UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES	)	
v.	)	**Criminal No. 15-10076-ADB**
WILLIAM FACTEAU, PATRICK FABIAN	)	**ORAL ARGUMENT REQUESTED**
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR JUDGMENT OF ACQUITTAL OR, ALTERNATIVELY, A NEW TRIAL

TABLE OF CONTENTS

INTRODUCTION

The Government repeatedly represented to the Court that, at its core, "this is a case about fraud: false and misleading speech, fraudulent conduct, false submissions to the FDA, wire fraud and securities fraud." *E.g.*, Gov't's Opp'n to Defs.' Mot. to Dismiss at 10 (Dkt. #224). That was the principal basis on which the Government opposed Defendants' motions to dismiss, justified its position on disputed evidentiary issues, and grounded its proposed jury instructions. In addition, the Government advanced the same fraud allegations in connection with its most incendiary assertions at trial, including that Defendants' alleged deception of the FDA and physicians placed patients at risk of blindness and other traumatic injuries from an allegedly untested and unsafe device.

Despite significant questions about the factual breadth and legal viability of the Indictment's charges and the nature and propriety of the Government's evidence, the Government was allowed to try the fraud case it claimed it had, and the jury unequivocally rejected it, acquitting Defendants of all counts (and charging theories) predicated on fraud, falsity, or misrepresentation. In so doing, the jury affirmed what Defendants have long maintained—that this case has never been about fraud (or patient safety). Rather, it is about whether—consistent with the facts and the governing law, including basic tenets of due process and justice—Defendants William Facteau and Patrick Fabian can lawfully be deemed strictly liable for misdemeanor adulteration and misbranding in a case where criminal scienter was neither required nor found and, instead, the principal evidence of "guilt" consisted of: (a) truthful, non-misleading speech; and (b) internal matters not communicated to customers, including iterative research and design records.

For multiple reasons, such convictions cannot stand. *First*, the Government's reliance on truthful, non-misleading speech to prosecute Defendants violates the First Amendment. *Second*,

Defendants cannot, consistent with due process, be held strictly liable for adulteration and misbranding based on the non-fraudulent conduct established at trial—*i.e.*, truthful speech and internal matters, such as iterative R&D efforts, not communicated to customers. *Third*, the Government failed to introduce evidence sufficient to prove adulteration or misbranding with respect to the specific Stratus shipments alleged in the sole counts of conviction (Counts 9-18). *Fourth*, the jury's adulteration and misbranding verdicts are mutually exclusive: the former requires a finding that Stratus required a PMA; the latter, that Stratus required a further 510(k). Both cannot be true. *Fifth*, the Government repeatedly put before the jury irrelevant and prejudicial evidence and arguments, including but not limited to inflammatory allegations regarding patient safety. The cumulative impact of the Government's misconduct compromised Defendants' right to a fair trial.

For these reasons and for the additional reasons set forth below, Defendants respectfully request that the Court grant Defendants a judgment of acquittal or, alternatively, a new trial on the strict-liability misdemeanors.

LEGAL STANDARD

"Rule 29(c)(2) provides that, 'if the jury has returned a guilty verdict, the court may set aside the verdict and enter an acquittal.'" *United States v. DiMasi*, 810 F. Supp. 2d 347, 351 (D. Mass. 2011) (quoting Fed. R. Crim. P. 29), *aff'd sub nom. United States v. McDonough*, 727 F.3d 143 (1st Cir. 2013). A judgment of acquittal may be based on legal deficiencies such as an unconstitutionally vague statute or regulation, *see United States v. Lachman*, 387 F.3d 42, 50 (1st Cir. 2004), and is required when the court finds the evidence is not "sufficient to permit a rational jury to find each essential element to have been proven beyond a reasonable doubt." *DiMasi*, 810 F. Supp. 2d at 351 (citing *United States v. Olbres*, 61 F.3d 967, 970 (1st Cir. 1995)).

"In contrast to an analysis under Rule 29, in deciding a Rule 33 motion for a new trial, the court may weigh the evidence, evaluate the credibility of the witnesses, and order a new trial if the evidence predominates heavily against the verdict and allowing them to stand would result in a miscarriage of justice." *Id.* at 350. A new trial may be granted, for example, because of government misconduct. *See United States v. Azubike*, 504 F.3d 30, 38-39 (1st Cir. 2007); *United States v. Manning*, 23 F.3d 570, 574 (1st Cir. 1994); *United States v. Hardy*, 37 F.3d 753, 758 (1st Cir. 1994); *see also* Fed. R. Crim. P. 33(a) ("[T]he court may vacate any judgment and grant a new trial if the interest of justice so requires.").

ARGUMENT

I. THE JURY'S VERDICT ESTABLISHES THAT DEFENDANTS' MISDEMEANOR CONVICTIONS WERE BASED ON TRUTHFUL, NON-MISLEADING SPEECH, IN VIOLATION OF THE FIRST AMENDMENT.

