Negotiations with VSI

Relying on the affidavit of former VSI lead criminal counsel R.J. Zayed,[17] Defendants take issue with the following alleged statements by prosecutors: (1) that salesperson Glen Holden was a "coat of paint away" away from a perjury charge, (2) that Vice Presidents Carrie Powers and Susan Christian had given prosecutors "a line of shit," and (3) that Glen Holden was "a poor fucker" who "just on principle may be indicted." Defendants claim that prosecutors sought to intimidate witnesses with these statements, which were coupled with "threats of criminal prosecution" and "economic ruin" if they refused to give false testimony. Docket No. 84 at 7, 12. Facts omitted by Defendants demonstrate that these charges are inaccurate.

[17] Zayed replaced William Michael as lead counsel in early April 2014. Four months later, Zayed was replaced by John Richter, VSI's current lead counsel.

First, the core claim that prosecutors sought false testimony is disproved by the evidence supporting prosecutors' reasonable belief that the witnesses initially made false statements and the evidence corroborating the corrected testimony, as detailed above. *Supra* at 6-27. Second, Defendants' motion suggests that prosecutors made these statements to witnesses, when in fact the statements were made during *plea negotiations with VSI counsel Zayed,* not *directly to witnesses* or their counsel. *Compare* Docket No. 84 at 2-3 (Def. Motion) (suggesting statements were made to witnesses) *with id.* at 18 (disclosing 15 pages after initial reference that "poor fucker" comment was made to VSI counsel). In fact, Zayed did not represent the witnesses. Third, Defendants misstate that prosecutors exposed witnesses to risks of criminal prosecution, HHS exclusion, and employment termination. In fact, these risks already existed as a result of Defendants' conduct. *Supra* at 1-6.

Fourth, Defendants omit relevant context from the corporate plea negotiations, thereby obscuring the stated objective behind the challenged statements – to encourage VSI to cooperate instead of "throwing its employees under the bus" to protect its CEO. Some of this missing context is set forth below.

The United States discloses the following statements and admissions made during plea negotiations, under seal and only for the purpose of rebutting Defendants' allegations of intentional prosecutorial misconduct in response to their selective disclosure of statements from the same negotiations. The United States does not intend to offer these admissions at trial, unless Defendants open the door by selectively introducing statements from plea negotiations. *See* Fed. R. Evid.

410(b)(1) (statements from plea negotiations may be admitted "in any proceeding in which another statement made during the same plea or plea discussions has been introduced, if in fairness the statements ought to be considered together").

1. Early Plea Negotiations and VSI's Offer to Cooperate

In early April 2014, VSI replaced its lead counsel, William Michael, with R.J. Zayed, who contacted prosecutors to pursue settlement negotiations. On April 14, prosecutors informed Zayed that VSI was not cooperating with the investigation because several current employees – Glen Holden, Shane Carlson, and Anthony Jakubowski[18] - had falsely denied their efforts to sell devices for unapproved perforator use. AUSA Paulissen told Zayed that Holden, in particular, "was a coat of paint away from perjury." Although Defendants' brief suggests otherwise (Docket No. 84 at 3), Paulissen did not use profanity during this call, though he did so later, as described below. Defendants' brief suggests that Paulissen's phrasing was inappropriate, but the use of colloquial but accurate terms to describe a target's non-cooperation is not misconduct.[19]

In the same conversation about cooperation, prosecutor Finley asked Zayed to review the company's documents and address, on behalf of the company, whether the company had intentionally sold devices for unapproved perforator use. Finley said that VSI's prior denials of the core conduct under investigation were inconsistent

[18] Jakubowski had left the company by that date but was a current employee at the time of his interview. The prosecutors ultimately did not pursue a follow-up interview with him before presenting the indictment.

[19] The Zayed affidavit states that Paulissen referred to another witness (salesperson Daniel McIff) as a "poor piece of roadkill." This was an obvious reference to VSI's attempt to scapegoat McIff and not a threat to a witness. VSI had fired McIff and had offered to cooperate against him – there was no chance that this statement would be communicated to McIff.

with the acceptance of responsibility and were an impediment to resolving the case. Zayed agreed to consider this request.

In a phone call on April 18, 2014, Zayed asked Paulissen what VSI could do to cooperate with the investigation. Paulissen responded that VSI should "[h]old accountable the individuals who are most responsible for the violations," which included cooperating in the investigation of Root and taking "appropriate steps to correct false statements or testimony by VSI employees (*e.g.*, Glen Holden, Tony Jakubowski, Shane Carlson)." Ex. 52 (4/22/14 Paulissen email).[20]

In an April 28 phone call to discuss these requests between Finley, Paulissen, Zayed, and another VSI attorney, Finley said that Root should "take responsibility for the illegal campaign that he led by pleading to a misdemeanor" and that "[h]is refusal to accept responsibility for his conduct has imperiled the company and its employees." Finley requested the company's cooperation against Root, stating that "[t]he choice for the company is between meaningful accountability or throwing everyone under the bus to try to protect Howard Root."[21] He added that if Root pled guilty to a misdemeanor, a written warning from the company to other employees

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[20] Other requests included "[i]mplement[ing] a compliance program designed to prevent future violations," discontinuing the Short Kit, stopping sales of Vari-Lase products for intended use in perforator treatment, and disclosing to customers that "((a) that Vari-Lase products are not FDA-approved for treating perforators, (b) that such procedures are not eligible for reimbursement from Medicare and many other insurers because of the lack of FDA approval, and (c) the endpoints of the RELIEVE trial (including closure rate of 69.7% and 14% rate of major adverse events involving DVT)."). Ex. 52 (Apr. 22, 2014 Paulissen email).

