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VIA OVERNIGHT AND ELECTRONIC MAIL

CONFIDENTIAL

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Mr. Jonathan Olin
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The Honorable Robert Pitman
United States Attorney
For the Western District of Texas
U.S. Department of Justice
601 NW Loop 410, Suite 600
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Submitted Pursuant to Fed. R. Evid. 408

Re: Vascular Solutions, Inc.

Dear Ms. Branda and Messrs. Pitman and Olin:

On behalf of our client, Vascular Solutions, Inc. ("the Company"), we write to request that the Department of Justice decline federal criminal charges against the Company. We have been informed by the line attorneys from the Consumer Protection Branch and the U.S. Attorney's Office that they intend to present an indictment to a federal grand jury in the Western District of Texas that would charge the Company with conspiracy and substantive counts of felony and misdemeanor misbranding and adulteration under 21 U.S.C. § 331, and health-care fraud under 18 U.S.C. § 1347. These charges would relate to the alleged off-label promotion of the Vari-Lase Endovenous Laser Ablation Short Kit device (the "Short Kit") for use on varicose veins. In lieu of indictment, we have been given an offer for this publicly-traded Company and its chief executive officer to plead guilty to misdemeanor misbranding and adulteration charges. On September 19, 2014, we presented the line attorneys with the facts and the evidence that we

believe compel the conclusion that a federal criminal conviction is not warranted. As the line attorneys were unwilling to reconsider their decision, we respectfully seek your review of the matter.

To put things in perspective, neither the sales of the Short Kit nor the history of this small Minnesota company warrants a federal criminal conviction and its attendant consequences, as this case:

- Involves no harm or increased risk of harm to any patient.
- Involves a medical device that generated insignificant sales -- less than one-tenth of one percent of the Company's revenue over a seven-year period. The case involves only one version of just one of the Company's more than 80 products.
- Involves a device that generated equally insignificant compensation for the sales force -- less than one-tenth of one percent of their total compensation over a seven-year period. In fact, of $58 million that was paid to sales representatives as commission on all products over the relevant time, only $40,000 was paid for sales of the Short Kit. And only one sales representative was paid more than $1,000 in a calendar year in compensation related to the Short Kit.
- Involves a device that most sales representatives never sold – in fact, more than two-thirds of the sales representatives never sold even a single Short Kit.
- Involves a device that no longer is on the market -- although FDA never took any regulatory action with respect to the Short Kit, the Company voluntarily withdrew the product in July 2014.
- Involves a Company that has no prior regulatory or enforcement history -- and beginning almost immediately after the Company learned of the investigation has continually updated and enhanced its compliance program.
- Involves a small company for which any criminal prosecution -- even a misdemeanor -- could threaten the livelihoods of hundreds of employees.
- Could result in exclusion from the Medicare and Medicaid programs or removal of the CEO, co-founder, and inventor of the majority of the Company's products.

- And involves a matter that the Company and the Department already have resolved through the settlement of a civil case for $520,000, an amount that approximates the gross sales of the device over its seven-year life, regardless of whether the uses were on- or allegedly off-label, whether they were paid for by a federal healthcare program (fewer than 25% were), and whether the devices were actually covered by and correctly reimbursed.

In addition to these factors, which alone tilt the balance decidedly against prosecution, there are significant legal hurdles to securing a conviction. The government's misbranding and adulteration case turns on the faulty premise that the use of the device on perforator veins in the leg, rather than the adjacent saphenous veins in the leg, necessarily constitutes misbranding. But a device is misbranded only if the Instructions For Use are not adequate to address the alleged off-label use. In this case, because the treatment of both veins is so similar, the instructions and precautions on the labeling specifically addressed the necessary clinical procedure and precautions associated with both uses. As a result, the device was not misbranded. For the same reason, a separate 510(k) pre-market notification was not required. This closeness between the on- and allegedly off-label uses distinguishes this case from the more common off-label promotion prosecution, which involves a drug or device that was cleared for one purpose but was being promoted for something entirely different, requiring an entirely different set of instructions and precautions. During our presentation on September 19, 2014, the line attorneys candidly acknowledged that they had not considered the adequacy of the Instructions For Use – an essential element of their misbranding theory.

Nor does the evidence show intent to defraud, which is necessary to establish felony misbranding (and to skirt *Caronia*'s protection of truthful speech). Contrary to the government's theory, the Company promptly disclosed both the success rate and outcomes (which approximated the success rate and outcomes of a competitor's FDA-cleared product). And several private payors and Medicare Administrative Contractor jurisdictions *do* cover treatments of perforator veins. Given the flaws in the fraud theory, this case presents squarely the issue of truthful and non-misleading promotion.

Furthermore, the investigatory tactics in this case raise serious questions about the credibility of the investigatory conclusions. First, witnesses were threatened with perjury charges, and asked to change their testimony to conform to the government's theory. Moreover, grand jury subpoenas were used to induce witnesses to agree to private interviews with the government – without the tempering presence of their own individual counsel and the grand jury members. And witnesses were examined in a manner that calls into question the admissible, factual bases for the investigatory conclusions. As former Department of Justice officials, we appreciate the gravity of raising these issues. We do not do so lightly. But these methods are directly relevant to the factual and legal conclusions that were presented to us by the line attorneys, and merit serious consideration in connection with the prosecution decision.

