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	)	**SEALED**
	)	
HOWARD ROOT, (2)	)	
	)	
Defendants.	)	

UNITED STATES' RESPONSE TO DEFENDANTS' MOTIONS TO DISMISS THE INDICTMENT BASED ON THE FIRST AMENDMENT

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INTRODUCTION

From 2007 to 2014, Defendants Vascular Solutions, Inc. (VSI) and VSI Chief Executive Officer, Howard Root, distributed medical devices for the laser treatment of "perforator" veins, despite the fact that (1) the United States Food and Drug Administration (FDA) had not cleared that use and warned VSI of legal consequences if it distributed the device without clearance; (2) VSI tried and failed to get clearance from FDA for that use; (3) VSI's own clinical trial raised both safety and efficacy concerns with the laser treatment of "perforator" veins; and (4) VSI knew that government health care programs would not pay for the treatment of perforator veins. Based on this conduct, a grand jury indicted Defendants, charging them with one count of conspiracy and eight counts of introducing adulterated and misbranded medical devices into interstate commerce under the Federal Food, Drug, and Cosmetic Act (FDCA).

Defendants now move jointly to dismiss the indictment on First Amendment grounds. Defendants argue that the indictment has criminalized truthful and non-misleading speech in violation of the First Amendment. This argument ignores the indictment's actual allegations.

First, the core of the indictment is comprised not of speech or expression, but of *conduct*, which the First Amendment does not protect. Second, to the extent that *some* of the allegations in the indictment involve speech, the indictment alleges that this speech was either false or misleading, which the First Amendment does not protect in the context of the commercial transactions at issue here. Third, the four counts predicated on inadequate instructions have nothing to do with promotional

speech and would survive unaffected regardless of how Defendants characterize the promotional speech in the indictment. Fourth, there is no First Amendment protection for actions that defraud the United States. Finally, Defendants' broad, unqualified *in limine* request is contrary to black letter law that allows truthful speech to demonstrate intent and overt acts of a conspiracy. For these reasons, Defendants' motion and *in limine* request should fail.

SUMMARY OF THE ARGUMENTS

I. The indictment seeks to punish conduct, not speech to doctors. Infra at 20-30. "The First Amendment protects expression, not conduct." *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, No. 15 CIV. 3588 PAE, 2015 WL 4720039, at *27 (S.D.N.Y. Aug. 7, 2015) (one of two cases at the heart of Defendants' motions). The facts set forth in the indictment demonstrate that this is precisely the type of conduct-based prosecution that the *Caronia* and *Amarin* cases that Defendants rely upon expressly authorize. Defendants ignore the indictment when they argue that the alleged criminal acts at issue are statements to doctors. In reality, there are no allegations in the indictment that treat promotion to doctors (truthful or otherwise) itself as a crime.

Rather, the charged crimes are based upon Defendants' conduct: they introduced into interstate commerce medical devices that were both adulterated and misbranded, and they conspired to commit those offenses and defraud the United States. The devices were adulterated and misbranded because Defendants

(i) failed to obtain "premarket approval" from FDA to sell them for perforator use (adulteration),

(ii) failed to obtain "510(k)" clearance from FDA to sell the devices for that purpose (misbranding), and

(iii) added to the labeling instructions for perforator use that were defective (misbranding).

They then distributed these misbranded and adulterated products in interstate commerce. None of this conduct involves promotional speech to doctors.

Notwithstanding that neither the indictment nor the charging statutes treat speech to doctors as a crime, Defendants claim that the prosecution instructed the grand jurors that truthful speech is a crime and that all off-label use is illegal. The record facts omitted from Defendants' motions disprove these inaccurate claims. In fact, the United States instructed the grand jury that "mere off-label speech or promotion was not a crime" (Ex. 1 at 4 (6/26/15 Finley letter)), and *the indictment itself* establishes that "[t]he FDCA [Federal Food, Drug, and Cosmetic Act] 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 at ¶ 6; *see also infra* Section I.B, at 25-26 (collecting witness testimony to same effect).

To be sure, as Defendants note, some out of the many overt acts alleged in the indictment involve speech. But even assuming these statements were truthful, non-misleading and thus entitled to First Amendment protection (and they were not, as discussed further below), Defendants ignore that the statements are alleged as *overt acts* and not *crimes*.

The evidentiary use of speech occurs in nearly every trial, and the Supreme Court, the Fifth Circuit, and other circuits have repeatedly held that this does not run afoul of the First Amendment. *See, e.g. Wisconsin v. Mitchell*, 508 U.S. 476, 489-90 (1993) and *infra* at 40-43 (discussing *Mitchell,* Fifth Circuit, and other precedent). *Caronia* and *Amarin*, the cases that are the foundation for Defendants' motion, do not contradict this controlling precedent. "The government is of course correct that truthful speech can serve as evidence of intent." *See Amarin*, 2015 WL 4720039, at *27; *United States v. Caronia*, 703 F.3d 149, 161 n.8 (2d Cir. 2012) (assuming that speech can be used to prove a drug's intended use). Because Defendants "engage[d] in non-communicative activities to promote off-label use[, they] cannot use the First Amendment as a shield." *Amarin*, 2015 WL 4720039, at *27.

Indeed, the final proof that the government is not criminalizing the Defendants' speech is that, even if all of the allegations involving promotional speech to doctors are stripped from the indictment (though they should not be), many other allegations having nothing to do with speech would remain–and the remaining allegations are more than sufficient to satisfy the counts in the indictment.

II. Defendants VSI and Howard Root had no First Amendment right to deceive doctors in order to sell medical devices for an unapproved use. Infra at 30-38. The First Amendment does not protect false or misleading commercial speech.

This settled rule, upheld in the *Caronia* and *Amarin* cases that Defendants rely upon, as well as many others, is fatal to their First Amendment motions.

Defendants claim that their promotional speech to doctors was truthful and not misleading, but this argument ignores or impermissibly contradicts the facts alleged in the indictment, which details in at least twelve paragraphs the many ways in which Defendants systematically misled doctors in order to sell them devices for an unapproved use. Specifically, Defendants concealed from doctors, both with affirmative misrepresentations and material omissions, the following key facts:

1. the devices lacked any FDA marketing authorization[1] for perforator vein treatment,
2. Medicare generally did not reimburse doctors for using Defendants' devices in perforator vein ablation procedures,
3. VSI's failed clinical trial showed that 14% of patients had suffered a "major adverse event" related to deep vein thrombosis (DVT), and
4. the failed trial showed that the VSI device was less effective than a competing device that the FDA had already cleared for perforator use.

Defendants ignore overwhelming evidence–from VSI executives, managers, salespeople, and the physicians who bought the devices–that they misled doctors and that Defendants would have made virtually no sales had they been truthful. Thus, each and every statement to a doctor set forth in the indictment was misleading because it omitted these material facts. The Court should deny

[1] The indictment summarizes the relevant statutory scheme regarding the required premarket review for medical devices. *See* Docket No. 1 at ¶¶ 3-10.

Defendants' motions because they rest entirely upon the erroneous premise that Defendants engaged in truthful promotion.

III. Defendants had no First Amendment right to sell devices bearing defective instructions. Infra at 38-39. Defendants do not meaningfully address the misbranding violation that forms a basis for four of the eight substantive FDCA counts and is also an object of the conspiracy charge–the distribution in interstate commerce of devices bearing inadequate directions for use. This violation exists independent of any promotional speech to doctors. More important, the defective instructions themselves prove the devices' intended use (perforator ablation), thus disproving the core false premise in Defendants' motion that the United States seeks to "establish" an intended use solely through evidence of promotional speech to doctors.

IV. Defendants had no First Amendment right to defraud the United States. Infra at 39-40. Defendants have not argued otherwise. This alone supports denial of their motions.

V. Defendants' request for an in limine *ruling lacks case law support and is contrary to settled law on the uses of truthful speech. Infra* at 40-43. Finally, in the alternative, Defendants move *in limine*, for an order precluding the United States "from relying on truthful speech to prove its case at trial." Docket No. 80 at 33. Such an order would conflict with the holdings of numerous courts that truthful speech can be used to demonstrate intent and that overt acts in furtherance of a conspiracy can be wholly legal.

