U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General *Washington, D.C. 20530*

SEP 0 6 2018

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Mike Lee
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Chairman Grassley and Senator Lee:

This responds to your letter to the Deputy Attorney General dated March 22, 2018, regarding the Department of Justice's (Department) prosecution of Howard Root and Vascular Solutions, Inc., in *United States v. Vascular Solutions, Inc.*, No. SA-14-CR-926 (W.D. Tex.).

In a June 23, 2016 letter, then-Assistant Attorney General Peter J. Kadzik of the Department's Office of Legislative Affairs informed you that misconduct allegations against the trial attorneys had been raised by the defendants in a motion to dismiss the indictment, and that in an opinion (enclosed) dated November 16, 2015, the District Court rejected each one as unfounded. OLA also informed you, however, that the Department's Office of Professional Responsibility (OPR) had initiated an inquiry into the conduct of the Department attorneys who handled the *Vascular Solutions* prosecution.

For background, OPR has jurisdiction to review and investigate allegations of misconduct involving Department attorneys that relate to the exercise of their authority to investigate, litigate, or provide legal advice. *See* 28 C.F.R. § 0.39(a)(1). During its inquiry, OPR requested and received detailed written responses to the allegations of misconduct from the Department attorneys involved in the investigation and prosecution of Vascular Solutions. Those attorneys submitted hundreds of documents to OPR, which OPR reviewed, along with additional documents and exhibits, interview reports, grand jury and trial transcripts, case law, and Department guidelines and policies. In June 2017, after carefully considering the allegations raised by Mr. Root's attorneys, OPR found no evidence that Department attorneys engaged in professional misconduct and closed its inquiry into this matter. OPR notified Mr. Root's attorneys of its conclusions.

During the course of the *Vascular Solutions* case, the defendants raised with the court their concerns regarding the prosecutors' conduct before the grand jury, including in a motion to dismiss the indictment because of prosecutorial misconduct. The defense raised many of the

same issues raised in your letter. Among other things, the defense alleged that the Department attorneys improperly threatened certain grand jury witnesses to try to make their testimony conform to the government's theory of the case, and that the Department attorneys disclosed grand jury testimony of witnesses to other grand jury witnesses in order to shape their testimony. In its November 16, 2015 order, the District Court rejected those allegations. The District Court noted that the law allows a prosecutor to inform a witness of the consequences of providing false testimony, including perjury charges, and concluded that the "attorneys for the government did not improperly threaten witnesses by giving them disclosures and warnings concerning their criminal exposure or the potential consequences for giving false testimony." The District Court further found that "[t]he record [did] not demonstrate that the attorneys for the government forced any witness to lie or that they misshaped the testimony of any witness." The court concluded that the prosecutors had not committed professional misconduct, and specifically considered and rejected the allegations that the prosecutors committed misconduct before the grand jury. OPR adduced no evidence to indicate that the court's findings were wrong, or reached without a full and thorough review of all of the pertinent facts and circumstances.

At your request, OPR also reviewed statements in a Vascular Solutions post-trial press release dated February 26, 2016, that criticized as "false and misleading" certain statements contained in two pretrial Department press releases. The first Department press release complained about by Vascular Solutions, dated November 13, 2014, describes the *Vascular Solutions* case as about "a deceptive sales campaign led by the CEO of a public company." The press release further stated that the company's "sales campaign persisted in the face of FDA warnings, a whistleblower's complaint to the CEO and a failed clinical trial showing that the device was less safe and less effective than a product that had already been approved." OPR concluded that the statements accurately reflected the charges in the indictment and that it was not improper for the charges to be restated in the press release. OPR noted that the quotes from the Department's press statement that Vascular Solutions found objectionable were nearly identical to the language used by the District Court in its order of November 16, 2015, in summarizing the charges in the indictment. OPR concluded that the fact that the jury ultimately acquitted the defendants did not render the description of the charges in the press statement either false or misleading.

The second Department press release at issue, dated July 28, 2014, announced that Vascular Solutions had agreed to pay $520,000 to settle a *qui tam* action, *United States ex rel. DeSalle Bui v. Vascular Solutions, Inc.*, No. A10CA883-SS (W.D. Tex.), in which the Company was accused of causing false claims to be submitted to federal health programs by marketing a medical device to seal perforator veins without FDA approval, despite its own failed clinical study. The press release contained a statement of a former Assistant Attorney General that "[t]he FDA approval process and clinical studies serve an important role in ensuring that federal health care participants receive devices that are medically appropriate and necessary," and that the Department "will not permit companies to circumvent [the FDA approval] process and put

profits over patient safety." OPR's review of this press release considered (1) that Section 1-7.500(D) of the United States Attorneys' Manual specifically permits Department officials to discuss the public policy significance of a case; *see* https://www.justice.gov/usam/usam-1-7000-media-relations#1-7.500; and (2) that the statements in the press release were also permissible under American Bar Association (ABA) Model Rule 3.6 (Trial Publicity). ABA Model Rule 3.6 permits an attorney to make an extrajudicial statement that he or she knows may be disseminated by means of public communication regarding the claim and offense involved in a case, the identity of the defendants, information in the public record, the result of litigation, and the risks to the public associated with the conduct of the defendant. OPR concluded that the statements in the press release were therefore both appropriate and not subject to reasonable dispute.