The tactics employed in this case are mirrored by the Trial Attorney's response when undersigned counsel placed a courtesy call this afternoon to alert him that we would be submitting this letter. The Trial Attorney contended that the government had an agreement with prior company counsel that if the government advocated on behalf of the Company with respect to the decision of the Department of Health and Human Services ("HHS") to exclude the Company from participation in the Medicare and Medicaid programs, company counsel would not appeal the line attorneys' prosecution decision to higher level officials in the Department of Justice. He further asserted that in reliance on this agreement, the government had taken steps with respect to HHS, and he warned that submission of this letter would be to "go against that" agreement. He admonished that "we would not look positively" on the submission of this letter, and that "you should think about that." He concluded by warning that "we did something for you with the understanding that you wouldn't do this. Send the letter if you want, but if you do, it will be a mistake." We nevertheless submit the following information for your consideration.

The Company has and continues to be willing to enter into an appropriate resolution. But for the reasons discussed below, a criminal conviction would not service the interests of justice.

I. Vari-Lase® Endovenous Laser Ablation Devices

A. Background of the Company

Vascular Solutions is a publicly-traded corporation based in Minneapolis, Minnesota that develops and manufactures medical devices. Formed in 1997, and led by its co-founder and CEO Howard Root, the Company invented, developed and launched over 80 new medical devices in the past ten years. Its products generally comprise three types of devices: catheters, hemostats, and vein products, which are sold to cardiologists, radiologists, electro-physiologists, and vein practitioners. As of 2014, the Company employed 455 individuals, including about 350 employees in Minneapolis in manufacturing, research and development, marketing, regulatory, and administrative positions, along with 98 sales employees spread across the country.

Over 85% of the Company's sales derive from catheters and hemostats, such as the Langston catheter (the only catheter in the US to simultaneously measure pressure in the aorta and heart to measure aortic valve stenosis), and the Twin-Pass catheter (the only catheter in the US that offers two independent lumens in one coronary catheter). The remaining sales derive from a number of products to treat vein disease, only one version of which is at issue in this case.

B. The Vari-Lase® Product Line

The Company's vein product line features the Vari-Lase® Endovenous Laser Ablation devices (of which there are many) to treat varicose veins. Varicose veins are enlarged veins near the surface of the skin caused by inoperable valves that fail to prevent the pooling of blood (known as venous reflux). Healthy valves open to let blood flow one-way into the deep veins

inside the leg muscle compartment, and then close to prevent back-flow. Muscle contraction then pumps venous blood through the deep veins in the legs up to the heart. Unhealthy valves allow blood to flow backwards through the valves, causing the veins to enlarge, swell, and become "varicose." Varicosities appear in both the saphenous veins and in the perforator veins (which connect the saphenous veins to the deep veins inside the muscle compartment of the legs). Varicose veins can cause itching, aching, swelling, and in severe cases, inflamed skin and open sores.

The Vari-Lase® product line allows surgeons to treat varicose veins by closing veins with laser energy, a procedure known as "endovenous laser ablation." This product line consists of consoles, which generate the laser energy, and a variety of procedure kits that deliver the energy to the veins. Procedure kits include needles used to access the veins, laser fibers that carry the energy and sheaths that guide the laser fiber to the vein to be treated. The Company sells different accessory kits of various lengths, sizes, and dimensions.

FDA cleared the first Vari-Lase® kit in June 2003, and cleared a slightly revised indication for the kits in 2005. In this context, FDA clearance simply means that the agency determined that the device was "substantially equivalent" to a cleared, predicate device. In all, the Company has marketed many different Vari-Lase® procedure kits and accessories for "the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein, and for the treatment of incompetence and reflux of superficial veins in the lower extremity." *See* Exhibit 1 (K051287). In September 2007, the Company launched the Vari-Lase® Short Kit, the kit at issue in this case. It is basically the same as the other kits, except that it is shorter, making it easier to treat short vein segments. Short vein segments can include perforator veins and saphenous veins. The Short Kit is approved in 17 other countries for treatment of perforator veins; the US indication does not expressly mention perforator veins. Following the introduction of the Short Kit, the Vari-Lase® Instructions For Use were revised specifically to address the treatment of short vein segments.

Although it was understood at the Company that perforator treatment was "considered to fall within the above [FDA cleared] indication,"[1] it was also understood that because of the ambiguity of the applicable laws and regulations, failing to secure FDA clearance would risk getting crossways with the FDA, should the agency adopt a different view. As a result, in June 2007, the Company submitted a pre-market notification to FDA seeking to "*clarify* [that] the indications for use statements of the currently marketed Vari-Lase Endovenous Laser System" included the treatment of perforator veins.[2] Specifically, the Company sought to:

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[1]/ *See* Exhibit 2 (Letter dated July 2007 from VSI to IRB regarding clinical trial).

[2]/ *See* Exhibit 3.

> clarify the intent of the term 'superficial veins' through incorporation of the following language: The VARI-LASE Bright Tip Procedure kit (and Console) is indicated for the treatment of varicose veins and varicosities in the lower extremity that is associated with superficial venous incompetency and reflux in the Great Saphenous Vein, Short Saphenous Vein, and perforator and tributary veins.

The 510(k) submission outlined certain Instructions For Use specific to perforator veins, which were substantially the same as those that appear after the Short Kit was launched.

Three months later, in September 2007, FDA responded and requested that the Company provide six categories of information. Most of the questions were posed under the mistaken belief that the Vari-Lase® device was not already cleared and on the market. Among other things, the FDA asked that the Company "provide performance data for your system," which "can either be in vivo animal data comparing your system to the VNUS predicate system" or "clinical trial data demonstrat[ing] that your device can safely and effectively treat perforator and tributary veins."[3] FDA told the Company it had required clinical data of its competitor VNUS Medical Technologies Inc. ("VNUS") when that company added the perforator indication. In fact, FDA had *not* required VNUS to submit clinical data to add the perforator indication. Nonetheless, the Company embarked on a clinical study (discussed below) and the application was considered withdrawn pending completion of that study.

