UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. WILLIAM FACTEAU, PATRICK FABIAN Defendants.	Criminal No. 15-10076-ADB

GOVERNMENT'S OPPOSITION TO DEFENDANTS' MOTION
FOR PRODUCTION OF LEGAL INSTRUCTIONS TO GRAND JURY

Defendants seek disclosure of the government's legal instructions to the grand jury in this case in the hope of finding some potential deficiency in those instructions. Their request should be denied because it is contrary to controlling precedent in this Circuit and unsupported by Defendants' arguments. Defendants' animating premise – that "failure to disclose the Governments' legal instructions would insulate the Indictment from review for legal defect" (Dkt. 91 at 1) – is wrong. Defendants are free to challenge the Indictment based on any of the legal theories in their motion. See, e.g., Fed. R. Crim. P. 12. They are not free, however, to disrupt or delay these proceedings with an irrelevant and time-consuming fishing expedition into the protected realm of the grand jury.

Defendants' contention that "materials produced by the Government to date strongly suggest that the grand jury was misinstructed" (Dkt. 91 at 1), is also wrong. Their claims of potential errors in the instructions about the charges of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq. ("FDCA"), are based upon incorrect statements of the law. Speculation about "misinstruction" to manufacture a basis to delay or escape trial is not permitted. The Government respectfully requests that the Defendants' motion be denied.

OVERVIEW OF THE INDICTMENT

The Indictment in this case alleges that Defendants William Facteau and Patrick Fabian and others engaged in a scheme to fraudulently drive up Acclarent revenues and stock valuation by illegally selling a medical device known as the Relieva Stratus Microflow Spacer ("Stratus") for intended use as a device to deliver steroids to the sinuses, when Acclarent had not obtained the required approvals from the United States Food and Drug Administration ("FDA") and instead had obtained FDA clearance only to market the device as a stent to hold open a space that could moisten the sinuses with saline. Indictment ¶¶ 5-8.

As explained in the Indictment, the FDCA prohibits the introduction or delivery for introduction of adulterated and misbranded medical devices into interstate commerce. 21 U.S.C. § 331(a). A medical device is adulterated if it is required to have but lacks an FDA-approved Premarket Approval Application ("PMA"). A medical device is misbranded if

(a) its labeling is false or misleading;

(b) its labeling lacks adequate directions for its intended use and it does not qualify for an exemption to that requirement; or

(c) a premarket notification ("510(k) notice") was required but had not been submitted to and cleared by the FDA.

Indictment ¶¶ 24-37. The Indictment here charges that the Defendants, acting with the intent to defraud and mislead, caused the introduction and delivery for introduction into interstate commerce of the Stratus, which was adulterated and misbranded. Count One charges a conspiracy to violate the FDCA and to commit securities fraud in connection with the sale of Acclarent to Ethicon, a Johnson & Johnson subsidiary. Counts Two through Eight are substantive counts of securities fraud and wire fraud arising out of the scheme. Counts Nine through Thirteen charge the distribution of adulterated devices and Counts Fourteen through

Eighteen charge the distribution of misbranded devices. Each of these charges in the Indictment is a facially valid and correct charge under controlling law.

ARGUMENT

I. CLEAR AUTHORITY ESTABLISHES THAT A COURT SHOULD NOT INQUIRE INTO THE GRAND JURY PROCESS HERE.

A. A Facially Valid Indictment Requires A Trial, Not An Investigation Into The Grand Jury Proceedings.

In United States v. Costello, the Supreme Court stated:

> An indictment returned by a legally constituted and unbiased grand jury, like an information drawn by the prosecutor, if valid on its face, is enough to call for trial of the charges on the merits. The Fifth Amendment requires no more.

350 U.S. 359, 363 (1956). Indictments are not "open to challenge on the ground that there was inadequate or incompetent evidence before the grand jury." Id. "If indictments were to be held open to [such] challenge, . . . [t]he result of such a rule would be that before the trial on the merits a defendant could always insist on a kind of preliminary trial to determine the competency and adequacy of the evidence before the grand jury." Id. Instead, "the law presumes, absent a strong showing to the contrary, that a grand jury acts within the legitimate scope of its authority." United States v. R. Enterprises, 498 U.S. 292, 300-301 (1991).

Furthermore, "[c]ourts . . . generally have found that the prosecutor satisfactorily explains the offense to be charged by simply reading the statute to the grand jury." United States v. Lopez-Lopez, 282 F.3d 1, 9 (1st Cir. 2002). The Indictment here recites the statutory language of each offense charged and is facially valid, reflecting the grand jury's determination that there is probable cause to believe that Defendants conspired to, and committed the charged violations. No more is required, and no inquiry into the grand jury proceedings is justified.