OPR also considered at your request, an allegation referenced in your letter of May 19, 2016, that the Department failed to adequately investigate the Company's conduct before seeking the indictment. OPR determined that this claim is not supported by the facts. The government's investigation lasted several years. The Department lawyers reviewed thousands of documents and examined dozens of witnesses before the grand jury. Even before the grand jury returned its indictment, the defense attorneys contested the case vigorously. The defense attorneys presented what they considered to be exculpatory evidence to Department officials, including in a 61-slide PowerPoint presentation. In that presentation, and in their letters to the Department in October and November 2014, they suggested that the grand jury, or the Department, needed to consider purportedly exculpatory evidence, including: (1) public and private insurance policies allegedly covering the laser treatment of varicose veins; (2) purportedly inconsistent statements by witnesses regarding the Company's alleged misconduct; (3) witness statements allegedly contradicting the prosecution's misbranding, adulteration, and health care fraud theories; (4) scientific information and medical literature purportedly probative of the safety and efficacy of the laser treatment of varicose veins; and (5) Instructions For Use, as revised, under which physicians allegedly could safely use VSI's medical device to treat varicose veins. OPR found no evidence to support a conclusion that the Department trial attorneys and officials acted inappropriately by making the litigation decisions they made, and which were extensively examined before indictment and during the trial. The defense filed motions to dismiss the indictment, which the District Court rejected in its November 16, 2015 order. Moreover, at the conclusion of the government's case at trial, the defense argued for a judgment of acquittal, arguing that the government had not established its *prima facie* case under any count of the indictment. The District Court denied the motion, ruling that there was sufficient evidence for the case to go to the jury on all counts.

Finally, with respect to your concerns about Department participation in certain conferences, we can inform you that it is not uncommon for Department attorneys to receive invitations to participate in conferences or other events related to their official duties. The decision to accept a particular invitation depends on a variety of factors, including the demands of existing workloads, the proposed content of the conference and the Department's requested

engagement in it, Departmental policies concerning extrajudicial statements, and whether participation would be in the interests of the Department and its mission.

We hope this information is helpful. Please do not hesitate to contact this office if we may provide additional assistance regarding this or any other matter.

Sincerely,

Stephen E. Boyd
Assistant Attorney General

Enclosure

cc: The Honorable Dianne Feinstein
Ranking Member

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA,	§	
	§	
Plaintiff,	§	
	§	
	§	**CRIMINAL NO. SA-14-CR-926-FB**
	§	
VASCULAR SOLUTIONS, INC. (1), and HOWARD C. ROOT (2),	§	
	§	
	§	
Defendants.	§	

ORDER REGARDING DEFENDANTS' MOTIONS TO DISMISS AND MOTION TO COMPEL PRODUCTION OF GRAND JURY INSTRUCTIONS

Before the Court are Defendant Howard C. Root's Motion to Dismiss the Indictment (docket no. 75), Defendants' Motion to Dismiss the Indictment Based on Government Misconduct (docket no. 78), Defendants' Motion to Dismiss the Indictment or, in the Alternative, to Preclude the Government from Using Defendants' Truthful Speech to Prove Misbranding and Adulteration Counts (docket no. 79), and Defendants' Motion to Compel Production of Legal Instructions to the Grand Jury (docket no. 87). After careful consideration, the Court is of the opinion the motions should be denied.

BACKGROUND

Vascular Solutions, Inc. ("VSI") and its chief executive officer, Howard Root, are charged with selling medical devices without U.S. Food and Drug Administration ("FDA") approval and conspiring to defraud the United States by concealing the illegal sales activity. The devices at issue are from VSI's "Vari-Lase" product line, a medical system designed to enable physicians to treat varicose veins by burning or "ablating" them with laser energy. VSI and Mr. Root are each charged with one count of conspiracy and eight counts of introducing adulterated and misbranded medical devices into interstate commerce.