Defendants seek to avoid responsibility for their crimes because, during a seven-year course of criminal conduct that defrauded the United States and misled doctors, they made a few statements to doctors that could be characterized as true if viewed in isolation, but were still misleading by omission. *See, generally,* 21 U.S.C. § 321(n) (regarding the appropriateness of taking into account omissions when determining if labeling or advertising is misleading). However, the charged crimes are not based on that speech. Crediting this novel argument would make it easier for any manufacturer to avoid accountability for FDCA criminal violations by simply speaking to doctors at some point during the criminal activity. This would largely gut a critically important public health statute that has protected consumers for decades. The law does not support this unjust result.

STATEMENT OF FACTS

A. Defendants Distributed Devices for Unapproved Use

This case concerns VSI's intentional distribution of Vari-Lase devices in interstate commerce for unapproved use and Howard Root's leadership of that effort. Docket No. 1 at ¶ 25. It also involves Defendants' efforts to conceal that conduct from the FDA and law enforcement agents. *Id.* at ¶¶ 33(c), 35, 58-63.

Vari-Lase devices use laser energy to "ablate" (burn) varicose veins. *Id.* at ¶ 11. This shuts the veins permanently, allowing healthier veins to move the blood. *Id.* The FDA has cleared the Vari-Lase system to be marketed for the treatment of the Great Saphenous vein and other superficial veins. *Id.* at ¶ 12. VSI's devices have never been cleared or approved for treating perforator veins, which connect the superficial vein system to the deep vein system. *Id.* at ¶ 13. Because of their

twisting shape and proximity to the deep vein system, perforator veins are more difficult and risky to ablate than superficial veins. *Id.*

VSI and Root were aware that the law required additional FDA marketing authorization to distribute Vari-Lase devices for intended use in perforator veins. *Id.* at ¶ 25. Nevertheless, they decided to sell the devices for this unapproved intended use without any such authorization, a course of conduct that began in 2007 and continued through at least May 2014. *Id.* They did this even after the FDA told VSI in September 2007 that its application for clearance to distribute the Vari-lase for this new use was deficient because VSI had not provided any evidence regarding the safety and efficacy of the device for treating perforator veins. *Id.* at ¶ 19. The conduct continued even after the FDA warned VSI, in September 2007 and again in March 2008, not to distribute the device without the proper authorization. *Id.* at ¶ 22. The conduct persisted even after VSI formally abandoned its plan to obtain FDA marketing clearance in late 2009, after concluding that the clinical trial it had sponsored in order to obtain such clearance had been a failure. *Id.* at ¶¶ 24, 25.

B. Defendants Defrauded the United States

Aware that they could not openly sell Vari-Lase devices for unapproved perforator use without triggering law enforcement action, VSI and Root devised a plan to distribute the devices for that purpose while avoiding regulatory scrutiny. *Id.* at ¶ 26. They designed and launched a special kit (the "Short Kit") specifically for operating on perforator veins. *Id.* at ¶¶ 17, 58c. They then instructed the sales force to promote the Short Kit for "short vein segments" or "short veins," a term

with no specific clinical meaning and one that VSI had not previously used. *Id.* at ¶¶ 26-27, 35, 58. Because the vague term "short veins" can refer both to perforator veins and to short segments of superficial veins, VSI distributed the Short Kit (and Vari-Lase system) for perforator use, while claiming in response to regulatory scrutiny that the kit was intended for short *superficial* veins. *Id.* At the same time, Defendants taught the sales force that the term "short veins" included perforator veins. *Id.*

The sales force openly sold the Short Kit (and Vari-Lase system) for perforator use, with the knowledge and encouragement of management, including Root. *Id.* When a former employee, DeSalle Bui,[2] raised this in a letter to Root, Root ordered an investigation that failed to uncover any of this conduct. *Id.* at ¶ 59. This was possible only because Root presumably did not share what he himself knew, no one was interviewed, a reasonable search of company files was not conducted, and the incriminating documents that Bui attached to his letter were ignored. *Id.* at ¶ 59.

In June 2011, the United States served a subpoena on VSI, alerting the company and its employees to the United States' investigation. *Id.* at ¶ 60. In response, members of the sales force, many of whom had been openly using the word "perforator" in their internal Field Trip Reports to describe their efforts to distribute the Short Kit began using the phrase "short vein" instead. *Id.* at ¶¶ 30, 34b, 61. Eastern Region Sales Manager Richard Steitzer and salesperson Robert

[2] Bui was the relator in the *qui tam* action *United States ex rel. Bui v. Vascular Solutions, Inc.*, Case No. A10CA883SS (W.D. Tex. filed Nov. 19, 2010).

Lehoullier admitted that they did this to conceal their continuing perforator sales activity. *Id.* at ¶ 61a.

In August 2012, Western Region Sales Manager Shane Carlson misled a Special Agent with the FDA Office of Criminal Investigations during an interview. *Id.* at ¶ 62. The manager falsely stated that he had repeatedly instructed salesperson Daniel McIff not to attempt to sell Vari-Lase for the treatment of perforator veins. *Id.* In fact, the manager was aware that McIff had promoted this use while selling Vari-Lase, but did not instruct him to stop. *Id.* By making this false statement, the manager concealed the role of company management in the perforator sales activity. *Id.* In July 2013, Salesperson Glen Holden gave false testimony to the Grand Jury in which he denied selling devices for perforator use. *Id.* at ¶ 63. His claim is contradicted by his trip reports, emails, and the testimony of his supervisor, Steitzer.

C. Defendants Misled Doctors

VSI faced four major obstacles to convincing doctors to purchase the Vari-Lase system for perforator use. First, it lacked FDA authorization to distribute these products for this use. *Id.* at ¶ 23. Second, because of the lack of approval, doctors who used the Vari-Lase system to treat perforators generally could not obtain reimbursement from Medicare and many private insurers. *Id.* at ¶ 31. Third, 14% of the patients in VSI's clinical trial had "major adverse events" involving DVTs. Fourth, the closure rate from that trial–69.7%–was less than the expected rate of 98% and less than the reported closure rate of the competitor's FDA-approved device, VNUS (70-93%), raising questions about both the device's

safety and effectiveness. *Id.* Had doctors known these material facts, many would not have used the Vari-Lase system to treat perforators, as confirmed by several doctors who purchased these devices. *Id.* VSI overcame these obstacles by misrepresenting and concealing the relevant facts. *Id.* at ¶¶ 31-32.

1. Lack of Approval

Defendants used a combination of express misstatements and material omissions to mislead doctors into believing that Vari-Lase products were actually approved for perforator use. For example, Defendants instructed the sales force to tell doctors that the Short Kit was FDA-approved for use on "short vein segments" and that this term had "no definition" because the "physician decides" what it means. *Id.* at ¶ 27. This is false. The FDA did not give VSI authorization to distribute the Short Kit or any other Vari-Lase equipment for "short vein segments." *Id.* at ¶ 12. Nor does the FDA grant clearances or approvals for stated uses that manufacturers are unwilling to define. Doctors may use devices off label in the exercise of medical judgment, but the physician does not "decide" on the scope of an FDA clearance. *Id.* at ¶ 6; Ex. 2 at 59:17-60:2 (Scavdis Tr.). The obvious effect of these misstatements is to mislead doctors into believing that perforator ablation is an FDA-approved use if that doctor "decides" that the term "short vein segments" includes such veins. *Id.* at ¶ 58d.

VSI representatives described the Short Kit to doctors as "our VSI perforator kit" or as a "perforator specific" device. *Id.* at ¶ 55c; Ex. 3 at VS-ESI00884399 (VS-ESI00884399-401). By using the term "perforator," Defendants invited doctors to mistakenly presume that the devices were approved for this use. *See* Ex. 4 at

12:16-21; 39:14-22 (Steitzer Tr.); Ex. 5 at 13:11-21 (Lehoullier Tr.); Ex. 6 (Matthews Stmnt).

Finally, VSI representatives often encouraged doctors to use Vari-Lase products on perforator veins without disclosing the lack of FDA approval. Docket No. 1 at ¶¶ 31-32 (doctors did not know about reimbursement problems caused by lack of approval and Defendants concealed this); ¶¶ 38-40 (communications to doctors encouraging perforator use without disclosing lack of approval). This too led them to believe that the devices were approved. *See* Ex. 7 at 3 (Dr. Black MOI) ("Not in their wildest dreams would [Dr. Black's clinic] think that VSI would put a product out into the market that wasn't indicated for the use they were promoting it for."); Ex. 8 at 1 (Dr. Doshi MOI) ("No one from VSI ever told Dr. Doshi that the short kit was not approved for the treatment of perforators."); Ex. 9 at 2 (Dr. Mackay MOI) ("He would hope that if a VSI sales rep. was in his office talking about the short kit, then that rep. would have told him if it wasn't approved."); Ex. 10 at 2 (Dr. Edmonson MOI) ("No one at VSI ever told Dr. Edmonson that the short kit was not approved by the FDA for perforator treatment."); Ex. 11 at 2 (Dr. Chopra MOI) (same); Ex. 12 at 2 (Dr. Goertzen MOI) (same); Ex. 13 at 3 (Dr. Marcaccio MOI), at 3 (same).