As Defendants have consistently maintained, a conviction for misbranding or adulteration cannot constitutionally be based on truthful, non-misleading speech regarding off-label use. In support, Defendants incorporate by reference the extensive briefing and argument previously provided to the Court concerning the application of the First Amendment to commercial speech, as exemplified by *Caronia*, *Amarin*, and the recent Supreme Court decisions on which these two cases are grounded. *See, e.g.*, Mem. Supp. MTD #2, at 10-20 (Dkt. #185); Reply Mem. Supp. MTD #2, at 9-17 (Dkt. #235).[1]

The Government has previously deflected Defendants' First Amendment arguments by contending that, unlike *Caronia* and *Amarin*, this is a case about fraud, with speech merely

[1] Rather than repeat their prior briefs, Defendants focus here on the significance of the jury verdict to the First Amendment analysis.

Defendants have not attached as exhibits the voluminous evidence cited in this brief. If desired, Defendants will promptly provide it upon request.

serving as evidence of that offense.[2] The Government insisted that "this whole First Amendment problem is not in existence here," 2/4/16 Mot. Hr'g Tr. 66:12-14, because the Government would "offer [evidence of] false and misleading external marketing claims," *id.* at 93:8-10, to induce the Court to allow the case to proceed to trial. *See id.* at 70:1-4 (Court: "What I heard [the Government] say is this is about the distribution of an unapproved off-label device with false and misleading statements.").

As a result of the jury's verdict, the Government no longer can avoid the First Amendment infirmities that undercut its case. In acquitting Defendants on all felony counts (Dkt. #432), the jury rejected the Government's allegations of false and misleading speech, fraudulent conduct, false submissions to the FDA and wire fraud. With the case thus stripped of the Government's "fraud" gloss, it is clear that, just as in *Caronia*, the factual predicate for the Indictment's misdemeanor adulteration and misbranding charges—the sole counts of conviction—was truthful, non-misleading speech. This, the First Amendment does not permit. *E.g.*, *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196, 237 (S.D.N.Y. 2015) ("[A

[2] *E.g.*, Gov't Opp'n to Defs.' Mot. to Dismiss at 10 (Dkt. #224) ("[U]nlike *Amarin* and *Caronia*, upon which Defendants so heavily rely, this is a case about fraud: false and misleading speech, fraudulent conduct, false submissions to the FDA, wire fraud and securities fraud."); *see also* 2/4/16 Mot. Hr'g Tr. 86:16-19 ("[T]he allegation at the core of this case, is that what they did with this device was false and misleading . . . ."); *id.* at 114:18-24 ("[F]raud . . . [T]hat's really what this case is about and it's fraud, it's false and misleading labeling . . . .").

The Government has conceded that "*Caronia* holds protected and outside the reach of the FDA's misbranding provisions off-label promotion . . . where it wholly consists of truthful and non-misleading speech." 2/4/16 Mot. Hr'g Tr. 66:6-11. Indeed, when defense counsel recounted how the *Vascular Solutions* court had "told the jury that the Food, Drug and Cosmetic Act does not prohibit truthful and non-misleading off-label promotion"—"In other words, if the promotion is truthful and not misleading, it is not a crime under the Act"—this Court asked the Government, "You're not disagreeing with that; right?" *Id.* at 56:25-57:5. The Government responded, "Not for purposes of this case." *Id.* at 57:6. The Court then reiterated that "that point at least here seems pretty noncontroversial." *Id.* at 57:7-10; *see also id.* at 87:3-6. (Government: "*Amarin* and *Caronia* are quite clear that as long as you are not talking about solely truthful non-misleading speech, you can have a misbranding action . . . .").

manufacturer] may engage in truthful and non-misleading speech promoting the off-label use of [its product] . . . and . . . such speech may not form the basis of a prosecution for misbranding."); *see also* Trial Tr. of Jury Instrs., *United States v. Vascular Solutions, Inc.*, No. SA-14-CR-926 (W.D. Tex. Feb. 25, 2016), at 3748:21-3759:1 (Ex. 2) (expressly instructing the jury that it is "not a crime for a device company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device. *If you find that VSI's promotional speech to doctors was solely truthful and not misleading, then you must find the defendants not guilty of the misbranding offense*.") (emphasis added).

The jury's verdict also undercuts any contention that the Indictment's misdemeanor charges target conduct and not speech. By acquitting Defendants on all felony counts, the jury necessarily rejected the Government's allegation that the 510(k) clearances issued by FDA for the Stratus device were fraudulently obtained through false submissions. Consequently, as a cleared device, Stratus lawfully could be shipped in interstate commerce, used by physicians for off-label purposes, and even—the Government acknowledges—be the subject of physician-manufacturer discussions concerning off-label use (as long as, according to the Government, any such conversations were initiated by doctors).[3]

In light of the foregoing, it is clear that the "crime" in this case was neither the act of shipping nor the act of off-label use. Nor was it even the fact that off-label discussions occurred. Given the jury's rejection of the Government's fraud charges, had Stratus—following receipt of its FDA clearance—been shipped in silence, or had any off-label discussions occurred solely at