Defendants argue, however, that the United States had to give the grand jury particular instructions beyond the statutory language in the Indictment. This position is contrary to First

Circuit law. "The prosecutor is under no obligation to give the grand jury legal instructions." Lopez-Lopez, 282 F.3d at 9 (quoting United States v. Zangger, 848 F.2d 923 (8th Cir. 1988)).

Defendants further contend that this Court should ignore the clear mandate of the First Circuit in Lopez-Lopez against looking behind a facially valid indictment, because of the "complexity of this case." They suggest that Lopez-Lopez applies only to what they term "run-of-the-mill cases." Def. Mem. at 8 n.6. There is no such exemption to the First Circuit's direction in Lopez-Lopez. Nonetheless, in support of their claim, Defendants cite a reference in United States v. Williams, 504 U.S. 36, 51 (1992), to a constitutional right to "an independent and informed grand jury." Def. Mem. at 8 n.6. Whatever the scope of that right, the Supreme Court in Williams held that exculpatory evidence need not be presented to the grand jury – i.e., that the grand jury was not required to be "informed" of exculpatory evidence. Id. at 51-54. Thus, a claim of suspected incorrect or insufficient legal instructions to the grand jury, like a claim of failure to offer exculpatory evidence, provides no basis to invade the grand jury process.

B. Courts Have Repeatedly Held That Speculation As To Incorrect Legal Instructions Does Not Provide The Required Particularized Need For Disclosure Of Grand Jury Instructions.

Courts have held that defendants must demonstrate "particularized need" to require the production of any grand jury materials, including legal instructions. Courts have routinely rejected such requests based upon claims of potentially erroneous legal instructions. The Supreme Court, in Douglas-Oil Co. of Cal. v. Petrol Stops NW, 441 U.S. 211, 222 (1978), set forth the particularized need showing required to obtain grand jury materials. The Court held:

> Parties seeking grand jury transcripts under Rule 6(e) must show that the material they seek is needed to avoid a possible injustice in another judicial proceeding, that the need for disclosure is greater than the need for continued secrecy, and that their request is structured to cover only material so needed.

Id. Thus, disclosure of grand jury material is permissible in only limited circumstances, and only where there is a "strong showing" of particularized need. See Fed. R. Crim. P. 6(e)(3)(E);

United States v. Capozzi, 486 F.3d 711, 727 (1st Cir. 2007) ("[T]he 'indispensable secrecy of grand jury proceedings' must not be broken except where there is a compelling necessity" and "[t]he burden of showing particularized need rests squarely on the defendant."); United States v. Barry, 71 F.3d 1269, 1274 (7th Cir. 1995) (The "compelling necessity" and "particularized need" requirements apply to the disclosure of grand jury instructions).

Rule 6(e) permits disclosure of grand jury material only where "a ground may exist to dismiss the indictment because of a matter that occurred before the grand jury." Fed. R. Crim. P. 6(e)(3)(E)(ii).

> Because grand jury proceedings are entitled to a strong presumption of regularity, a defendant seeking disclosure of grand jury information under Fed. R. Crim. P. 6(e)(3)(E)(ii) bears a heavy burden of establishing that particularized and factually based grounds exist to support the proposition that irregularities in grand jury proceedings may create a basis for the dismissal of an indictment.

United States v. Rodriguez-Torres, 570 F. Supp. 2d 237, 242 (D.P.R. 2008).

This heavy burden cannot be satisfied by suggesting that the grand jury *may have been* improperly instructed. See United States v. George, 839 F. Supp. 2d 430, 437 (D. Mass. 2012) (finding defendant's positing of potential defect did not meet burden of showing required "particularized need" for requested instructions); United States v. Prange, 2012 WL 3263606, at *1 (D. Mass. 2012) (same); United States v. DiMasi, 2011 WL 468213, at *3 (D. Mass. 2011) (same); United States v Kantengwa, 2010 WL 3023871, at *4 (D. Mass. 2010) (denying request for grand jury instructions). The Court in DiMasi explained,

> Here, disclosure is not necessary to avoid possible injustice because protection against the grand jury's conceivable misunderstanding of the requirements of 18 U.S.C. § 1346 is not accomplished by review of the prosecutor's legal instructions. Rather, the First Circuit requires substantial particularity in the text of an indictment for conspiracy to commit fraud, with which at least 12 grand jurors must concur. Because the Amended Superseding Indictment is facially adequate and demonstrates that the grand jury found probable cause to believe defendants conspired to engage in a quid pro quo bribery and kickback scheme, which has long been, and remains, a valid theory of honest services fraud, any

> lack of instructions or mistakes in instructions to the grand jury would not be sufficiently prejudicial to justify relief.

