UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA	§	CRIMINAL NO.
	§	
Plaintiff	§	INDICTMENT
	§	
V.	§	VIOLATIONS:
	§	18 U.S.C. § 1623 (Perjury – 5 counts)
GLEN HOLDEN,	§	18 U.S.C. § 1503 (Obstruction – 1 count)
	§	
Defendant.	§	

SA14CR0927DAE

THE GRAND JURY CHARGES:

INTRODUCTION

At all times relevant to this indictment:

I. THE DEFENDANT

1. Defendant GLEN HOLDEN was an "account manager" or sales representative at a corporation named Vascular Solutions, Inc. ("VSI"). VSI sold medical devices throughout the United States, including in the Western District of Texas.

II. THE MEDICAL DEVICE INVESTIGATION

2. HOLDEN testified before a federal grand jury on July 17, 2013. The grand jury was investigating whether VSI had distributed in interstate commerce medical devices for an intended use that had not been approved by the Food and Drug Administration (FDA), in violation of the Food, Drug and Cosmetic Act (21 U.S.C. §§ 301-397, the "FDCA")

A. The Vari-Lase System and Its FDA Approved Use

3. The devices at issue were from the VSI product line hereafter referred to as the Vari-Lase System. The Vari-Lase System included the laser console, needles, fibers, sheaths, and other accessories needed to treat incompetent veins (sometimes referred to as varicose veins) with laser energy. This process used heat to shut incompetent veins permanently, allowing the

body to recruit healthier veins to move the blood. Vari-Lase System accessories were available individually, and were also packaged into procedure kits. The kits generally contained fibers and sheaths, as well as introducer needles, which doctors used to puncture the skin and introduce the sheath into the vein.

4. In 2005, VSI received approval from the FDA to sell the Vari-Lase System solely for treatment of superficial veins and began selling the system throughout the United States.

5. The Vari-Lase System was not approved for treatment of perforator veins, which are small, twisting veins that connect the superficial vein system to the deep vein system. Treating perforator veins with lasers was more difficult and posed greater risks than treating superficial veins.

6. Because Vari-Lase System did not have FDA approval for perforator use, it could not legally sell the system in the United States for that purpose. However, the FDCA did not prohibit doctors, in the exercise of medical judgment, from using medical devices for unapproved uses. This meant that VSI would not be charged with violating the FDCA if it sold the Vari-Lase System for intended use on superficial veins and doctors later decided independently to use the system on perforator veins. However, VSI could not sell the Vari-Lase System in interstate commerce with the intent that those devices be used for unapproved perforator treatment.

B. VSI's Failure to Get Perforator Approval and the FDA Warning

7. In 2007 VSI was planning to launch a special "short kit" designed to make the Vari-Lase System easier to use on perforator veins. In June 2007, VSI sought approval from the FDA to market the Vari-Lase system for perforator use. The FDA did not grant the application because it had concerns about whether using lasers to treat perforator veins was safe and

effective. In September 2007 the FDA requested data from VSI showing that the Vari-Lase system could safely and effectively treat perforator veins.

8. VSI responded to the lack of perforator approval by launching the short kit in October 2007 for "short vein segments," a term it did not define.

9. At the same time, VSI sponsored a clinical trial to prove that the Vari-Lase system could safely and effectively treat perforator veins. That trial, which ended in 2008, failed to produce adequate evidence of safety and effectiveness. As to safety, 14% of the patients in the trial experienced a "major adverse event" involving deep vein thrombosis (DVT), a blood clot in a deep vein that can lead to potentially life-threatening pulmonary embolisms. The Vari-Lase was less effective than VSI had hoped at accomplishing its intended purpose of closing incompetent veins. The percentage of perforators that were still closed after six months (the "closure rate") was 69.7%, much lower than expected.

10. In March 2008, as the clinical trial was coming to an end, the FDA informed VSI that based on the lack of response to its earlier request for data, the FDA "now considered [VSI's application] to be withdrawn." The FDA's letter warned: "If you market the device without FDA clearance/approval, you will be in violation of the [FDCA]."

11. VSI never renewed its application because of the disappointing results of the clinical trial. In October 2009, VSI ultimately informed its Board of Directors that "Clinical data for the [Vari-Lase System] Perforator Vein indication was not adequate to support [FDA] clearance, so there will be no [FDA application] submitted."