[21] In light of the evidence set forth above, Finley's statements were supported by the United States Attorneys' Manual. U.S. Dep't of Justice, U.S. Attorneys' Manual § 9-28.300 (2015) (in determining whether to charge a corporation, prosecutors should consider "the corporation's remedial actions, including any efforts … to replace responsible management, to discipline or terminate wrongdoers, . . . and to cooperate with the relevant government agencies"); *Infra* at 44 (quoting relevant sections).

involved in the conduct would satisfy the United States' request that responsible employees be held accountable, provided that those employees did not mislead the investigators.

2. VSI Admits the Core Conduct While Its Representatives Falsely Deny It

In a May 12 phone call with Paulissen and Finley, Zayed responded to the United States' request that VSI review the documents and address whether it had intentionally sold devices for unapproved perforator use. He stated that he "would not run from the documents." He continued, "Did it happen? Yes, it happened. Did management know about it? Yes, management knew about it. Did they do anything to stop it? No. Should they have stopped it? Yes." Zayed then denied that the company had planned "from the beginning" to do it, and argued instead that it had failed to deal with issues properly in a timely manner. Zayed's agreement to some of the prosecutors' basic factual positions[22] would provide the foundation for his tentative proposal, approximately one month later, that the parties resolve the case with misdemeanor pleas for VSI and Root, as discussed below.

On May 13, Paulissen and Finley called Zayed to raise concerns about VSI's non-cooperation, which took place when corporate officers Carrie Powers and Susan Christian falsely denied that management approved the illegal sales activity of its sales force. *Supra* at 22-27. Prosecutors pointed out that these witnesses had been less candid than Zayed himself had been the day before. Defendants criticize

[22] Zayed did express his view that he could win an acquittal on the felony charge at trial, but likely could not defeat the misdemeanor charges.

Paulissen's characterization of the corporate officers' denials as a "line of shit," but this was a reasonable, albeit unrefined, assessment based upon the evidence. *Supra* at 30. Nor was it improper for a prosecutor to inform a corporate target that was seeking credit for cooperation that its officers – and hence it – were not cooperating.

Defendants also omit context from Paulissen's June 12 conversation with Zayed about Glen Holden. Paulissen's characterization of Holden as a "poor fucker" who might be "indicted on principle" was a comment on the company's mistreatment of him.[23] In addition to the facts set forth previously (*supra* at 4-6, 13), what was unfair to Holden, as well as the other VSI employees who were standing by their false testimony, was that VSI had by now admitted the core illegal conduct in private plea negotiations, while Root continued to publicly deny the same conduct.[24] As part of their request for cooperation, the prosecutors had requested that VSI share its more recent finding of wrongdoing with the non-cooperators who had made false denials similar to Root's, a disclosure that might convince them to correct their false testimony. VSI did not respond to this request and presumably left these employees in the dark. This was the mistreatment that Paulissen's profanity[25] was describing.

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[23] Defendants' use of quotation marks seems to suggest there was something improper about the phrase "indicted on principle." This referred to prosecutors' belief that they would be compelled to charge Holden if he did not cure his perjury, though they would have preferred truthful testimony and cooperation from him.

[24] *See, e.g.,* Ex. 54 (VSI Form 10-K for 2012) ("The Company believes the allegations are factually inaccurate and without merit . . . ."); *supra* at 4-6 (discussing company-wide messages denying conduct).

[25] Paulissen's occasional use of profanity, despite suggestions to the contrary in Defendants' motion, was limited almost entirely to conversations that he had with Zayed, with the exception of one interaction with pool counsel Hopeman (*supra* at 24) ("on the verge of pissing us off"), also mischaracterized. Docket No. 84-2 at 16-18 (Zayed Aff.) The profanity was not directed at Zayed himself, whom Paulissen treated with courtesy and respect. Zayed himself used profanity on at least

Moreover, the prosecutors were offering a solution to a problem that both sides recognized. As part of any resolution, VSI wanted to avoid any prosecutions of its employees. Ex. 55 (Zayed email) (offering to terminate Holden and Matthews, give warnings to Powers and Christian in exchange for non-prosecution of same employees). At the same time, the United States could not reach a resolution with a company that was not cooperating and had not meaningfully accepted responsibility. To solve the problem, the prosecutors, as they had on prior occasions, proposed that Holden avoid charges simply by correcting false testimony and telling the truth. Inviting Holden to "bend the knee" and admit that he misled the investigation was an act of leniency that gave him an opportunity to cure his perjury and avoid charges.[26]

On June 20, Zayed called Paulissen and proposed a plea deal that included corporate and CEO misdemeanor pleas, a fine, and a corporate integrity agreement. The proposal was tentative, non-binding, and conditioned on Defendants' ability to obtain assurance from the Department of Health and Human Services, Office of Inspector General (HHS-OIG), that Defendants' convictions would not cause them to be excluded from government programs such as Medicare. Following Zayed's replacement as lead counsel in late July, the parties pursued a resolution roughly along these lines for several months, but their efforts ultimately fell short after Root

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one occasion during plea negotiations, an event that prosecutors did not find remarkable.