This information was material to doctors' purchase decisions. *See* Ex. 8 at 1 (Dr. Doshi MOI) ("[Dr. Doshi] would have absolutely wanted to know that, and if he had known that he would have done a lot more due diligence before deciding to purchase it."); Ex. 9 at 3 (Dr. Mackay MOI) ("[Dr. Mackay] wouldn't have used [the

short kit] for the treatment of perforators had he known."); Ex. 10 at 2 (Dr. Edmonson MOI) ("It might have dissuaded him from using the [short kit]."); Ex. 11 at 2 (Dr. Chopra MOI) ("[Dr. Chopra] wouldn't have purchased it for the treatment of perforators."); Ex. 12 at 2 (Dr. Goertzen MOI) (same); Ex. 13 at 3 (Dr. Marcaccio MOI) ("[Dr. Marcaccio] would not have been interested in it.").

2. Lack of Reimbursement

VSI understood that doctors are less likely to buy a device if they cannot get reimbursed for using it. Medicare generally did not pay for laser perforator ablations. Docket No. 1 at ¶ 34e. VSI's executives and the Medicare contractors who actually made these decisions agreed on this fact. *See* Ex. 14 at VS-ESI00021086; Ex. 15 at 133:16-135:6 (Schmalz-Kern Tr.); Ex. 16 at 21:7-22:7 (Powers Tr.) ("Q And this use for perforators is not approved, correct? A Correct. Q So the physician cannot bill for it, correct? A That's my understanding, correct."); Ex. 17 at 1 (Dr. Goel (CMS contractor Palmetto) MOI) ("If the device used is not an FDA approved device, it will be determined that the procedure was not medically necessary, and thus not coverable."); Ex. 18 at 2 (Dr. Capehart (CMS contractor Novitas)) (LCD does not provide for coverage for the laser treatment of perforators); Ex. 19 at 1 (Dr. Humpert (CMS contractor Cahaba) MOI) (same).

Despite this, in two World Sales Meeting Presentations that Root approved, VSI included misleading information about whether physicians could get reimbursed for laser perforator procedures. Docket No. 1 at ¶ 41. In the July 2007 presentation, on a slide entitled "Reimbursement for Perforators," the question "How much will a physician get paid for perforator treatment?" had the following

answer: "The same Medicare Physician's Fee Schedule applies. The 2007 national average . . . is $1867 (CPT code 36478) [for the first vein] and $410 (CPT code 36479) [for a subsequent vein]." *See* Ex. 20, at VS161334 (VS161308-40). The July 2009 presentation stated, as one of the answers to the question "Why Treat Perforators?", that "[r]eimbursement is generally the same for treating a perforator as treating an incompetent GSV [greater saphenous vein] (>$1400)." Docket No. 1 at ¶¶ 51-52.

Consistent with these presentations, salespeople gave similar misinformation to doctors and, in some cases, told management about it in field trip reports. Root received these reports. In February 2008, salesperson Vince Lee suggested to a doctor that he could get reimbursed for laser perforator procedures by concealing that he had treated a perforator vein. In his field trip report about the visit, Lee wrote: "Dr. Mountcastle tried to get authorization for doing laser on a perforator and got denied. I told him I thought that was an isolated situation, most providers aren't specifying anything other than an incompetent vein." *See* Ex. 21 at VS0443245 (VS044324-26).

Danny McIff's 2008 "Treating Perforator Veins" presentation, which he sent to health care providers and to other members of the sales force, stated, "Blue Cross DOES NOT PAY for Perforators, but Medicare does." Docket No. 1 at ¶ 45. His "Tips for Treating Perforator Veins" document contains similar misinformation. *Id.* at ¶ 43. As noted above, McIff gave these presentations at Western Region Sales Meetings, and his manager, Kip Theno, sent them to National Sales Director Mark

Valls and members of the Western Region as examples of "best practices." *Id.* at ¶ 44.

Perhaps the best example of encouraging billing fraud is an October 18, 2011, email exchange between sales representatives John DeVito and Glen Holden, both of whom worked in the Eastern Region and actively marketed Vari-Lase devices for perforator use. *Id.* at ¶ 56. In response to DeVito's question about whether Holden's customers were "able to bill for any Perf work," Holden responded, "Can't bill for perfs. Not approved." *Id.* The email chain ends with DeVito's reply, "Txt me what they call them then." *Id.* DeVito testified that Holden responded by calling him and telling him to use the term "short veins." Ex. 22 at 40:3-17 (DeVito Tr.). DeVito admitted that, in retrospect, the conduct reflected in his "text-me-what-they-call-them" email "looks devious." *Id.* at 42:3-5 (DeVito Tr.).

Several witnesses, including members of senior management, knew Medicare and many private insurers would not pay for laser perforator procedures. In March 2008, Fred Reuning, Vice President of the Vari-Lase Business, aware of rumors that some salespeople were misinforming doctors about reimbursement, sent a corrective email to the entire sales force. *See* Ex. 14 at VS-ESI00021086. He wrote that "as long as there is no approved clearance for perforator treatment by the FDA, it is not possible to submit a claim to Medicare for the treatment of a perforator vein" and that the same was true for many private insurers. *Id.* Many other executives at VSI knew this rule, including two Vari-Lase product managers and Deborah (Neymark) Schmalz-Kern, former Vice President of Regulatory Affairs and the

company's compliance officer. *See* Ex. 23 at 2 (Dabruzzi MOI); Ex. 24 at 4 (Thielen MOI); Ex. 15 at 133:16-135:6 (Schmalz-Kern Tr.).

Some members of the sales force who admitted knowing this rule nevertheless misinformed health care providers about reimbursement, including Western Region Manager Kip Theno, Southwest Region Manager Shane Carlson, and salespersons Anthony Paszkeicz and John DeVito. *See* Ex. 25 (Carlson Stmnt); Ex. 26 at 17:14-18:6, 21:3-22:2 (Paszkeicz Tr.); Ex. 22 at 32:19-33:9, 40:21-41:9; 41:19-42:5 (DeVito Tr.).

Salespeople supervised by Carlson, specifically Danny McIff and Chris Harrelson, repeatedly told doctors that Medicare and other insurers would reimburse laser perforator procedures. *See* Ex. 25 (Carlson Stmnt); Ex. 27 at 21:2-19; 31:8-12 (Harrelson Tr.). In a signed statement, Carlson said, "I also believed that it was improper to suggest to health care providers that Medicare and other insurers would reimburse them for laser perforator procedures, because I understood Medicare and many private insurers generally did not pay for procedures involving unapproved devices." Ex. 25 (Carlson Stmnt).

3. Risk of DVT

Shortly after VSI's own clinical trial investigating the safety and efficacy of using the Vari-Lase to treat perforator veins (the "RELIEVE trial") ended, VSI misled doctors about its original safety objective in an effort to characterize the failed study as a success. At a November 2008 conference of vein doctors in Marco Island, Florida, the doctor who conducted the RELIEVE trial, Daniel Pepper, gave a

presentation that had been written by a VSI consultant and approved by VSI management. Docket No. 1 at ¶ 49. The presentation claimed that the RELIEVE trial was a success, but VSI was only able to make this claim because it moved the goalposts. *Id.* The trial was originally designed and performed to measure patient safety based on the rate of "major" adverse events. *Id.* The trial resulted in 14% of patients experiencing "major" adverse events involving DVT. *Id.* In order to claim that the trial was successful, the presentation crafted by VSI changed the safety objective of the trial from measuring the rate of "*major*" adverse events to measuring "*serious*" adverse events. *Id.* Raising the bar on what counted as an "adverse event" allowed VSI to claim in the presentation that the trial resulted in a 0% rate of adverse events. *Id.* VSI omitted the "major" adverse event rate, which was in the trial's protocol, from the presentation all together. *Id.* This after-the-fact switching of the safety objective enabled VSI to claim that the trial had achieved its safety objective, when under the original safety measurement it had not. *Id.*

VSI salespeople, on the other hand, used a different method to conceal the same major adverse event information–they avoided disclosure of the trial altogether. *See* Docket No. 1 at ¶¶ 31-32; *see also* Ex. 8 at 1-2 (Dr. Doshi MOI) ("No one from VSI ever told Dr. Doshi that [VSI] had conducted a clinical trial on the laser treatment of perforators"; "If he had known [of the clinical trial results]" it "would have at least caused him to evaluate [the short kit for perforator treatment] further."); Ex. 9 at 3 (Dr. Mackay MOI) ("Dr. Mackay would have wanted to know

that VSI conducted a clinical trial on the laser perforator treatment . . . ."; "That knowledge [of the RELIEVE results] would have 'scared him to death' and he wouldn't have used the short kit for the treatment of perforators."); Ex. 10 at 2 (Dr. Edmonson MOI) (same); Ex. 11 at 2 (Dr. Chopra MOI) (same); Ex. 12 at 2 (Dr. Goertzen MOI) (same); Ex. 13 at 3 (Dr. Marcaccio MOI) (same).