[3] The Court explicitly instructed the jury on each of these points—that off-label use of a cleared device is lawful, that mere shipment (distribution) of a cleared device with knowledge it will be used off-label is not a crime, and that it is permissible for a manufacturer to discuss off-label use in response to an unsolicited request by a physician—*i.e.*, if the doctor initiates the conversation. Jury Instrs. at 26-28 (Dkt. #436).

the initiative of physicians, Defendants undisputedly would not have run afoul of any laws. The basis for the jury's finding of guilt on misdemeanor adulteration and misbranding must therefore have been the act of speech—specifically, promotional speech by Acclarent employees concerning off-label use of the Stratus device.[4]

The First Amendment forbids such content- and speaker-based constraints on commercial speech, absent a compelling governmental interest and narrowly tailored restrictions, which the Government never established. *See* Mem. Supp. MTD #2, at 11-15, 17-18 (Dkt. #185) (discussing *Sorrell*, 131 S. Ct. at 2663-64; *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2222-23, 2231 (2015); and *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564, 566 (1980)). On this ground alone, the Court should enter a judgment of acquittal.

II. DUE PROCESS DOES NOT PERMIT HOLDING DEFENDANTS STRICTLY LIABLE FOR MISDEMEANOR ADULTERATION AND MISBRANDING BASED ON THE NON-FRAUDULENT CONDUCT ESTABLISHED AT TRIAL.

Defendants likewise have provided the Court with extensive briefing concerning the significant Due Process issues raised by the Government's adulteration and misbranding charging theories. *See, e.g.*, Mem. Supp. MTD #2, at 2-10 (Dkt. #185); Mem. Supp. MTD #3 (Dkt. #186-1); Mem. Supp. MTD #6 (Dkt. #194). Those issues include: (a) the confusion,

[4] *E.g.*, *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 59 (D.D.C. 1998) (holding that FDA guidance documents concerning manufacturer-supported scientific and educational activities regulated speech, not conduct), *appeal dismissed, judg't vacated in part sub nom. Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000); *see also Commonwealth Brands, Inc. v. United States*, No. 1:09-CV-117-M, 2009 WL 3754273, at *5 (W.D. Ky. Nov. 5, 2009) (treating FDA regulations, for purposes of First Amendment analysis, as regulating speech, not conduct); *United States v. Caronia*, 576 F. Supp. 2d 385, 394-95 (E.D.N.Y. 2008) (same), *vacated on other grounds*, 703 F.3d 149 (2d Cir. 2012); *cf. Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2664-67 (2011) (holding that statute governing dissemination of pharmaceutical information regulated speech not conduct); *IMS Health, Inc. v. Ayotte*, 550 F.3d 42, 79-81 (1st Cir. 2008) (Lipez, J., concurring and dissenting) (same), *abrogated on other grounds by Sorrell*, 131 S. Ct. 2653; *Holder v. Humanitarian Law Project*, 130 S. Ct. 2705, 2722-24 (2011) (holding that statute at issue regulated speech, not simply conduct).

ambiguity, and corresponding lack of fair notice that surrounds the meaning of FDA's "intended use" regulations generally; (b) the exacerbation of that uncertainty by the Government's efforts in this case to recast "intended use" as encompassing not only truthful promotional speech but also Stratus's iterative design history files and other internal communications; and (c) the heightened concern that arises when, as here, the Government seeks to apply its novel theories to hold Defendants strictly liable in a case where criminal scienter was both not required and the jury affirmatively rejected such a finding.

The Court, although denying Defendants' motions to dismiss, did so with leave to renew, and expressly cautioned that the Due Process concerns would be at their most compelling if Defendants were acquitted of the fraud counts and only convicted on strict-liability misdemeanors. *See* 6/3/16 Jury Instrs. Hr'g Tr. 55:17-56:5 ("[E]verybody would benefit by rewriting the statute. . . . You know, it's no secret. I am wrestling with this. I mean . . . it will be interesting to see what happens if they're just convicted on *Park*, or they are convicted on FDCA violations, but not on the wire fraud. Those are going to be significant [developments]. . . ."). That precise outcome has now occurred. With it, Defendants renew their Due Process objections.

To avoid repeating their prior briefs, Defendants incorporate their previous Due Process arguments by reference, and instead focus this memorandum on the Government's improper expansion of "intended use"—on which the legal viability of Defendants' strict-liability convictions turns[5]—to encompass not only evidence of truthful, non-misleading speech, *see* Section I, *supra*, but also, most particularly, evidence of internal communications, such as

[5] *See generally* Jury Instrs. at 33 & 36 (Dkt. #436) (including "intended use" as a necessary component of the adulteration and misbranding counts on which Defendants were convicted).

Stratus's internal, iterative design history files,[6] and also "probing questions."[7] *See* Section II.A-D, *infra*. Such evidence cannot, consistent with the governing law and principles of due process, ground strict-liability convictions for misdemeanor adulteration and misbranding.

A. As a Matter of Law, Matters Not Communicated to Customers, Such as Design History, May Not Be Considered as Evidence of "Intended Use."

