UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF TEXAS

SAN ANTONIO DIVISION

UNITED STATES OF AMERICA	§	
	§	
Plaintiff	§	
	§	
V.	§	CRIMINAL NO. SA:14-CR-926-RCL
	§	
VASCULAR SOLUTIONS, INC.	§	
HOWARD C. ROOT	§	
	§	
Defendants.	§	

PROPOSED JURY INSTRUCTIONS

The UNITED STATES OF AMERICA, by Richard Durbin, Jr., United States Attorney for the Western District of Texas, respectfully submits the following proposed jury instructions.

Respectfully submitted,

Richard L. Durbin, Jr.
United States Attorney

By: _____
for Bud Paulissen

INTRODUCTION TO FINAL INSTRUCTIONS

Members of the Jury:

In any jury trial there are, in effect, two judges. I am one of the judges; the other is the jury. It is my duty to preside over the trial and to decide what evidence is proper for your consideration. It is also my duty at the end of the trial to explain to you the rules of law that you must follow and apply in arriving at your verdict.

First, I will give you some general instructions which apply in every case, for example, instructions about burden of proof and how to judge the believability of witnesses. Then I will give you some specific rules of law about this particular case, and finally I will explain to you the procedures you should follow in your deliberations.[1]

[1] Pattern Jury Instructions, Fifth Circuit, Number 1.03.

DUTY TO FOLLOW INSTRUCTIONS

You, as jurors, are the judges of the facts. But in determining what actually happened—that is, in reaching your decision as to the facts—it is your sworn duty to follow all of the rules of law as I explain them to you.

You have no right to disregard or give special attention to any one instruction, or to question the wisdom or correctness of any rule I may state to you. You must not substitute or follow your own notion or opinion as to what the law is or ought to be. It is your duty to apply the law as I explain it to you, regardless of the consequences.

It is also your duty to base your verdict solely upon the evidence, without prejudice or sympathy. That was the promise you made and the oath you took before being accepted by the parties as jurors, and they have the right to expect nothing less.[2]

[2] Pattern Jury Instructions, Fifth Circuit, Number 1.04.

PRESUMPTION OF INNOCENCE, BURDEN OF PROOF, REASONABLE DOUBT

The indictment or formal charge against a defendant is not evidence of guilt. Indeed, the defendant is presumed by the law to be innocent. The defendant begins with a clean slate. The law does not require a defendant to prove his innocence or produce any evidence at all [and no inference whatever may be drawn from the election of a defendant not to testify].

The government has the burden of proving the defendant guilty beyond a reasonable doubt, and if it fails to do so, you must acquit the defendant. While the government's burden of proof is a strict or heavy burden, it is not necessary that the defendant's guilt be proved beyond all possible doubt. It is only required that the government's proof exclude any "reasonable doubt" concerning the defendant's guilt.

A "reasonable doubt" is a doubt based upon reason and common sense after careful and impartial consideration of all the evidence in the case. Proof beyond a reasonable doubt, therefore, is proof of such a convincing character that you would be willing to rely and act upon

it without hesitation in making the most important decisions of your own affairs.[3]

[3] Pattern Jury Instructions, Fifth Circuit, Number 1.05

EVIDENCE—EXCLUDING WHAT IS NOT EVIDENCE

As I told you earlier, it is your duty to determine the facts. To do so, you must consider only the evidence presented during the trial. Evidence is the sworn testimony of the witnesses, including stipulations, and the exhibits. The questions, statements, objections, and arguments made by the lawyers are not evidence.

The function of the lawyers is to point out those things that are most significant or most helpful to their side of the case, and in so doing to call your attention to certain facts or inferences that might otherwise escape your notice. In the final analysis, however, it is your own recollection and interpretation of the evidence that controls in the case. What the lawyers say is not binding upon you.

During the trial I sustained objections to certain questions and exhibits. You must disregard those questions and exhibits entirely. Do not speculate as to what the witness would have said if permitted to answer the question or as to the contents of an exhibit. Also, if certain testimony or evidence has been ordered removed from the record and you have been instructed to disregard this evidence do not consider that testimony or other evidence which has been removed from your consideration in reaching your decision. Your verdict must be based solely on the legally admissible evidence and testimony.