4. Closure Rate

The primary effectiveness objective of the RELIEVE trial was success at closing veins at six weeks and six months after the procedure. The final six-month closure rate was a disappointing 69.7%, less than VSI's goal of 98% and less than the competitor product VNUS's claimed perforator closure rate of 70-93%.[3] Docket No. 1 at ¶ 23. This result, along with the major adverse events relating to DVT, eventually led VSI to conclude that the data from the study was "inadequate" to gain FDA clearance. However, when the trial concluded, VSI misrepresented to the sales force that the rate achieved by the trial was 91%. *Id.* at ¶ 47. This was actually the closure rate at two weeks–an irrelevant interim number. Specifically, in August 2008, Fred Reuning, Vice President of Vari-Lase Business, wrote an email to the sales force with "key points" to make when selling against VNUS. *Id.* at ¶ 48. These included the claim that the VNUS RFS Stylet was "difficult to use on perforators," whereas VSI had "completed a successful clinical trial on using laser for perforators (91% closure) and [was] just waiting for FDA clearance to market the

[3] VNUS relied on two small studies conducted by different doctors at different times. One had a closure rate of 70%; the other, 93%. Docket No. 1 ¶¶ 18, 23; Docket No. 77-1 at 26 (Riach Aff. Ex. 6).

Short Kip [sic] for laser treatment of perforators."[4] *Id.* at ¶ 48. The July 2008 World Sales Meeting presentation, which was approved by Root, also claimed that RELIEVE had achieved 91% closure. *Id.* at ¶ 47.

After Dr. Pepper published the true closure rate from the trial at the November 2008 vein conference, VSI disclosed the real closure rate to the sales force in the January 2009 National Sales Meeting presentation. *Id.* at ¶ 49. Perhaps unsurprisingly, members of the sales force did not share the disappointing 69.7% figure with doctors. Ex. 8 at 2 (Dr. Doshi MOI); Ex. 9 at 2 (Dr. Mackay MOI); Ex. 10 at 2 (Dr. Edmonson MOI); Ex. 11 at 2 (Dr. Chopra MOI); Ex. 12 at 2 (Dr. Goertzen MOI); Ex. 13 at 3 (Dr. Marcaccio MOI).

ARGUMENT

Defendants' arguments only succeed if the indictment is ignored and the First Amendment is stretched to cover conduct and statements it has never before protected. Defendants' attempts to either ignore or litigate the facts alleged in the indictment contradict the black letter law which holds that the allegations in an indictment are taken as true. In his separate motion, Defendant Root takes a different approach and directly contradicts the indictment. As the Fifth Circuit has stated, "in testing the sufficiency of an indictment, a court must not pierce the pleadings and make a premature resolution of the merits of the allegations. Rather,

[4] Reuning's August 2008 email is also misleading because neither was VSI "just waiting" for FDA approval, nor was RELIEVE considered "successful." VSI was not "just waiting" on the FDA because in March 2008, some five months earlier, FDA had alerted VSI that its 510(k) application had been considered withdrawn. Docket No. 1 at ¶ 22. And RELIEVE could not be considered a "successful" trial when VSI later informed its board that the study "was not adequate to support 510k clearance." *Id.* at ¶ 24. VSI declined to resubmit a 510(k) application to the FDA because of the disappointing study results. *Id.*

. . . the court must look to the allegations and, taking the allegations to be true, determine whether a criminal offense has been stated." *United States v. Cadillac Overall Supply Co.*, 568 F.2d 1078, 1082 (5th Cir. 1978) (citation omitted). Defendants' arguments are an improper attempt to take fact decisions away from the jury.

A review of the entire indictment demonstrates that Defendants' claim that it criminalizes speech, let alone the kind of truthful and non-misleading expression discussed in *Caronia* and *Amarin*, is simply wrong.

First, the indictment focuses on conduct, not speech. Second, to the extent that the indictment includes some allegations involving Defendants' promotional speech, the indictment further alleges that speech to be false and misleading–and thus not protected by the First Amendment. Third, the misbranding counts of the indictment based on inadequate directions for use survive regardless of how Defendants characterize the promotional speech in the indictment. Fourth, Defendants receive no First Amendment protection for defrauding the United States. Finally, Defendants' expansive *in limine* request is contrary to black letter law that allows truthful speech to demonstrate intent and overt acts of a conspiracy.

I. The Indictment Seeks to Punish Conduct, Not Speech

The First Amendment protects expression, not conduct. To support their argument for dismissal, Defendants cite to an imagined version of the grand jury instructions in which the United States inappropriately instructs that truthful off-label speech is a crime, and they then ignore the bulk of the allegations of the indictment pertaining to their conduct. The reality is the United States properly

instructed the grand jury, and that Defendants have been charged for what they did, not what they said. Indeed, while the facts in the two cases on which Defendants rely, *Caronia* and *Amarin*, are easily distinguished from the facts alleged here, the framework used by the Second Circuit (in *Caronia*) and the Southern District of New York (in *Amarin*) is entirely consistent with this case.

A. The Charges Focus on Conduct

The Supreme Court has only extended First Amendment protection to "conduct that is inherently expressive." *Rumsfeld v. Forum for Academic and Institutional Rights, Inc.*, 547 U.S. 47, 66 (2006); *accord Voting for Am., Inc. v. Steen*, 732 F.3d 382, 388 (5th Cir. 2013) ("Conduct does not become speech for First Amendment purposes merely because the person engaging in the conduct intends to express an idea."); *Amarin* 2015 WL 4720039, at *27 ("[T]he First Amendment protects expression, not conduct."). The prohibited acts detailed in the indictment involve non-expressive conduct.

Defendants urge the Court to disregard the crimes for which they were actually indicted, asserting that "the speech here *is* the crime," Docket No. 80 at 29, but that is not true. The substantive counts in the indictment are based on conduct: Defendants' shipment of adulterated and misbranded medical devices from Minnesota to Texas. *See United States v. Endotec, Inc.,* 563 F.3d 1187, 1190 (11th Cir. 2009) ("To show a violation of § 331(a) and (k), the Government must prove: (1) Appellees' products are 'devices' within the meaning of the FDCA; (2) the devices are adulterated or misbranded; and (3) the devices move in interstate commerce."); *Lytle v. U.S. Dep't of Health & Human Servs.*, No. 14-3715, 2015 WL 4978975, at *1

(8th Cir. Aug. 21, 2015) (same). The devices became adulterated or misbranded when Defendants failed to obtain required authorization from the FDA to sell them for perforator use (adulteration and misbranding) and failed to include adequate instructions for perforator use in the labeling (misbranding), but nevertheless distributed them for this use.[5] 21 U.S.C. § 331(a). The conspiracy count charges defendants with conspiring to commit those offenses and defraud the United States. Speech to doctors is not an element of any of these offenses.