"Analysis begins with the text of [the] [r]egulation" in question. *Chase Bank USA, N.A. v. McCoy*, 562 U.S. 195, 204 (2011). 21 C.F.R. § 801.4 defines a device's "intended use" for purposes of post-clearance regulation as the "objective intent of the persons legally responsible for the labeling of devices." § 801.4. While the term "objective intent" is oxymoronic, multiple tools of statutory and regulatory construction demonstrate that internal communications and files such as design history do not fall within its scope.

First, "[u]nder the familiar interpretative canon *noscitur a sociis*, 'a word is known by the company it keeps.'" *McDonnell v. United States*, 136 S. Ct. 2355, 2368 (2016) (quoting *Jarecki*

[6] Over Defendants' repeated objection, *e.g.*, 27 Trial Tr. 184:6-9, 186:9-11, the jury was presented extensive evidence of, and explicitly told to consider, not only external promotional statements to determine Stratus's "intended use," but also "how the device was designed." 26 Trial Tr. 78:10-16 (Gov't's Closing); *see, e.g.*, 2 Trial Tr. 30:25-34:23, 42:18-43:14 (Gov't's Opening) (repeatedly asserting that Stratus's being "designed" to deliver Kenalog showed that the "intended use" was drug delivery rather than as a spacer with saline); 3 Trial Tr. 68:19-69:6; 4 Trial Tr. 153:15-154:25; 7 Trial Tr. 115:15-19, 164:15-165:15, 173:17-22; 10 Trial Tr. 25:13-23, 60:8-18, 72:12-18, 124:1-13; 21 Trial Tr. 90:25-91:16; 23 Trial Tr. 54:22-56:15 (testimony focusing on Stratus's design history); 26 Trial Tr. 40:7-16, 64:14-65:14, 78:13, 89:13-22 (Gov't Closing) (emphasizing Stratus's design history); *cf.* Jury Instrs. at 27 (Dkt. #436) (including, *inter alia*, 21 C.F.R. § 801.4's definition of "intended use").

[7] The Government repeatedly elicited testimony from sales representatives regarding the use of so-called "probing questions," and then suggested that asking such questions was improper off-label promotion that could be considered evidence of a new intended use. *See, e.g.*, 2 Trial Tr. 48:9-18 (Govt. Opening) (discussing training on probing questions); 4 Trial Tr. 187:25-188:1, 200:11-201:17, 5 Trial Tr. 79:12-83:9, 88:9-20, 101:1-3, 7 Trial Tr. 57:22-58:3, 9 Trial Tr. 37:8-39:22, 42:21-45:25, 91:7-22, 10 Trial Tr. 35:1-15, 111:23-113:1, 11 Trial Tr. 27:20-28:2 (testimony focusing on the use of probing questions to sell Stratus); 26 Tr. 93:9-16, 126:10-127:6, 27 Tr. 127:7-13 (Gov't Closing) (claiming that asking probing questions was felony off-label promotion and otherwise "solicit[ed] the doctor to ask about drug delivery").

v. G.D. Searle & Co., 367 U.S. 303, 307 (1961)). "[T]his canon 'is often wisely applied where a word is capable of many meanings in order to avoid the giving of unintended breadth to the Acts of Congress.'" *Id.* (quoting *Jarecki*, 367 U.S. at 307). In *Gustafson v. Alloyd Co.*, 513 U.S. 561 (1995), for example, the Supreme Court was tasked with interpreting a statute that defined the word "prospectus" as a "prospectus, notice, circular, advertisement, letter, or communication." *Id.* at 573-74 (citation omitted). The Court "held that although the word 'communication' could in the abstract mean any type of communication, 'it is apparent that the list refers to documents of wide dissemination,' and that inclusion 'of the term 'communication' in that list suggests that it too refers to a public communication.'" *McDonnell*, 136 S. Ct. at 2369 (quoting *Gustafson*, 115 S. Ct. at 575). So too here, § 801.4's examples of "objective intent"—"labeling claims, advertising matter, or oral or written statements by such persons or their representatives," § 801.4—confirm that "intended use" is based on statements or actions directed at doctors, patients, or other members of the public for marketing purposes—not on internal documents or discussions, such as future product plans or other necessary manifestations of the stepping-stone approach to device clearances.

"That more limited reading also comports with the presumption 'that statutory [and regulatory] language is not superfluous.'" *McDonnell*, 136 S. Ct. at 2369 (quoting *Arlington Central Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 299 n.1 (2006)); *see, e.g.*, *id.* at 2367, 2369 (rejecting the Government's broader construction of "any decision or action on any *question, matter,* cause, suit, proceeding or controversy" for purposes of the bribery statute, because "[i]f 'question' and 'matter' were as unlimited in scope as the Government argues, the terms 'cause, suit, proceeding or controversy' would serve no role in the statute—every 'cause, suit, proceeding or controversy' would also be a 'question' or 'matter'"). So too here. If

§ 801.4's references to "oral or written statements" or "the circumstances surrounding the distribution of the article" were as all-encompassing as the Government has argued, *see* 26 Trial Tr. 78:10-16 (Gov't's Closing) (providing an effectively limitless scope), there would be no reason for the delineation of "labeling claims" and "advertising matter"—such evidence would already be included.