This case involves an allegedly deceptive sales campaign led by Mr. Root. The indictment charges that the illegal promotion persisted in the face of FDA warnings, a whistleblower's complaint to the CEO, and a failed clinical trial showing that the device was less safe and less effective than a product which had already been approved. According to the indictment, the Vari-Lase products were approved by the FDA only for the treatment of superficial veins, but VSI and Mr. Root sold them for the ablation, or removal, of "perforator" veins, which connect the superficial vein system to the deep vein system. Because perforator veins come into direct contact with deep veins, treating them with lasers is a more difficult and risky procedure.

Mr. Root is charged with leading the illegal sales campaign, which purportedly lasted from 2007 to 2014, and conspiring with others to conceal it from the FDA. The indictment alleges that Mr. Root authorized the campaign after VSI failed to obtain FDA authorization to sell the Vari-Lase system for ablation of perforator veins. The sales campaign is purported to have ignored FDA concerns about the safety and effectiveness of the procedure and specific warnings from the FDA not to sell Vari-Lase products for treatment of perforator veins. The indictment charges that, with Mr. Root's approval, the sales continued even after the company sponsored an unsuccessful clinical trial which showed that the Vari-Lase system was less safe and effective than a competing device the FDA had cleared for perforator vein treatment. According to the indictment, the sales continued even after a whistleblower complained to Mr. Root in 2009 and the government told the company about its investigation in 2011.

The indictment also charges VSI and Mr. Root with deceiving the FDA. According to the government, in late 2007, Mr. Root introduced a special "Short Kit" designed for perforator vein treatment, without FDA marketing authorization, contending that the product was intended for "short vein segments" or "short veins." At the same time, the government alleges that internal company

documents approved by Mr. Root taught the VSI sales force that these terms included perforator veins and urged salespeople to suggest to physicians that Vari-Lase could be used to treat perforator veins. The indictment states that, after learning about the government's investigation, VSI salespersons were still selling Vari-Lase devices for perforator vein treatment. Two other members of the sales force are alleged to have misled investigators. In addition, the indictment charges that one member falsely denied his conduct and another blamed a lower-level salesperson for any wrongdoing.[1]

DISCUSSION

I. Dismissal Based on the First Amendment

Defendants argue the indictment is preventing them from engaging in constitutionally protected truthful speech. VSI and Mr. Root move for dismissal arguing that the indictment seeks to make criminal their truthful statements to doctors relating to the use of its Vari-Lase devices in an "off-label" procedure–that is, a use other than the one approved by the FDA. Defendants rely on *United States v. Caronia,* 703 F.3d 149, 168 (2d Cir. 2012), and *Amarin Pharma, Inc. v. United States Food & Drug Admin.,* No. 1:15-cv-03588-PAE, 2015 WL 4720039 (S.D.N.Y. Aug. 7, 2015) .

In *Amarin Pharma,* the Court set out the legal landscape on this issue leading up to the *Caronia* decision.

> Before *Caronia*, only limited First Amendment challenges to the FDA's policies with respect to the off-label promotion of approved drugs had reached the courts, and none had challenged the FDA's application of the misbranding provisions to truthful and non-misleading promotional statements.

[1] In July of 2014, VSI agreed to pay $520,000 to resolve allegations that it caused false claims to be submitted to federal health programs by marketing the Vari-Lase devices for treating perforator veins. In that civil action, the government alleged that VSI knowingly caused physicians and other purchasers of the Short Kit to submit false claims to federal health care programs for uses of the Short Kit which were not reimbursable.

> Most notable of these First Amendment challenges was the 1998 decision in [*Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998)]. The plaintiff there, a public interest group, sought to enjoin as facially unconstitutional FDA policies (expressed in guidance documents) that had restricted manufacturers from distributing textbook excerpts and article reprints from medical and scientific journals to the extent they (1) addressed off-label uses of FDA-approved drugs and (2) were truthful and non-misleading. The district court rejected the FDA's argument that these communications proposed an illegal transaction and thus were unprotected. 13 F. Supp. 2d at 62–65; see *Wash. Legal Found. v. Henney*, 202 F.3d 331, 334 (D.C. Cir. 2000). It held that the communications were commercial speech and that the FDA's restrictions were unconstitutional under the test for commercial speech of *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 100 S. Ct. 2343, 65 L. Ed. 2d 341 (1980). Although recognizing that the FDA's policies advanced a substantial government interest in requiring manufacturers to submit supplemental applications for new drug uses, 13 F. Supp. 2d at 70–73, the court held the FDA's restrictions on such speech were more extensive than necessary, and thus breached the First Amendment, *id.* at 65–69, 72–74. It enjoined the FDA from prohibiting manufacturers from distributing the reprints and excerpts "regardless of whether such [materials] include[ ] a significant or exclusive focus" on off-label uses. *Id.* at 74–75. However, while the case was on appeal, the FDA adopted a much narrower construction of its guidance documents. This mooted the controversy and caused the injunction to be lifted.