C. VSI's Sales for Unapproved Perforator Use and Holden's Role

12. Despite the failure to get approval and the FDA's warning, VSI intentionally sold the Vari-Lase system for unapproved perforator use from early 2007 until at least May 2014.

13. As a member of the sales force and the company's top salesperson for several years, HOLDEN participated in the perforator sales campaign, with the knowledge and approval of VSI management.

14. HOLDEN knew that intentionally selling a medical device for an unapproved use was illegal.

III. HOLDEN'S GRAND JURY TESTIMONY

15. On July 17, 2013, Holden gave false and evasive testimony in an effort to mislead the grand jury and conceal the fact that he and VSI had intentionally sold the Vari-Lase System for unapproved perforator use.

Statement 1
(falsely denying efforts to increase business by selling for perforator use)

16. On many occasions, HOLDEN tried to increase his sales by selling the Vari-Lase short kit for use on perforators. He falsely denied this fact in the underlined portion of the following testimony:

> Q. Okay. Did you try to increase VSI's sales by selling the Short Kit for use on perforators?
>
> A. Not for use on perforators. I try to increase VSI's sales on every product I have, but it's not for a specific – not for a specific – specific perforator treatment with that kit. No. Short vein segments.

Statement 2
(false and evasive testimony about perforator sales efforts documented in trip report)

17. In a Field Trip Report dated August 10, 2008, HOLDEN described a visit to an account that he made jointly with a sales rep from another company: "I did an inservice with ["A" Company] rep. The combination of laser o[n] perforators and ["A" Company 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."

18. Even after reading this portion of his trip report, HOLDEN falsely denied, in the underlined excerpts below, that he was trying to increase business during this visit involving the use of Vari-Lase equipment to treat perforators. In addition, HOLDEN gave evasive and non-responsive testimony in the italicized excerpts below for the purpose of misleading the grand jury and concealing the truth.

Q. So this inservice involving the treatment of lasers with – or perforators with [VSI's] laser was a means of increasing business for you?

A. *This – this is an inservice on this particular site that treat the perforators with laser in some cases, or, again, they use RF and sclero. But the physician here is showing great results by treating a perforator with a laser, following up with ["A" Company product], in healing non-healing ulcers that have been in a patient's leg for over a year and getting great results within three months recovery time. That's what we were presenting.*

Q. Can you answer the question I asked you?

A. Okay. What's the question again?

Q. You're – you're at an inservice –

A. Correct

Q. – where your device is being used to treat perforator veins and that was a means to increase business.

A. *It's a – it's a means to heal a patient population that needs help. Sometimes it's with laser. Sometimes with RF. Sometimes sclerotherapy.*

Q. So –

A. *The laser's not the only modality to treat that. I just presented some findings that they had in this particular account.*

Q. So is the answer to my question a no, then? You weren't trying to increase business?

A. No. I – I would say I'm trying to help the patient population. That's first and foremost. That's – that's my job.

Q. Can you answer my question yes or no, if you can?

A. No.

Q. So the answer to my question is no or you can't answer it yes or no?

A. Oh, the answer is – is no. It's not to increase my laser sales.

Statement 3
("I don't target a specific vein")

19. Consistent with the false statements quoted above, HOLDEN testified falsely that he did not sell the short kit for any specific use in the underlined portions below.

Q. You call on doctors?

A. Correct.

Q. You try to sell them medical equipment?

A. Correct.

Q. Okay. So in that sense of you're trying to sell medical equipment, did the company ever tell you look, we're not approved for perforators so don't try to sell it to doctors for that?

A. No. Again, they don't target a specific vein. We sell the kit. And I present all of our seven kits and then it's up to the doctor to choose which one he wants to use and where. I don't target a specific vein to treat a specific – to use with that kit.

Statement 4
("I don't push our products for a specific use")

20. When asked about a July 2007 VSI presentation to its sales force, HOLDEN again testified falsely that he did not sell Vari-Lase products for a specific use in the underlined excerpt below.

Q. The next slide talks about VSI's response to RFS [a competitor's perforator product]

A. Uh-huh.

Q. Do you see those bullets there? Is what the company's doing in this presentation is – it's telling you how to respond to the competitor's device for perforators that was just launched into the market. Is that how you read that?

A. No, I read that as just telling me that this product isn't designed well for that application.

Q. Oh, so this isn't something that you're gonna go out and tell doctors?

A. I don't – I – the doctors, again, come to me when they want to use a certain product. I don't – I don't push our products for a specific use. I tell them what catheters we have and it's up to them whether they use them.