Defendants point to only a few out of the many overt acts that are set forth in the indictment to support their argument that speech is the crime here. Even assuming these statements are truthful, non-misleading and thus protected by the First Amendment (which, as discussed below, they are not), Defendants fail to mention that they are alleged as overt acts. It is well-established that an overt act in furtherance of a conspiracy can be a lawful act. *See United States v. Archbold-Newball*, 554 F.2d 665, 684 (5th Cir. 1977) ("A prosecution for conspiracy is not the equivalent of a prosecution for having done or performed the overt act, for an overt act may not, itself, be unlawful at all.") (citing *Yates v. United States*, 354 U.S. 298,

[5] The indictment contains nine counts. Count One, brought under 18 U.S.C. §371, alleges Defendants conspired to (a) introduce adulterated medical devices into interstate commerce, (b) introduce misbranded medical devices into interstate commerce, and (c) defraud the United States by concealing their sale of medical devices for unapproved uses, based on a number of overt acts. Docket No. 1 ¶¶ 1-63. Counts Two through Five allege adulteration and are brought under 21 U.S.C. §§331(a), 351(f)(1)(B) and 333(a)(1). These counts allege that Defendants introduced devices that were adulterated, because they lacked the required premarket approval from the FDA, into interstate commerce, by shipping them to Austin, Texas. *Id.* at ¶¶ 64-65. Counts Six through Nine charge that Defendants introduced misbranded devices into interstate commerce in violation of 21 U.S.C. §§331(a), 352(o); 352(f)(1) and 333(a)(1) and also pertain to the four shipments to Austin, Texas. The devices charged in these counts were also misbranded because (1) VSI failed to provide FDA with premarket notification (510(k)) regarding the company's intention to distribute the Varilase for perforator treatment and (2) they lacked adequate directions for their intended use. *Id.* at ¶¶ 66-67.

334 (1956)); and *Direct Sales Co. v. United States*, 319 U.S. 703, 714-15 (1943). Thus, these overt act allegations obviously do not describe the actual crimes at issue.

Moreover, even if the challenged overt acts were omitted from the indictment, all of the counts would remain viable. This is because the indictment alleges many overt acts that do not involve speech to doctors, and the United States can prove a conspiracy with a single overt act. *See United States. v. Michelena-Orovio*, 719 F.2d 738, 751 (5th Cir. 1983) (affirming sufficiency of evidence based on one overt act which knowledge and participation in conspiracy may be inferred); *United States v. Vettre*, 591 F.2d 347, 350 (5th Cir. 1979) ("[P]roof of a single act in furtherance of [the unlawful] agreement by a single conspirator establishes the guilt of each member of the conspiracy."). This simple fact eliminates any possibility that the grand jury's decision to indict depended on the criminalization of truthful speech.

Similarly, the prosecution can (but does not need to) prove intended use exclusively through conduct that does not involve any protected speech to doctors. This conduct includes:

1. Defendants' decision to launch a special kit designed specifically for perforator veins in response to a competitive threat (establishing intended use before any speech to a doctor even occurred);

2. their manufacture of that kit with perforator-specific modifications (manufacturing process for a device is not speech);

3. their application to the FDA for authorization to market that use (an FDA application is a legal act and does not contain any speech to doctors);

4. their investment in a clinical trial for the purpose of gaining that authorization (Defendants do not suggest this was protected speech);

5. their decision to launch the product without approval or clearance while adding new directions for perforator use to the labeling (Defendants do not claim that their instructions for use were protected speech) (*see infra* Section III, at 38-39);

6. their efforts to defraud the United States by concealing evidence and lying about their perforator sales activity (not protected, *see infra* Section IV, at 39-40.);

7. testimony of VSI salespeople and managers that they used the term "perf kit" internally to describe the modified kit (internal nickname proves intended use whether or not repeated to doctors); and

8. testimony from VSI personnel that they made sales of devices with the intent that they be used to treat perforator veins (state of mind existed irrespective of any statements to doctors).

These actions did not involve any promotional speech to physicians, the focus in Defendants' brief and the foundation for the *Amarin* and *Caronia* cases that Defendants suggest should guide this Court's decision. *See* Document No. 80 at 6 ("[T]he government seeks to prosecute the defendants, Vascular Solutions and its CEO, Howard Root, for Vascular Solutions' sales representatives speaking truthfully to doctors . . . ."), 7 (same), 8 ("*Caronia* and *Amarin* rejected the government's theory, which prohibits off-label promotion and thereby punishes truthful speech."), 12, 15, 22; *see also Caronia*, 703 F.3d at 156-59; *Amarin*, 2015 WL 4720039, at *12-15, 17-19, 21, 28, 31-33, 35-36 (plaintiffs "challenge FDA regulations that prohibit Amarin 'from making completely truthful and non-misleading statements about its product to sophisticated healthcare professionals'") (quoting complaint).

In addition, Defendants' false and misleading statements to doctors also serve as evidence of intended use. *See infra* Section II.B., at 32-34. Thus, the

United States does not need to rely on the challenged overt acts in any way to prove its case. This is the clearest possible proof that this case is not premised upon truthful speech to doctors.

B. Defendants' Motion Depends Upon Mischaracterizing the Instructions to the Grand Jury

Defendants attempt to overcome the lack of any support in the indictment for their arguments by claiming that the prosecution mis-instructed the grand jury. That claim is inaccurate. Defendants omit that the United States correctly instructed the grand jury that truthful speech to doctors is not a crime. Ex. 1 at 4 (6/26/15 Finley letter) ("We did advise the grand jury that mere off-label speech or promotion was not a crime.").[6]

Defendants claim that prosecutors instructed the grand jury to consider all off-label use illegal by relying on a single misstatement in an exchange with a witness (not an instruction as Defendants suggest) (Docket No. 84 at 34). Defendants omit all of the other occasions where prosecutors elicited testimony that off-label use by doctors is legal. Ex. 28 at 13:5-7 (Holden Tr.) (acknowledging "[d]octors are . . . allowed to use things off label"); Ex. 22 at 23:13-17 (DeVito Tr.) (same); Ex. 4 at 16:18-17:8 (Steitzer Tr.) (same). Even more important, Defendants omit the dispositive fact that the *indictment itself* alleges that "[t]he FDCA does not prohibit doctors, in the exercise of medical judgment, from using medical devices for

[6] Defendants focus on the fact that certain VSI witnesses testified that they understood off-label promotion to be illegal, based on the training they received from VSI. Ex. 4 at 16:18-17:13 (Steitzer Tr.) (testifying that truthful off-label promotion was illegal based on official VSI training presentation and information given to him by the company). The fact that a witness may have misstated the law does not mean that the grand jury was improperly instructed.

unapproved uses not included in the FDA-approved labeling." Docket No. 1 at ¶ 6. This means that the Grand Jury accepted this statement of the law.

Because Defendants' motions depend on these inaccurate claims, they should be denied. Moreover, even assuming an error in the legal instructions to the grand jury, this is not a basis for dismissing an indictment valid on its face. *See Costello v. United States*, 350 U.S. 359, 363 (1956); *accord United States v. Slepicoff*, 524 F.2d 1244, 1247 (5th Cir. 1975); *see also United States v. Buchanan,* 787 F.2d, 477, 487 (10th Cir.1986); *United States v. Battista*, 646 F.2d 237, 240-2 (6th Cir. 1981); *United States v. Dimasi*, No. CR 09-10166-MLW, 2011 WL 468213, at *3 (D. Mass. Feb. 4, 2011); *United States v. Graham*, 247 F. Supp. 2d 923, 925 (S.D. Ohio 2002). This is especially true where, as here, the error could not have had any effect on the grand jury's decision. *See supra* Sect. I.A., at 21-25 (demonstrating how challenged allegations in the indictment could be stricken without affecting any count).

C. *Caronia* and *Amarin* Are Inapplicable

As set forth above, *Caronia* and *Amarin* do not apply here because the First Amendment protects only truthful, non-misleading commercial speech and does not protect non-expressive conduct. Detailed comparison of the material factual differences between this case and those decisions reveals that this prosecution is not only factually distinct, but also that the indictment is fully consistent with what *Caronia* and *Amarin* recognize to be constitutionally permissible.[7]

[7] While the United States does not believe that *Caronia*, and *Amarin's* interpretation of *Caronia* correctly reflect the law, there is no need to re-litigate those cases here because this indictment complies with these decisions.

In *Caronia*, the Second Circuit, in a divided panel opinion, overturned a pharmaceutical salesman's conviction for conspiracy to distribute a misbranded drug. *Caronia*, 703 F.3d at 152. The evidence of the defendant's participation in the conspiracy consisted of a handful of audio recordings that the majority found consisted of promotional speech to doctors. *Id.* at 156-57. The court assumed, for purposes of the appeal, that these promotional statements were true, noting that the government had failed to argue that they were false or misleading. *Id.* at 165 n.10.

