**UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF TEXAS**
**SAN ANTONIO DIVISION**

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| UNITED STATES OF AMERICA,<br>Plaintiff,<br>v.<br>VASCULAR SOLUTIONS, INC. & HOWARD C. ROOT,<br>Defendants. | No. 5:14-CR-00926 |

# MEMORANDUM OF LAW OF CHAMBER OF COMMERCE OF THE UNITED STATES AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE INDICTMENT


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## INTEREST OF *AMICUS CURIAE*

The Chamber of Commerce of the United States is the world's largest business federation. It directly represents over 300,000 members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. It thus regularly files *amicus curiae* briefs in cases raising issues of concern to the nation's business community.

The Chamber's members include pharmaceutical and medical device manufacturers subject to the regulatory regime at issue here. Consequently, the Chamber has an interest in preserving its members' ability to speak truthfully about their products without the threat of criminal prosecution.[1]

## INTRODUCTION AND STATEMENT OF THE CASE

The government has filed criminal charges against Vascular Solutions, Inc. and its CEO, Howard Root, (collectively, "Vascular Solutions") for engaging in truthful, non-misleading speech about so-called "off-label" uses of its Vari-Lase system. Because such an indictment is antithetical to core First Amendment principles, it must be dismissed.

The Food, Drug, and Cosmetics Act (FDCA) regulates the manufacture and distribution of, inter alia, drugs and medical devices. 21 U.S.C. §§ 301-97. Under the FDCA, manufacturers must obtain approval or clearance from the Food and Drug Administration (FDA) before distributing a medical device. *Id.* §§ 360(k), 360c(f), 360e. "As part of the approval [or clearance] process, the FDA . . . reviews the proposed 'labeling' for the drug [or device,] which includes . . . all proposed claims about the [product's] risks and benefits, [its intended use, and] adequate directions for [that] use." *Wash. Legal Found. v. Friedman* ("*WLF*"), 13 F. Supp. 2d 51, 55 (D.D.C. 1998), *appeal dismissed*

[1] No party's counsel authored this brief in whole or in part, and no entity or person, aside from *amicus curiae*, its members, and its counsel, made any monetary contribution intended to fund to the preparation or submission of this brief.

202 F.3d 331 (D.C. Cir. 2000); 21 C.F.R. § 807.87(e). "The FDA will only approve [or clear] the [product] if the labeling conforms with the uses that the FDA has approved." 13 F. Supp. 2d at 55.

Once the FDA approves or clears a device, however, physicians may lawfully use that device for *any* purpose. The FDA does not purport to regulate the practice of medicine (nor is it permitted to do so), 21 U.S.C. § 396, and the agency has long recognized that once a device is approved or cleared "healthcare professionals may lawfully use or prescribe that product for uses or treatment regimens that are not included in the product's approved labeling [or] statement of intended uses." FDA, *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* § III (Jan. 2009), http://www.fda.gov/Regulatory Information/Guidances/ucm125126.htm (hereinafter "*Good Reprint Practices*"). In other words, so-called "off-label" uses are perfectly legal and "generally accepted." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 (2001); *WLF*, 13 F. Supp. 2d at 56 (describing this practice as "an established aspect of the modern practice of medicine"). Indeed, the FDA itself has acknowledge[d] that "off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care." *Good Reprint Practices*, *supra*, § III.

At the same time, the government broadly restricts a manufacturer's ability to make these lawful and beneficial off-label uses known to physicians. In fact, the "FDA has consistently prohibited" manufacturers—and only manufacturers—from "the promotion . . . [of] unapproved uses of approved products." 62 Fed. Reg. 64,074-01, 64,081 (Dec. 3, 1997). The government has created this selective ban on the promotion of off-label uses through an atextual interpretation of the FDCA's prohibition on the "introduction . . . into interstate commerce of any food, drug, [or] device . . . that is adulterated or misbranded." 21 U.S.C. § 331(a). According to the government, if a manufacturer "promote[s a medical device] for a use that has not been approved or cleared by FDA," that medical device is, by definition, "adulterated and misbranded." *Good Reprint Practices*,

*supra*, § III; *see also United States v. Caronia*, 703 F.3d 149, 154-55 (2d Cir. 2012) (stating that the FDA "has construed the FDCA to prohibit promotional speech as misbranding itself"). The government's theory appears to be that the promotion or marketing of off label-uses creates a new "intended use" for the product, 21 C.F.R. § 801.4, which necessitates supplemental FDA approval or clearance—as well as additional labeling—before the device can be distributed. *See Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, No. 14-civ-3588, 2015 WL 4720039, at *5 (S.D.N.Y. Aug. 7, 2015).