Amarin Pharma, Inc., 2015 WL 4720039, at *7. The District Court's decision in *United States v. Caronia*, 576 F. Supp. 2d 385, 393-94 (E.D.N.Y. 2008), *vacated and remanded by United States v. Caronia,* 703 F.3d 149 (2d Cir. 2012), observed that, at that time, "[t]he seminal case on the FDA's regulation of guidance relating to the off-label use of prescription drugs is Judge [Royce C.] Lamberth's decision in *Washington Legal Foundation v. Friedman* . . .." *Id.* Then came the Second Circuit's decision in *Caronia.*

In *Caronia,* 703 F.3d at 168, the Court of Appeals for the Second Circuit vacated a pharmaceutical sales representative's conviction for conspiring to introduce a misbranded drug into interstate commerce. The conviction was based on Mr. Caronia's having promoted a drug for off-label use. *Id.* Mr. Caronia's conduct to promote the off-label use, however, had consisted solely of truthful

and non-misleading speech. *Id.* The Second Circuit undertook an analysis under *Central Hudson* and held that, to avoid infringing the First Amendment, the misbranding provisions of the federal Food, Drug and Cosmetic Act ("FDCA") must be construed "as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs" where the off-label use itself is lawful. *Id.* (discussing *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 563-66). The Second Circuit also noted that "off-label promotion that is false or misleading is not entitled to First Amendment protection." *Id.* at 165 n.10 (citing *Central Hudson Gas & Elec. Corp.*, 477 U.S. at 566).

In *Amarin Pharma,* the District Court granted preliminary relief to Amarin Pharma Incorporated, the maker of the triglyceride-lowering drug Vascepa. 2015 WL 4720039, at *7. The District Court rejected the FDA's contention that it could bring an enforcement action against the company on the basis of statements that the Court said were "derived largely from an FDA-approved study of Vascepa's off-label use, and from writings by the FDA itself on that subject." *Id.* at *1. The District Court held that, under the decision of *Caronia,* 703 F.3d at 159, the FDA may not bring a misbranding action against a manufacturer "based on truthful promotional speech alone, consistent with the First Amendment." *Id.* at *23. The District Court also observed:

> the First Amendment does not protect false or misleading commercial speech. *Caronia*'s construction of misbranding provisions so to exclude truthful promotion speech affords no protection to a manufacturer that uses false or misleading communications to promote an off-label use.

Id. at *27. Defendants allege this case grows out of the decisions in *Caronia* and *Amarin Pharma.*

Defendants' reliance on *Caronia* and *Amarin Pharma* is misplaced because those cases held that the misbranding provisions of the FDCA did not prohibit off-label promotion of FDA-approved prescription drugs that is solely truthful. The United States' claims are premised on allegations that

defendants' off-label promotion of the Vari-Lase devices for the treatment of perforator veins was not solely truthful, but rather was misleading and false. The FDCA does prohibit untruthful off-label promotion. *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 702 (S.D. Tex. 2014) ("federal law bars off-label promotion when it is false or misleading"). The First Amendment does not protect off-label promotion that is false or misleading. *Caronia,* 703 F.3d at 165 n.10; *Amarin Pharma, Inc.*, 2015 WL 4720039, at *27.

II. Defendant Root's Motion to Dismiss the Indictment

Defendant Root seeks to have the indictment dismissed because the statutes on which the indictment is based are unconstitutionally vague; the indictment violates the First Amendment; the indictment fails to state a claim of conspiracy; and count one of the indictment is duplicitous. Defendant's First Amendment claims lack merit, as discussed above. Also, defendant argues the promotional speech was not false or misleading. Those are factual matters to be resolved at trial.

Defendant moreover contends that the statute and regulations are unconstitutionally vague because they do not provide notice to enable ordinary people to understand what conduct is prohibited and because they authorize and encourage arbitrary and discriminatory enforcement. *See City of Chicago v. Morales*, 527 U.S. 41, 56 (1999). Defendant's argument that is premised on the First Amendment lacks merit, because there is no First Amendment protection for false and misleading off-label promotion, as discussed above.