[26] Defendants state that prosecutors withheld from discovery its disclosures to Zayed during corporate plea negotiations concerning the lack of cooperation by VSI personnel and the risks they faced as a result. In fact, these disclosures are accurately described in the prosecutors' May 27 letter. Ex. 14 at 3, 5.

could not obtain, in advance of a plea, HHS-OIG's assurance that Root's conviction would not lead to his exclusion from participation in federal healthcare programs.

I. Evidence Supporting the Testimony of Special Agent Scavdis

Contrary to Defendants' motion, the lead case agent told the truth when he testified that Defendants' devices "had not received any form of marketing authorization." Ex. 56 at 8-9, 21 (Scavdis Tr.). FDA witnesses consistently confirmed this. Ex. 57 (collecting statements and documents from the FDA Branch Chief, the Lead Scientific Reviewer, and Dr. Morales (a medical officer) stating that VSI lacks authorization to market for perforator use). VSI's own officers and employees uniformly admitted this. Ex. 58 (collecting admissions of former VP of Regulatory Affairs Deborah Schmalz-Kern, VP of Sales Operations Susan Christian, and at least fifteen other VSI witnesses). The company's own documents say the same thing. Ex. 59 (2007 VSI Sales Meeting); Ex. 60 (Regulatory Plan for Short Kit).

Dr. Morales's interview, contrary to Defendants' selective quotation of his analysis of only a small portion of the label, was fully consistent with all of these witnesses. As to the label as a whole, Dr. Morales said, "That label, not in my wildest dreams covers the treatment of perforators." Ex. 57 at 20 (10/02/2014 Morales MOI). Even assuming Dr. Morales interprets the Vari-Lase label to include perforator ablation (he does not), this interpretation does not bind the agency or change the historical fact that the FDA never cleared the marketing of the Vari-Lase device for treatment of perforator veins. That is why VSI applied for clearance

(unsuccessfully), and it is why the FDA repeatedly instructed VSI not to sell devices for this use. Docket No. 1 ¶¶ 18, 19, 22. VSI understood this. Ex. 60 (Regulatory Plan for the Short Kit).

J. Statements Under Oath In Lieu of Grand Jury Appearances

Four witnesses – two former VSI executives from the Midwest and two doctors from Connecticut – gave statements under oath in lieu of appearing before the grand jury.[27] Each witness had the option of appearing before the grand jury or voluntarily giving testimony under grand jury conditions near their homes, and each chose the latter option because travel to San Antonio was a hardship. Ex. 61 at 7-9 (04/03/2014 Snyder Tr.); Ex. 7 at 7 (02/12/2014 Schmalz-Kern Tr.); Ex. 62 at 7-8 (06/20/2014 Huribal Tr.); Ex. 63 at 7 (06/20/2014 Manoni Tr.) Witnesses were grateful for the accommodation, as reflected in the transcripts. Ex. 61 at 7-9 (04/03/2014 Snyder Tr.); Ex. 62 at 7-8 (06/20/2014 Huribal Tr). No witness objected to this procedure.[28] These transcripts were made available to the grand jurors.

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[27] Defendants describe these four statements under oath as a "series of private examinations." Docket No. 84 at 27. Defendants suggest that six witnesses gave these allegedly compelled statements by including two who did not. *Id.* at 26 (citing wholly voluntary interview by Dr. Daniel Pepper ("Witness Y")) and 27 (suggesting Kate Davis ("Witness E") was pressured to give a private examination, though she actually testified before the grand jury).

[28] Non-witness Daniel Scott, pool counsel for all *former* VSI employees who sought payment of their fees from VSI, has submitted an affidavit in support of Defendants' motion objecting to this procedure. There is no evidence that these objections originated with his actual clients. When the United States specifically requested that he share the United States' offer to use this alternative arrangement with his client, Deborah Schmalz-Kern, it was his client's desire to do so that compelled him to accept – "you have me between a rock and a hard place *with my client*." Ex. 64 (Scott email) (emphasis added). Omission of the italicized words inaccurately suggests that the client was objecting when in fact the client was overriding pool counsel's objection. Docket No. 84 at 26 (eliding italicized words).

K. Prosecutors Did Not Prevent Witnesses from Conferring with Counsel

Defendants claim that Finley invaded the attorney-client privilege and prevented Deborah Schmalz-Kern, the former Vice President of Regulatory Affairs at VSI, from conferring with her counsel. Both charges are inaccurate. Prior to the challenged exchange, Schmalz-Kern asked for and received permission to confer with her attorney on seven occasions. Ex. 7 at 11, 14, 15, 29, 59, 97, 105. During the same period, she would object that questions were hypothetical or speculative. *Id.* at 58-59, 89-90, 106. After her seventh consultation, she again objected to a question on the ground that it was speculative. *Id.* at 106. Finley then asked the following question: "I've 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?" Defendants omit that Finley told her "don't tell me any attorney advice." *Id.* at 106.

Schmalz-Kern asked for an eighth consultation with counsel in order to answer the pending question, which would have defeated its purpose. *Id.* at 107. Finley gave her the option of answering or terminating the interview, which might result in her having to come back at a later date. *Id.* at 107. She chose to answer the question and said, "No." *Id.* Out of more than 60 interviews and examinations, this was the only instance in which a prosecutor pressed for an answer first before granting a request to confer with counsel.