The prosecution focused on these statements promoting the unapproved use to doctors. The majority cited at least ten specific examples of the prosecution equating this speech with the crime itself. *See id.* at 158 (including prosecutor's argument to the jury that "[Caronia] conspired through some act of misbranding, and that act of misbranding . . . was the promotion . . . [of a] drug for unapproved uses"); and *id.* at 158 n.6 ("[Caronia is] misbranding. He's promoting a drug . . . ."). The majority also took issue with the district court's instruction that promotional speech alone could support a conviction. *Id.* at 159 (instructing "[a] misbranded drug may be shown by a promotion of the drug by a distributor for an intended use different from the use for which the drug was approved by the [FDA]"). Based on this record, the court concluded that "the government prosecuted Caronia for mere off-label promotion and the district court instructed the jury that it could convict on that theory." *Id.* at 160.

The court in *Caronia* made clear that it was *not* holding that promotional speech could not be used as evidence to prove intended use. *See Caronia*, 703 F.3d at 161 and 161 n.8 (citing *Mitchell*, 508 U.S. at 489 (concluding First Amendment "does not prohibit the use of speech to establish . . . intent")). Rather, the majority relied heavily on its extensive review of the trial record to reject, as a factual matter, the government's claim that it used Caronia's speech only as evidence of intended use. *See id.* at 161 ("[T]hat is not what happened in this case."; "[T]he government's assertion . . . is simply not true."). Instead, "the government's summation and the district court's instruction left the jury to understand that Caronia's speech was itself the proscribed conduct." *Id.*

Every material fact relied upon by the majority in *Caronia* is missing here. As set forth above, Defendants misled doctors and defrauded the United States. There are no allegations in the indictment that equate truthful speech to doctors with the crime itself, as demonstrated by the simple fact that the United States can prove every count in the indictment without introducing a single truthful promotional statement to a doctor (although it is not required to restrict its proof in this manner). Further, the United States instructed the grand jurors in this case that truthful speech was not a crime.

This case bears even less resemblance to *Amarin*. There, plaintiff Amarin, unlike Defendants, filed for declaratory and injunctive relief to authorize certain proposed communications with doctors about an off-label use for its drug, after failing to obtain FDA approval for that same off-label use. *Amarin,* 2015 WL

4720039, at *1. Unlike Defendants' communications, Amarin's proposed communications expressly disclosed material facts concerning the drug's lack of approval, the potential lack of reimbursement, and the results of the company's clinical trial. *Id.* at *14. The court relied on these disclosures in holding that the communications were non-misleading.

The fundamental holding in *Amarin* is its rejection, under *Caronia*, of the United States' argument that it "may bring a misbranding action where Amarin's *only acts constituting promotion of [its drug] for an off-label use are its truthful and non-misleading statements* about that use, provided that these acts support an inference that Amarin intended to promote that off-label use." *Id.* at *22 (citing the United States' brief) (emphasis added). The prosecution has not made that argument here, and this prosecution does not in any way violate *Amarin*'s holding that the government may not bring an action "based on truthful promotional speech alone." *Id.* at *23.

Indeed, in concluding its discussion of this issue, the court made clear that "[t]he Government is of course correct that truthful speech can serve as evidence of intent." *Id.* at *27. The court then gave specific guidance, omitted by Defendants, that authorizes prosecutions like this one and disposes of their motions:

> [C]ontrary to the FDA's concern, *Caronia* leaves room for prosecuting off-label marketing as misbranding. Two limits to *Caronia*'s holding are worth highlighting. First, the First Amendment does not protect false or misleading commercial speech. Caronia*'s construction of the misbranding provisions so to exclude truthful promotion speech affords no protection to a manufacturer that uses false or misleading communications to promote an off-label use.* Second, the First Amendment protects expression, not conduct. *A manufacturer that*

> *engages in non-communicative activities to promote off-label use cannot use the First Amendment as a shield*. *Caronia* holds protected, and outside the reach of the FDCA's misbranding provisions, off-label promotion only where it wholly consists of truthful and non-misleading speech.

Id. (emphasis added).

The indictment here fits squarely within what *Amarin* specifically sanctions: The indictment alleges that VSI "engage[d] in non-communicative activities to promote off-label use," *supra* Sect. I, at 20-30, and "false or misleading communications to promote an off-label use," *infra* Sect. II, at 30-38. Thus Defendants "cannot use the First Amendment as a shield." 2015 WL 4720039, at *27. Defendants do not and cannot credibly argue that the indictment is reaching "off-label promotion . . . [that] wholly consists of truthful and non-misleading speech." *Id.* Indeed, Defendants admit this, stating "[t]o be sure, the indictment . . . alleges that the defendants engaged in false and misleading promotion . . . ." Docket No. ¶ 1, at 9.

II. Defendants Had No First Amendment Right to Mislead Doctors

The promotional speech in the indictment is alleged to be false and misleading and thus is not protected by the First Amendment. In particular, the indictment alleges that Defendants misled doctors about the following material facts: (1) the Short Kit lacked FDA clearance for perforator treatment, (2) Medicare generally did not reimburse laser perforator ablation procedures, (3) VSI's clinical trial showed that 14% of patients had a "major adverse event" related to deep vein thrombosis (DVT), and (4) the same trial showed that the VSI device was less effective than a competing device that the FDA had already cleared for perforator

use. The statements that Defendants single out are either misleading by omission or demonstrably false.

A. The First Amendment Does Not Protect False or Misleading Commercial Speech

"For commercial speech to come within [the First Amendment], it at least must concern lawful activity and not be misleading." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 566 (1980). "The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading . . . ." *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 638 (1985).

The Fifth Circuit has repeatedly reaffirmed this rule. *See Eastman Chem. Co. v. Plastipure, Inc.*, 775 F.3d 230, 237 (5th Cir. 2014) (affirming injunction prohibiting company from making false and misleading advertising claims and rejecting the defendants' First Amendment challenge); *Pub. Citizen, Inc. v. La. Att'y Disciplinary Bd.*, 632 F.3d 212, 218-19 (5th Cir. 2011) (affirming prohibition on attorney promises to prevail in a future case because these communications are "necessarily misleading"); *Joe Conte Toyota, Inc. v. La. Motor Vehicle Comm'n*, 24 F.3d 754, 756 (5th Cir. 1994) (rejecting First Amendment challenge on the grounds that use of the term "invoice" in auto dealer's advertising was inherently misleading).

The two cases from the Second Circuit at the heart of Defendants' motion confirm this longstanding precedent. In *United States v. Caronia*, the Second Circuit stated, "[o]f course, off-label promotion that is false or misleading is not

entitled to First Amendment protection." 703 F.3d at 165 n.10; *see also Amarin,* 2015 WL 4720039, at *27.

B. Defendants Systematically Misled Doctors about Material Facts

Defendants concede that false or misleading commercial speech is not protected by the First Amendment. Docket No. 80 at 14. To avoid the precedent set forth above, Defendants' argument relies entirely on the erroneous premise that this case is about truthful promotion.[8] Defendants can make this argument only by ignoring allegations in the indictment detailing how Defendants misled doctors in order to sell the offending devices.[9]

Defendants concealed from doctors, using an interlocking combination of affirmative misrepresentations and material omissions, the following key facts: (1) the devices lacked FDA approval for perforator vein ablation, (2) Medicare did not reimburse doctors for using Defendants' devices in perforator vein ablation procedures, (3) VSI's clinical trial showed that 14% of patients had a "major adverse event" related to deep vein thrombosis (DVT), and (4) the same trial showed that

[8] Based on their erroneous assertion that this case is primarily about truthful speech, Defendants argue that this prosecution fails First Amendment scrutiny under the test outlined in *Central Hudson*, relying on the analysis the Second Circuit conducted in *Caronia*. *See* Docket No. 80 at 20-28. Because the indictment in this case relies primarily on conduct and not speech, and any speech-based evidence mentioned in the indictment is in any event false and misleading, there is no need to engage in a substantive First Amendment analysis. However, the United States has substantial interests that are directly advanced by this prosecution, and the alternatives posed in *Caronia* and proposed by Defendants here fail to advance those substantial interests. In the event that the Court deems it necessary to apply the *Central Hudson* test, the United States requests the opportunity to develop a factual record on these issues.

[9] Defendants concede that the "indictment . . . alleges that the defendants engaged in false and misleading promotion . . . about the availability of reimbursement and the result of a clinical trial," Docket No. 80, at 14, but then ignore this fact in their arguments.

the VSI device was less effective than a competing device that the FDA had already cleared for perforator use. *See supra* Stmnt of Facts, at 7-19.