Furthermore, the Government's construction would lead to absurdities, which further compels against such a reading. In *United States v. Sun-Diamond Growers of California*, 526 U.S. 398 (1999), for example, the Supreme Court was tasked with interpreting the meaning of "any decision or action on any question, matter, cause, suit, proceeding, or controversy, which may at any time *be pending*, or which *may by law be brought before any public official*." *McDonnell*, 136 S. Ct. at 2367, 2370 (emphasis added) (citation omitted). Concluding that it was "not an 'official act' . . . for the President to host a championship sports team at the White House, the Secretary of Education to visit a high school, or the Secretary of Agriculture to deliver a speech to 'farmers concerning various matters of USDA policy,'" the Supreme Court "recognized that 'the Secretary of Agriculture *always* has before him or in prospect matters that affect farmers, just as the President always has before him or in prospect matters that affect college and professional sports, and the Secretary of Education matters that affect high schools.'" *Id.* at 2370 (quoting 526 U.S. at 407). "It was possible to avoid the 'absurdities' of convicting individuals on corruption charges for engaging in such conduct, [the Court] explained, '*through the definition of that term*,' *i.e.*, by adopting a more limited definition of 'official acts.'" *McDonnell*, 136 S. Ct. at 2370 (quoting *Sun-Diamond*, 526 U.S. at 407-08). Likewise, medical device manufacturers are always striving to innovate and improve their products. If strategic development plans, design history, and related communications could be considered evidence of

"intended use," all manufacturers seeking improvement of their product line would, absurdly, be criminals. *See, e.g.*, Declaration of Jeffrey Shapiro ¶ 15 ("Shapiro Decl.") (Ex. 1).

Indeed, FDAMA's statutory requirement that FDA clear devices as substantially equivalent based only on the intended use identified in the proposed labeling rather than on design features allowing other uses of the device, *see* 21 U.S.C. § 360c(i)(1)(E)(i), would be rendered nearly meaningless; manufacturers would be subject to criminal prosecution for misbranding and adulteration as soon as their properly cleared products were on the market.

Finally, § 801.4's placement within the larger regulatory framework—*i.e.*, in Part 801 of the Code of Federal Regulations, titled "Labeling"—confirms that "intended use" is limited to externally directed statements, and certainly does not encompass design history, future plans, and other internal communications. *See, e.g.*, *Mead Corp. v Tilley*, 490 U.S. 714, 723 (1989) (relying on title of statute to resolve "any possible ambiguity").

It is thus unsurprising that courts "read the clauses in the statutory definitions employing the term 'intended' to refer to specific marketing representations." *Am. Health Prods. Co. v. Hayes*, 574 F. Supp. 1498, 1505 (S.D.N.Y. 1983) (citations omitted), *aff'd on other grounds*, 744 F.2d 912 (2d Cir. 1984); *see, e.g.*, *United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497, 500 (8th Cir. 1995) (holding that internally maintained product literature was *not* evidence of intended use, because materials are "promotional" and "relevant to intent" only if they have actually been "distributed" to customers); *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 163 (4th Cir. 1998) ("[N]o court has ever found that a product is 'intended for use' or

'intended to affect' within the meaning of the [Act] absent manufacturer claims as to that product's use.") (second alteration in original) (citation omitted), *aff'd*, 529 U.S. 120 (2000).[8]

In addition to the text and case law, FDA itself has both implicitly and explicitly opined that "intended use" is based only on external marketing statements. There is no valid reason for disregarding FDA's long-maintained public position in favor of the Department of Justice's theory in this particular criminal case. In 1994, for example, FDA issued a notice in the *Federal Register* addressing § 801.4 and changes in "intended use" for a cleared device. Citizen Pet'n Regarding the FDA's Policy on Promotion of Approved Drugs & Devices; Request for Cmts., 59 Fed. Reg. 59,820 (Nov. 18, 1994) (Ex. 3). FDA nowhere suggested, much less stated, that design history, plans, or other internal statements could be considered as evidence of "intended use" or require a new 510(k) or PMA to avoid misbranding and adulteration liability. It was only *promotion* that was identified as a consideration and trigger of liability. *See id.* at 59,825 ("Under the act, manufacturers must obtain new marketing approvals or clearances *when they promote* an approved or cleared device for a new intended use.") (emphasis added); *see also id.* at 59,821 ("FDA has long regulated drugs and devices . . . based on the intended uses for the

[8] Defendants are not aware of any case to date holding that design history is a permissible basis for determining "intended use." And they are only aware of one case allowing internal statements—a 2016 decision post-dating not only Defendants' charged conduct but their indictment. *See United States v. Vascular Solutions, Inc.*, No. SA-14-CR-926, slip op. at 7, (W.D. Tex. Jan. 27, 2016). For the reasons contained herein and previously set forth on the record, the Court should not find that decision persuasive. In any event, the Government here did not simply introduce internal statements regarding how to market Stratus without a drug indication; it introduced documents and communications from well before Stratus was put on the market as evidence of Stratus's "intended use" later on. *E.g.*, GX259 (August 2007 Project Charter); GX240; GX260; GX281; GX309; GX346.