ARGUMENT

I. LEGAL STANDARD

A defendant seeking the extreme remedy of dismissal of the indictment based on alleged errors in the grand jury proceedings bears a "heavy burden." *In re Grand Jury Investigation*, 610 F.2d 202, 219 (5th Cir. 1980). The grand jury sits "not to determine guilt or innocence, but to assess whether there is an adequate basis for bringing a criminal charge." *United States v. Williams,* 504 U.S. 36, 51 (1992). As the Fifth Circuit has explained:

> By its very nature, the grand jury process is not an adversary proceeding. Its function is merely to determine if there is probable cause which warrants the defendant's being bound over for trial. A defendant has no right to require that the Government present all available evidence at this proceeding. The grand jury proceeding is a one-sided affair. The defendant is protected from such one-sidedness when, at the trial on the merits, he is "accorded the full protections of the Fifth and Fourteenth Amendments" and is "permitted to expose all of the facts bearing upon his guilt or innocence."

United States v. Brown, 574 F.2d 1274, 1275-76 (5th Cir. 1978) (quoting *United States v. Chanen*, 549 F.2d 1306, 1311 (9th Cir. 1977)). For this reason, "[a]n indictment returned by a legally constituted and unbiased grand jury, like an information drawn by the prosecutor, if valid on its face, is enough to call for trial of the charge on the merits. The Fifth Amendment requires nothing more." *Costello v. United States*, 350 U.S. 359, 363 (1956).

Even false or misleading testimony before the grand jury does not itself warrant dismissal. *Bank of Nova Scotia v. United States*, 487 U.S. 250, 260 (1988) (agents' "misleading and inaccurate summaries to the grand jury just prior to the indictment" provided no ground for dismissal). Rather, to obtain dismissal of an

indictment based on false testimony, a defendant must prove the prosecutor knowingly sponsored material, perjured, and prejudicial testimony. *See United States v. Strouse*, 286 F.3d 767, 772, 775 (5th Cir. 2002) (citing *Bank of Nova Scotia,* 487 U.S. at 260-61).

An indictment returned by a legally constituted grand jury "is not subject to challenge on the ground that the grand jury acted on the basis of inadequate or incompetent evidence." *United States v. Calandra*, 414 U.S. 338, 345 (1974); *see also Kaley v. United States*, 134 S. Ct. 1090, 1097 (2014); *Williams*, 504 U.S. at 54; *Bank of Nova Scotia*, 487 U.S. at 261; *United States v. Johnson*, 615 F.2d 1125, 1127 (5th Cir. 1980). Nor are prosecutors required to present exculpatory evidence to the grand jury. *Williams*, 504 U.S. at 52-53, 55. "A complaint about the quality or adequacy of the evidence can always be recast as a complaint that the prosecutor's presentation was 'incomplete' or 'misleading,'" but that "[r]eview of facially valid indictments on such grounds 'would run counter to the whole history of the grand jury institution.'" *Id.* at 54-55 (quoting *Costello*, 350 U.S. at 364).

Dismissal of an indictment is appropriate only 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*, 487 U.S. at 256 (reversing dismissal of indictment where record did not support conclusion that defendants were prejudiced); *see also United States v. Greer*, 137 F.3d 247, 251 (5th Cir. 199) (upholding district court's refusal to dismiss indictment where government witness allegedly lied before the grand jury because

defendant did not demonstrate that the testimony plainly constituted a violation of one of the "few, clear rules" governing the grand jury). 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; *see also Berger v. United States*, 295 U.S. 78, 88 (1935) (reversing conviction for serious prosecutorial misconduct during trial, *e.g.*, knowingly introducing false evidence); *United States v. Hogan*, 712 F.2d 757 (2d Cir. 1983) (prosecutors intentionally prejudiced grand jury with characterization of defendant as a "hoodlum," encouraged indictment as "a matter of equity," and deceived jurors by testifying that defendant was suspected for other serious crimes).

Defendants' motion is inconsistent with these standards. They have failed to show any misconduct, and they have failed to establish prejudice.

II. THERE WAS NO MISCONDUCT

A. Prosecutors Did Not Force Any Witness to Lie

Confronted with statements or testimony of five witnesses that sharply conflicted with field trip reports, emails, official sales presentations and training materials, as well as the testimony of other witnesses, prosecutors reasonably concluded that the five witnesses were not being truthful. Defendants' motion does not establish otherwise. At no time did prosecutors force or seek to force witnesses to lie. Efforts to test their contradictory testimony and persuade witnesses to testify truthfully were not improper. Moreover, no evidence supports Defendants' claims

that witness testimony has been "tainted," "distorted," "misshaped," "polluted," or "constructed." Each of the witnesses (except for Holden, who is indicted) will be subject to cross-examination if called at trial, at which time a jury will determine which testimony and statements to credit.

B. Prosecutors Did Not Mistreat Subjects or Witnesses

As set forth in the statement of facts, prosecutors gave four immunized subjects an opportunity to correct specific, materially false statements (misdescribed or omitted by Defendants) after reviewing with them documentary evidence that contradicted those statements (also missing from their motion). *Supra* at 6-22. Based on this evidence, prosecutors used the following accepted methods to seek cooperation and truthful testimony from these subjects.

1. The United States charged Glen Holden with perjury and obstruction of justice after he declined multiple opportunities to correct his false testimony. The evidence supporting those charges is detailed above. *Supra* at 14-15; *United States v. Norris,* 217 F.3d 262, 274 (5th Cir. 2000) ("Perjury, regardless of the setting, is a serious offense that results in incalculable harm to the functioning and integrity of the legal system as well as to private individuals.") (internal quotation marks omitted). Defendants accuse prosecutors of bringing the charges with bad motives, but do not address the evidence of Holden's guilt.