2011 WL 468213, at *3 (citations omitted). See United States v. Welch, 201 F.R.D. 521, 523 (D. Utah 2001) (rejecting claim that grand jury instructions should be disclosed or reviewed *in camera* because indictment is complex or due to potential legal error and noting "[d]istrict courts should not be obligated to conduct *in camera* review on bare speculation, generalized complaint, or a fishing expedition.").[1] But see United States v. Sampson, 01-CR-10384-MLW (8/19/14 Order, Dkt. 1505) (ordering, in special context of capital case, disclosure of grand jury instructions based on argument that lack of notice to grand jury that special findings rendered defendant death penalty eligible could be basis for dismissal of indictment).

Where, as here, an indictment "is facially adequate and demonstrates that the grand jury found probable cause" with respect to all required elements, courts have repeatedly denied access to instructions, recognizing that "any lack of instructions or mistakes in instructions to the grand jury would not be sufficiently prejudicial to justify relief." DiMasi, 2011 WL 468213, at *3. See also United States v. Buchanan, 787 F.2d 477, 487 (10th Cir. 1986) ("Challenges going only to the instructions given to the grand jury as to the elements of the offenses are not grounds for dismissal of an indictment valid on its face."); United States v. Battista, 646 F.2d 237, 240-2 (6th Cir. 1981) ("[E]ven if an incorrect instruction was given to the grand jury, which did not occur in the present case, the indictment was valid on its face and was sufficient to require a trial of the indictment on its merits."); United States v. Graham, 247 F. Supp. 2d 923, 925 (S.D. Ohio 2002)

[1] See also United States v. Huntress, 2015 WL 631976, at *27-28 (W.D.N.Y. 2015) (denying disclosure of grand jury instruction for lack of particularized need); United States v. Smith, 2015 WL 2445813, at *4-8 (W.D.N.Y. 2015) (same); United States v. Chalker, 2013 WL 4547754, at *5-8 (E.D. Pa. 2013) (same); United States v. Hazelwood, 2011 WL 2565294, at *18 (N.D. Ohio 2011) (same); United States v. Larson, 2012 WL 4112026, at *4 (W.D.N.Y. 2012) (same); United States v. Mariani, 7 F. Supp. 2d 556, 567-68 (M.D. Pa. 1998) (same, listing cases); United States v. Trie, 23 F. Supp. 2d 55, 61-63 (D.D.C. 1998) (same).

(declining *in camera* review of grand jury instructions because, even if prosecutor did not define an element of the crime properly, the court "could not dismiss the prosecution as a result").

Despite First Circuit precedent and other authority to the contrary, Defendants rely upon a Ninth Circuit case, United States v. Alter, 482 F.2d 1016, 1029 n.21 (9th Cir. 1973), to claim they need not show particularized need to obtain the prosecutor's legal instructions to the grand jury. Alter, however, held only that particularized need was not needed for the "ground rules by which the grand jury conducts those proceedings" and provided the defendant the court's general instructions, such as those in the grand jurors' handbook. Id. There was no order to compel the production of the prosecutors' instructions in that case. As explained in United States v. Pacific Gas & Electric, 2015 WL 3958111, at *8-12 (N.D. Cal. 2014), district courts in the Ninth Circuit have split as to whether particularized need is required for the prosecutor's instructions (as opposed to the court's general instructions). Id.[2] Outside of a few district courts in the Ninth Circuit, however, as discussed above, courts have denied requests for a prosecutor's grand jury instructions for failure to show particularized need, including for *in camera* review. "Prosecutors' instructions are part of the grand jury proceeding and are entitled to a presumption of regularity." United States v. Keystone Auto. Plating., 1984 WL 2946, at *7 (D.N.J. 1984). See Welch, 201 F.R.D. at 523 ("The instructions to the grand jury are intimately associated with the deliberation and judgment aspects of the grand jury function [and] are matters occurring before the grand jury and require meeting standards for release of grand jury information.").

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[2] Compare United States v. Morales, 2007 WL 628678, at *4 (E.D. Cal. 2007) (holding prosecutor's legal instructions are covered by grand jury secrecy) with United States v. Belton, 2015 WL 1815273, at *3 (N.D. Cal. 2015) (holding particularized need not required for prosecutor's legal instructions); United States v. Talao, 1998 WL 1114043, at *12 (N.D. Cal. 1998) (assuming without analysis that "ground rules" includes government's legal instructions). In the other three California cases relied upon by Defendants, Def. Mem. at 10 & n.7, only the court's general instructions, not the prosecutor's case-specific instructions, were ordered produced. See United States v. Jack, 2009 WL 435124, at *3-4 (E.D. Cal. 2009), United States v. Fuentes, 2008 WL 2557949, at *4 (E.D. Cal. 2008); United States v. Diaz, 236 F.R.D. 470, 477-78 (N.D. Cal. 2006) (granting access to ministerial records such as empaneling instructions but denying requests for grand jury proceedings for lack of particularized need).