Also, do not assume from anything I may have done or said during the trial that I have any opinion concerning any of the issues in this case. Except for the instructions to you on the law, you should disregard anything I may have said during the trial in arriving at your own

verdict.[4]

EVIDENCE—INFERENCES—DIRECT AND CIRCUMSTANTIAL

In considering the evidence, you are permitted to draw such reasonable inferences from the testimony and exhibits as you feel are justified in the light of common experience. In other words, you may make deductions and reach conclusions that reason and common sense lead you to draw from the facts which have been established by the evidence.

Do not be concerned about whether evidence is "direct evidence" or "circumstantial evidence." You should consider and weigh all of the evidence that was presented to you.

The law makes no distinction between the weight to be given either direct or circumstantial evidence. But the law requires that you, after weighing all of the evidence, whether direct or circumstantial, be convinced of the guilt of the defendant beyond a reasonable doubt before you can find the defendant guilty.[5]

[4] Pattern Jury Instructions, Fifth Circuit, Number 1.06
[5] Pattern Jury Instructions, Fifth Circuit, Number 1.07

CREDIBILITY OF WITNESSES

I remind you that it is your job to decide whether the government has proved the guilt of the defendant beyond a reasonable doubt. In doing so, you must consider all of the evidence. This does not mean, however, that you must accept all of the evidence as true or accurate.

You are the sole judges of the credibility or "believability" of each witness and the weight to be given to the witness's testimony. An important part of your job will be making judgments about the testimony of the witnesses [including the defendant] who testified in this case. You should decide whether you believe all, some part, or none of what each person had to say, and how important that testimony was. In making that decision I suggest that you ask yourself a few questions: Did the witness impress you as honest? Did the witness have any particular reason not to tell the truth? Did the witness have a personal interest in the outcome of the case? Did the witness have any relationship with either the government or the defense? Did the witness seem to have a good memory? Did the witness clearly see or hear the things about which he testified? Did the witness have the opportunity and ability to understand the questions clearly and answer them directly? Did the witness's testimony differ from the testimony of other witnesses? These are a few of the considerations that will help you determine the accuracy of what each witness said.

[IF THE DEFENDANT TESTIFIES: The testimony of the defendant should be weighed and his credibility evaluated in the same way as that of any other witness.]

Your job is to think about the testimony of each witness you have heard and decide how much you believe of what each witness had to say. In making up your mind and reaching a verdict, do not make any decisions simply because there were more witnesses on one side than

on the other. Do not reach a conclusion on a particular point just because there were more witnesses testifying for one side on that point. You will always bear in mind that the law never imposes upon a defendant in a criminal case the burden or duty of calling any witnesses or producing any evidence.[6]

[6] Pattern Jury Instructions, Fifth Circuit, Number 1.08

ACCOMPLICE—INFORMER—IMMUNITY

The testimony of an alleged accomplice, and/or the testimony of one who provides evidence against a defendant as an informer for pay, for immunity from punishment, or for personal advantage or vindication, must always be examined and weighed by the jury with greater care and caution than the testimony of ordinary witnesses. You, the jury, must decide whether the witness's testimony has been affected by these circumstances, by the witness's interest in the outcome of the case, by prejudice against the defendant, or by the benefits that the witness has received either financially or as a result of being immunized from prosecution.

You should keep in mind that such testimony is always to be received with caution and weighed with great care. You should never convict any defendant upon the unsupported testimony of such a witness unless you believe that testimony beyond a reasonable doubt.[7]

[7] Pattern Jury Instructions, Fifth Circuit, Number 1.14

ACCOMPLICE—CO-DEFENDANT—PLEA AGREEMENT

In this case the government called as one of its witnesses an alleged accomplice, with whom the government has entered into a plea agreement. Such plea bargaining, as it is called, has been approved as lawful and proper, and is expressly provided for in the rules of this court.

An alleged accomplice, including one who has entered into a plea agreement with the government, is not prohibited from testifying. On the contrary, the testimony of such a witness may alone be of sufficient weight to sustain a verdict of guilty. You should keep in mind that such testimony is always to be received with caution and weighed with great care. You should never convict a defendant upon the unsupported testimony of an alleged accomplice unless you believe that testimony beyond a reasonable doubt.