While manufacturers are thus forbidden from promoting off-label uses, virtually any other speaker may tout the benefits of such uses. The "government's application of the FDCA permits physicians and academics, for example, to speak about off-label uses without consequence, while the same speech is prohibited when delivered by pharmaceutical [or device] manufacturers." *Caronia*, 703 F.3d at 165. In short, the government's regulatory scheme "'has the effect of preventing [manufacturers]—and only [manufacturers]—from communicating with physicians in an effective and informative manner'" regarding the off-label uses of drugs and devices. *Id.* (quoting *Sorrell v. IMS Health Inc.,* 131 S. Ct. 2653, 2663 (2011)). Manufacturers who violate this speech ban have been subjected to aggressive prosecutions. *Id.* at 154 (citing examples); *Amarin*, 2015 WL 4720039, at *6-8.

This case is typical of the government's enforcement efforts. Vascular Solutions manufactures and markets the Vari-Lase® Endovenous Laser Procedure Kit, a medical device used to treat varicose veins with laser ablation. Indict. ¶ 11, 12. It is undisputed that the FDA has cleared the use of Vari-Lase devices "for treatment of superficial veins and the Great Saphernous Vein." *Id.* ¶ 12. The FDA, however, maintains that "Vari-Lase devices d[o] not have any form of FDA marketing authorization for treatment of perforator veins"—shorter veins that "connect the superficial and deep vein systems." *Id.* ¶ 13. Despite the fact that it is perfectly legal for doctors to treat perforator veins with the Vari-Lase system, the government has indicted Vascular Solutions for "market[ing]" and "promoting the Vari-Lase system for perforator use." *Id.* ¶¶ 16, 29. Among other

things, the government accuses Vascular Solutions of encouraging its sales employees to provide doctors with "arguments for why lasers were better for treating perforators" than competing products, *id.* ¶ 41, "articles suggesting that lasers were effective at treating perforators," *id.* ¶¶ 41, 54(c), and information regarding "the benefits of [using the Vari-Lase system] for perforator treatment" as well as the "success that other doctors had using the kit for this purpose," *id.* ¶ 53.

In sum, two points are clear. First, the government permits physicians to employ medical devices for any off-label use they find medically appropriate. Second, the government prohibits manufacturers from communicating with doctors regarding such off-label uses. This regime—which allows doctors to treat perforator veins with the Vari-Lase system, but bars Vascular Solutions from giving doctors information on such a use—cannot survive First Amendment scrutiny.

## ARGUMENT

The First Amendment precludes the government from prosecuting individuals for engaging in truthful, non-misleading speech, and that ban operates with particular force where the government discriminates on the basis of content or speaker.

As detailed below, the government's ban on off-label promotion is both content and speaker based, and reflects an inherently paternalistic judgment about the information to which trained medical professionals may be exposed. Such regulations cannot be sustained under any form of heightened scrutiny. Where the government has made the decision to allow doctors to use medical devices for off-label purposes and to allow any individual or entity except medical device manufacturers to speak about such uses, it cannot subject manufacturers to a selective criminal ban against conveying truthful and non-misleading information to doctors about the devices they use.

Insofar as the government asserts that it is prosecuting Vascular Solutions for its conduct, rather than its speech, its claims "may be addressed quickly." *WLF*, 13 F. Supp. 2d at 59. As an initial matter, the Supreme Court has squarely held that laws that burden speech, even if ostensibly

regulating conduct, are subject to heightened scrutiny. *Sorrell*, 131 S. Ct. at 2667. In any event, regulation of marketing and promotional activities is regulation of "conduct" only "to the extent that moving one's lips is 'conduct,' or to the extent that affixing a stamp and distributing information through the mails is 'conduct.'" *WLF*, 13 F. Supp. 2d at 59. And even assuming *arguendo* the off-label regime does not facially target speech, the government's past statements, the nature of its prosecutorial activities here and elsewhere, and the essential role a manufacturer's communications play in its theory of liability, eliminate any doubt that the regime is necessarily a speech restriction.

It is thus no surprise that the Second Circuit struck down a similar prosecution on the grounds that the First Amendment prohibits the government from seeking to hold "pharmaceutical manufacturers and their representatives [liable] for speech promoting the lawful, off-label use of an FDA-approved drug." *Caronia*, 703 F.3d at 169. Just last week, the Southern District of New York followed suit, enjoining the government from taking action "against a manufacturer based solely on truthful and non-misleading speech evincing the intent to promote an off-label use." *Amarin*, 2015 WL 4720039, at *23. Here, the government is prosecuting Vascular Solutions for virtually indistinguishable speech—the promotion and marketing of medical devices for off-label uses. This Court should join those courts and hold that prosecution for truthful, non-misleading speech about the off-label uses of medical devices violates the First Amendment. At the least, the canon of constitutional avoidance counsels that the FDCA should not be read to prohibit such speech. *E.g.*, *NLRB v. Catholic Bishop of Chi.*, 440 U. S. 490, 506-07 (1979).