The regulation challenged by defendant concerns when to file premarket notifications with the FDA, and it does not involve First Amendment freedoms. *United States v. Caputo*, 288 F. Supp. 2d 912, 917-18 (N.D. Ill. 2003). Defendant has not shown the statute or regulations are unconstitutionally vague. *See United States v. Caputo*, 517 F.3d 935, 940-41 (7th Cir. 2008) (rejecting vagueness claim

regarding phrase "major change . . . in the intended use" in FDA regulations and noting any uncertainty was offset by notice from the FDA regarding the need for new approval of a device). Courts have rejected similar vagueness challenges in drug misbranding cases. *United States v. Reece*, Crim. No. 12-00146, 2013 WL 5234124, at *7-8 (W.D. La. Sept. 13, 2013) ("*United States v. Sullivan*, 332 U.S. 689, 695 (1948) (finding no ambiguity in the misbranding language of the Act and accordingly upholding provision requiring adequate directions for use and adequate warning against use); *United States v. Forester*, 346 F.2d 685, 685 (4th Cir. 1965) (per curiam) (upholding provision deeming prescription drug to be misbranded if not dispensed pursuant to a prescription); *United States v. General Nutrition, Inc.*, 638 F. Supp. 556, 564 (W.D. N.Y. 1986) (upholding provision requiring adequate directions for use and adequate warnings and noting unawareness of any case invalidating any provision of the FDCA 'in any circumstance')").

"Objections to vagueness . . . rest on the lack of notice, and hence may be overcome in any specific case where reasonable persons would know that their conduct is at risk." *Maynard v. Cartwright*, 486 U.S. 356, 361 (1988). The indictment alleges facts that suggest defendants received notice from the FDA about the marketing of the device at issue in this case. Regarding defendant's claim of arbitrary enforcement, defendant has not shown the regulations are so vague that there is no consistent standard being applied when comparing his prosecution to the failure to prosecute situations involving devices for pediatric surgery and biliary stents. *See United States v. General Nutrition, Inc.*, 638 F. Supp. at 560-61.

Defendant's argument that the indictment fails to state a claim of conspiracy lacks merit. *See United States v. Arlen*, 947 F.2d 139 (5th Cir. 1991). Defendant's claim that the indictment is duplicitous also lacks merit. An indictment may allege in one count both a conspiracy to commit an

offense against the United States and a conspiracy to defraud the United States. *See United States v. Wiley*, 979 F.2d 365, 367-68 (5th Cir. 1992); *see also United States v. Rigas*, 605 F.3d 194, 210-11 (3rd Cir. 2010); *United States v. Hauck*, 980 F.2d 611, 615 (10th Cir. 1992); *United States v. Smith*, 891 F.2d 703, 711-12 (9th Cir. 1989). Defendant's reliance on dicta in *United States v. Haga*, 821 F.2d 1036 (5th Cir. 1987), is misplaced, because *Haga* is a variance case. *United States v. Arlen*, 947 F.2d at 142-43.

III. Dismissal Based on Government Misconduct

Defendants argue the indictment must be dismissed as a matter of law because of prosecutorial misconduct. Specifically, defendants allege prosecutors told witnesses to testify to the prosecutors' version of events or face consequences; prosecutors read grand jury testimony of witnesses to other witnesses; prosecutors provided the grand jury with false and misleading testimony; prosecutors used grand jury subpoenas to induce witnesses to submit to sworn private examinations outside the presence of the grand jury; prosecutors discouraged testimony contrary to its theory by interfering with witnesses' attorney-client relationship; prosecutors misinstructed the grand jury on the law; and prosecutors elicited legal opinions from lay witnesses.

"[A] district court may use its supervisory power to dismiss an indictment because of misconduct before the [grand] jury, at least where that misconduct amounts to a violation of one of those few, clear rules which were carefully drafted and approved by [the United States Supreme Court] and by Congress to ensure the integrity of the grand jury's function." *United States v. Strouse*, 286 F.3d 767, 771-72 (5th Cir. 2002) (internal quotation marks omitted). "[D]ismissal of the indictment is appropriate only if it is established that the violation substantially influenced the grand jury's decision to indict, or if there is grave doubt that the decision to indict was free from the substantial influence of such violations." *Bank of Nova Scotia v. United States*, 487 U.S. 250, 256 (1988) (internal quotation

marks omitted). "A district court may not dismiss an indictment for errors in grand jury proceedings unless such error prejudiced the defendant. Whether or not prosecutorial misconduct prejudiced a defendant depends on whether it affected the grand jury's decision to indict." *United States v. Whitfield*, 590 F.3d 325, 359 (5th Cir. 2009) (internal quotation marks and citation omitted).

A. Alleged threatening of witnesses

Defendants argue that witnesses who contradicted the prosecution theory were threatened by the government with criminal prosecution, loss of employment, and exclusion from participation in federal healthcare programs unless the witnesses changed their testimony to coincide with the government's theory of the case. A review of the record reveals that in some instances the government attorney expressed a belief that witnesses were not necessarily lying, but that witnesses were not forthcoming. In other words, the government attorney stated a belief that those witnesses were being misleading or were not telling the whole truth.