Doctors who purchased these devices for perforator use had no knowledge of these facts, and VSI witnesses admitted that they either did not disclose or affirmatively misled doctors on these points. Docket No. 1 ¶¶ 32, 47-49; s*ee also* Ex. 22 at 9:4-14 (DeVito Tr.) (did not discuss the results of the trial "because I never received the results of the trial."); Ex. 5 at 29:13-18 (Lehoullier, Tr.) (never discussed the results of the trial because "I just thought it was still ongoing"); Ex. 29 at 26:20-27:1 (Ramiro Tr.) ("[T]hey may have talked about [RELIEVE] and then [we] never heard anything more about it kind of thing."). VSI witnesses and physicians alike agreed that this was highly relevant information that VSI should have truthfully disclosed. Docket No. 1 at ¶ 31; Ex. 30 at 3 (Dr. Wolschleger MOI); Ex. 8 at 2 (Dr. Doshi MOI); Ex. 9 at 2 (Dr. Mackay MOI); Ex. 10 at 2 (Dr. Edmonson MOI); Ex. 11 at 3 (Dr. Chopra MOI); Ex. 12 at 3 (Dr. Goertzen MOI).

Significantly, Defendants would have made virtually no sales had they been truthful and forthcoming about this information. Indeed, VSI's Eastern Region Sales Manager, Richard Steitzer, testified to the impossibility of selling the Short Kit without false and misleading statements:

> Q: So, it would be impossible to sell this product to doctors if you told them Medicare won't pay for it, closure rate is 69.7, and 14 percent of the patients had a major adverse event involving DVT?
>
> A: I agree with that, yes, sir.

See Ex. 4 at 55:6-10 (Steitzer Tr.).

The doctors who bought these devices confirmed that the omissions were material. Ex. 30 at 2 (Dr. Wolschleger MOI) ("[I]t absolutely would have changed [Dr. Wolschleger's decision] to use laser ablation for the treatment of perforator veins."); *See supra* Stmnt of Facts, at 10-19. Thus, each and every statement to a doctor set forth in the indictment was misleading because it omitted these material facts.

C. Defendants Rely Upon a Handful of Statements that Were Misleading by Omission

In order to avoid these facts, Defendants focus narrowly on a handful of allegations in the indictment that they argue are truthful communications with doctors. Docket No. 80 at 32 (citing Docket No. 1 at ¶¶ 37-44, 46). These paragraphs mention three types of speech: (1) Defendants' encouragement to doctors to use Vari-Lase devices to treat perforator veins, (2) Defendants' communications to the sales force describing the differences between Vari-Lase and competing products, and (3) the "Tips for Treating Perforator Veins" presentation.

The first category of communications describes misleading, not truthful, promotion. VSI failed to disclose that its equipment was not FDA approved or cleared for perforator use and that Medicare likely would not reimburse for the procedure (the statements predated VSI's failed clinical trial). Docket No. 1 at ¶¶ 38-40. Indeed, the target of one of these communications stated that, by promoting perforator use without disclosing the lack of approval, VSI misled him into believing that the equipment was actually approved. *See* Ex. 7 at 3 (Dr. Black MOI).

The remaining categories are similarly misleading by omission (¶¶ 37, 41-44, 46) and also contain false statements about Medicare reimbursement (¶¶ 41, 43-44). The First Amendment does not protect such "incomplete" and "one-sided" promotion. *See Amarin*, 2015 WL 4720039, at *27 ("*Caronia* holds protected, and outside the reach of the FDCA's misbranding provisions, off-label promotion only where it wholly consists of truthful and non-misleading speech. . . . A manufacturer that leaves its sales force at liberty to converse unscripted with doctors about off-label use of an approved drug invites a misbranding action if false or misleading (e.g., one-sided or incomplete) representations result.").

D. Defendant Root's Separate Motion Contradicts the Indictment and the Evidence

In his individual motion, Defendant Root directly contradicts the indictment and argues that (1) Medicare allowed reimbursement, (2) the adverse event disclosures from the RELIEVE trial were not misleading, and (3) communications to doctors about the efficacy rate in the RELIEVE trial were not misleading. Docket No. 76 at 24-32.

With regard to Medicare reimbursement, Defendant Root mischaracterizes this as a question of law. Although there are laws that govern reimbursement generally, the indictment alleges that Medicare, as a matter of *historical fact*, did not pay for laser perforator ablations. Docket No. 1 at ¶ 34e. VSI's executives and the Medicare contractors who actually made these decisions agreed that this is how the Medicare program was understood and applied. *See* Ex. 14 at VS-ESI00021086; Ex. 15 at 133:16-135:6 (Schmalz-Kern Tr.); Ex. 16 at 21:7-22:7 (Powers Tr.) ("Q And

this use for perforators is not approved, correct? A Correct. Q So the physician cannot bill for it, correct? A That's my understanding, correct."); Ex. 17 at 1 (Dr. Goel (CMS contractor Palmetto) MOI) ("If the device used is not an FDA approved device, it will be determined that the procedure was not medically necessary, and thus not coverable."); Ex. 18 at 2 (Dr. Capehart (CMS contractor Novitas)) (LCD does not provide for coverage for the laser treatment of perforators); Ex. 19 at 1 (Dr. Humpert (CMS contractor Cahaba) MOI) (same). Root's *post hoc* attempt to question the legal basis for that policy is irrelevant to the indictment's allegations that he and VSI made misleading statements about prevailing reimbursement practices.

Defendants cannot overcome the facts alleged in the indictment and the above fact witnesses by hiring an expert to contradict them. *See* Docket No. 84, at 36 (citing an expert witness as only relevant support for reimbursement argument). Moreover, the expert's legal opinion is not supported by citation to any law that actually covers laser perforator ablation, underscoring that this is a factual issue for the jury. *Id.*

Similarly, Root contests the truth of statements in the indictment about the RELIEVE trial. Docket No. 76 at 29-33. First, he takes aim at whether a presentation on the rate of adverse events was misleading, as alleged in paragraph 49 of the indictment. *Id.* at 29-31. This argument overlooks the admissions of the witnesses on this point, Fred Reuning, former Director of Marketing, and Mike Swierzewski, former Clinical Research Associate. Ex. 31 at 2 (Reuning Stmnt)

("The presentation stated that the primary safety objective of the trial was to measure the rate of 'serious' adverse events. This statement is false because the actual primary safety objective of the trial was to measure the rate of major adverse events."); Ex. 32 at 116:6-13 (Swierzewski Tr.) ("[The relevant slide] is misleading in the fact that the major adverse events reported for the study are not present anywhere."); Ex. 33 at 116:1-18 (Pepper Tr.) (agreeing that "your point is that the bottom line conclusion that's stated in the presentation is roughly correct, but it is misleading not to tell them what the safety question from the study was"); Ex. 34 at 90:20-92:23 (Abbs Tr.) ("Q: . . . [T]he serious device treatment related adverse events is being described as a primary objective result and that is false. It was not. A: Right."). Root also fails to address the fact that VSI sales representatives failed to disclose the study results to doctors at all, thus keeping doctors in the dark about the safety result of the trial. Docket No. 1 at ¶¶ 31-32.

Defendant Root also defends the closure rate communications as non-misleading. Docket No. 76 at 31-33. Again, this argument overlooks the admission of the person who made the statement and called it "materially false." *See* Ex. 31 (Reuning Stmnt). Defendant Root also misses the point that sales representatives omitted any mention of closure rate from the trial when selling the subject devices. Docket No. 1 at ¶¶ 31-32.

Finally, Root does not address Defendants' misleading statements to doctors that the Short Kit was approved for "short vein segments" (it was not). See *supra*

Stmnt of Facts, at 10-13. Root also does not address the related false statement that the "physician decides" if this supposed approval covered perforator veins. *Id.*

III. Defendants Had No First Amendment Right to Distribute Devices Bearing Defective Instructions for Use

The indictment sets forth three independent misbranding and adulteration violations. Docket No. 1 at ¶¶ 64-67. One set of misbranding violations occurred when Defendants distributed devices in interstate commerce which bore inadequate instructions for intended perforator use. *Id.* at ¶¶ 66-67. This prohibited course of conduct consists solely of introducing medical devices into interstate commerce with labeling that lacked adequate instructions for perforator ablation, the intended use for which those devices were distributed. In addition, this was one object of the conspiracy. *Id.* at ¶¶ 58, 64-67. Defendants' motion fails to address this course of conduct.

The instructions were inadequate because they merely told doctors, unhelpfully, to maintain a "safe distance" from the deep vein system when treating "short vein segments" (which includes perforator veins) in order to avoid DVTs. Ex. 2 at 60:25-63:17 (Scavdis Tr.). The instructions (1) did not specify what that distance was, (2) did not disclose VSI's conclusion, as reflected in the instructions they submitted with their withdrawn 510(k), that this distance was at least 1 cm, (3) did not disclose relevant safety and effectiveness results from the clinical trial, and (4) did not include any other instructions based on the kind of clinical data necessary to generate instructions for safe and effective use. *Id.;* Docket No. 1 at ¶¶ 23, 24, 31, 32.