C. The Cases Cited By Defendants Do Not Support Disclosure Based Upon Speculation That Government Provided Incorrect Legal Instructions.

The other cases cited by the Defendants also provide no support for disclosure of the grand jury legal instructions here. The facts of the few cases outside of this Circuit in which courts have ordered the disclosure of grand jury transcripts based upon erroneous legal instructions are distinguishable. In United States v. Twerksy, 1994 WL 319367, at *2-5 (S.D.N.Y. June 29, 2004), the court ordered *in camera* review of grand jury transcripts in light of a Supreme Court opinion that changed the understanding of the law in that circuit on a key element between the time of indictment and the defendant's motion. Id. There has been no intervening change in controlling authority on the elements since the Indictment here. See also DiMasi, 2011 WL 468213, at *3 (declining even *in camera* review, despite recent Supreme Court precedent change in the complex area of honest services law).

In United States v. Stevens, 771 F. Supp. 2d 556, 564-67 (D. Md. 2011), the court ordered disclosure of grand jury instructions only after the government disclosed that the grand jury had asked and been instructed about the "advice of counsel defense." The court held that advice of counsel was not an affirmative defense, ordered the instruction produced, and dismissed the indictment on the ground that the instruction was incorrect and could have misled the grand jury on the element of intent. Id. In contrast, as discussed below, in the case before this Court, there is no basis to believe that the grand jury was improperly instructed on the elements of the crimes. Nor would such a disclosure order be consistent with the First Circuit precedent discussed above.

Defendants also rely on United States v. Naegele, 474 F. Supp. 2d 9, 10-11 (D.D.C. 2007). The court in Naegele, however, ordered grand jury testimony produced not because of a potentially erroneous instruction, but because of possible government misconduct in not

disclosing a critical piece of evidence to the grand jury, i.e., that the defendant had not filed the signature page of the charged false bankruptcy filing. Id. No such misconduct is alleged here.

In most of the other cases Defendants cite to support disclosure, Dkt. 91 at 9, 12, n.8, it appears that the government voluntarily disclosed the instructions, not that the courts found particularized need to look behind the indictment to the grand jury instructions.[3] These cases do not support the claim that a court can order grand jury instructions produced based upon a claim that the government *may* have given the grand jury an instruction that *may* have been incorrect.

As explained below, Defendants' submissions provide no basis to conclude or even suspect that there was such an erroneous grand jury instruction, let alone provide a basis to suggest that dismissal of the Indictment could be appropriate. Dismissal 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. See Bank of Nova Scotia v. United States, 487 U.S.

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[3] See, e.g., United States v. Jefferson, 534 F. Supp. 2d 645, 649 (E.D.Va. 2008), aff'd, 546 F.3d 300, 306 (4th Cir. 2008) (noting government voluntarily made transcripts available to defense counsel to allay concerns that Speech and Debate Clause materials were provided to grand jury and declining to dismiss indictment); United States v. Bowling, 2015 WL 3541475, at *8 (E.D.N.C. 2015) (dismissing indictment for legal errors, noting government acknowledged that it instructed the grand jury in way court concluded was erroneous); United States v. Monzon-Luna, 2014 WL 223100, at *1-3 (E.D.N.Y. 2014) (denying motion to dismiss after *in camera* review where it appears government voluntarily provided instruction); United States v. Peralta, 763 F. Supp. 14, 19-21 (S.D.N.Y. 1991) (finding transcript of agent testimony provided by the government showed testimony was different from testimony at trial, ordering further transcript of grand jury minutes, and dismissing based on both erroneous instruction and inaccurate testimony and extensive use of hearsay); United States v. Vetere, 663 F. Supp. 381, 386-87 (S.D.N.Y. 1987) (concluding that transcripts provided voluntarily by the government demonstrated prosecutorial misconduct and that agent had testified incorrectly). See also United States v. Kern, 2007 WL 4377839, at *1 (S.D. Tex. 2007) (denying motion to dismiss after review of instructions; no mention of order requiring disclosure); United States v. Cerullo, 2007 WL 2683799, at *1-4 (S.D. Cal. 2007) (dismissing indictment after finding prosecutors and agent erroneously answered grand jury question contrary to Supreme Court authority, no discussion of how court obtained grand jury transcripts); United States v. Breslin, 916 F. Supp. 438, 442-46 (E.D. Pa. 1996) (concluding that accumulation of errors, including bringing donuts to grand jurors and incorrect instructions, supported the rare dismissal; no discussion as to how transcripts obtained). Moreover, in Williams, the Supreme Court made clear that to support dismissal of an indictment, even misconduct before the grand jury must amount to a violation of one of those "few, clear rules which were carefully drafted and approved by [the Supreme Court] and by Congress to ensure the integrity of the grand jury's functions." 504 U.S. at 46-47.