Moreover, while the Government has tried to discredit the above case law by citing a subsequent district court decision purportedly finding intended use based only on the physical location of the sale, *United States v. Travia*, 180 F. Supp. 2d 115 (D.D.C. 2001), FDA itself did not consider *Travia* to undermine the proposition that intended use is determined by external marketing statements. *See infra* (discussing FDA's 2002 letter reaffirming the limited meaning of "intended use").

products. . . The agency . . . regulates products based not only on information provided 'with' the product, but also based on information disseminated by manufacturers in other contexts, such as scientific and educational meetings and symposia, books, and articles, in part because all of these materials can create new intended uses for the products . . . ."); *id.* at 59,822 ("A product's intended use is usually primarily a function of the manner in which a company characterizes its product in the marketplace.").

In 2000, FDA issued another notice in the *Federal Register* equating "intended use" for purposes of adulteration and misbranding liability with marketing statements. *See* Decision in *Wash. Legal Found. v. Henney*, 65 Fed. Reg. 14,286, 14,286 (Mar. 16, 2000) (Ex. 4) ("[A]n approved new drug that is *marketed* for a 'new use' becomes an unapproved new drug with respect to that use. . . [and] is also 'misbranded' under the FDCA, because the labeling of such a drug would not include 'adequate directions for use.' Similarly, a medical device that is distributed for a 'new use' is 'adulterated,' and 'misbranded.' An adulterated or misbranded product is prohibited from distribution in interstate commerce . . . as is a drug that is *marketed* for a 'new use.'") (emphases added).

And in its 2015 *Federal Register* notice addressing "How Intended Use Is Determined," FDA again made no mention of design history, plans, or internal statements. Clarification of When Prods. Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Prods.; Amends. to Regulations Regarding "Intended Uses," 80 Fed. Reg. 57,756, 57,757 (Sept. 25, 2015) (to be codified at 21 C.F.R. pts. 201, 801, 1100) (Ex. 5). Instead, it described the "variety of direct and circumstantial evidence" that may be considered, including the "circumstances surrounding the distribution of the product or the context in which it is sold," *id.*, as evidence that may be (a) less than "express claims," *id.*, and (b) more than "claims made in a

product's labeling or advertising materials." *Id.* at 57,762; *see also id.* at 57,759 (explaining, in the context of tobacco, that "[t]he phrase 'sold or distributed for'" means "represent[ing] in its label, labeling, or advertising, either implicitly or explicitly"; "us[ing] [certain] descriptors . . . in its label, labeling, or advertising"; or "tak[ing] any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising . . . that would be reasonably expected to result in consumers believing [something]").

Consistent with this line of authority, FDA's Chief Counsel stated explicitly and unequivocally on behalf of the agency, in 2002, that "[i]t is well settled that intended use is determined with reference to marketing claims." Ltr. from Daniel E. Troy to Jeffrey N. Gibbs, Esq. at 3 (Oct. 17, 2002), http://www.fda.gov/ohrms/dockets/dailys/03/dec03/120503/81n-0033p-sup0003-vol86.pdf ("FDA Letter") (Shapiro Decl. Ex. C); *accord id.* at 4 ("[T]hat intended use is determined by manufacturer marketing claims 'has now been accepted as a matter of statutory interpretation' by the federal courts.") (citation omitted). "This is what has traditionally been understood as 'objective intent.'" *Id.* at 3. The Government's attempts in this case to discredit the value of the FDA Letter should be rejected. Contrary to the Government's earlier insinuation, the letter was written not on behalf of the General Counsel in his individual capacity but on behalf of the "FDA." *See id.* at 7 ("So long as no medical claims are made for the personal ID/security VeriChip, *FDA can confirm* that it is not a medical device.") (emphasis added); *id.* at 4 (same)[9]; *see also* Ltr. from William B. Schultz (FDA) to Daniel J. Popeo & Richard A. Samp (Wash. Legal Found.) at 18 (Dec. 3, 1997) (Ex. 6) ("The term 'intended use' is broadly defined to capture the manner in which a company *characterizes its product in the*

[9] Tellingly, the design of the product in question in the FDA Letter allowed access to medical history, FDA Letter at 2, yet FDA stated that only marketing claims about medical purposes could be evidence of the "intended use." *Id.* at 4, 7.

marketplace. The agency thus examines the various means by which manufacturers and their representatives *provide information about their products to health care professionals and consumers* . . . to determine whether the products are being improperly promoted, and therefore misbranded or adulterated.") (emphasis added).

Furthermore, it is not only the courts' and FDA's interpretation but congressional intent that "intended use" is limited to a manufacturer's external marketing claims. *See* S. Rep. No. 74-361, at 4 (1935) (Ex. 7) ("The manufacturer of the article, through *his representations in connection with its sale, can determine the use* to which the article is to be put.") (emphasis added); *Foods, Drugs, and Cosmetics: Hr'gs on S. 2800 Before the S. Comm. on Commerce*, 73d Cong. 517-18 (1934) (Ex. 8) (reiterating that it is "only when" a manufacturer makes "representations to the public" that there is an intended use under the misbranding statute); FDA Letter at 4 (recognizing that "[t]he pertinent legislative history supports this [narrow] interpretation" of "intended use").