## I. CONTENT AND SPEAKER-BASED BURDENS ON TRUTHFUL SPEECH ARE PRESUMPTIVELY UNCONSTITUTIONAL

### A. Discrimination on the Basis of the Content of Speech or the Speaker Is Subject to Heightened Scrutiny

Time and again, the Supreme Court has held that restrictions on truthful speech that discriminate based on content and speaker are presumptively invalid, whether those restrictions

burden political speech, commercial speech, or any other speech. *E.g.*, *Reed v. Town of Gilbert*, 135 S. Ct. 2218 (2015); *Sorrell*, 131 S. Ct. at 2671. This result follows from core First Amendment principles. The constitutional protection of speech is premised on the belief "that 'information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.'" *Sorrell*, 131 S. Ct. at 2671 (quoting *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976)). Thus, "above all else, the First Amendment means that government has no power to restrict expression because of its . . . content." *Police Dep't of Chi. v. Mosley*, 408 U.S. 92, 95 (1972). It also means that government may not restrict the expression of certain speakers, because "[s]peech restrictions based on the identity of the speaker are all too often simply a means to control content." *Citizens United v. FEC*, 558 U.S. 310, 340 (2010). Instead, "[t]he First Amendment protects speech and speaker," *id.* at 341, demanding "heightened scrutiny" when the government discriminates against either. *Sorrell*, 131 S. Ct. at 2664.

To avoid heightened scrutiny for a content-based or speaker-based speech restriction, the government must proffer a "neutral justification" for the ban that is unrelated to the message conveyed or to the speaker's identity. *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 429-30 (1993). Several alleged "neutral" justifications are always invalid. For example, the government may not rely on the "justification" that the speaker's expression is "uttered for a profit." *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 482 (1989). "While the burdened speech results from an economic motive, so too does a great deal of vital expression." *Sorrell*, 131 S. Ct. at 2665. Nor may the government ban a message simply because, in its view, the message would adversely affect its audience. L*inmark Assocs., Inc. v. Twp. of Willingboro*, 431 U.S. 85, 96-97 (1977); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 375 (2002). "[T]he fear that people would make bad decisions if given truthful information cannot justify content-based burdens on speech." *Sorrell*, 131 S. Ct. at 2670-71.

For similar reasons, a selective speaker-based restriction cannot be premised on the notion that certain speakers are more influential: here, that manufacturer speech is somehow more likely to lead to off-label uses than speech by other parties. "That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers." *Id.* at 2671.

Significantly, the Supreme Court has held that "[c]ommercial speech is no exception" to these anti-discrimination principles because a "consumer's concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue." *Sorrell*, 131 S. Ct. at 2664 (internal quotation marks omitted). And "[t]hat reality has great relevance in the fields of medicine and public health, where information can save lives." *Id.* Thus, "strict scrutiny," *id.* (citing *Turner Broad. Sys. v. FCC*, 512 U.S. 622, 658 (1994)), should apply to content and speaker-based burdens on truthful commercial speech just as it does to such restrictions on political speech. *Sorrell*, 131 S. Ct. at 2672.

The Supreme Court's decision in *Sorrell* plainly establishes this rule. There, the Court struck down Vermont's "Prescription Confidentiality Law," which prohibited pharmaceutical companies from using physician prescribing records in their marketing. *Id.* at 2662-63. Critical to the Court's holding was the fact that the Vermont law imposed content and speaker-based burdens on truthful speech promoting prescription drugs. *Id.* at 2663-64. The law disfavored only certain speakers (pharmaceutical manufacturers) and only certain types of speech (pharmaceutical marketing). *Id.* at 2663. Due to this discriminatory treatment, the Court held that it must apply "heightened judicial scrutiny," *id.* at 2664, and that the Vermont law could not survive that scrutiny, *id.* at 2667-72.

Indeed, even before *Sorrell*, the Supreme Court held that "the First Amendment imposes . . . a 'content discrimination' limitation upon a State's prohibition of proscribable speech," like obscenity or defamation. *R.A.V. v. City of St. Paul*, 505 U.S. 377, 387 (1992). Thus, while the government may freely ban all "fighting words," strict scrutiny applies to a content-based ban on

"fighting words" that invoke anger on the basis of "race" or "religion," rather than "political affiliation" or "union membership." *Id.* at 391 ("The First Amendment does not permit [the government] to impose special prohibitions on those speakers who express views on disfavored subjects."). Because strict scrutiny applies to content-based burdens on types of speech (like fighting words or fraudulent speech) that the government may *prohibit entirely*, it *a fortiori* applies to such burdens on constitutionally protected commercial speech.

Here, the ban on off-label promotion is both speaker based and content based, and thus is subject to heightened scrutiny. *See Caronia*, 703 F.3d at 165. The government's prohibition is speaker-based because, as noted above, it allows nearly everyone to discuss the off-label uses of a medical device except for the device's manufacturer. *Supra* p.3. For example, academics may freely discuss those uses in scholarly articles, and many doctors undoubtedly promote those uses in consultations with their patients. Thus, "[t]he explicit structure of the [FDA's regime] allows [off-label promotion] to be . . . [made] by all but a narrow class of disfavored speakers." *Sorrell*, 131 S. Ct. at 2668; *see Caronia*, 703 F.3d at 165. The result is that the government is attempting to subject Vascular Solutions to criminal liability for statements—allegedly encouraging the use of Vari-Lase on perforator veins—that any other speaker could make without fear of prosecution.