In the primary case on which defendants rely, *United States v. Linder*, No. 12-CR-22, 2013 WL 8123842 (N.D. Ill. March 5, 2013), the Court dismissed an indictment based on threats to witnesses. The Court stated:

> it is within the Executive Branch's power and authority to candidly warn a target of a prosecution that he can be charged with criminal offenses of which the prosecutor is aware and has evidence to support. This aggressive questioning can even include the candid threat of various sentences that a target could receive based on the evidence. But there is a difference between candidly and aggressively threatening a target with prosecution for offenses for which the target can be charged and the flippant threat that a target will be prosecuted for lying simply because that witness is not answering the investigator's questions in the way that the investigator believes they should be answered. Without support for such an accusation, the threat of prosecution for perjury or for conspiring with the defendant crosses the line and becomes of threat from an overbearing investigator used to bully the witness into compliance.

Id. at *50.

Defendants maintain government attorneys did not tell witnesses to tell the truth or suffer the consequences. Instead, defendants assert the prosecutors told witnesses to provide testimony consistent with other witnesses or suffer the consequences. Defendants note government attorneys mentioned "the truth" to witnesses and their attorneys, but defendants contend the prosecutors were referring to the government's version of "the truth." Defendants may disagree with the government about what is the truth regarding this case and the allegations in the indictment, but defendants have not shown the government attorneys had no basis for their belief that witnesses were not being truthful or were being less than completely truthful. Thus, this case is distinguishable from *Linder*.

A prosecutor may inform a grand jury witness he or she would be subject to prosecution for lying to the federal grand jury. *See United States v. Holloway*, 778 F.2d 653, 657 (11th Cir. 1985). A prosecutor may inform a witness that the government could bring charges against the witness if the witness does not cooperate as a witness for the government, *id.* at 657-58, at least provided there is a basis for such a prosecution. *Linder*, 2013 WL 8123842, at *50. "[A] warning of the consequences of perjury 'even if carried out in a caustic manner, is no cause to dismiss [an] indictment . . .." *United States v. Girod*, 646 F.3d 304, 312 (5th Cir. 2011) (quoting *United States v. Thompson*, 130 F.3d 676, 687 (5th Cir. 1997)).

Defendants have not presented evidence that any of the prosecutors' complained of conversations with witnesses caused a witness to testify falsely before the grand jury, *see United States v. Holloway*, 778 F.2d at 657, and that any such perjury was knowingly sponsored by the government. *United States v. Strouse*, 286 F.3d at 772.

B. Reading of grand jury testimony

Defendants argue the indictment must be dismissed as a matter of law under Fed. R. Crim. P. 6(e) because prosecutors disclosed to grand jury witnesses other witnesses' grand jury testimony without a court order. This rule provides that grand jurors and attorneys for the government may not "disclose a matter occurring before the grand jury" in the absence of permission from the court. Fed. R. Crim. P. 6(e)(2)(B)(i), (vi). In *United States v. Bazzano,* 570 F.2d 1120, 1125-126 (3d Cir. 1977), *cert. denied,* 436 U.S. 917 (1978), the Court of Appeals for the Third Circuit held that Rule 6(e) is violated whenever a government attorney discloses verbatim grand jury testimony of one witness to another in order to "shape" either or both the witnesses' trial testimony.

Defendants argue there were two witnesses to whom a portion of grand jury testimony was read. Defendants mention prosecutors read testimony to a third witness, but defendants state they are still exploring the incident.

According to the government, a witness testified before the grand jury, then she was read some other witness's testimony, but the identity of that other witness was not disclosed to her. The government states that witness who was exposed to grand jury testimony did not thereafter testify again before the grand jury. Defendants do not contradict the government's statement of these events.

Also according to the government, another witness testified before the grand jury, then he was read some other witness's testimony, but the identity of that other witness was not disclosed to him. The government states the witness who was read grand jury testimony did not thereafter testify again before the grand jury, but that witness executed a statement regarding his direction to another person that contradicted his grand jury testimony. The grand jury was informed about the witness's new statement. The grand jury testimony read to the witness was not about that witness's actions or

statements while directing that other person. Defendants do not contradict the government's statement of these events.