2. Prosecutor Finley warned Elizabeth Mathews that he would recommend perjury charges against her if she did not correct her false testimony. The evidence

supporting this warning is set forth above. *Supra* at 18-19; *see* 18 U.S.C. § 1623 (knowingly giving materially false testimony to a grand jury is perjury).

3. Finley warned Matthews that if she did not correct her false testimony, he would refer her to HHS as a candidate for possible exclusion from participation in government programs. Having delivered a misbranded and adulterated "VSI perforator kit" to a doctor, supervised others engaging in similar conduct, and misled a grand jury about it (*supra* at 18-19), Matthews was eligible for HHS exclusion. *See* 42 U.S.C. § 1320a-7(b)(2) and (b)(15). Thus, a referral would have been appropriate. *See* USAM § 9-27.250, Non-Criminal Alternatives to Prosecution ("Attorneys for the government . . . should consider pursuing [referrals to civil or administrative authorities] if they are available in a particular case.").

4. Finley warned Matthews that if she did not correct her false testimony he would ask VSI to terminate her employment. This warning was based on the evidence set forth above and specific guidance in the United States Attorneys' Manual governing corporate plea negotiations, which were ongoing at that time. *See* USAM § 9-28.300 (in determining whether to charge a corporation, prosecutors should consider "the corporation's remedial actions, including any efforts . . . to *replace responsible management, to discipline or terminate wrongdoers*, . . . and to cooperate with the relevant government agencies") (emphasis added); USAM § 9-28.900 ("Among the factors prosecutors should consider and weigh are whether the corporation *appropriately disciplined wrongdoers*, once those employees are identified by the corporation as culpable for the misconduct. . . . *Prosecutors should be*

satisfied that the corporation's focus is on the integrity and credibility of its remedial and disciplinary measures rather than on the protection of the wrongdoers.") (emphasis added).

5. Finley told Carrie Powers and Susan Christian about the risks they would face as corporate officers of a convicted corporation, and gave them an opportunity to reduce those risks through cooperation. This was an accurate description of risks that they faced. *See* 42 U.S.C. § 1320a-7(b)(15); U.S. Dep't of Health and Human Servs., Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act (2010) (hereinafter "HHS Guidance"), *available at* http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf, at 1 (last accessed Oct. 1, 2015) ("Officers and managing employees . . . may be excluded . . . based solely on their position within the [excluded] entity."). It was also accurate to state that cooperation could mitigate this risk. *See* HHS Guidance, at 4 (in considering whether to exclude a corporate officer of a convicted entity, HHS asks, "Did the individual cooperate with investigators and prosecutors and respond in a timely manner to lawful requests for documents and evidence regarding the involvement of other individuals in a particular scheme?").

6. *Prosecutors warned Powers and Christian that they would consider charging them, based on evidence predating their grand jury appearances, as responsible corporate officers.* As Vice Presidents with direct responsibility for preventing the FDCA violations that occurred under their watch, they were strictly

liable for misdemeanor misbranding and adulteration. *United States v. Park,* 421 U.S. 658, 673-74 (1975). Prosecutors did not mistreat these executives by offering them the opportunity to avoid such charges simply by cooperating and telling the truth.

7. *Prosecutors showed Carlson and Powers evidence so they could make an informed decision about cooperating.* This is a common practice in proffer negotiations, especially when seeking cooperation from a co-conspirator. *See* Stephanos Bibas, *Plea Bargaining Outside the Shadow of Trial*, 117 Harv. L. Rev. 2463, 2525 (2004) (recommending as "effective" the use of "reverse proffers" where prosecutors "show many of their cards" to a defendant).

* * * * *

In light of the foregoing authorities and evidence, Defendants' claim that prosecutors threatened witnesses with "economic ruin" and "disastrous personal consequences" is overstated. Docket No. 84 at 7, 18, 19. If a jury finds that the allegations in the indictment are true, it was Defendants, not prosecutors, who exposed these witnesses to those risks, first by instructing them to engage in illegal conduct and then by inviting them to mislead investigators. Prosecutors offered these witnesses a chance to reduce these risks by cooperating and telling the truth.

C. Any Potential Violation of Rule 6(e) Was Harmless

Prosecutors should not run from their mistakes. In furtherance of that goal, prosecutors Finley and Paulissen acknowledge that they neglected to follow the Justice Department's guidance by reading aloud selected quotations from two grand

jury transcripts, at consecutive proffer meetings with Elizabeth Matthews and Shane Carlson, without first obtaining a court order. *See* U.S. Dep't of Justice, Federal Grand Jury Practice (2008) (hereinafter "Grand Jury Manual"). Section 3.53 of the Manual, entitled "Disclosure to a witness of another witness's grand jury transcript or testimony," provides:

> Occasionally, an attorney may consider revealing the substance of one witness's testimony to another in the hope of eliciting truthful testimony. If undertaken, however, the attorney should be careful not to reveal information that would identify the prior witness. Because it is unsettled whether a prosecutor may disclose grand jury testimony of one witness to another grand jury witness, the prosecutor should seek a court order under 6(e)(3)(E)(i) permitting disclosure.