The government's ban is content-based because it "applies to particular speech because of the topic discussed or the idea or message expressed." *Reed*, 135 S. Ct. at 2227. In other words, the bar on manufacturer speech pertaining to off-label uses "depend[s] entirely on the communicative content" of the company's marketing. *Id.* Speech discussing *off-label* uses is "disfavor[ed]," while speech on *approved* uses is encouraged. *Sorrell*, 131 S. Ct. at 2663. Worse still, the prohibition is "aimed at a particular viewpoint," *id.* at 2664—namely, the viewpoint that doctors should employ medical devices for an off-label use. The government freely permits speech (by manufacturers or anyone else) to *discourage* off-label uses. *See Caronia*, 703 F.3d at 165.

### B. The Prohibition on Off-Label Promotion Cannot Survive Any Form of Heightened Scrutiny

"In the ordinary case it is all but dispositive to conclude that a law is content-based and, in practice, viewpoint-discriminatory." *Sorrell*, 131 S. Ct. at 2667. At that point, strict scrutiny applies, and the government must satisfy the nearly insurmountable burden of "prov[ing] that [its regulations] are narrowly tailored to serve compelling state interests." *Reed*, 135 S. Ct. at 2226. But even if it were to be subjected to the scrutiny typically applied to commercial speech regulations, the government's prosecution of Vascular Solutions cannot pass constitutional muster. Under that test, the government may only proscribe commercial speech if it proves (1) that the speech promotes unlawful activity or inherently misleads its audience, or (2) that the government has a substantial interest; that "the [ban] [on speech] directly advances the governmental interest"; and that it "could [not] achieve its interests in a manner that does not restrict speech, or that restricts less speech." *W. States*, 535 U.S. at 367 (internal quotation marks omitted). This it cannot do.

Indeed, *Western States* essentially controls the analysis on this point. In that case, the Supreme Court applied the commercial speech test to strike down a law that permitted pharmacists to sell "compounded drugs [i.e., drugs modified to meet the needs of a particular patient] without first . . . obtaining FDA approval," so long as they did not advertise those drugs. 535 U.S. at 370. "If they advertise[d] their compounded drugs . . . FDA approval [would be] required" before the drugs could be sold. *Id.* There, as here, a manufacturer's liability turned on his speech. There, as here, the government sought to preclude the public from obtaining information about medical products that were perfectly legal to use. And there, as here, the government's concern was that drug or device manufacturers would circumvent the FDA-approval process. *See id.* at 370-71. Thus, for all the reasons the law at issue in *Western States* could not survive First Amendment scrutiny, the government's prosecution must fail.

### 1. Speech Promoting Off-Label Uses to Physicians Concerns Lawful Conduct and Is Not Inherently Misleading

The government is free to regulate speech that "concerns unlawful activity," *W. States*, 535 U.S. at 367, or that is "inherently misleading," *In re R. M. J.*, 455 U.S. 191, 203 (1982). Speech about the off-label use of medical devices plainly does not fall into either category. Because the use of a medical device for off-label purposes is entirely *legal*, speech promoting that *legal* conduct does not concern unlawful activity. *See Caronia*, 703 F.3d at 165-66. "[O]nly at such time as off-label [uses] are proscribed by law could the [government] legitimately claim that speech [about those uses] addresses 'illegal activities.'" *WLF*, 13 F. Supp. 2d at 66.

Nor can the government contend that all manufacturer speech about off-label uses is "inherently misleading." *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999). If the government were to maintain that "all scientific claims about the safety[ and] effectiveness" of off-label uses for medical devices "are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them," it would "exaggerate [the FDA's] overall place in the universe." *WLF*, 13 F. Supp. 2d at 67. But the government does not so maintain, either in the indictment here or generally. The FDA itself confirms that public health generally benefits from the "dissemination of objective, balanced, and accurate information on important unapproved uses of approved products." 63 Fed. Reg. 64,556, 64,579 (Nov. 20, 1998), and the American Medical Association has indicated that "[i]t is imperative that physicians have access to accurate and unbiased information about unlabeled uses of prescription drugs." 1997 Annual Meeting of the Am. Med. Ass'n, Reports of the Council on Scientific Affairs at 4, https://download.ama-assn.org/resources/doc/csaph/x-pub/csaa-97.pdf.