II. THE SHORT KIT WAS NOT "MISBRANDED"

A. BECAUSE THE CLEARED INDICATION FOR USE ENCOMPASSED THE TREATMENT OF PERFORATOR VEINS, A NEW 510(K) WAS NOT REQUIRED

The Food, Drug, and Cosmetic Act prohibits the introduction of a misbranded device in interstate commerce. *See* 21 U.S.C. § 331(a). A device can be misbranded if a required 510(k) pre-market notice is not made. *See* 21 U.S.C. § 360(k). With respect to a cleared device already in commercial distribution, such as the Short Kit, a premarket notification is required where the device "is about to be significantly changed or modified in ... intended use." *See* 21 C.F.R. §807.81(a)(3) (a significant change in intended use means a "major change or modification" in the intended use of the device).

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[3]/ *See* Exhibit 4.

In this case, there is no daylight between the plain language of the cleared indication for use and the treatment of perforator veins. The indication covers "the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein, and . . . the treatment of incompetence and reflux of superficial veins in the lower extremity." A reasonable interpretation of that language is that it encompasses the treatment of perforator veins, as long as the varicosities are associated with reflux in the adjacent vein.

The fact that the plain language of the clearance encompassed the treatment of perforator veins is supported by FDA's own actions in connection with the clearance of the VNUS device. VNUS marketed a device that uses radiofrequency energy rather than laser energy to treat veins (called radiofrequency ablation). Initially, the indication for the VNUS device did not refer specifically to the treatment of perforator veins, covering only "coagulation of blood vessels in patients with superficial vein reflux." In October 2005, VNUS sought and secured FDA clearance to expand this indication to include the treatment of perforator veins. In its 510(k) submission, VNUS cited as predicate devices its own cleared products, *which were not specifically cleared to treat perforator veins.* Applying the 510(k) criteria, FDA determined that the device for which it sought clearance to treat perforators was substantially equivalent to the predicate devices.[4] FDA concluded, with respect to the VNUS device, that the intended use for the treatment of perforator veins and other veins constituted "***the same intended use***." *See* 21 C.F.R. §807.100(b)(1)(emphasis added). The fact that FDA made this determination undermines the notion that Vascular Solutions was required to submit a 510(k) to specifically cover perforator treatment.

The fact that the Company sought to "clarify" that its existing indication encompassed the treatment of perforator veins does not change the analysis of whether the law required such a submission. As discussed above, most responsible device manufacturers defer to FDA's likely interpretation of the rules whenever any ambiguity exists. Here, erring on the side of caution, the Company sought "clarification" that the indication covered perforator treatment.

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[4]/ FDA will make such a determination only if the two devices have "the same intended use." *See* 21 C.F.R. § 807.100(b)(1). It necessarily follows that, in FDA's view, specific inclusion of the perforator indication did not constitute a change in the intended use of the device. *See* 21 C.F.R. § 807.81(a)(3). Because specifically adding the perforator treatment was not a change in the intended use (let alone a "significant change"), no 510(k) pre-market notification was required. Applying FDA's reasoning to the Vari-Lase® 510(k), even accepting that perforator treatment was an intended use, it would not constitute a "significant change," *see* 21 C.F.R. §807.81(a)(3), and, therefore, Vascular Solutions was not required to make a 510(k) pre-market notification submission.

B. The Device Labeling Reflected Adequate Instructions for Use

A device can also be misbranded if its labeling does not bear "adequate directions for use." *See* 21 U.S.C. § 352(f).[5] The government's theory turns on the faulty premise that the labeling did not bear adequate Instructions For Use.

When the Short Kit was launched in the fall of 2007, the Instructions For Use were *specifically revised* to detail complications, precautions and treatment procedures with respect to shorter vein segments.[6] For example, the revised IFU instructed that when "treating shorter vein segments, the VARI-LASE Bright Tip laser fiber should be exposed 1cm from the micro-introducer sheath and located a safe distance from the deep venous system." *Id.* Regarding the energy to be used, the IFU directed that "[w]hen treating shorter vein segments, the power setting of the Vari-Lase console can be lowered and speed of withdrawal slowed to deliver approximately 110 joules/cm." *Id.* The revised IFU further explained that "[w]hen treating shorter vein segments, the distal tip of the VARI-LASE Bright Tip laser fiber must maintain a safe distance from the deep venous system as confirmed by ultrasound visualization or fluoroscopy to protect from venous thrombus embolization." *Id.*

Coupled with the other information on the labeling, these precautions and instructions adequately explained the procedures for using the device on shorter vein segments, which would also be adequate for treatment of perforator veins, and the relevant hazards and precautions for doing so, under which physicians could use the device safely. *See* 21 C.F.R. §801.109(d). Consequently, under these circumstances, the device was not misbranded.

III. The Evidence Does Not Establish Fraud

Felony misbranding requires proof beyond a reasonable doubt that the Company committed the misbranding violation with "intend to defraud or mislead." *See* 21 U.S.C. § 333(2). As evidence of such intent, the government has advanced three theories: that the Company (1) overstated the success rate of the device, and understated the occurrence of adverse events, in the clinical study, (2) intended to defraud Medicare and private insurance companies by falsely claiming that perforator treatment was covered (which mirrors the health-care fraud theory), and (3) used the phrase "Short Kit" or "Short Vein" as code for perforators. The facts do not support these contentions.

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[5]/ Prescription devices such as the Vari-Lase® system need not display adequate directions for use, as long as the labeling "contains adequate information for such use ... and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented." See 21 C.F.R. § 801.109(d).

[6]/ *See* Exhibit 5 (6th IFU, *Vari-Lase Bright Tip Fiber. Endovenous Procedure Kit and Components* (October 2007, 42-0664-01 Rev F 10/07).