Statement 5
(evasive testimony concerning the targeting of perforator doctors)

21. In addition to the false testimony detailed above, HOLDEN gave evasive and non-responsive testimony when presented with evidence documenting VSI's and HOLDEN's perforator sales efforts.

22. At its January 2008 National Sales Meeting, VSI management gave a presentation to the sales force, including HOLDEN. On a slide titled "Selling the Short Kit," management instructed the sales force to "Target experienced laser MD's – perforators are NOT for beginners." The slide further instructed the sales force to "Target laser owners who also use RF for perforators." In the italicized excerpts below, HOLDEN gave evasive and non-responsive testimony about this slide in order to mislead the grand jury and avoid admitting that VSI had instructed him and others to target perforator doctors.

Q. The way you read these slides is your company telling you to sell the Short Kit for perforator veins?

A. *For me they're still harping on selling it for short vein segments. They do mention the perforators in that.*

Q. Yeah, twice.

A. Twice on this slide.

Q. Right. So they're telling you go out and sell this for perforators. That's what the slide's talking about.

A. *They – they're saying target the physicians. So what you would do is present a Short – if they're treating with RF or with another laser, you present your kit as a Short Kit. Again, it's up to the physician –*

Q. Right.

A. *– at that point to use whatever he'd like to use. But if the they're already treating a perforator with a short RF kit –*

Q. Yeah.

A. *Then they –*

Q. Right. So –

A. *– may be interested in a laser for that.*

Statement 6
(evasive testimony concerning promoting the short kit)

23. When presented with an email from his regional manager discussing perforator sales strategy, HOLDEN gave evasive and non-responsive testimony in the italicized excerpts below for the purpose of misleading the grand jury and concealing that he had promoted the short kit for unapproved perforator use.

Q. Okay. Your [regional sales manager] writes to you on the second line: I have high hopes that a day on perfs with them will open the door to that procedure for new business and more down the road.

A. Uh-huh.

Q. So on this call that [your manager is] writing about, were you trying to increase sales by promoting the Short Kit?

A. *Well, if you probably go back on this string of e-mails for the meeting with the doctors, they called me in to discuss what I can offer in laser kits to treat certain veins. I don't initiate a call to treat a vein with – a perf, you know, to treat a perforator with a specific kit. But they'll ask me what we have to treat a certain situation that they're looking for.*

And I – I don't recall the meeting with the physician. Again, that was years ago, but I'm sure they have asked me what I have for that specific case.

Statement 7
(evasive testimony concerning selling short kit for perforator use)

24. In a March 2010 email to VSI's CEO and Vice President of Sales Operations,

HOLDEN's regional manager praised him for his perforator sales efforts at an account. The regional manager described how HOLDEN "got into a good discussion 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." HOLDEN's manager concluded, "This was a great call by Glen and I believe the many, many months of calling on this group and being persistent and helpful in the right way will pay off for him once he does perf cases with them!!"

25. HOLDEN gave evasive and non-responsive testimony about this email in the italicized excerpts below, for the purpose of misleading the grand jury and concealing that he had promoted the short kit for perforator use.

Q. And what's happening in this segment is that you're trying to sell the kit to these doctors for use in perforators; right?

A. *I showed – if you read that there, you get into a discussion on treating perforators. And then I – I had showed them our Short Kit and they wanted further discussion on that.*

Statement 8
(evasive testimony concerning HOLDEN'S description of a "perforator specific" kit)

26. After denying that he had sold Vari-Lase products for perforator use or pushed products for any specific vein, as set forth in Statements 1-5 above, HOLDEN was asked about a June 2011 email in which he informed a health care provider that VSI sold a "short perforator specific" kit. HOLDEN gave evasive and non-responsive testimony in the italicized excerpts below for the purpose of misleading the grand jury and concealing that he had sold the short kit specifically for perforator veins.

Q. So is this an example of you telling an account that you've got a perforator specific kit for them to use?

* * *

Q. Do you remember the question that was pending when you left the room?

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

You know, I'm trying to explain that we have everything for a Short Kit all the way up to 100 centimeter kit. I assume they're used for perforator cases and I assume they're used for others. But I mentioned perforator in this – in this particular instance.