Indeed, the government cannot rationally maintain that statements about off-label uses are inherently misleading, because the government allows *everyone but the manufacturer* to make those statements. *See Caronia*, 703 F.3d at 165-66. "Were [off-label promotion] either actually or inherently misleading, one would have to conclude that the FDA would be derelict to not proscribe

dissemination under all circumstances." *WLF*, 13 F. Supp. 2d at 68. And, "[u]nder current FDA policy, companies may . . . disseminate information on unapproved uses in response to unsolicited requests for scientific information from health care professionals." 59 Fed. Reg. 59,820, 59,823 (Nov. 18, 1994). If the government thought such communications were always misleading, it could not draw distinctions based on who originated the communication at issue.

Finally, any "inherently misleading" claim is facially implausible because the audience here is not unsophisticated consumers but physicians whom the government itself finds sufficiently knowledgeable to make decisions about unapproved uses. If anything, manufacturer speech should be particularly helpful to physicians given manufacturers' "superior access to information about their [products]." *Wyeth v. Levine*, 555 U.S. 555, 578-79 (2008); 59 Fed. Reg. at 59,823 (manufacturers' "[s]cientific departments . . . generally maintain a large body of information on their products").

### 2. A Ban on Off-Label Promotion Is Not Necessary to Advance a Substantial Governmental Interest

The government routinely asserts two interests for its ban on off-label promotion—(1) protecting the public health from potentially dangerous uses of drugs or devices; and (2) providing manufacturers with an incentive to get previously unapproved uses on label. Neither suffices to justify the government's broad ban on speech.

*Protecting Public Health.* If the government has any concerns with the underlying practice of doctors prescribing off-label uses, or with particular types of off-label uses, it is free to regulate those practices. However, having eschewed any direct prohibition on such conduct (because many off-label uses are in fact beneficial rather than harmful), it may not pursue the same purported goal by banning speech. *See W. States*, 535 U.S. at 371. Since the government can claim no valid interest in stamping out the activity promoted by manufacturers' speech, it follows that truthful, non-misleading speech about the activity cannot be harmful in the eyes of the First Amendment. Indeed, by allowing off-label uses while prohibiting speech about those uses, the government has created the

worst of all worlds—doctors are free (and in some cases obligated) to prescribe these uses but are deprived of critical sources of information in their decisionmaking. *Caronia*, 703 F.3d at 167 (noting that the "government's construction of the FDCA essentially legalizes the outcome—off-label use—but prohibits the free flow of information that would inform that outcome").

Indeed, any purported interest in discouraging off-label uses by "keep[ing] people in the dark for what [the government] perceives to be their own good" is automatically invalid. *W. States*, 535 U.S. at 375 (internal quotation marks omitted). "If there is one fixed principle in the commercial speech arena, it is that 'a State's paternalistic assumption that the public will use truthful, non-misleading information unwisely cannot justify a decision to suppress it." *WLF*, 13 F. Supp. 2d at 69-70 (quoting *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 497 (1996) (plurality opinion)). Such paternalism is particularly forbidden because the speech here is directed to sophisticated medical professionals the government entrusts to make informed medical judgments about off-label uses. "[P]rohibiting off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use 'paternalistically' interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public's detriment, informed and intelligent treatment decisions." *Caronia*, 703 F.3d at 166.

In any event, the claim that prohibiting *manufacturer* speech about off-label uses serves a substantial purpose is conclusively undermined by the fact that *everyone else* may engage in precisely the same speech. *Cf. Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 186-94 (1999) (noting that the government's "unwillingness to adopt a single national policy" on gambling undermined the legitimacy of its interest in "alleviating the societal ills" of gambling and showed that its selective ban on gambling advertisements did not advance that interest).

*Incentivizing Manufacturers*. Likewise, any interest the government may have in providing manufacturers with an incentive to get off-label uses "on-label" cannot justify the sweeping speech restrictions at issue here. At the threshold, because prior FDA approval of a device's use is concededly not needed to protect the public health (since, as established above, the government *permits* unapproved uses), any interest in having FDA pre-approval of all uses is inherently and concededly not a *public health* interest. That being so, the FDA's desire to pre-approve all uses of approved devices is little more than a self-interested effort to monopolize all decisions about whether a use is safe and effective. The FDCA, however, denies the FDA such monopoly power by recognizing that medical professionals are also capable of making such judgments without the FDA's prior endorsement. *See* 21 U.S.C. § 396. Thus, since the statutory scheme recognizes that the FDA is not the font of all wisdom on unapproved uses, any interest in providing it with this monopoly to the detriment of medical professionals actually undermines the statute's "purpose," and thus cannot be deemed "substantial."

Nevertheless, even assuming that government has a public health interest in establishing an FDA monopoly over doctors' prescribing authority, a ban on providing doctors with truthful, non-misleading information about off-label uses does not directly advance that interest and is not narrowly tailored to achieve it. Even where the government's interests are substantial, "[i]f the First Amendment means anything, it means that regulating speech must be a last—not first—resort." *W. States*, 535 U.S. at 373. Here, because the government targeted speech ostensibly to reduce conduct it has failed to pursue in numerous more direct ways, it cannot show that the speech ban directly advances the government's interest or is narrowly tailored to do so.