The fact that an accomplice has entered a plea of guilty to the offense charged is not evidence of the guilt of any other person.[8]

[8] Pattern Jury Instructions, Fifth Circuit, Number 1.15

EXPERT OPINION TESTIMONY

During the trial you heard the testimony of experts, who expressed opinions concerning various subjects. If scientific, technical, or other specialized knowledge assists you in understanding the evidence or in determining a fact in issue, a witness qualified by knowledge, skill, experience, training, or education may testify and state an opinion concerning such matters.

Merely because such a witness has expressed an opinion does not mean, however, that you must accept this opinion. You should judge such testimony like any other testimony. You may accept it or reject it and give it as much weight as you think it deserves, considering the witness's education and experience, the soundness of the reasons given for the opinion, and all other evidence in the case.[9]

[9] Pattern Jury Instructions, Fifth Circuit, Number 1.17

ON OR ABOUT

You will note that the indictment charges that the offense was committed on or about a specified date. The government does not have to prove that the crime was committed on that exact date, so long as the government proves beyond a reasonable doubt that the defendant committed the crime on a date reasonably near the date stated in the indictment.[10]

[10] Pattern Jury Instructions, Fifth Circuit, Number 1.18

CAUTION—CONSIDER ONLY CRIME CHARGED

You are here to decide whether the government has proved beyond a reasonable doubt that the defendant is guilty of the crime charged. The defendant is not on trial for any act, conduct, or offense not alleged in the indictment. Neither are you called upon to return a verdict as to the guilt of any other person or persons not on trial as a defendant in this case, except as you are otherwise instructed.[11]

[11] Pattern Jury Instructions, Fifth Circuit, Number 1.19

CAUTION—PUNISHMENT

If a defendant is found guilty, it will be my duty to decide what the punishment will be. You should not be concerned with punishment in any way. It should not enter your consideration or discussion.[12]

[12] Pattern Jury Instructions, Fifth Circuit, Number 1.20

DUTY TO DELIBERATE

To reach a verdict, whether it is guilty or not guilty, all of you must agree. Your verdict must be unanimous on each count of the indictment. Your deliberations will be secret. You will never have to explain your verdict to anyone.

It is your duty to consult with one another and to deliberate in an effort to reach agreement if you can do so. Each of you must decide the case for yourself, but only after an impartial consideration of the evidence with your fellow jurors. During your deliberations, do not hesitate to reexamine your own opinions and change your mind if convinced that you were wrong. But do not give up your honest beliefs as to the weight or effect of the evidence solely because the opinion of your fellow jurors, or for the mere purpose of returning a verdict.

Remember at all times, you are judges—judges of the facts. Your duty is to decide whether the government has proved the defendant guilty beyond a reasonable doubt.

When you go to the jury room, the first thing that you should do is select one of your number as your foreperson, who will help to guide your deliberations and will speak for you here in the courtroom.

A verdict form has been prepared for your convenience. [Explain verdict form.]

The foreperson will write the unanimous answer of the jury in the space provided for each count of the indictment, either guilty or not guilty. At the conclusion of your deliberations, the foreperson should date and sign the verdict.

If you need to communicate with me during your deliberations, the foreperson should write the message and give it to the court security officer. I will either reply in writing or bring

you back into the court to answer your message.

Bear in mind that you are never to reveal to any person, not even to the court, how the jury stands, numerically or otherwise, on any count of the indictment, until after you have reached a unanimous verdict.[13]

[13] Pattern Jury Instructions, Fifth Circuit, Number 1.24

CONSPIRACY TO COMMIT OFFENSE, DEFRAUD UNITED STATES

Title 18, United States Code, Section 371, makes it a crime for anyone to conspire with someone else to commit an offense against the laws of the United States or to defraud the United States or any agency thereof in any manner of for any purpose.

The defendants are charged with conspiring to introduce misbranded medical devices into interstate commerce and conspiring to defraud the United States by concealing their distribution of medical devices for unapproved use on perforator veins in order to impair and defeat the lawful function of the FDA and other law enforcement agencies.

The word "defraud" here is not limited to its ordinary meaning of cheating the government out of money or property; it also includes impairing, obstructing, defeating, or interfering with the lawful function of the government or one of its agencies by dishonest means.