* * *

A. Yeah. *Obviously – obviously, it's a poor choice of words.*

Statement 9
(falsely denying knowledge of Medicare reimbursement rule)

27. The grand jury was also investigating whether VSI and its employees caused doctors to submit false claims to Medicare. Specifically, the grand jury was considering whether the VSI sales force encouraged doctors to conceal that they had treated perforator veins when they billed Medicare for laser perforator procedures. These procedures were not eligible for reimbursement from Medicare and a number of private insurers because they involve unapproved devices.

28. In an October 2011 email, an VSI salesperson asked HOLDEN if doctors were able to "bill for any Perf work." HOLDEN replied, "Can't bill for perfs. Not approved." The salesperson responded, "Text me what they call them then." In a phone call, HOLDEN advised him to use the term "short vein" instead of perforator. This would help doctors get paid by preventing Medicare or other insurers from learning that they were being billed for unapproved perforator procedures.

29. As shown in the email exchange above, HOLDEN knew that Medicare typically does not pay for procedures involving unapproved devices. HOLDEN falsely denied any knowledge of this policy in the following underlined excerpt.

Q. Have you ever heard of a Medicare rule that says that you can't – as a doctor, you can't get paid, usually, for using a device in an unapproved way?

A. I don't know that.

Q. You've never heard of that –

A. Never.

Q. – in all your years in the medical device industry?

A. No. Never heard of that.

Q. That's never come up when doctors ask you can I get paid for using this or that?

A. Not that I know of. It's never come up.

COUNT ONE
[18 U.S.C. § 1623 – perjury, Statement 1]

30. The allegations of paragraphs 1 through 29 are realleged as if fully set forth here.

31. On or about July 17, 2013, in the Western District of Texas, Defendant

GLEN HOLDEN

while under oath and testifying in a proceeding before a Grand Jury of the United States, knowingly did make a false material declaration as set forth in Statement 1 above.

All in violation of Title 18, United States Code, Section 1623.

COUNT TWO
[18 U.S.C. § 1623 – perjury, Statement 2]

32. The allegations of paragraphs 1 through 29 are realleged as if fully set forth here.

33. On or about July 17, 2013, in the Western District of Texas, Defendant

GLEN HOLDEN,

while under oath and testifying in a proceeding before a Grand Jury of the United States, knowingly did make a false material declaration as set forth in Statement 2 above.

All in violation of Title 18, United States Code, Section 1623.

COUNT THREE
[18 U.S.C. § 1623 – perjury, Statement 3]

34. The allegations of paragraphs 1 through 29 are realleged as if fully set forth here.

35. On or about July 17, 2013, in the Western District of Texas, Defendant

GLEN HOLDEN

while under oath and testifying in a proceeding before a Grand Jury of the United States, knowingly did make a false material declaration as set forth in Statement 3 above.

All in violation of Title 18, United States Code, Section 1623.

COUNT FOUR
[18 U.S.C. § 1623 – perjury, Statement 4]

36. The allegations of paragraphs 1 through 29 are realleged as if fully set forth here.

37. On or about July 17, 2013, in the Western District of Texas, Defendant

GLEN HOLDEN

while under oath and testifying in a proceeding before a Grand Jury of the United States, knowingly did make a false material declaration as set forth in Statement 4 above.

All in violation of Title 18, United States Code, Section 1623.

COUNT FIVE
[18 U.S.C. § 1623 – perjury, Statement 9]

38. The allegations of paragraphs 1 through 29 are realleged as if fully set forth here.

39. On or about July 17, 2013, in the Western District of Texas, Defendant

GLEN HOLDEN

while under oath and testifying in a proceeding before a Grand Jury of the United States, knowingly did make a false material declaration as set forth in Statement 9 above.

All in violation of Title 18, United States Code, Section 1623.

COUNT SIX

[18 U.S.C. § 1503 – obstruction of justice, Statements 1-9]

40. The allegations of paragraphs 1 through 29 are realleged as if fully set forth here.

41. On or about July 17, 2013, in the Western District of Texas, Defendant

GLEN HOLDEN

did corruptly endeavor to influence, obstruct, and impede the due administration of justice in that HOLDEN did knowingly and willfully make false, evasive and misleading declarations, as set forth in Statements 1-9 above, before the Grand Jury with intent to obstruct and impede the Grand Jury investigation.

All in violation of Title 18, United States Code, Section 1503.

A TRUE BILL.

[redacted]

FOREPERSON OF THE GRAND JURY

ROBERT PITMAN
UNITED STATES ATTORNEY

BY: _____
BUD PAULISSEN
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_____
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