However, notwithstanding the prosecutors' acknowledged failure to follow the Manual's non-binding recommendation, there is no authority that holds that the limited use of quotations here violated Rule 6(e). Section 3.53, in discussing the only relevant case on this specific issue, continues:

> In *United States v. Bazzano,* 570 F.2d 1120, 1124-26 (3d Cir. 1977), the court held that Rule 6(e) is violated whenever a government attorney or agent discloses verbatim grand jury testimony of one witness to another *in order to shape either or both witnesses'[] trial testimony*. The court distinguished such improper disclosure, however, from the acceptable practice of a prosecutor who, in a pretrial interview, restates in general terms the evidence the prosecutor anticipates other witnesses will give without identifying the identity of those witnesses.

(Emphasis added).

The only difference between the acceptable practice described in *Bazzano* and what happened here was that prosecutors quoted small portions of transcripts, rather than describe the testimony generally. Prosecutors did not follow the improper practice in *Bazzano* of "*read[ing] selected pages of each witness'[s] grand*

jury testimony in the presence of both witnesses" in an effort to align stories. *See Bazzano,* 570 F.2d at 1124 (emphasis added). Despite its condemnation of this method, the *Bazzano* court declined to reverse the conviction, reasoning that "the evidence of improper influence affects the credibility, not the admissibility, of the testimony." *Id.* at 1127.

Here, by contrast, prosecutors took the precaution described in *Bazzano* and used the titles "regional manager" (approximately eight people) and "vice president" (approximately five) instead of disclosing names. "[W]hen potential trial witnesses who testified before the grand jury are not identified by name, there is no violation of the purpose of Rule 6(e) to encourage witnesses to testify without fear of retaliation." *Id.* at 1125. Moreover, the testimony was read as part of a broader discussion of evidence that included witness admissions and documents obtained without grand jury process.

In large part, prosecutors only disclosed information that Carlson and Matthews likely already knew. *See United States v. Kouba*, 632 F. Supp. 937, 941-42 (D.N.D. 1986) (no Rule 6(e) violation based on prosecutor's disclosure of the grand jury target to witnesses, where target was obvious and likely already known to the witnesses). A review of the specific exchanges (missing from Defendants' motion) reveals little more than that an unnamed manager and vice president, along with many others who were also not named, had made broad admissions of the conduct. This was already well known to pool counsel at that point. *Supra* at 10-11. Disclosing the exact wording of some of these broad admissions revealed only

that prosecutors had not exaggerated when they had previously described them to pool counsel as unequivocal.

The purpose of these limited disclosures would be obvious to anyone familiar with conspiracy investigations – to ease the two managers' fear of testifying against their boss. The need to address that fear was real, as shown by the retaliation Root now visits upon them for telling the truth. In accusing Finley and Paulissen of suborning perjury and witness tampering, he necessarily accuses his subordinates of giving perjured written statements, even though they did little more than confirm the facts reported in their own documents. Docket No. 84 at 18 (Def. Motion) (citing witness tampering statute, 18 U.S.C. § 1512(b)(1)); *id.* at 40 ("The witnesses cannot now forget the government's threats of prosecution and career destruction if they refuse to testify as directed . . .").

Even assuming that prosecutors knowingly violated Rule 6(e), the remedy would not be dismissal. It would instead be a contempt hearing. *See* Fed. R. Crim. P. 6(e)(7); *United States v. Malatesta*, 583 F.2d 748, 753 (5th Cir. 1978), *modified on other grounds,* 590 F.2d 1379 (en banc); *United States v. Dunham Concrete Products, Inc.,* 475 F.2d 1241, 1249 (5th Cir. 1973).[29] This is especially true here because these disclosures did not prejudice Defendants. Carlson and Matthews were two out of at least 18 witnesses who admitted that the illegal conduct had occurred. The

[29] No such hearing is necessary because: (i) there is no factually relevant case law establishing that these disclosures violated Rule 6(e); (ii)), there is authority to suggest the disclosures did not violate Rule 6(e) (discussed above); (iii)), there is no evidence that prosecutors knowingly violated the Rule; (iv), there is evidence (discussed above) that they acted with proper motives; and (v) there was no prejudice to Defendants or anyone else.

same conduct is evidenced by hundreds of contemporaneous VSI documents. Carlson's and Matthews's ultimate statements were consistent with their own documents, and Defendants have offered no evidence of any kind that the statements were false. Not only did the disclosures here not cause harm, they were part of an evidentiary presentation that persuaded Carlson and Matthews to make an informed decision to cooperate and give truthful testimony.[30]

D. The Lead Case Agent Told the Truth

Contrary to Defendant's motion, the lead case agent told the truth when he testified that the FDA had not granted VSI any form of authorization to market Vari-Lase devices for perforator use. All of the FDA and VSI witnesses agreed on this point. *Supra* at 37-38.