First, a speech ban riddled with "exemptions and inconsistencies" concerning the speech and speakers that it covers cannot satisfy the "directly and materially advance" requirement. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 489 (1995). In *Rubin*, the Court found that a ban on listing alcohol

content in beer labels did not directly advance any government interest because consumers could get that information in other ways. *See id.* Here, as noted, the government's speech ban permits speech encouraging off-label uses from everyone but manufacturers. *See supra* pp. 3, 10-11. Indeed, the government even allows manufacturers to speak about unapproved uses under various exceptions, such as in response to an unsolicited request from a doctor. 59 Fed. Reg. at 59,823. Thus, while a speech ban obviously provides some incentive for manufacturers to proceed through the FDA regulatory process, that incentive is substantially weakened because other entities may fully promote those off-label uses with impunity. If a particular unapproved use has become the standard of care, for example, that information will get to doctors through other channels. As in *Rubin*, therefore, these "exemptions and inconsistencies" call into doubt the government's claim that its speech ban directly advances its interests.

Second, "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *W. States*, 535 U.S. at 371. Here, the government appears to assert that off-label promotion must be banned to avoid the misuse of drugs or devices caused by doctors' lack of accurate information. That assertion is an entirely unsupported and *post hoc* rationalization of the government's enforcement position; however, even accepting it *arguendo*, the government has numerous alternatives at its disposal that restrict less speech. For example, the government could engage in its own speech to "guide physicians . . . in differentiating between misleading and false promotion, exaggerations and embellishments, and truthful or non-misleading information," while reminding them of "the legal liability surrounding off-label . . . treatment decisions."*Caronia*, 703 F.3d at 168. Alternatively, the Supreme Court has "repeatedly point[ed] to disclaimers as constitutionally preferable to outright suppression" of speech. *Pearson*, 164 F.3d at 657. The government could thus require manufacturers, when they speak about unapproved uses, to disclose to physicians that the uses have not been approved by the FDA. Those

disclaimer requirements would provide substantial incentives for manufacturers to obtain FDA approval for those uses, especially if FDA approval is viewed by physicians as important as the government believes it to be. (Conversely, if physicians are indifferent to prior FDA approval, this severely undermines the already weak interest in securing such approval for all uses.) Lastly, the government could "cap[] the amount" of the device that a manufacturer may sell for off-label uses or adopt a "limitation on the percentage of [a device's] total sales that [off-label uses] may represent." *W. States*, 535 U.S. at 372; *Caronia*, 703 F.3d at 167. The First Amendment does not allow the government to impose a flat speech ban without trying obvious alternatives that could directly further its purported interest while restricting less speech.

## II. ANY CLAIM THAT THE PROHIBITION ON OFF-LABEL PROMOTION REGULATES CONDUCT RATHER THAN SPEECH IS MERITLESS

Elsewhere, the government has argued that its regulatory scheme does not prohibit speech but only uses it as evidence of "intent" to engage in unlawful conduct. *See Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993); *Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004) (same). This argument has rightly been rejected by every court to consider the question (and by numerous commentators). *E.g.*, *Caronia*, 703 F.3d at 160-62; *WLF*, 13 F. Supp. 2d at 59-60; *Amarin*, 2015 WL 4720039 , at *25; Rodney A. Smolla, *Off-Label Drug Advertising and the First Amendment*, 50 Wake Forest L. Rev. 81, 111-18 (2015); Coleen Klasmeier & Martin H. Redish, *Off- Label Prescription Advertising, the FDA and the First Amendment*, 37 Am. J. of L. & Med. 315, 342-44 (2011).

As an initial matter, even if the government is correct that its regime regulates conduct, not speech, *Sorrell* confirms that it would still be subject to heightened scrutiny. In that case, Vermont made a similar argument—that the "sales, transfer, and use of prescriber-identifying information" at issue in that litigation was "conduct, not speech." 131 S. Ct. at 2666. "[E]ven assuming" that to be true, the Court applied "heightened scrutiny" due to Vermont's content and speaker-based discrimination. *Id.* at 2667. While purporting to regulate conduct, the law imposed "a speaker- and

content-based *burden* on protected expression, and that circumstance [was] sufficient to justify application of heightened scrutiny." *Id.* (emphasis added). Thus, even assuming the regime at issue here does not outlaw speech promoting off-label uses, the government has clearly "impose[d] a speaker- and content-based *burden* on [that] protected expression" by treating such speech as at least partial grounds for criminal prosecution. *Id.* "[T]hat circumstance is sufficient to justify application of heightened scrutiny." *Id.* Indeed, were there any doubt that *Sorrell* subjects the FDA's off-label regime to First Amendment scrutiny, the dissent explicitly acknowledged that the Court's decision would "apply to similar regulatory actions taken . . . by the . . . Food and Drug Administration" and would restrict the government's ability to "control in detail just what a pharmaceutical firm can, and cannot, tell potential purchasers about its products." *Id.* at 2675-76, 78 (Breyer, J., dissenting).