250, 254-264 (1988) (reversing dismissal of indictment despite findings of repeated prosecutorial misconduct in grand jury proceedings, including that agents mischaracterized testimony to the grand jury). In the First Circuit, dismissal of an indictment "will be ordered only for serious and blatant prosecutorial misconduct that destroys the integrity of the judicial process." United States v. Rivera-Santiago, 872 F.2d 1073, 1088 (1st Cir. 1989) (internal citations omitted). No such misconduct is alleged here. There is no basis, therefore, to find that disclosure of legal instructions could support dismissal of the Indictment.

II. DEFENDANTS' CHALLENGES TO THE APPLICABLE LAW ARE INCORRECT AND DO NOT JUSTIFY PRODUCTION OF GRAND JURY INSTRUCTIONS.

Defendants are also incorrect in their legal assertions regarding the FDCA and the scope of evidence relevant to an investigation of FDCA violations. Defendants misstate the law and ignore controlling precedent in an attempt to manufacture an "irregularity" to justify their extraordinary request. Moreover, Defendants' arguments about the implications of questions asked of witnesses do not come close to showing a "compelling necessity" or "particularized need" for the grand jury material they seek. Barry, 71 F.3d at 1274

A. The 1997 Amendments To The FDCA Do Not Preclude FDA From Discerning The Intended Use Of A Device From A Variety Of Sources When Seeking To Enforce Criminal Adulteration And Misbranding Provisions

Defendants contend that the amendments to the FDCA in the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115 ("FDAMA"), prevent the FDA and the grand jury from looking at any source other than a device's proposed labeling to discern the device's intended use. This argument is contrary to the statute's language, context, purpose, and legislative history, and Defendants cite no case supporting their interpretation. Defendants also do not cite the only case to address this claim, United States v. Bowen, 172 F.3d 682, 686-87 (9th Cir. 1999), in which the Ninth Circuit firmly rejected Defendants' suggested reading of

these amendments.

The provision Defendants rely on to argue that the FDA cannot look outside a device's proposed labeling to discern intended use is in fact limited to the context of FDA's premarket notification review. Under the FDCA, one way to obtain FDA permission to market a medical device is by submitting to the agency information demonstrating that the device is "substantially equivalent" to one or more other legally marketed devices. A would-be marketer of a new device can attempt to obtain this substantial equivalence determination by filing a premarket notification ("510(k)") submission with FDA, pursuant to section 510(k) of the FDCA, 21 U.S.C. § 360(k). See 21 C.F.R. § 807.81; see also Medtronic, Inc. v. Lohr, 518 U.S. 470, 478-79 (1996) (describing 510(k) process). In this premarket notification context only, 21 U.S.C. § 360c(i)(1)(E) clarifies that, for the purpose of determining substantial equivalence, the FDA shall base its decision on the intended use stated in the labeling in the 510(k) submission.

FDAMA, at 21 U.S.C. § 360c(i)(1)(E), amended the definition of "substantial equivalence" to read "[a]ny determination by the Secretary [of Health and Human Services, delegated to the FDA] of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 360(k) of this title." Defendants argue that the grand jury should but may not have been instructed that, because of this amendment, the doctrine of intended use that is set forth in other provisions of the FDCA is "no longer applicable," and that not only the Secretary, but the grand jury, can only consider the stated intended use of the device in the label submitted in the 510(k) application. Thus, under this theory, a manufacturer could never be sanctioned for distributing a medical device for a new and unapproved intended use once it filed any 510(k) application. Instead, the FDA would have to consider whatever the manufacturer stated in its 510(k) application, truthful or untruthful, as the only intended use, no matter for what the product was actually designed, intended or promoted. Defendants also

suggest that this would be true even if the 510(k) submitted to the FDA were false or fraudulent. Defendants' interpretation would mean that any manufacturer's fraudulent conduct in distributing a device for a new and totally unapproved or unlabeled intended use – as long as it was not in the 510(k) application -- has been immune from prosecution since 1997.

FDAMA did not produce such an absurd result. Section 360c(i)(1)(E) of Title 21, by its terms, concerns only FDA's determination of a device's intended use for the purpose of evaluating a 510(k) application and determining whether the device with its proposed intended use is substantially equivalent to a product already legally on the market. The Senate and House Reports further demonstrate the limited scope of this provision. The Senate Report states:

> With the "Medical Device Amendments of 1976," Congress intended that *device classification and approval decisions* be made based on the intended use of devices as described in labeling. . . . This section includes two provisions that express the committee's specific intention to limit FDA's review of premarket submissions to the proposed labeling before the agency. *For premarket notification submissions*, the labeling proposed in the submission will be controlling of a device's intended use.