III. THERE IS NO BASIS FOR DISMISSAL

A. Without Proof of Improper Motives, Defendants Remaining Arguments Fail

No matter how many times Defendants say they are "astonished," "startled," or "troubled," characterizations are not evidence. The evidence shows that prosecutors did not pressure anyone to lie or present any perjured testimony, and once that becomes clear, many of Defendants' remaining complaints become trivial. *See United States v. McKenzie,* 678 F.2d 629, 631 (5th Cir. 1982) ("[W]e will dismiss

[30] Defendants allege that prosecutors committed other Rule 6(e) violations that do not involve reading any testimony. Rather, they relate to prosecutors asking witnesses who were testifying before the grand jury about whether they would contradict the testimony of other witnesses, which was only generally described. Docket No. 84 at 21. This was not improper. *See* Grand Jury Manual § 3.53 ("Occasionally, an attorney may consider revealing the substance of one witness's testimony to another in the hope of eliciting truthful testimony.")

an indictment only when prosecutorial misconduct amounts to overbearing the will of the grand jury so that the indictment is, in effect, that of the prosecutor rather than the grand jury."). Without the assumption that prosecutors had improper motives, it was not misconduct for prosecutors to:

- Apologize to a witness for the inconvenience caused when a flight cancellation caused her to fly to San Antonio only to miss her grand jury appearance, then offer to take her testimony in Chicago near her home (Docket No. 84 at 27);
- Express a desire to hold corporate leadership accountable for instructing employees to commit crimes (*id.* at 17);
- Use colloquialisms such as "the cat is out of the bag" or "not buying the company line" in an accurate manner, notwithstanding Defendants' use of quotation marks to make these phrases seem inappropriate (*id.* at 16-17);
- Use plain terms such as "work with" to describe obtaining cooperation or "fix" to describe correcting false statements, despite the use of quotation marks to suggest this was improper (*id.* at 2-3, 16);
- Inform an immunized subject (Christine Snyder) who consented to a voluntary interview near her home that if she persisted in refusing to answer a question she would be called to the grand jury to answer it (*id.* at 26);
- Elicit testimony from co-conspirators admitting that their conduct was illegal[31] (notwithstanding Defendants' claim that this calls for a legal conclusion) (*id.* at 37); or
- Present testimony (not a legal instruction as Defendants claim) from VSI witnesses and Medicare contractors that Medicare did not authorize reimbursement for laser perforator ablations, notwithstanding that Defendants have hired an expert to contradict these fact witnesses post-indictment (*id.* at 36).

[31] *See* Pattern Jury Instructions: Fifth Circuit, Criminal Cases, § 2.15A (2015) ("the defendant and at least one other person *made an agreement to commit the crime* of . . .") (emphasis added).

B. Taking Testimony Under Grand Jury Conditions Did Not Affect Defendants

Prosecutors' taking of testimony under grand jury conditions in lieu of actual grand jury testimony, on four occasions as an accommodation to witnesses for whom travel was a hardship, resulted in no prejudice to any witness, *see United States v. Pang,* 362 F.3d 1187, 1194 (9th Cir. 2004) ("Nothing prohibits a subpoenaed grand jury witness from voluntarily consenting to an interview."), nor did it prejudice Defendants.

First, to be clear, the witnesses chose this option. No witness complained, although Defendants splice a quote from pool counsel Daniel Scott's affidavit to misstate that a client consented to the procedure under pressure. Docket No. 84 at 26 (altering quote from Scott Affidavit from – "you have *me* between a rock and a hard place *with my client*" – to "*counsel and the witness* agreed to submit to the extrajudicial examination because *they* were 'between a rock and a hard place'") (emphasis added). In fact, the witness had no objection. Ex. 7 at 7 (02/12/2014 Schmalz-Kern SUO).

The distinction between Scott's affidavit and the characterization of his statement in defendants' motion is critical. The cases cited by Defendants involve using a grand jury to *compel* interviews outside the grand jury. That did not happen here. Prosecutors made a non-compulsory offer, *solely at the witness's option*, to take testimony in a more convenient location. This is not improper. *Durbin v. United States,* 221 F.2d 520, 522 (D.C. Cir. 1954) (no choice offered to witness; prosecutor conducted inquisition in his office without explaining it was not a grand

jury proceeding); *United States v. Wadlington*, 233 F.3d 1067, 1075, 1083 (8th Cir. 2000) (no choice offered to witness; subpoena summoned witness a full day before grand jury proceedings for lengthy questioning); *United States v. DiGilio*, 538 F.2d 972, 985 (3d Cir. 1976) (no choice offered; witness summoned for grand jury, but instead was taken to government attorney's office for questioning).

The voluntary procedure used here was consistent with relevant precedent. *Pang,* 362 F.3d at 1194 ("We see no impropriety" where witness received subpoena but gave an interview and produced documents voluntarily before the return date); *United States v. Int'l Paper Co.,* 457 F. Supp. 571, 573 (S.D. Tex. 1978) (interviews conducted outside the grand jury but with the "trappings" of grand jury appearances (*i.e.* subpoenas, immunity, and sworn testimony) were not improper where witnesses consented); *United States v. Van Engel*, 809 F. Supp. 1360, 1364 (E.D. Wis. 1992), *rev'd on other grounds*, 15 F.3d 623 (7th Cir. 1993) (no prejudice to target where United States "did not interview witnesses for any reason other than efficiency of the grand jury and the convenience of the witnesses and their attorneys").[32]

Second, this practice had no effect on *Defendants'* rights. To argue otherwise, Defendants assert, without evidence, that prosecutors' motive was to hide exculpatory evidence from the grand jury.[33] The argument fails as a matter of law

[32] Defendants complain that prosecutors excluded pool counsel from the sworn examinations, but the witnesses and not Defendants have the standing to make this objection, and the witnesses consented. Moreover, having counsel outside the room and available for consultation is exactly what would have occurred in the grand jury. Rule 6(d)(1) (witness counsel not permitted in grand jury); *see also In re Groban,* 352 U.S. 330, 333 (1957) (witness has no right to counsel a pre-custodial forum).