Finally, "[i]n addition to being inconsistent with both text and precedent, the Government's expansive interpretation . . . would raise significant constitutional concerns." *McDonnell*, 136 S. Ct. at 2372. *See infra* Section II.B (discussing the due process concerns if more than external marketing statements, and in particular design history and future product plans, were allowed as evidence of "intended use").

For all these reasons, evidence of "intended use" should be restricted, as a matter of law, so as to exclude internal communications such as design history and future product plans. Because the jury was allowed to convict Defendants based on an overbroad definition of "intended use," and there was insufficient competent evidence on which to convict, a judgment of acquittal on Counts Nine through Eighteen is necessary.

B. To Now Consider Design History and Other Internal Communications as Evidence of "Intended Use" Deprives Defendants of Due Process.

"A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012); *accord id.* ("[All persons] are entitled to be informed as to what the State commands or forbids.") (alteration in original) (quoting *Papachristou v. Jacksonville*, 405 U.S. 156, 162 (1972)). "A conviction or punishment fails to comply with due process if the statute or regulation under which it is obtained 'fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement.'" *Id.* (quoting *United States v. Williams*, 553 U.S. 285, 304 (2008)). Under a notoriously complex statutory and regulatory scheme governing food, drugs, devices, and cosmetics, what this Court has acknowledged as the "incredibly complicated and convoluted" concept of "intended use" in particular, 2/4/16 Mot. Hr'g Tr. 155:5-7, rises to the level of a due process violation when interpreted to encompass design history, future product plans, and other internal communications.

Two recent Supreme Court decisions are particularly instructive. In *Johnson v. United States*, 135 S. Ct. 2551 (2015), the Supreme Court considered a vagueness challenge to the residual clause of the Armed Career Criminal Act, which provided for increased punishment when a convicted felon in possession of a firearm had three prior felonies involving "conduct that presents a serious potential risk of physical injury to another." *Id.* at 2555 (citation omitted). Overruling several recent decisions that had rejected that constitutional challenge to the law, the Supreme Court this time ruled the provision void for vagueness, explaining that "the failure of 'persistent efforts . . . to establish a standard can provide evidence of vagueness.'" *Id.* at 2558 (omission in original) (citation omitted).

The failure of persistent efforts to understand and explain the meaning of "intended use" and the circumstances under which manufacturers can promote and sell a cleared medical device evince the unconstitutional vagueness of the statutes Defendants were convicted of violating. For *decades*, it has been well-recognized both within and outside FDA that "[t]he unlabeled use of approved drugs has been a complex, little understood, and controversial topic." Stuart L. Nightingale (Assoc. Comm'r for Health Affairs, FDA), *Unlabeled Uses of Approved Drugs*, 26 Drug Info. J. 141, 141 (1992) (Ex. 9). Part of this confusion stems from the fact that "[w]hile the FDCA makes it a crime to misbrand or conspire to misbrand a drug" or device, or to adulterate such a product, "the statute and its accompanying regulations do not expressly prohibit or criminalize off-label promotion." *United States v. Caronia*, 703 F.3d 149, 160 (2d Cir. 2012). Instead, FDA has historically equated off-label promotion and adulteration/misbranding. *See id.* at 155; *supra* Section II.A.

Even before modern First Amendment jurisprudence began to "thwart[] actions FDA has wished to pursue," Request for Cmt. on First Amend. Issues, 67 Fed. Reg. 34,942, 34,943 (May 16, 2002) (Ex. 10), industry was seeking, and FDA conceded the lack of, clarity as to unlawful conduct. *See, e.g.*, Nightingale, *supra*, at 144-47 (acknowledging complaints that "relying on FDA guidance in the form of a never-finalized proposed rule, speeches, medical literature authored by FDA officials, and even the April 1982 *FDA Drug Bulletin*, the most official 'stand alone' source yet utilized, is not sufficient for proper guidance emanating from a Federal agency," and asking, "How can the FDA further address this problem? Should it?"); Citizen Pet'n at 4-5, 12 (July 5, 2011) (Ex. 11) (lamenting the "significant lack of clarity as to the practices . . . permit[ted]" by FDA's "explicitly recognized important mechanisms for the sharing

of truthful and non-misleading scientific information," and requesting that FDA "affirm and clarify the contours of these policies").

Recent First Amendment decisions protecting truthful and non-misleading off-label speech from prosecution further muddied the waters, as this Court recognized at the motion-to-dismiss phase. *See* 2/4/16 Mot. Hr'g Tr. 43:15-16 ("[W]e have overtaken history or history has overtaken us."); *id.* at 158:8-15 ("[I]f you are chugging along in this industry and you have this approval strategy which is that you get the 510(k) for some little use and then you get it out in the market and people are using it for what they use it for, and then *Caronia* comes out, could you not be at your desk thinking . . . as long as I don't say anything false and misleading I can continue to promote it?"); *see also* 67 Fed. Reg. at 39,943 (discussing the new First Amendment "challenge to FDA," because FDA's long-held position "explicitly limit[s] speech").