A. The Company Accurately Disclosed the Success Rate and Adverse Events from the Clinical Trial

The government contends that the Company overstated the success rate of the device and concealed certain adverse events in the clinical study. In connection with its 510(k) submission, the Company embarked on a clinical study regarding the Short Kit's use on perforators (called the RELIEVE study). The Company developed and initiated a clinical trial to assess the safety and efficacy of laser treatment of perforator veins. The Company submitted the proposal to an independent review board, which approved the trial as one of non-significant risk. The principal investigator considered a 70% closure rate to be "good," and 90% to be "great."[7] This success rate is consistent with at least one study regarding the closure rate for the competitor's FDA-cleared device, which reported a 71% closure rate.[8] Nevertheless, the target rate for closure of the vein six months after the procedure (*i.e.* success) was set at an unrealistically high 98%. The first subject was enrolled in October 2007, and enrollment was completed by January 2008. The purpose of the trial was to satisfy FDA's request for performance data regarding the treatment of perforator veins.

On March 21, 2008, the principal investigator issued an Interim Report stating that after treatment of 82 perforator veins, 91% were successfully closed after two week and 86% remained closed after six weeks. The last patient in the trial was seen on August 8, 2008. Following the last clinical visit, the CEC had to complete its analyses for all patients in the study and aggregate data had to be analyzed. On August 14, 2008, and consistent with information known at the time, a VSI manager informed the sales force of the 91% closure rate that had been stated in the Interim Report. Three months later, in and around November 6, 2008, the principal investigator reported the final results of the trial at an American College of Phlebology Annual Congress (the "Annual Congress"). The investigator accurately reported that at six weeks, 87% of veins remained closed, and that at six months, 70% remained closed.

The government has characterized the August 14, 2008 email to the sales force reporting the 91% rate as evidence of "fraud." Far from evidencing fraud, the email was accurate.[9] According to the Interim Progress Report, the study showed a 91% success rate at two weeks. Furthermore, the August email to the sales force was sent *only six days* after the last patient was seen in the study. The government has presented no evidence (and we have not seen any) that so

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[7]/ *See* Exhibit 6.

[8]/ *See* Lawrence, P.F. et al., *Endovenous ablation of incompetent perforating veins is effective treatment for recalcitrant venous ulcers.* J Vasc Surg. 2011; 54: 37-42.

[9]/ When we made this point to the government attorney at our meeting on September 19, they were unable to offer any convincing rebuttal or point to any evidence that an employee used this figure in connection with communicating to a physician about the device.

soon after the last patient was seen the final closure rate of 70% was known by the investigator or the Company, let alone the author of the email. And the investigator reported the 70% occlusion rate in a national presentation only months later -- in November 2008. And only a couple of months after that, at the very next national sales meeting, the Company reported the 70% occlusion rate to the sales force.[10] The Company made this report even before the principal investigator issued his final written report in June 2009. The contention that the Company misrepresented the closure rates is not supported by the evidence.

Likewise, the contention that the Company failed to accurately describe adverse events is unsupported. At the Annual Congress in November 2008, the principal investigator also made his final report regarding adverse events. The investigator disclosed publicly *all* events of deep vein thrombosis ("DVT") – serious, major and otherwise – and stated that there were no "serious adverse events."[11] This statement from the primary investigator was accurate. The case report form clearly specified the circumstances that would be deemed "serious adverse events,"[12] and using this definition, the *independent* Clinical Events Committee[13] – not the investigator or the Company -- classified each event as not serious. The fact that some DVT would be detected was not surprising from a clinical standpoint. The risk of DVT is present during any medical procedure involving varicosities, and thrombosis was clearly identified as a risk in the device's labeling. The labeling also admonished that the device should be used by physicians thoroughly trained in this procedure, who would accordingly be familiar with that risk. Importantly, the principal investigator also accurately reported that all the events of DVT were adjudicated to be "clinically insignificant" by the independent Clinical Events Committee.[14] He concluded that the "study has demonstrated that [incompetent perforator veins] can be safely and effectively treated

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[10]/ *See* Exhibit 7.

[11]/ *See* Exhibit 8.

[12]/ In this study, an adverse event was categorized as serious if it: (1) required 24 hours of hospitalization or prolongation of an existing hospitalization; (2) resulted in persistent or significant disability/incapacity; (3) was life threatening; (4) resulted in cancer or a congenital anomaly/birth defect; or (5) resulted in death; or it resulted in an important medical event that required medical intervention to prevent an outcome listed above.

[13]/ The CEC members were William Omlie, M.D. and Eric Irwin, M.D. According to the Clinical Study Report, "A Clinical Events Committee was utilized for the purpose of providing an independent review of all clinical events reported during the investigation. The CEC consisted of surgeons, independent of Vascular Solutions and this investigation, with knowledge and experience in various surgical indications." Clinical Study Report, ¶2.4, p. 8.

[14]/ "Clinically insignificant" meant that there was no propagation causing occlusion of a major leg vein, pulmonary embolism, or other serious and/or severe adverse event associated sequelae along with an objective and subjective improvement at follow-up.

by laser.[15] The contention that the Company failed to disclose adverse events likewise is not supported by the evidence.

B. Medicare and Private Payor Policies Covered Perforator Treatments

The government also contends that the Company made fraudulent statements because there were sales representatives who told physicians that they could be reimbursed for the device if it were used to treat a perforator vein and sales representatives were given conflicting reimbursement advice. To be sure, in a few instances, company representatives told physicians that the treatment of perforators with the Short Kit would be reimbursed. Others said that it was not a covered procedure. While there is no doubt that a few sales representatives discussed reimbursement with providers, there is no evidence that Company personnel engaged in an effort to disseminate comprehensive reimbursement advice for the Short Kit. The fact that the sales representatives' statements are conflicting is not surprising -- the question of coverage for the treatment of perforator veins very much depended on the payor. Most importantly, and putting aside the use of the device during one procedure to treat multiple types of veins, Medicare and private payors *covered laser ablation of perforator veins* in many instances.