A "conspiracy" is an agreement between two or more persons to join together to accomplish some unlawful purpose. It is a kind of "partnership in crime" in which each member becomes the agent of every other member.

For you to find each defendant guilty of this crime, you must be convinced that the government has proved each of the following beyond a reasonable doubt:

First: That the defendant and at least one other person made an agreement to commit at least one of the following crimes: (1) introducing misbranded devices into interstate commerce, as charged in the indictment, or (2) defrauding the United States, as charged in the indictment;

Second: That the defendant knew the unlawful purpose of the agreement and joined in it willfully, that is, with the intent to further the unlawful purpose; and

Third: That one of the conspirators during the existence of the conspiracy knowingly committed at least one of the overt acts described in the indictment, in order to accomplish some object or purpose of the conspiracy.

One may become a member of a conspiracy without knowing all the details of the unlawful scheme or the identities of all the other alleged conspirators. If a defendant understands the unlawful nature of a plan or scheme and knowingly and intentionally joins in that plan or scheme on one occasion, that is sufficient to convict him for conspiracy even though the defendant had not participated before and even though the defendant played only a minor part.

The government need not prove that the alleged conspirators entered into any formal agreement, nor that they directly stated between themselves all the details of the scheme. Similarly, the government need not prove that all of the details of the scheme alleged in the indictment were actually agreed upon or carried out. Nor must it prove that all of the persons alleged to have been members of the conspiracy were such, or that the alleged conspirators actually succeeded in accomplishing their unlawful objectives.

Mere presence at the scene of an event, even with knowledge that a crime is being committed, or the mere fact that certain persons may have associated with each other, and may have assembled together and discussed common aims and interests, does not necessarily establish proof of the existence of a conspiracy. Also, a person who has no knowledge of a

conspiracy, but who happens to act in a way which advances some purpose of a conspiracy, does not thereby become a conspirator.[14]

[14]Pattern Jury Instructions, Fifth Circuit, Numbers 2.15A and 2.15B; Docket No. 128 at 7-8 (Order denying Defendants' Motions to Dismiss) ("An indictment may allege in one count both a conspiracy to commit an offense against the United States and a conspiracy to defraud the United States.") (collecting cases).

CONSPIRATOR'S LIABILITY FOR SUBSTANTIVE COUNT

A conspirator is responsible for offenses committed by other conspirators if the conspirator was a member of the conspiracy when the offense was committed and if the offense was committed in furtherance of, or as a foreseeable consequence of, the conspiracy.

Therefore, if you have first found the defendant guilty of the conspiracy charged in Count One and if you find beyond a reasonable doubt that during the time the defendant was a member of that conspiracy, other conspirators committed the offenses in Counts Two through Five in furtherance of and as a foreseeable consequence of that conspiracy, then you may find the defendant guilty of Counts Two through Five, even though the defendant may not have participated in any of the acts which constitute the offenses described in Counts Two through Five.[15]

[15] Pattern Jury Instructions, Fifth Circuit, Number 2.17.

VENUE – CONSPIRACY

The events presented at trial happened in various places. There is no requirement that the entire conspiracy take place in the Western District of Texas, but in order for you to return a guilty verdict, the government must prove by a preponderance of the evidence that either the agreement or an overt act took place in this district, even if the defendant never set foot in the district. An overt act is an act performed to effect the object of a conspiracy, although it remains separate and distinct from the conspiracy itself. Though the overt act need not be of criminal nature, it must be done in furtherance of the object of the conspiracy.

Unlike the other elements of the offense, this is a fact that the government has to prove only by a preponderance of the evidence. This means the government has to convince you only that it is more likely than not that part of the conspiracy took place in the Western District of Texas. All other elements of the offense must be proved beyond a reasonable doubt. You are instructed that Austin and San Antonio are located in the Western District of Texas.[16]

[16] Pattern Jury Instructions, Fifth Circuit, Number 1.18A

THE FDCA

The Federal Food, Drug, and Cosmetic Act, also referred to as the FDCA, is the law that governs medical devices. Its purpose is to protect the public from potentially unsafe and ineffective medical products. The FDCA prohibits the introduction or causing the introduction into interstate commerce of misbranded medical devices.[17]

[17] 21 U.S.C. § 331(a) (prohibiting introduction into interstate commerce of misbranded devices); *United States v. An Article of Drug... Bacto-Unidisk...*, 394 U.S. 784, 798 (1969) ("overriding purpose" of the FDCA is "to protect the public health").