Defendants complain about grand jury testimony being read to these two witnesses. Neither witness testified after being read grand jury testimony. One of those witnesses made a statement after being read grand jury testimony, and the grand jury was informed about one matter in that statement. However, the witness's new statement did not involve the matters in the grand jury testimony read to that witness. Defendant's have not shown that the reading of grand jury testimony to witnesses substantially influenced the grand jury's decision to indict defendants. Defendants have not shown they were prejudiced by the reading of grand jury testimony to witnesses.[2]

C. Alleged use of false and misleading testimony

Defendants assert prosecutors provided the grand jury with false and misleading testimony. Specifically, they complain a prosecutor asked a case agent a question regarding FDA marketing authorization for treatment of perforator veins. Defendants contend the case agent's testimony was false, based on one interview the agent had with an FDA medical officer who recognized "in some sense" that the indication would include the treatment of perforator veins under some circumstances and, although not very common, it was possible. However, as defendants recognize, the medical officer also stated in his opinion that the indication did not include perforator ablation. Given what may be contradictions in the medical officer's statements in an interview, and because it is not clear what other

[2]In defendants' reply to the government's response to defendants' motion to dismiss based on misconduct, defendants ask that the witnesses who were read grand jury testimony be prohibited from testifying at trial. The defendants' motion to dismiss sought dismissal of the indictment, not exclusion of those witnesses from trial. The question of whether these witnesses may testify at trial is not properly before the Court. Additionally, it is not clear whether their testimony at trial will have been shaped by their having been read portions of grand jury testimony.

interviews the case agent relied on as bases for his testimony, defendants have not shown the government knowingly sponsored false testimony.

D. Private examinations outside grand jury's presence

Defendants contend prosecutors used grand jury subpoenas to induce witnesses to submit to sworn private examinations outside the presence of the grand jury. They argue government attorneys may not use grand jury subpoenas to compel witnesses to attend private interviews or examinations outside of the grand jury room. Defendants rely on *Durbin v. United States*, 221 F.2d 520 (D.C. Cir. 1954); *United States v. Wadlington*, 233 F.3d 1067 (8th Cir. 2000); and *United States v. DiGilio*, 538 F.2d 972 (3rd Cir. 1976). The government points out that the taking of testimony under grand jury conditions was an accommodation to witnesses so they would not have to travel to where the grand jury was located and the witnesses consented, which is permissible under *United States v. Pang*, 362 F.3d 1187, 1194-95 (9th Cir. 2004); and *United States v. International Paper Co.*, 457 F. Supp. 571 (S.D. Tex. 1978). The government notes that in the cases cited by defendants, the witnesses were not given a choice of where to provide testimony. Even if the choice was a difficult one because of the inconvenience of traveling or inconvenience of scheduling conflicts, that does not make it any less voluntary.

Defendants contend the government provided the grand jury the testimony of these witnesses by placing the transcripts on a table in the grand jury room on the morning of the indictment. Defendants contend by doing this the government failed to read or summarize exculpatory testimony to the grand jury. The government disputes that the testimony of these witnesses provided exculpatory evidence. Moreover, the failure to present exculpatory evidence to a grand jury is not a basis for dismissing an indictment. *United States v. Williams*, 504 U.S. 36 (1992). Defendants have not shown

that the indictment should be dismissed based on the taking of grand jury testimony outside the presence of the grand jury from subpoenaed witnesses who agreed to that procedure.

E. Alleged interference with witnesses' attorney-client relationship

Defendants assert government attorneys discouraged testimony contrary to its theory by interfering with witnesses' attorney-client relationship. Specifically, defendants claim prosecutors questioned witnesses about attorneys' advice regarding what their testimony should be or what they should emphasize. Defendants also argue that prosecutors also refused to permit a witness to consult with counsel when asked whether counsel told the witness to say something.

Prosecutors may ask witnesses whether they have been coached by counsel. *Geders v. United States*, 425 U.S. 80, 89-90 (1976). Also, defendants have not shown they were prejudiced and that the complained of incidents substantially influenced the grand jury's decision to indict defendants.

F. Alleged misstatement of law

Defendants contend government attorneys misstated law to the grand jury. For the reasons defendants' motion to compel grand jury instructions is denied, set out below, this claim also lacks merit. Defendants contend the case agent incorrectly testified about whether Medicare reimburses for certain procedures. Defendants point to opinion evidence they assert disputes the case agent's testimony. However, that does not conclusively establish the case agent lied and that the government attorneys knowingly sponsored perjury.

G. Alleged eliciting of legal opinions from lay witnesses

Defendants also contend government attorneys asked lay witnesses before the grand jury whether conduct was legal. Defendants argue this was improper, citing *United States v. El-Mezain*, 664 F.3d 467 (5th Cir. 2011); and *United States v. Riddle*, 103 F.3d 423 (5th Cir. 1997). However, those

cases involved testimony at trial, not before a grand jury. Moreover, an indictment may not be dismissed on the basis of incompetent evidence or the character of the evidence. *United States v. Calandra*, 414 U.S. 338, 344-45 (1974) (holding that indictment may not be dismissed on ground that grand jury acted on basis of inadequate or incompetent evidence); *United States v. Johnson*, 615 F.2d 1125, 1127 (5th Cir. 1980)("Indictments may not be challenged merely upon the ground that there was inadequate or incompetent evidence before the Grand Jury.") (citing *Costello v. United States*, 350 U.S. 359, 363 (1956)).