Medicare covers indications not expressly described in a device's labeling, unless they are "not reasonable and necessary for the diagnosis or treatment of illness or injury." *See* 42 U.S.C. § 1395y(a)(1)(A). Reimbursability generally turns not on whether the use was off-label, but on whether the use of the device was reasonable and necessary — a factually intensive (and case-by-case) inquiry. The only limitation to that rule is that Local Coverage Determinations ("LCD") sometimes specify the conditions under which certain treatments will be covered. Although the LCDs differed in this case, many of them covered the laser ablation of perforator veins.

In Medicare Administrative Contractor ("MAC") Jurisdiction 11 (currently administered by Palmetto GBA), an LCD (issued in March 2011) covered endovenous laser ablation for perforator veins where medically necessary, and describes particular circumstances supporting treatment. Moreover, the LCD required that the patient's medical record "specifically state the vessel(s) and perforator(s) treated for each procedure, as well as the vessel diameter." In MAC Jurisdiction L (currently administered by Novitas Solutions Inc.), the LCD (issued in July 2008) likewise covered endovenous laser ablation where medically necessary, which encompasses "incompetent perforating veins." Since August 2012, the LCD for MAC Jurisdiction H (also currently administered by Novitas Solutions Inc.) covered endovenous laser ablation for

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[15]/ *See* Exhibit 9 at 24. In addition to the fact that the independent CEC determined that all the detected DVTs were clinically insignificant, it should be noted that the DVT rate from the study in and of itself was not alarming as it consistent with the DVT rate associated with treating venous insufficiency with other FDA-cleared devices. For example, one study found a DVT rate of 16% associated with treatment of the great saphenous vein. *See Deep venous thrombosis after radiofrequency ablation of greater saphenous vein: A word of caution*, A.P. Hingorani, *et al.*, Presented at the 16th Annual Meeting of the American Venous Forum, The Society for Vascular Surgery (2004).

perforator veins if determined to be reasonable and necessary by the MAC. Together, these LCDs expressly covered the treatment of incompetent perforator veins in Arkansas, Delaware, the District of Columbia, Colorado, Louisiana, Maryland, Mississippi, New Jersey, New Mexico, North Carolina, Oklahoma, Pennsylvania, South Carolina, Texas, Virginia, and West Virginia. Notably, the LCD for the jurisdiction of the contemplated prosecution currently permits coverage for treating perforators.[16]

LCDs in other MAC jurisdictions covered endovenous laser ablation treatment only for treatment of the lesser or greater saphenous veins and their tributaries; still others cover endovenous laser ablation treatment only when performed with devices used in a manner consistent with their FDA-approved labeling; and at least one jurisdiction currently has no LCD addressing endovenous laser treatment of veins, which meant that the default rule that Medicare would reimburse applied.[17] LCD revisions are common, so the state of coverage for laser ablation of perforators was in constant flux, depending on the jurisdiction and the time period in question.[18]

During the relevant time period, private health insurers also specifically covered laser treatment of perforator veins (the vast majority of varicose vein patients are insured by private payors, not federal health care programs). For example, United Healthcare's "Ablative Procedures for Venous Insufficiency and Varicose Veins" (effective 8/1/2010) covered ablation (endovenous laser ablation, radiofrequency ablation, surgical excision) of perforator veins when the following criteria were present: (1) evidence of perforator venous insufficiency measured by duplex ultrasonography; (2) perforator vein size 4 mm or greater; and (3) presence of venous stasis ulcerations(s) due to the insufficiency. Similarly, Blue Cross Blue Shield of North

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[16]/ Despite the fact that Medicare sometimes pays for perforator procedures involving Vari-Lase products, the government drafted the following statement for a witness to sign: "[s]ince before March 2008, I and others at the company knew that doctors could not bill Medicare for perforator procedures involving Vari-Lase products because they were not FDA approved for treatment of perforator veins." Of course, the statement also reflects a misconception on the prosecutors' part that reimbursability of a medical device by Medicare necessarily turns on whether it was used off-label. Absent guidance from a LCD, reimbursability turns on whether the use of the device was reasonable and necessary — a factually intensive (and case-by-case) inquiry. *See* 42 U.S.C. §1395y(a)(1)(A) (Medicare can and does cover indications not expressly described in a device's labeling unless they are "not reasonable and necessary for the diagnosis or treatment of illness or injury").

[17]/ Cahaba GBA, which covers Alabama, Georgia, and Mississippi, does not currently have an LCD in place for laser treatment of perforators. However, there was an LCD in place from 2007-2008. In November 2008, the LCD was retired, but Cahaba indicated that "the service may continue to be covered under Cahaba GBA Part B provided the service is medically reasonable and necessary."

[18]/ Highmark Medicare Services (L27539) (Delaware, Maryland, District of Columbia) began covering laser ablation of perforator veins in July 11, 2008, and Trailblazer Health Enterprises (L26729) (New Mexico, Oklahoma) began covering laser treatment of perforator veins in March 1, 2008. But LCDs often are retired or superseded by newer policies, so these jurisdictions may very well have different coverage policies in effect today.

Carolina's Corporate Medical Policy on Treatment for Varicose Veins has included language covering laser ablation therapy for perforator veins since July 20, 2010.