In any event, the "off-label" regime clearly does not use speech to prove impermissible "intent" about proscribed "conduct," because the underlying statutory offense to be "proved"—*misbranding*—is itself a *speech* restriction, and "intent" is not an "element" of the offense under either the FDCA or the FDA's regulations.

Far from being a restriction on "conduct," the "misbranding" prohibition is a government-*compelled speech* requirement, mandating that a product be accompanied by certain government-approved speech on its label. 21 U.S.C. § 352(f)(1); 21 C.F.R. § 801.5 (requiring labeling to include "[s]tatements of all conditions, purposes, or uses for which such device is intended").[2] Moreover, the FDA's (erroneous) interpretation has expanded this speech *compulsion* into a speech *restriction*, effectively forbidding manufacturers from making any statements to doctors that depart from the

[2] On its face, the adulteration provision only prohibits distribution of unapproved devices, 21 U.S.C. § 351(f)(1)(B), which cannot reach Defendants because it is conceded that the FDA has cleared the Vari-Lase system. If the Court accepts the Government's atextual interpretation of that provision to proscribe promotion of approved devices for unapproved uses, it suffers from the same First Amendment flaws as the Government's misinterpretation of the misbranding provision.

government-compelled message on the product's label. Stated differently, the FDCA does not prohibit manufacturers from selling a drug or device with the intent that it be used in a manner not approved by the FDA; rather, on the FDA's theory, the FDCA prohibits the sale of a drug or device without a label that describes the use and directions for use intended by the manufacturer. The underlying offense, especially under the FDA's interpretation, is thus a regulation of speech, not conduct. Accordingly, *Mitchell*'s exception, which allows speech to be used for the limited purpose of establishing "intent" to engage in proscribed "conduct," is clearly inapplicable here.

*Mitchell* itself makes this clear. There, the Court recognized that while the government could use speech as "evidence of intent" to commit a non-speech-based crime (i.e., battery), it could not do likewise where the underlying regulation itself involved a restriction on expression. 508 U.S. at 487. It thus distinguished *R.A.V.*, where the Court had struck down an ordinance that "only proscribed a class of 'fighting words' deemed particularly offensive by the city—i.e., those 'that contain messages of 'bias-motivated' hatred." *Id.* (quoting *R.A.V.*, 505 U.S. at 392).

In other words, while the Court has narrowly allowed speech to prove the prohibited scienter for non-expressive conduct, it has never endorsed the bizarre principle that speech can be used to "prove" an underlying *speech restriction* without implicating the First Amendment. The underlying speech restriction is *exacerbated* by the *additional* use of the speaker's words to condemn the speaker; it cannot be used to *justify* such hostile use of speech. Smolla, *supra*, at 114 ("[The] evidentiary-use principle is valid *only* when the elements of the underlying crime or tort do not *themselves* require expressive activity. [Then,] it is possible to coherently separate the use of speech as evidence of a nonspeech element from the imposition of liability for the speech itself. When expressive activity is a necessary element of the crime or tort, no such separation is possible."). The government could not, for example, avoid First Amendment scrutiny in a defamation prosecution by claiming to use the defendant's defamatory speech as mere "evidence of defamatory intent,"

because the offense at issue is a speech restriction. Thus, *Amarin* expressly rejected the government's argument that *Mitchell* applies where the underlying offense is based on speech, i.e., "jury tampering, insider trading, [or] blackmail." *Amarin*, 2015 WL 4720039, at *23.

In any event, the "intent" requirement allegedly being "proved" can be found nowhere in the statute—it is solely a *post hoc* interpretation that the FDA devised in order to justify its naked speech restrictions. The government pretends that the FDCA proscribes selling products if the manufacturer has a certain "intent." But that word is not in the misbranding provision. Rather, it prohibits sale of the product unless accompanied by certain *speech*; *i.e.*, a *label* reciting the government-approved uses. *E.g.*, 21 U.S.C. § 352(f)(1). And the FDA's expansion of the misbranding provision is even more obviously a speech restriction; indeed, a content-based one. It effectively forbids manufacturers from saying anything other than what appears on the label. If they echo the label's direction for approved uses, that is permissible. But they can say nothing about an *unapproved use*, even if they echo the label's directions for an approved use. The government obviously cannot justify this pure speech restriction by rewriting the statute to have an "intent to sell" requirement, and then pretending the banned speech is evidence of this invented, proscribed "conduct." This is particularly true since even the FDA's regulations only outlaw a proscribed "objective" intent. 21 C.F.R. § 801.4. Thus, under both the statute and the regulations, the speaker's *subjective* intent—that the "off-label" speech purportedly "proves"—is *irrelevant*.