H. Conclusions regarding motion to dismiss for prosecutorial misconduct

Having considered the pleadings of the parties, as well as the exhibits and affidavits attached thereto, and in light of the foregoing analysis, the Court rules as follows on Defendants' Motion to Dismiss Based on Government Misconduct (docket no. 78):

1. The Court finds that this matter does not require a hearing. The pleadings have been extensive and the issues can be resolved on the record before the Court.

2. The Court finds that attorneys for the government did not commit prosecutorial misconduct.

3. The record does not demonstrate that the attorneys for the government forced any witness to lie or that they misshaped the testimony of any witness.

4. The Court finds that the attorneys for the government gave four immunized subjects an opportunity to correct what they reasonably could have believed were materially false statements after considering contemporaneous documents and information that contradicted the witnesses' statements.

5. The Court finds that the attorneys for the government did not improperly threaten witnesses by giving them disclosures and warnings concerning their criminal exposure or the potential consequences for giving false testimony.

6. The Court further finds that the record does not demonstrate that the attorneys for the government knowingly provided false and misleading testimony to the grand jury.

7. The Court finds that the attorneys for the government did not improperly prevent witnesses from conferring with counsel.

8. The Court finds that the record does not demonstrate that the attorneys for the government endeavored to distort or influence testimony in violation of Federal Rule of Criminal Procedure 6(e).

9. The Court further finds that any potential violation of Federal Rule of Criminal Procedure 6(e) was harmless.

10. The Court finds no evidence to support the defendants argument that the attorneys for the government misused the grand jury process to induce examinations outside the grand jury.

11. The Court further finds that taking testimony under grand jury conditions did not affect the defendants.

12. The Court finds that the attorneys for the government did not endeavor to distort the law when they instructed the grand jury.

13. The Court finds that there is no evidence of any prejudice to defendants caused by any alleged misconduct by the attorneys for the government.

14. The Court further finds that the defendants have not demonstrated that the alleged misconduct challenged here raises a substantial and serious question about the fundamental fairness of the process which resulted in the indictment.

15. Even if this Court found the defendants' allegations of misconduct to be true and conclusively proven, the remedy would not be dismissal of the indictment.

16. The Court finds that dismissal of the indictment is appropriate only when the government misconduct "substantially influenced the grand jury's decision to indict or if there is grave doubt about the decision to indict was free from the substantial influence of such violations."

17. Because the Court concludes that the defendants have not demonstrated intentional prosecutorial misconduct or substantial prejudice to justify dismissal of the indictment, the defendants are not entitled to any relief.

IV. Defendants' Motion to Compel Production of Legal Instructions to the Grand Jury

Defendants ask for the production of the legal instructions to the grand jury. They argue the United States failed to instruct the grand jury that the defendants' statements were protected by the First Amendment.

The motion rests upon defendants' incorrect argument that the First Amendment bars this prosecution. As set forth above, the First Amendment does not protect off-label promotion that is false or misleading. *Caronia,* 703 F.3d at 165 n.10; *Amarin Pharma, Inc.,* 2015 WL 4720039, at *27. The indictment alleges defendants made false or misleading statements, which are not protected by the First Amendment. Defendants have not shown that any failure to instruct the jury regarding the First Amendment could have had any effect on the grand jury's decision to indict. Accordingly, defendants have failed to demonstrate particularized need for this request. *United States v. Miramontez,* 995 F.2d 56, 59 (5th Cir. 1993) (affirming denial of motion to compel grand jury materials based on lack of particularized need); *see also United States v. Procter & Gamble Co.,* 356 U.S. 677, 682 (1958) (finding that disclosure of grand jury materials requires showing of "compelling necessity" which is "proof that without the transcript a defense would be greatly prejudiced or that without reference to it an injustice would be done").

V. Conclusion

Based on the foregoing and the arguments and authorities presented, IT IS HEREBY ORDERED that Defendant Howard C. Root's Motion to Dismiss the Indictment (docket no. 75) is DENIED; Defendants' Motion to Dismiss the Indictment Based on Government Misconduct (docket no. 78) is DENIED; Defendants' Motion to Dismiss the Indictment or, in the Alternative, to Preclude the Government from Using Defendants' Truthful Speech to Prove Misbranding and Adulteration

Counts (docket no. 79) is DENIED; and Defendants' Motion to Compel Production of Legal Instructions to the Grand Jury (docket no. 87) is DENIED.

It is so ORDERED.

SIGNED this 16th day of November, 2015.

FRED BIERY
CHIEF UNITED STATES DISTRICT JUDGE