We presented the government with this information with respect to the coverage by both Medicare and private payors during our September 19, 2014 presentation. The state of coverage was such that any representation that the treatment of perforator veins would be covered would not likely have been inaccurate, much less made with the requisite intent to defraud. Nevertheless, we were told that fraud is evidenced by testimony of witnesses who apparently believed that use of the device was not covered. From this response, it would appear that the government is contemplating charging healthcare fraud even when laser ablation of perforator veins was actually covered, including in the district in which the case would be prosecuted.

C. The Short Kit Product Name Was Not Misleading

The government also has suggested it will argue that the Company's use of the phrase "Short Kit" or "Short Vein" somehow evidenced intent to defraud. At the time the device was developed, the Company contemplated that the Short kit could be used for treating short segments of veins, including perforator veins. Indeed, as early as September 2007 the device was approved in Europe for the treatment of perforator veins. But perforator veins were not the only short vein segments being treated. Prior to the introduction of the Short Kit, physicians were already treating short segments of the saphenous vein. In fact, before introducing the Short Kit, the Company was already selling versions of the Vari-Lase kits ranging from 100 cm to 5 cm in length to treat different length superficial veins. The Company also was not alone in using the term. Notably, even Medicare LCDs use the term "short vein" when discussing coverage for the laser ablation of varicose veins.

IV. A Criminal Prosecution Presents First Amendment Hurdles

The weakness in the government's fraud theory brings to the forefront the First Amendment hurdles in this case. The evidence will show that the sales representatives engaged in truthful non-misleading speech about a device that was being marketed under a cleared indication and was paid for by Medicare in many states. As you know, in 2012, the Court of Appeals for the Second Circuit reversed a misbranding conviction based on so-called off-label promotion, construing "the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs." *See United States v. Caronia*, 703 F.3d 149, 169 (2d Cir. 2012). Criminally prosecuting this conduct thus raises serious First Amendment issues not just in this matter, it creates significant risk for the continued viability of a criminal theory that recently has generated more than $10 billion for the government.

Aside from the policy imperative that the federal government should not prosecute an individual in Texas for conduct that was legal in Connecticut (where one-third of the sales took place), the state of misbranding law presents substantial litigation risk for the government. In the event of an indictment, the Company will move to dismiss the misbranding counts based on so-

called off-label promotion under the First Amendment. While the *Caronia* decision is not controlling in the Western District of Texas, it will be highly persuasive as the only appellate decision on the issue. Moreover, the conclusion in *Caronia* was compelled by the Supreme Court's decision in *Sorrell v. IMS Health, Inc*, 131 S.Ct. 2653 (2011), which found that Vermont's law restricting pharmaceutical marketing violated the First Amendment, reasoning that "speech in aid of pharmaceutical marketing ... is a form of expression protected by the Free Speech Clause of the First Amendment."

Finally, even if the government achieves success at every turn, in that it (1) successfully resists a motion to dismiss, (2) secures a conviction for the misdemeanor misbranding counts, and (3) is able to defend those verdicts on appeal, the government will achieve a circuit split between the Second and Fifth Circuits, which ripens the matter for the Supreme Court review that the government eschewed following *Caronia*. In short, by pursuing this prosecution, the government risks the continued viability of a multi-billion dollar criminal theory to secure the conviction of a small company and its CEO with no negative compliance history, no harm and miniscule financial implications. This prosecution serves neither justice nor the Department's broader policy interests.

V. THE DOCUMENTS DO NOT EVIDENCE A CONCERTED EFFORT BY EXECUTIVES

Nor does the evidence establish any sort of concerted effort by Company executives to misbrand the product by promoting for the treatment of perforators. This point is only underscored by the government's reliance on two documents that specifically discuss the treatment of perforator veins. The documents were never approved through the Company's well-established document approval system. In fact, they were not even created on the Company's computer system. Rather, a former sales representative created them on a computer from his former place of employment (a vein clinic). That sales representative even tried to destroy these documents when the Company began collecting documents to provide to the government in this case. The Company recovered the documents, produced them to the government, and terminated the employee.

Far from evidencing the involvement of Company executives, the sales representatives' field trip reports actually demonstrate the absence of pervasiveness of the promotion at issue. The government's draft Statement of Facts alleges that during the relevant period the CEO "received more than one hundred field trip reports documenting off-label discussions."[19] During this period, the approximately 98 sales representatives submitted field trip reports on a weekly basis to document their sales calls. Each report had 20 or more entries describing efforts to sell

[19]/ The line attorneys presented the Company's lawyers with a draft Statement of Facts and a draft Information that they contend support misdemeanor pleas by the Company and its CEO. *See* Exhibit 10. The Company disagrees with fundamental aspects of that statement. In addition to being inaccurate, the allegations pose a serious risk of exclusion for the CEO and possibly the Company as well.

the Company's 80 devices. Even if we credit the contention that 100 entries documented "off label discussions," the fact remains that only 100 entries out of millions of entries contained in more than 23,000 weekly reports during a seven-year period indicate that sales representatives had discussions about treatment of perforators. This amounts to less than one-one hundredth of a percent of the field trip reports. Of course, these often-lengthy and dense reports constitute only a portion of the over 85,000 emails the chief executive received over the relevant period. Significantly, we have not seen any reports that suggest false or misleading information was being provided.

Nor do emails to executives that mention the treatment of perforator veins establish any sort of concerted effort at the top. The government points to an email sent to the CEO in April 2007, six months *before* the introduction of the Short Kit. But in the email, which did not address the Short Kit, a sales person recounts only that a doctor was "quite impressed" with the Bright Tip feature on the laser fiber (which allows the doctor to see the end of the fiber in the vein during the procedure through ultrasound), in a saphenous vein procedure, and noted that one of the "biggest obstacles with perforator cases is seeing where your fiber is in the vein," and that the Bright Tip will "alleviate that problem." Focusing on the Bright Tip feature – not the potential future perforator treatment -- the CEO responded by writing: "I know it's getting to be old news, but *here's another great Bright Tip case* ... Thanks ... and congratulations on the great result."[20] The functionality of the Bright tip was important in April 2007, as it had been placed on all of the Company's Vari-Lase fibers because of a patent infringement lawsuit by a competitor against Vascular Solutions that required the Company to modify the tip on these devices. The timing and plain language of the CEO's email do not evidence any intent to condone off-label marketing of the device.