MISBRANDING – ELEMENTS

Counts Two through Five of the indictment charge the defendants with the introduction of a misbranded device into interstate commerce, a crime that is often referred to as "misbranding." In order to find the defendants guilty of misbranding, you must find the following elements beyond a reasonable doubt:

One: That the Vari-Lase products listed in Counts Two through Five were "devices";

Two: That those products were "misbranded";

Three: That the defendants caused those products to be introduced into interstate commerce.

I will define each of these elements in the instructions that follow.[18]

[18] *See* 21 U.S.C. §§ 331(a) (" The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any . . . device . . . that is . . . misbranded."); *United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750, 754 (6th Cir. 1999) ("To show a violation of § 331(a) . . ., the Government must prove: (1) Appellants' products are "devices" within the meaning of the FDCA; (2) the devices are adulterated or misbranded; and (3) the devices move in interstate commerce.")

MISBRANDING ELEMENTS – INTERSTATE COMMERCE

"Interstate commerce" means commerce between any state and any place outside of that state, including another state. The Vari-Lase products were introduced into interstate commerce if VSI distributed them across state lines.[19]

[19] 21 U.S.C. § 321(b)(1) ("The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof . . . .").

MISBRANDING ELEMENTS - DEVICE

A "device" is "an instrument, . . . machine, . . . or related article, including any component, part, or accessory, which is . . . intended for use . . . in . . . treat[ing] or prevent[ing] of disease" or is "intended to affect . . . [the] function[ing] of the [human] body . . . ."[20]

[20] *See* 21 U.S.C. § 321(h)(2) and (3) ((h) (full text: "(h) The term 'device' (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is— … (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and [new paragraph] which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.")

MISBRANDING ELEMENTS – MISBRANDED – TWO REASONS

The Indictment alleges that the Vari-Lase products were misbranded for two reasons. First, the Indictment alleges that Vari-Lase products were misbranded because VSI did not provide the FDA with a premarket notification (referred to as a "510(k) notification") as required by law before distributing the Vari-Lase in interstate commerce. Second, the Indictment alleges that the Vari-Lase products were misbranded because their labeling did not have adequate directions for use. You must find beyond a reasonable doubt that the Vari-Lase products were misbranded for at least one of these two reasons in order to find either defendant guilty of misbranding.

MISBRANDING ELEMENTS–MISBRANDED–FAILURE TO GIVE 510(k) NOTICE

According to the allegations in the Indictment, the first reason why the Vari-Lase products were misbranded is that VSI failed to provide the FDA with a 510(k) notification as required by law. A device is misbranded if the manufacturer was required to, but failed to provide, a 510(k) notification or information related to that notification as required by law before distributing the device.[21] When a device is already in commercial distribution but is about to be significantly changed in its design or intended use, the manufacturer must submit a new 510(k) notification to the FDA at least 90 days before the manufacturer introduces the modified device into interstate commerce. Significant changes that require a premarket notification include: (1) a change in the device that could significantly affect the safety or effectiveness of the device, or (2) a major change in the intended use of the device.[22]

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[21] **Misbranding based on failure to provide 510(k) notice or other information respecting it.** *See* 21 U.S.C. § 352(o) ("A drug or device shall be deemed to be misbranded – (o): … if a notice or other information respecting it was not provided as required by … section 360(k) [510(k)] of this title…."); 21 U.S.C. § 360(k) [510(k)] (titled "Report preceding introduction of devices into interstate commerce"; "Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the [FDA] … (in such form and manner as the Secretary shall by regulation prescribe)— (1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified ….").

[22] **510(k) required if major change is made.** *See* 21 C.F.R. § 807.81(a) (titled "When a premarket notification submission is required"; "Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:"), (a)(3) ("The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly

The 510(k) notification must include appropriate supporting evidence to show that the manufacturer has considered what consequences and effects the changes might have on the safety and effectiveness of the device. A 510(k) notification also must contain proposed labeling sufficient to describe the device, its intended use, and the directions for its use.