S. Rep. No. 105-43 at 27-28 (1997) (emphasis added). See also H.R. Rep. No. 105-307, at 24 (1997) (the new section "provides that the Secretary's determination of the "intended use" of a device for purposes of determining substantial equivalence with a legally marketed device must be based upon the proposed labeling submitted by the manufacturer in a 510(k) report").

Further, the Defendants' interpretation makes little sense when read in conjunction with the rest of the provision they cite. Section 360c(i)(1)(E) of Title 21 provides in the same subsection that the FDA may require additional warnings if the agency component responsible for regulating devices determines "(I) that there is a reasonable likelihood that the device will be used for *an intended use not identified in the proposed labeling* for the device; and (II) that such use could cause harm." 21 U.S.C. § 360c(i)(1)(E)(i) (emphasis added). Thus, this very provision

makes clear that the FDA can find that there are intended uses of the product other than those intended uses identified in the proposed labeling.

The Ninth Circuit in Bowen, 172 F.3d at 686-87, addressed and rejected Defendants' argument. The Court explained:

> Read out of context, defendant's argument is plausible. However, as noted, statutory meaning depends on context. The provision that defendant cites is part of a subsection dealing only with determinations by the FDA of substantial equivalency. See 21 U.S 360c(i). Read in context, the provision plainly applies only to such determinations.

Id. The Court in Bowen concluded:

> [T]he recent amendment altered the "intended use" inquiry only for substantial equivalency determinations. In other circumstances, courts can continue to look beyond the product's label. See 21 C.F.R. § 801.4 (Intended use "may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.").

Id. See also United States v. Caputo, 517 F.3d 935, 938-941 (7th Cir. 2008) (upholding conviction for distributing device for intended use other than intended use listed in 510(k)). It is not an "irregularity" to decline to instruct the grand jury on an interpretation of a statute that has been rejected by the only court to have addressed it. Thus, far from identifying some clear change in controlling precedent as to a core element of the charges, Defendants' legal claim is incorrect, and fails to provide a prima facie basis to intrude upon the grand jury process.

B. Defendants' Claims About Knowledge Of Off-Label Use Are Contrary To Existing Law And Regulations.

Defendants also argue a manufacturer's knowledge that its device will be used for an unapproved use is wholly irrelevant to the manufacturer's legal obligations and that questioning about this could be an "irregularity" that justifies invading the grand jury process. Defendants are mistaken. The regulation describing intended use is clear on this topic. It states:

> The words *intended uses* . . . refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of

> the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. . . . But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

21 C.F.R. § 801.4. It is not misconduct or improperly instructing the grand jury to provide the grand jury with existing law or regulations -- let alone the kind of extraordinary irregularity needed to upset the presumption of regularity in grand jury proceedings.

Moreover, it would set an unacceptable precedent if, as Defendants contend, legitimate questions asked of witnesses about their understanding of the law and regulations were sufficient to justify invading the grand jury process. Such questions do not constitute misconduct or erroneous instruction. Nor is there a single case where a court has found particularized need based merely on the implications from questions asked of witnesses. See generally United States v. Weiss, 752 F.2d 777, 786 (2d Cir. 1985) (use of leading questions before grand jury is not error); United States v. Bryson, 2014 WL 1653244, at *2-3 (D. Conn. 2014) (denying request for additional grand jury minutes based on claim that "government's questions created misimpression"). Defendants' position suggests that the government has to censor questions asked and answers provided by witnesses as to their view of the law so as to only permit them to express views consistent with the government's understanding of the law. The Supreme Court has made clear that the scope of the grand jury's inquiry is not so limited. See Bank of Nova Scotia, 487 U.S. at 261 ("[A] challenge to the reliability or competence of the evidence presented to the grand jury" will not be heard.); United States v. Calandra, 414 U.S. 388, 349 (1974)

(rejecting application of exclusionary rule to the grand jury evidence); Costello, 350 U.S. at 363 (declining to apply hearsay rules to grand juries).

Defendants' out-of-context snippets of transcripts also often misstate the source of the view referenced in the questions. For example, Defendants object to the question: "Did you understand that to mean that a company could not sell a product for a use that it knew was not cleared and on its label?" Dkt. 91 at 20, n.17. Defendants neglect to mention that this statement paraphrases a slide from Acclarent's outside legal counsel. See Urban Decl., Dkt. 92, Exh. Q at 79. The witness, a regulatory professional, described a presentation by outside counsel and was asked and answered as follows:

> Q: And if you look to page 17 [of the outside counsel's presentation], you see that it says that "a manufacture may sell products only for cleared or approved uses."
> A. Yes.
> Q: And did you understand that to mean that a company could not sell a product for a use that it knew was not cleared and on its label?
> A. Yes.
> Q: Even though that, physicians, after they purchase a product, may decide to use it for an unlabeled use?
> A. Yes.