VI. Proportionality and Fairness Weigh Against a Criminal Conviction

Underscoring the relative scope of conduct at issue, and evidencing the absence of a meaningful motive of executive involvement, is the minimal financial benefit to the Company and its sales force. Proportionality is imperative to a just outcome.

The vanishingly small contribution of the Short Kit to the bottom line of the Company and the sales representatives' compensation belies any meaningful motive to commit a federal crime, and makes clear that any alleged misconduct was far from pervasive under the Principles of Federal Prosecution. It is undisputed that the conduct in question comprised an exceedingly small part of the sales force's focus and the Company's business. About 87% of the Company's sales derived from catheter products and hemostats (as of the second quarter 2014). Only 13% of sales involved vein products – and the Short Kit accounted for less than one-third of one

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[20]/ The Statement of Facts prepared by the line attorneys omitted the reference to the Bright Tip, making it look as though the CEO was applauding the fact that a physician planned to treat a perforator. *See* Exhibit 9 (draft Statement of Facts ¶34).

percent of those sales. Only about 1,800 Short Kits were ever sold, each of which retailed for less than $300. During its seven-year life, Short Kit sales averaged less than $77,000 per year, contributing *less than one-tenth of one percent* to the company's sales total. More than two-thirds of the customers that bought Vari-Lase consoles never purchased a Short Kit. And, most importantly, there is no evidence of any harm or increased risk of harm from the use of the Short Kit by physicians who used it to treat perforator veins. All of these facts are relevant to the government's determination of a fair resolution of this case. *See* U.S.A.M. § 9-28.400 (the nature and seriousness of the offense, including the risk of harm to the public, and applicable policies and priorities, if any, governing the prosecution of corporations for particular categories of crime) & .500 (the pervasiveness of wrongdoing within the corporation, including the complicity in, or the condoning of, the wrongdoing by corporate management).

The Company employed about a hundred sales representatives across the nation. Far from a concerted effort to boost Short Kit sales, more than two-thirds of those sales representatives never sold a Short Kit. That the great majority of sales personnel never sold a single Short Kit undermines the notion that any off-label promotion was a top-down scheme. And the sales force compensation from Short Kit sales constituted a miniscule portion of the total sales force's compensation – again less than one-tenth of one percent. The modest financial incentive to the sales force to sell Short Kits matches the insignificant corporate motivation. The extraordinarily small contribution to the bottom line of the Company and its sales force belies any meaningful motive to commit a federal crime. Even crediting fully the facts developed by the Government, therefore, this is simply not a case warranting a plea to any crime.

The Company also has no prior regulatory or enforcement history. And, beginning in 2011, almost immediately after the company learned of this investigation, it began updating and enhancing its compliance program. The Principles of Federal Prosecution of Business Organizations emphasize the important role compliance, history, and remedial actions play in determining the fair treatment of a company in the negotiations process. *See* U.S.A.M. § 9-28.600 (history of similar misconduct, including prior criminal, civil, and regulatory enforcement actions against it) & .800 (remedial actions, including any efforts to implement an effective corporate compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, to pay restitution, and to cooperate with the relevant government agencies).

VII. METHODS OF OBTAINING TESTIMONY UNDERMINES ITS USEFULNESS

Finally, the methods by which testimony was obtained raise serious questions, not the least of which is the value, usefulness and credibility of the testimony.[21]

First, on numerous occasions, grand jury subpoenas were issued to witnesses in Minneapolis and elsewhere. This grand jury process was used to force witnesses to submit to private examinations by the government outside the presence of both the grand jury and their individual counsel. These examinations had all of the trappings of a grand jury examination – except the presence of the grand jury. Excluding both the grand jury and counsel from these examinations raises serious questions.

The grand jury's "historic office has been to provide a shield against arbitrary or oppressive action, by insuring that serious criminal accusations will be brought only upon the considered judgment of a representative body of citizens acting under oath and under judicial instruction and guidance." *See United States v. Mandujano*, 425 U.S. 564, 571-72 (1976). Consistent with that role, the grand jury has broad latitude to compel persons to appear and provide testimony. *See United States v. Calandra*, 414 U.S. 338, 345 (1974). Consequently, when called by the grand jury, witnesses are legally bound to give testimony. *Mandujano*, 425 U.S. at 572. But this power of compulsory process is vested entirely in the grand jury -- not the Department of Justice:

> The Constitution of the United States, the statutes, the traditions of our law, the deep rooted preferences of our people speak clearly. They recognize the primary and nearly exclusive role of the Grand Jury as the agency of compulsory disclosure. They do not recognize the United States Attorney's office as a proper substitute for the grand jury room and they do not recognize the use of a grand jury subpoena, a process of the District Court, as a compulsory administrative process of the United States Attorney's office.