If a 510(k) notification does not contain sufficient information, the FDA may request additional information. If the additional information is not provided within 30 days of the request, the 510(k) notification is considered withdrawn.[23]

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changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification: (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. (ii) A major change or modification in the intended use of the device.").

[23] **Information required in the 510(k) notification, request for additional information, withdrawal for failure to provide.** *See* 21 C.F.R. § 807.87 (titled "Information required in a premarket notification submission"; "Each premarket notification submission shall contain the following information: ... (e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use.... (g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.... (l) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.").

MISBRANDING ELEMENTS – MISBRANDED – INADEQUATE DIRECTIONS

According to the allegations in the Indictment, the second reason why the Vari-Lase products were misbranded is because their labeling failed to provide adequate directions for use. A device is misbranded if the labeling contained in its packaging fails to bear adequate directions for use. "Adequate directions for use" means directions under which the layman can use a device safely and for the purposes for which it is intended.

Defendants claim that the Vari-Lase products are exempt from the "adequate directions" requirement under a legal exemption for certain prescription devices. To qualify for this exemption, Defendants must prove, by a preponderance of the evidence, that the labeling for the Vari-Lase products contained information for use, including methods of administration and any relevant hazards and precautions, under which a doctor can use the device safely and for the purpose for which it is intended.[24]

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[24] *See* 21 U.S.C. § 352(f)(1) ("A drug or device shall be deemed to be misbranded – … (f) Unless its labeling bears (1) adequate directions for use;"); 21 C.F.R. § 801.5 ("Adequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended…."); 21 C.F.R. § 801.109 ("Part 801 – LABELING" and "Subpart D – Exemptions From Adequate Directions for Use", entitled "Prescription devices"; "A device which … is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which 'adequate directions for use' cannot be prepared, shall be exempt from [§ 352(f)(1)] if all the following conditions are met: … (c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented."); *United States v. An Article of Device*, 731 F.2d 1253, 1261 (7th Cir. 1984) ("Adequate directions" means directions under which a layman can use the device safely, but the labeling regulations (quoted above) establish an exemption for prescription devices focusing on information that would allow a licensed practitioner to safely use the device. The defendant/appellant had the burden of meeting the requirements of the exemption.); *Articles of*

INTENDED USE

The Indictment alleges that perforator vein ablation was an intended use of the Vari-Lase products. The term "intended use" refers to the objective intent of VSI when it sold the devices. In determining intended use, you may consider, for example, the devices' labeling, oral or written statements by VSI or its representatives, the circumstances surrounding the distribution of the devices, or any other relevant source.[25] Further, a doctor's independent decision to use the Vari-Lase products to ablate perforator veins is not evidence of VSI's intended use for those products.

Device {Acuflex; Pro-Med}, 426 F. Supp. 366, 370 (W.D. Pa. 1977) (holding that directions for device were insufficient under 21 C.F.R. §§ 801.109(b)(2), (c), and (d)).

[25] *See* 21 C.F.R. § 801.4 ("The words *intended uses* or words of similar import … refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives."); Courts have repeatedly found that they may look to any relevant source to determine intended use. *See United States v. Article of 216 Cartoned Bottles, "Sudden Change,"* 409 F.2d 734, 739 (2d Cir.1969) ("It is well settled that the intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant source."); *V.E. Irons, Inc. v. United States*, 244 F.2d 34,44 (1st Cir. 1957); ("[I]t may be pointed out that we are free to look to all relevant sources in order of ascertain what is the 'intended use' of a drug, and are not merely confined to the labels on the drug or the 'labeling'"); *United States v. Travia*, 180 F.Supp.2d 115, 119 (D.D.C. 2001)(" 'It is well established 'that the intended use of a product, within the meaning of the [FDCA], is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source'").