Id. Thus, the statement of law that Defendants complain about is not an instruction of the law from the Government, but from Acclarent's counsel at the time, which had been presented to, among others, the Defendants. Ironically, this snippet also demonstrates that it was the Government's questioning that elicited that physicians were still free to use the product off-label.

In any event, the Indictment in this case does not allege mere distribution of the Stratus knowing it would be used for an unapproved use, but the distribution of the Stratus with the *intention* that it be used for an unapproved use. Defendants are wrong in their legal claims, and their snippets of questions do not support any implication of erroneous instruction, let alone clear and substantial error as to a critical element that could support piercing the grand jury's secrecy.

C. The Indictment Alleges False And Misleading Claims, But Controlling Law Is That Speech May Be Evidence of Intended Use.

Defendants also argue that the Court should believe that the Government misinstructed the grand jury because the Second Circuit in United States v. Caronia, 703 F.3d 149 (2d Cir. 2012), held that truthful, non-misleading speech is not itself a violation of the FDCA. Dkt. 91 at 20-23. Defendants further argue that the Second Circuit in Caronia held that "truthful statements about off-label use" could not be included "within the ambit of criminal off-label promotion." Id. at 13, 20-22. In fact, however, the Second Circuit in Caronia assumed that speech may be used as evidence of intended use to support an FDCA violation. See Caronia, 703 F.3d at 155. The court in Caronia stated, "Off-label promotional statements could thus presumably constitute evidence of an intended use of a drug that the FDA has not approved." Id. at 155. In Caronia, the court held that the prosecution of a sales representative for off-label, non-misleading promotion of a drug ran afoul of the First Amendment by criminalizing speech, because the government's case at trial, and the court's instructions, suggested that truthful, non-misleading speech *itself* was illegal, rather than describing the crime as the distribution of an unapproved drug or the distribution of a drug for a new intended use. Id. at 168. The Caronia court stated, however, that FDA "regulations do recognize that promotional statements by a pharmaceutical company or its representatives can serve as proof of a drug's intended use." Id. at 154. The court also noted: "The FDCA defines misbranding in terms of whether a drug's labeling is adequate for its intended use, and permits the government to prove intended use by reference to promotional statements made by drug manufacturers or their representatives." Id. at 162.[4]

Moreover, the Second Circuit (even after Caronia), the Supreme Court, the First Circuit and many other courts, have held that speech can be evidence of intent. "The First Amendment .

[4] Also, while not mentioned by Defendants, Caronia left undisturbed the Second Circuit's prior holding that "it is well settled that the intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant source." United States v. An Article Consisting of 216 Cartoned Bottles, 409 F.2d 734, 739 (2d Cir. 1969).

. . does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent." Wisconsin v. Mitchell, 508 U.S. 476, 489 (1993) (holding that a sentencing enhancement due to defendant's targeting victim based on race did not violate defendant's free speech rights). Defendants' claim that the Supreme Court in Thompson v. Western States, 535 U.S. 357, 370-71 (2002), overruled Wisconsin and other Supreme Court precedent on this point is without basis. Dkt. 91 at 22 n.24. Thompson overturned a statutory prohibition against advertising compounded drugs that the Court held was itself protected speech. The Court did not prohibit or even address the evidentiary use of speech. Id.

Also, the courts of appeals, including this circuit and the Second Circuit post-Caronia, have repeatedly continued to uphold the evidentiary use of speech post-Thompson. See, e.g., Wine And Spirits Retailers v. Rhode Island, 418 F.3d 36, 50-51 (1st Cir. 2005) ("[T]he State does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of that activity."). In Wine and Spirits Retailers, for example, the First Circuit explained that if First Amendment freedoms were abridged merely because conduct was initiated, evidenced, or carried out by language, it would be "practically impossible ever to enforce laws against agreements in restraint of trade as well as many other agreements and conspiracies deemed injurious to society." Id. See also, e.g., United States v. Kaziu, 559 Fed. App'x 32, 35 (2d Cir. 2014) (noting that the First Amendment does not "prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent. Wisconsin, 508 U.S. 476, 489"); United States v. Pierce, 785 F.3d 832, 841 (2d Cir. 2015) (same).

Other circuits have also specifically held that speech may be used as evidence of intended use under the FDCA. See Whitaker v. Thompson, 353 F.3d 947, 953 (D.C. Cir. 2004) (holding it is constitutionally permissible for FDA to use speech, specifically labeling, to infer intent in determining if a product is a "drug"); United States v. Storage Spaces Nos. "8" & "49", 777 F.2d

1363, 1366 (9th Cir. 1985) (noting that drug vendor's intent may be derived from "labeling, promotional material, advertising or any other relevant source").