*Western States* is again instructive. *Supra* p.9. In striking down a law that made the legality of the sale of compounded drugs turn on whether they had been "advertised," 535 U.S. at 370, the Supreme Court made clear that the government could not transform a speech restriction into a "conduct" prohibition "proved" by speech. Even though—unlike here—the law in *Western States* could have reached the same result if it had been recast as a ban on modifying drugs with the "intent"

to provide them to the general public (with advertising used as "evidence" of this intent), the Court subjected the statute to First Amendment scrutiny and invalidated it. This Court should do likewise.

In reality, the government's intent/conduct argument is nothing more than a sham to justify its regulation of protected expression. For years, the government made no effort to hide that its regulations amounted to a naked restriction on manufacturers' speech. *E.g.*, 74 Fed. Reg. 48,083, 48,087 (Sept. 21, 2009) ("Under the act, companies are prohibited from promoting approved . . . drugs . . . for unapproved uses."); 62 Fed. Reg. at 64,081 (stating that the FDA "has consistently prohibited the promotion of . . . unapproved uses of approved products"); 37 Fed. Reg. 16,503, 16,504 (Aug. 15, 1972) (forbidding "a manufacturer or his representative" from doing "anything that directly or indirectly suggests to the physician . . . that an approved drug may properly be used for unapproved uses"). Likewise, in *Caronia*, the Second Circuit explained that "the government's theory of prosecution *identified* . . . *speech alone* [i.e., marketing and promotion] as the proscribed conduct." 703 F.3d at 159; *see also id.* at 158 & n.6, 160-61 (citing numerous examples). Indeed, the government obtained a jury instruction stating that the "'promotion of [a] drug by a distributor for an intended use different from the use for which the drug was approved by the FDA'" was a criminal offense. *Id.* at 159. Only after courts began to strike down its patently unconstitutional regime did the government's tune begin to change: the language of "promotion" and "marketing" was replaced with the language of "intent." *Compare Good Reprint Practices*, *supra*, § III ("Similarly, a medical device *that is promoted* for a use that has not been approved or cleared by FDA is adulterated and misbranded." (emphasis added)), *with* FDA, *Distributing Scientific and Medical Publications on Unapproved New Uses* § III (Revised Feb. 2014) ("Similarly, a medical device *that is intended* for an unapproved use is considered adulterated and misbranded." (emphasis added)), www.fda.gov/down loads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm387652.pdf. This sleight of hand cannot obscure the fact that the government is, and always has been, regulating speech.

The government's claim to be regulating conduct, not speech, is particularly brazen when its only evidence of "adulteration" or "misbranding" is the *speech* of the manufacturer. *E.g.*, Indict. ¶¶ 41, 53, 44 (accusing Vascular Solutions of encouraging its sales employees to provide doctors with "arguments for why lasers were better for treating perforators than . . . competing" products, "articles suggesting that lasers were effective at treating perforators," and information regarding "the benefits of [using the Vari-Lase system] for perforator treatment" as well as the "success that other doctors had using the kit for this purpose"). "[I]f the FDA were truly concerned with the manufacturer's non-expressive act of sale with intent that the product be used off-label, it would logically prohibit *all* sales of a drug [or device] widely used off-label, because *any* time the manufacturer sells its drug [or device], it would do so with knowledge that it will be used for off-label purposes." Klasmeier & Redish, *supra*, at 343. But "there is no indication that the FDA has *ever* pursued a manufacturer for selling its drug [or device] with knowledge that it will be used for off-label purposes, absent off-label promotion." *Id.*; Smolla, *supra*, at 114. "Off-label promotion, then, constitutes both a necessary and sufficient condition for FDA action against a manufacturer." Klasmeier & Redish, *supra*, at 343. Contrary to its claims, therefore, the government "is not seeking to regulate the *act* of sale for the purpose of off-label use; it is, rather, seeking to regulate solely the expression itself—nothing more, nothing less." *Id.*

In short, if the government cannot obtain a conviction without establishing that Vascular Solutions promoted Vari-Lase for off-label use, it cannot claim to be regulating anything other than speech. Using the content of a defendant's speech as the *sine qua non* of whether he has engaged in lawful or unlawful conduct is constitutionally indistinguishable from directly outlawing that speech.

## CONCLUSION

For these reasons, because the indictment seeks to hold Vascular Solutions liable for truthful, non-misleading speech about off-label uses of the Vari-Lase system, it must be dismissed.

Dated: August 13, 2015

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## CERTIFICATE OF SERVICE

I hereby certify that, on August 13, 2015, I caused a true and correct copy of the foregoing document to be transmitted via email and UPS Overnight to the Clerk of the United States District Court for the Western District of Texas, San Antonio Division, and a true and correct copy to be sent via U.S. Mail to all counsel of record, including:

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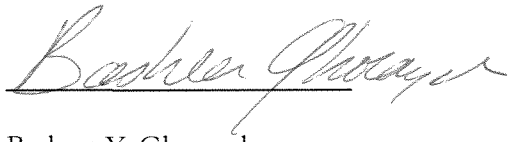

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