Defendants do not argue that they have a First Amendment right to give doctors vague, incomplete, and defective instructions. There is no law to support a constitutional right to jeopardize consumer safety in this manner. Defendants affirmatively chose to add faulty perforator instructions to the devices' labeling. This act, standing alone, does not just establish an independent misbranding violation, it also independently proves the intended use element for all of the FDCA charges. This fact distinguishes all of Defendants' cases, none of which involve an intended use that was proven by defective instructions in the labeling. This means that even assuming Defendants never spoke to any doctors about perforator use, they would still be guilty of misbranding and adulteration because they shipped devices across state lines for an unapproved intended use that is proven by the defective instructions for perforator use that they added to the devices' labeling. This fact alone disposes of Defendants' First Amendment motions.

IV. Defendants Had No First Amendment Right to Defraud the United States

Even if the First Amendment permits Defendants to introduce misbranded and adulterated devices into interstate commerce (which it does not), Defendants make no attempt to explain how the First Amendment would require dismissal of the charge of conspiracy to defraud the United States. None of the cases Defendants rely upon involve efforts to defraud the United States. *See United States v. Harkonen*, 510 Fed. Appx. 633, 636 (9th Cir. 2013) ("The First Amendment does not protect fraudulent speech . . . ."); *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1123 (D.C. Cir. 2009) ("Of course, it is well settled that the First

Amendment does not protect [wire] fraud.") (citing *McIntyre v. Ohio Elections Comm'n,* 514 U.S. 334, 357 (1995)). This warrants denial of Defendants' motions.

V. Defendants Are Not Entitled to an *In Limine* Ruling Barring Evidentiary Use of Speech

Defendants argue in the alternative for an *in limine* ruling barring the United States "from relying on truthful speech to prove its case at trial." Docket No. 80 at 33. Defendant's argument for such a broad, unrestricted prohibition is not supported by any of the cases Defendants cite. Controlling precedent allows for the use of truthful speech in establishing intent and demonstrating overt acts.

For example, in *Wisconsin v. Mitchell*, a criminal defendant's sentence was enhanced on the ground that his actions were racially motivated, and the government proved his racial animus by introducing evidence of his speech. 508 U.S.at 479. The Supreme Court unanimously rejected the defendant's claim that this was error, holding categorically that "[t]he First Amendment . . . does not prohibit the evidentiary use of speech to establish the elements of a crime *or to prove motive or intent*." *Id*. at 489 (emphasis added).

Evidentiary use of a party's speech to draw inferences about the party's intent is routinely approved in this Circuit. *See, e.g.*, *United State*s *v. Cannon*, 750 F.3d 492, 508 (5th Cir. 2014) (affirming admission of defendant's comments to show intent in hate-crime prosecution); *United States v. Jefferson*, 751 F.3d 314, 320 n.5 (5th Cir. 2014) (affirming admission of defendant's tape-recorded statements to prove her intent to retaliate against housing authority employees and rejecting her First Amendment argument); *Palasota v. Haggar Clothing Co.*, 342 F.3d 569, 577

(5th Cir. 2003) (citing comments in company memorandum and comments made by corporate managers as evidence of employer's intent to discriminate based on age); *United States v. Barlow*, 17 F.3d 85, 88 (5th Cir. 1994) (intent to abandon property "may be inferred from words spoken, acts done, and other objective facts").[10]

The same principle applies in FDCA cases, where courts consistently hold that evidentiary use of speech does not violate the First Amendment. *See, e.g.*, *Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004); *United States v. Caputo*, 517 F.3d 935, 940-41 (7th Cir. 2008)[11]; *United States v. Article of Drug Designated B-Complex Cholinos Capsules*, 362 F.2d 923, 927 (3d Cir. 1966); *United States v. Cole*, No. 3:13-CV-01606-SI, 2015 WL 471594, at *4 (D. Or. Feb. 5, 2015); *United States v. Livdahl*, 459 F. Supp. 2d 1255, 1267-68 (S.D. Fla. 2005); *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 579-80 (D.N.J. 2004). *See Amarin*, 2015 WL 4720039, at *27 ("The government is of course correct that truthful speech can serve as evidence of intent."; "A manufacturer that engages in non-communicative activities to promote off-label use cannot use the First Amendment as a shield.").

The D.C. Circuit's decision in *Whitaker v. Thompson* is instructive. 353 F.3d at 947. There the FDA determined that a particular dietary supplement could not

[10] *See also United States v. Pierce*, 85 F.3d 832, 841 (2d Cir. 2015) (use of defendant's rap lyrics as evidence of motive in RICO case did not violate First Amendment because "here the speech is not 'itself the proscribed conduct.'" (quoting *Caronia*, 703 F.3d at 161)); *United States v. Kaziu*, 559 Fed. App'x 32, 35-36 (2d Cir. 2014) (upholding evidentiary use of defendant's radical political beliefs to prove intent because the First Amendment does not "prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent" (quoting *Mitchell*, 508 U.S. at 489)).

[11] The indictment charged Caputo both with distributing adulterated and misbranded medical devices based on the failure to obtain either premarket approval or 510(k) clearance for a new and physically different version of a device, intended for broader use, than the device that had previously been cleared by FDA. These are the same charges the government brings in this case. *See United States. v. Caputo*, 288 F. Supp. 2d 912, 915-16 (N.D. Ill. 2003). The court in *Caputo* also refused to dismiss the indictment on First Amendment grounds. *Id.* at 922.

be marketed without FDA approval because the manufacturer's proposed claims demonstrated that the product was intended to treat a disease and therefore meant that the product was a "drug" within the meaning of the FDCA. *Id.* at 948-49. The court determined that the manufacturer had no constitutional right to make its proposed claims, holding that the "use of speech to infer intent, which in turn renders an otherwise permissible act unlawful, is constitutionally valid" and hence "it is constitutionally permissible for the FDA to use speech [by the manufacturer] . . . to infer intent for purposes of determining that [the manufacturer's] proposed sale . . . would constitute the forbidden sale of an unapproved drug." *Id.* at 953.[12]

Moreover, corporate documents, such as the "Tips for Treating Perforator Veins" marketing document (*supra* Stmnt of Facts, at 14), are routinely used as evidence against corporations and their officers to establish intent without raising First Amendment concerns. *See Coffel v. Stryker Corp.*, 284 F.3d 625, 634-35 (5th Cir. 2002) (internal corporate planning documents, including new commission program for sales managers, cited as evidence of corporation's fraudulent intent).[13]

Finally, truthful speech can also establish overt acts of the conspiracy. *See supra* Sect. I.A., at 21-25. It is well-established that an overt act in furtherance of a

[12] As set forth throughout this brief, the United States does not intend to use any truthful promotional speech to doctors to prove intent. Nevertheless, these cases show that Defendants' alternative *in limine* motion should be rejected.

[13] *See also United States v. Vernon*, 723 F.3d 1234, 1256-59 (11th Cir. 2013) (finding ample evidence that CFO acted willfully in violating the Anti-Kickback statute, based on corporate emails, charts, and compliance plan); *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1118-19 (D.C. Cir. 2009) (citing internal corporation communications, such as research studies, memoranda and strategy documents, as evidence that corporate officers knew their statements to the public were false and possessed intent to defraud).

conspiracy can be a lawful act. *See Archbold-Newball*, 554 F.2d at 684 (quoting *Yates*, 354 U.S., at 334); *Direct Sales Co.*, 319 U.S. at 714-15.

The law does not support Defendants' novel effort to use the First Amendment to prevent the jury from considering incriminating evidence. Defendants' request for an *in limine* ruling should be denied.

CONCLUSION

The Court should deny Defendants' motions to dismiss the indictment based on the First Amendment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing United States' Response to Defendant's Motions to Dismiss the Indictment Based on the First Amendment, 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 DENYING DEFENDANTS' MOTIONS TO DISMISS THE INDICTMENT BASED ON THE FIRST AMENDMENT

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' Motions to Dismiss the Indictment Based on the First Amendment is hereby DENIED.

It is so ORDERED.

Signed this _____ day of _____, 2015.

_____
FRED BIERY
CHIEF UNITED STATES DISTRICT JUDGE