In United States v. Caputo, the Seventh Circuit upheld a defendant's conviction for distribution of a medical device for a new intended use, because the crime there, as charged here, was not the speech, but the illegal conduct in distributing a medical device for an unapproved use. Caputo, 517 F.3d at 941-42. Thus, the Seventh Circuit in Caputo held, on facts similar to those charged here, that the defendant had made "a major change in its intended use" by promoting the device for use with different instruments. The Court thus held that the promotion could serve as evidence that the defendant intended a different use, one that was not approved, and distributed the device for that unapproved use. Id. The Court in Caputo concluded: "So the large Plazylte, with its expanded 'intended use' was not covered by the FDA's approval of the small Plazylte and could not lawfully be sold at all." Id. at 940. Likewise, the Indictment in this case recites Defendants' promotion of the Stratus as a steroid delivery device as evidence of a significant change in the intended use submitted to and cleared by the FDA, and charges Defendants with distributing unapproved devices. See, e.g., Indictment ¶¶ 44-45, 51-55.

In addition, in Caputo, as in the Indictment in this case, the defendant was charged with fraud and false and misleading speech. As the Second Circuit said in Caronia, the First Amendment does not protect false and misleading speech: "[O]ff-label promotion that is false or misleading is not entitled to First Amendment protection." 703 F.3d at 166 n.10.[5]

Speech demonstrating the intended use for which Stratus was distributed is relevant to the grand jury's inquiry in this matter. Thus, there was ample and valid reason for the Government

[5] Defendants argue (Dkt. 92 at 22) that the government was required to instruct about an inapplicable regulation relating to a safe harbor for some types of scientific exchange about investigational new drugs (but not devices). See 21 C.F.R. § 312.7. As noted above, not only is the Government not required to instruct at all, Lopez-Lopez, 282 F.3d at 9, it certainly is not required to instruct about inapplicable regulations.

to inquire in the grand jury into speech, whether or not false and misleading, that was evidence of the Defendants' and their co-conspirators' intent with respect to the Stratus. Such inquiry was proper. It does not constitute gross misconduct or clear error as to an element of the crime as required in the few cases cited by the Defendants from other jurisdictions where courts have required production of grand jury instructions.

D. Claimed Impropriety In Testimony As To Duty To Report Off-label Use

Defendants' arguments about evidence purportedly suggesting an affirmative duty to report any off-label use are also unavailing and constitute a misreading of the very evidence they cite. See Dkt. 91 at 24-25. The Ethicon witness cited by Defendants testified, not to a general affirmative duty to report any off-label use, but that he believed that given what the company knew about the predominant off-label use, the company needed to contact the FDA. See Dkt. #92, Exh. BB. He testified that this was his belief after consulting with compliance professionals and that he shared this view with the Defendant, Facteau, who felt Ethicon was "being too conservative." Id. It is not an irregularity to allow a witness to testify as to his view, especially when he shared that view with the Defendant. To the contrary, to invade the grand jury process and suggest limitations on the grand jury's inquiry based upon legitimate and relevant questioning would be unprecedented and contrary to Supreme Court authority.

Defendants also complain that the Indictment alleges that Ethicon instructed Acclarent to notify FDA's Office of Compliance about the predominant off-label use of the Stratus. Defendants do not deny that this is true. They fail to explain how it is an irregularity to allege this true fact in the Indictment or submit it to the grand jury. Defendants' speculation as to how the grand jury interpreted this fact is just that – speculation. The grand jury is entitled to hear the facts and eliciting of such facts before the grand jury is not erroneous. Defendants should not be allowed to attempt to censor the evidence that a grand jury can hear.

CONCLUSION

Defendants have offered no evidence of any improper conduct or irregularity in the Government's presentation to the grand jury, or of any change in controlling law that could support an inquiry into the Government's legal instructions to the grand jury, let alone the kind of extraordinary circumstances necessary to justify such an intrusion into the grand jury proceedings. Defendants' Motion for legal instructions to the grand jury should be denied.

Respectfully submitted,

CARMEN M. ORTIZ
United States Attorney

Date: August 6, 2015 By: *<u>/s/ Sara Miron Bloom</u>*

SARA MIRON BLOOM (BBO No. 552351)
PATRICK CALLAHAN (BBO No. 648173)
Assistant U.S. Attorneys
1 Courthouse Way
John Joseph Moakley U.S. Courthouse
Boston, MA 02210
(617) 748-3100
Sara.Bloom@usdoj.gov
Patrick.Callahan@usdoj.gov

<u>CERTIFICATE OF SERVICE</u>

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Date: August 6, 2015 By: *<u>/s/ Sara Miron Bloom</u>*

SARA MIRON BLOOM
Assistant U.S. Attorney