UNAPPROVED USE BY DOCTORS

Doctors may use medical devices that have been approved or cleared for one use for a different use that has not been cleared or approved by the FDA. This is often referred to as unapproved use or off-label use. This is not illegal. It is also not a crime for a device company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device.[26]

[26] *See* 21 U.S.C. § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals."); Docket No. 128 at 5-6 (Order denying Defendants' motions to dismiss) (distinguishing *Caronia* and *Amarin Pharma* because those cases "held that the misbranding provisions of the FDCA did not prohibit off-label promotion of FDA-approved prescription

STRICT LIABILITY FOR MISBRANDING / RESPONSIBLE CORPORATE OFFICER

The United States is not required to prove that Defendants knew about or intended to commit the misbranding violations in Counts Two through Five. If Defendants caused the introduction into interstate commerce of misbranded devices, then they are guilty of misbranding.

In order to find that Defendant Howard Root caused a misbranding violation, you must find beyond a reasonable doubt that, by reason of his position in the corporation, he had the responsibility and authority either to prevent or promptly correct the violation, and that he failed to do so.[27]

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drugs that is solely truthful"; "The First Amendment does not protect off-label promotion that is false or misleading").

[27]*See* 21 U.S.C. § 333(a)(1) (statutory language does not require intent for misdemeanor violation); *United States v. Dotterweich*, 320 U.S. 277, 281 (1943) (the FDCA "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. And so it is clear that . . . the article may be misbranded (or adulterated) without any conscious fraud at all."); *United States v. Park*, 421 U.S. 658,673-74 (1975) ("Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so."); *and id.* at 669, 673-74 (the offense was committed 'by all who . . . have . . . a responsible share in the furtherance of the transaction which the statute outlaws'; criminal liability does not turn on 'awareness of some wrongdoing' or 'conscious fraud') (citing *Dotterweich*, 320 U.S. at 281, 284-85); *United States v. Watkins*, 278 F.3d 961, 964 (9th Cir. 2002) ("An article may be misbranded pursuant to the misdemeanor provision without any conscious fraud at all, thus creating a form of strict criminal liability.") (internal quotation marks omitted).

CORPORATE RESPONSIBILITY FOR ACTIONS OF CORPORATE AGENTS

One of the defendants, VSI, is a corporation. As a corporation, VSI can only act through its officers and employees. VSI is not automatically guilty of anything that its employees do. VSI is criminally responsible for the unlawful actions of its agents, who are acting with an intent to benefit the corporation, provided that the conduct is within the scope of the agent's authority, whether actual or apparent. A corporation may be criminally responsible even if there is no actual benefit to the corporation.

Actual authority means that the corporation's management authorized the action. Apparent authority is authority that outsiders would normally assume the agent to have, judging from his position with the company and the circumstances surrounding his past conduct. If the agent's action benefits the corporation, this is a relevant fact that can support a finding of apparent authority.

A corporation can be criminally responsible even for the actions of a low-level employee, if the employee acted with actual or apparent authority. A corporation can be responsible for the criminal actions of an employee even if there is a general corporate policy prohibiting the conduct, if the employee acted with actual or apparent authority.[28]

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[28] *See Standard Oil Co. v. United States*, 307 F.2d 120, 127 (5th Cir. 1962) ("[T]he corporation may be criminally bound by acts of subordinate, even menial employees," who are acting with intent to benefit the corporation/employer, even if no benefit is actually accrued, and are acting within scope of employment/authority); *id.* (Employee's violation of instructions given by the corporation does not shield corporation from criminal responsibility for actions which its agents have taken for its benefit.); *accord. United States v. Cadillac Overall Supply Co.*, 568 F.2d 1078, 1090 (5th Cir. 1978); *see also United States v Bi-Co Pavers, Inc.*, 741 F.2d 730, 737 (5th Cir. 1984) ("[A] corporation is criminally liable for the unlawful acts of its agents, provided that such conduct is within the scope of the agent's authority, *actual or apparent* . . . . Apparent authority is the authority which outsiders would normally assume the agent to have, judging

from his position with the company and the circumstances surrounding his past conduct.") (emphasis added); *United States v. Chon*, 713 F.3d 812, 820 (5th Cir. 2013) ("[A] corporation is criminally liable for the unlawful acts of its agents, provided that the conduct is within the scope of the agent's authority, whether actual or apparent.") (citation omitted).

CERTIFICATE OF SERVICE

This is to certify that on this 7th day of October, 2015, I filed the foregoing pleading using the CM/ECF system which will automatically serve a copy of the pleading upon counsel for defendants, and the current Attorneys representing the Government. These counsels are:

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