[33] To bolster that claim, Defendants accuse the case agent of lying when he testified that the procedure was for the convenience of remote witnesses, despite the corroborating testimony of the

because prosecutors are not required to present exculpatory evidence to the grand jury. *Williams*, 504 U.S. at 54.

The argument is also wrong as a matter of fact because Defendants rely on evidence that is not remotely exculpatory, much less evidence that directly negates guilt.[34] Drs. Huribal and Manoni did not contradict the overwhelming evidence from FDA employees, VSI witnesses and VSI documents establishing that Vari-Lase devices lacked approval from the FDA for perforator use. *Supra* at 37-38. Dr. Pepper agreed that the perforator study was a disappointment and not well designed, and he agreed the presentation that a VSI consultant wrote for him was "misleading." Ex. 65 at 48, 116 (Dr. Pepper Tr.). And the claim that the Short Kit could also be used on superficial veins is irrelevant. The United States has not alleged that it could only be used on perforator veins, and the grand jury was specifically advised that the term "short vein" included both superficial and perforator veins. Ex. 15 at 34-35 (Steitzer Tr.).

C. Efforts to Discourage Coaching Had No Effect on Defendants

It does not invade the attorney-client privilege to ask witnesses who are avoiding questions with objections or non-responsive sound bites whether their lawyers are putting words in their mouths. *See, e.g., Geders v. United States,* 425

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witnesses themselves. The proof he was lying, they claim, was that prosecutors did not offer this accommodation to other witnesses. This is both irrelevant and not true. The prosecutors proposed this procedure to VSI, pool counsel Hopeman, and pool counsel Scott. They declined the offers (except as to two of Scott's clients), as they were free to do.

[34] This rebuts Defendants' claim that prosecutors violated ethical rules and Department policy requiring disclosure of "substantial evidence that directly negates the guilt of a subject of the investigation." USAM 9-11.233.

U.S. 80, 88-90 (1976) (trial judge did not err by allowing prosecutor to cross-examine defendant about whether he had discussed his testimony with his lawyer because "prosecutor[s] may cross-examine a defendant as to the extent of any 'coaching' during a recess, subject, of course, to the control of the court"); *In re Earnest,* 90 F.R.D. 698, 700 (M.D. Ga. 1981) (a witness may not "consult with his lawyer for the purpose of formulating an answer to questions put to him" or else grand jurors would just get the testimony of the lawyer). This is especially true where company witnesses had given materially false testimony, there was evidence of coaching by a company lawyer during a grand jury appearance at which a witness committed perjury, and company or pool counsel were ignoring conflicts of interest. *Supra* at 13-16.

Prosecutor Finley inquired about improper coaching, not legal advice, as evidenced by his instructions not to reveal attorney-client communications and the fact that no such communications were revealed. Defendants fail to explain how such questions could have substantially affected the grand jury's decision.

D. Prosecutors Correctly Instructed the Grand Jury

Defendants make two main claims of error, which are fully addressed in the United States' response to their motion to compel the legal instructions to the grand jury.[35] In short, their primary claim of error – that prosecutors instructed the grand jury that truthful off-label promotion was a crime – is inaccurate. *See* Ex. 66 at 4

[35] A third claim – that grand jurors were improperly instructed regarding Medicare reimbursement – is addressed above. *Supra* at 52.

(6/26/15 Finley letter) ("We did advise the grand jury that mere off-label speech or promotion was not a crime.").

As to their second claim, Defendants exploit a single misstatement in an exchange with a witness (not an instruction as Defendants suggest) (Docket No. 84 at 6), to argue that prosecutors deliberately misled grand jurors that mere off-label use by doctors is illegal. That claim is contradicted by the three other occasions, omitted by Defendants, where prosecutors asked questions suggesting that off-label use by doctors is legal. Ex. 67 (collecting examples). In any event, Defendants overlook that the indictment itself alleges that "[t]he FDCA does not prohibit doctors, in the exercise of medical judgment, from using medical devices for unapproved uses not included in the FDA-approved labeling." Docket No. 1 ¶ 6. This means that the grand jury accepted this statement of the law was accurate.

CONCLUSION

Defendants have not presented sufficient evidence of intentional prosecutorial misconduct or substantial prejudice to justify dismissal of the indictment. Defendants' motion should be denied without hearing.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing United States' Response to Defendants' Motion to Dismiss the Indictment Based on Alleged Misconduct, has been served electronically on defense counsel, Christopher L. Peele, Jeffrey S. Bucholtz, John C. Richter, Johnny K. Sutton, Michael R. Pauze, John E. Murhpy, Dulce J. Foster, John W. Lundquist, and Kevin C. Riach, on October 2, 2015.

/s/
BUD PAULISSEN
Assistant US Attorney, WDTX

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CRIMINAL NO.: SA-14-CR-926-FB
	)	
VASCULAR SOLUTIONS, INC., (1) and	)	
	)	
HOWARD ROOT, (2)	)	
	)	
Defendants.	)	

ORDER ON DEFENDANTS' MOTION TO DISMISS
THE INDICTMENT BASED ON PROSECUTORIAL MISCONDUCT

The Court has considered the pleadings of the parties, the exhibits attached thereto, the indictment, and the applicable law. After due consideration the court finds that Defendants' Motion to Dismiss the Indictment Based on Prosecutorial Misconduct is hereby DENIED.

It is so ORDERED.

Signed this _____ day of _____, 2015.

_____
FRED BIERY
CHIEF UNITED STATES DISTRICT JUDGE