See Durbin v. United States, 221 F.2d 520, 522 (D.C. Cir. 1954). Consequently, federal prosecutors may not issue grand jury process to compel interviews outside the presence of the grand jury. *See id.* (holding that it "was clearly an improper use of the District Court's process for the Assistant United States Attorney to issue a grand jury subpoena for the purpose of conducting his own inquisition"); *United States v. Wadlington*, 233 F.3d 1067, 1075, 1083 (8th Cir. 2000) (holding that grand jury subpoenas were improperly issued to compel witnesses to attend interviews, reasoning that Rule 17(a) "does not authorize the Government to use grand jury subpoenas to compel prospective grand jury witnesses to attend private interviews with government agents."); *United States v. Standard Oil Co.*, 316 F.2d 884, 897 (7th Cir. 1963)

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[21]/ The Principles of Federal Prosecution require not simply probable cause, but a judgment that the admissible evidence will probably be sufficient to obtain -- and sustain -- a conviction. See USAM 9-27.220.

(explaining that Rule 17 "does not authorize the government . . . to subpoena a witness and require him to report at some place other than where the trial is to be held").

From what we understand, each examination began with the administration of the oath to the witness. Although Federal Rule of Criminal Procedure 6(c) empowers the foreperson to administer oaths to witnesses, the grand jury foreperson was not present. Prosecutors are not authorized to administer the oath to the grand jury witnesses. *See* 28 U.S.C. §§ 459 & 953 (providing for the administration of oaths by judges and courtroom clerks). Administration of the oath is a hallmark of the grand jury – not an informal interview in lieu of a grand jury appearance. In addition, counsel was forbidden from attending the examination, which is consistent with a grand jury proceeding – not an informal interview. Instead, counsel was forced to remain outside the room where the examination was being conducted – precisely the procedure when a witness testifies before the grand jury, not the typical procedure for an interview in lieu of a grand jury appearance. Absent the leverage of the grand jury process, counsel would not have permitted an *ex-parte* examination of his client outside his presence.

Also concerning are the admonitions given to these witnesses and counsel. Using threats of perjury, the government repeatedly urged witnesses to alter testimony to support the government's theory. At least five fully immunized employees were informed that if they did not change their testimony, they could be subject to prosecution for perjury or recommended for exclusion from participation in Medicare and Medicaid. Others were told that if they did not "fix" their testimony, they would receive target letters. Some employees were told that if they did not change their testimony, then their employment was in jeopardy.[22] Another witness has been informed that he could either agree that the Company "acted with intent to defraud" or be indicted. The perjury warnings, along with the threats of exclusion or termination from employment, coupled with the prosecutors' request that the witnesses change their testimony, raise serious questions – about the veracity of the testimony elicited after such warnings at best.

The method of questioning also has been designed not to elicit the facts, and then shape the theory, but to shape the facts to conform to the theory. The government outlined their theory – including their legal conclusions about the conduct at issue – and solicited agreement, even absent personal knowledge. At our meeting with the line attorneys on September 19, 2014, they featured excerpts of testimony, which were replete with leading questions seeking agreement with legal conclusions. Answers to such questions certainly are not admissible, do not lead to the meaningful development of admissible evidence, and most importantly, do not appear to have been designed to determine the truth. Given the nature of these questions and answers, which no doubt are important to the government's case, we urge you to commission a review of these transcripts to assess the reliability of the characterization of the evidence.

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[22]/ In fact, as part of a proposed plea agreement, the goverment required that the Company terminate certain employees because the government challenged their veracity.

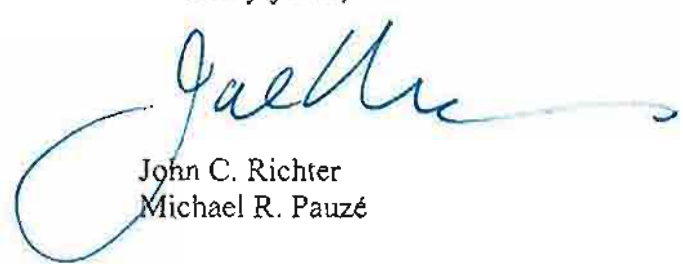
Together, these tactics, examination methods, and perjury threats raise a host of significant issues, not the least of which will be satisfaction of the government's *Brady* and *Giglio* obligations. In light of the potentially shifting witness statements, in the event that this matter proceeds to pre-trial discovery, the government will be required to produce the substance of differences between anticipated testimony and prior statements, whether in recorded testimony or in interviews, recorded or otherwise. Compliance with this obligation will require an assiduous record of all prior statements.

VIII. CONCLUSION

Based on the foregoing, we submit that a federal criminal conviction – through indictment or otherwise -- is neither proportional to the conduct in question, nor reflects an appropriate application of the Principles of Federal Prosecution and the Principles of the Federal Prosecution of Business Organizations. Any criminal prosecution would have a damaging and possibly irreparable effect on this small, publicly-traded company. Even a misdemeanor conviction could be extremely damaging, especially where the line attorneys insist on a conviction of the co-founder and CEO, who invented most of the Company's products. It simply is not enough for the line attorneys to claim that they do not think there should be any exclusion in this case, as the agency need not defer to the line attorneys' view about exclusion, especially since the line attorneys this afternoon threatened that if we seek an appeal of this matter within the Department that they will withdraw their support for non-exclusion. A federal criminal conviction simply is not warranted for this small, historically compliant company, and its founder, the inventor of its devices, and CEO, regarding a product that contributed less than one-tenth of one percent to the Company's bottom line and that caused no patient harm. This is especially the case where the Company already has entered into a civil settlement and disgorged an amount that equates to *all revenue ever received* from sales of the Short Kit (regardless of whether the use was allegedly off-label and regardless of whether a federal healthcare program paid for it). The Company is willing to engage in an appropriate resolution, including a financial component, which fairly reflects the facts and the law. But for the reasons discussed above, we respectfully submit that a criminal conviction is not an appropriate resolution.

For these and other reasons, we respectfully request the opportunity to meet with you as soon as possible to discuss this matter. We appreciate your consideration of this matter.

Sincerely yours,



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