In 2014, FDA granted the 2011 Citizen Petition, stating its intent to "clarify the distinction between permissible and impermissible conduct," "in light of the importance of the . . . free speech and due process principles at stake." Ltr. from Leslie Kux (Ass't Comm'r for Policy, HHS) to Alan Bennet et al. (June 6, 2014) (Ex. 12). In 2015, FDA proposed to amend its "intended use" regulations, including § 801.4, in an effort to "reduce"—but not eliminate—the "regulatory ambiguity in the research, development and marketing of drugs, devices, and tobacco products." 80 Fed. Reg. at 57,763. And as recently as this past month, FDA issued another iteration of "nonbinding," "draft guidance" recognizing the continued "[c]onfusion" surrounding "intended use." FDA, Draft Guidance for Industry & FDA Staff, *Deciding When to Submit a 510(k) for a Change to an Existing Device*, at 11 (Aug. 8, 2016) ("510(k) Guidance") (Ex. 13).

To date, however, the regulations have not been amended, and the meaning of "intended use" has remained vague for industry and been the subject of days' worth of intense, good-faith

debates among the parties' experienced legal counsel and the Court, to no avail, in this case. *See, e.g.*, 19 Trial Tr. 13:21-14:1 (Court stating that, "the amount of time that we've spent on the jury instructions and how difficult they are – you know, I sort of lie in bed at night and think if we can't figure out the law, maybe there is a due process problem, but I'm unlikely to rule on those sorts of issues before this goes to the jury"); 6/3/16 Jury Instrs. Hr'g Tr. 37:2-15 (counsel expressing frustration, on day 4 of the charge conference, that "we're all just spinning around, repeatedly, for hours, trying to grapple with the fact that [the] regulation was written prior to the First Amendment commercial speech cases, and frankly, if we can't figure it out, ourselves, having devoted hours — THE COURT: That thought has crossed my mind.").

All of this shows that, "under the Government's interpretation, the term . . . is not defined 'with sufficient definiteness that ordinary people can understand what conduct is prohibited,' or 'in a manner that does not encourage arbitrary and discriminatory enforcement.'" *McDonnell*, 136 S. Ct. at 2373 (citation omitted). And although the Supreme Court has rejected the "theory that a vague provision is constitutional merely because there is some conduct that clearly falls within the provision's grasp," *Johnson*, 135 S. Ct. at 2560-61, the evidence adduced at trial here confirms that Defendants could not have been expected to resolve this hopeless indeterminacy or to understand that Acclarent's conduct would be considered unlawful.[10]

[10] Tellingly, Acclarent's experienced Regulatory department employees approved the sales and marketing of Stratus. *See, e.g.*, GX2415 (Cogan's approval of probing questions in a pre-call sales plan); GX1153 (approved Physician Discussion Guide). The jury's rejection of the conspiracy charges reinforces that these regulatory experts did not understand the conduct in question to be unlawful. Internal FDA documents also revealed uncertainty within the agency as to the proper classification—and thus need for a 510(k) or PMA—for Stratus. *See, e.g.*, GX2513 (Clupper finding Stratus not to be a Class III device, and thus not requiring a PMA, in 2011, despite knowing of high off-label use and Acclarent's intent for a steroid indication); GX2127 (Michele describing Stratus as Class I in 2010). Non-regulatory experts such as Defendants could not have been on notice of where the line was. *See also, e.g.*, 11 Trial Tr. 46:12-48:9

The second recent Supreme Court case reinforcing the due process violation is *FCC v. Fox Television Stations, Inc.*, which rejected government arguments similar to those previously advanced by the Government here, and set aside FCC orders finding two broadcasts indecent, because the defendants lacked fair notice as to what was prohibited. 132 S. Ct. 2307 (2012). More specifically, the Government has contended that "the Government's theory here about what, how you prove intended use is not novel. . . . [T]here was a case going back to 1963, . . . *U.S. versus 250 Jars U.S. Fancy Pure Honey*, 218 F. Supp. 208 [(E.D. Mich. 1963)]." 2/4/16 Mot. Hr'g 93:19-23, 97:1-3. As an initial matter, *Honey* does not even address using anything other than external statements as evidence of intended use.[11] But assuming *arguendo* that it did, the *Fox* Court rejected the government's effort to use a similarly "isolated and ambiguous statement from a 1960 Commission decision" as "fair notice . . . when the Government intends to impose over a $1 million fine for allegedly impermissible speech." *Fox*, 132 S. Ct. at 2319. The *Fox* Court further reasoned that the Commission had, subsequent to that 1960s decision, "declined to find" conduct similar to the petitioner's to be actionable. *Id.* So too here, subsequent decisions have declined to find "intended use" based on factors other than external marketing statements. *See, e.g.*, *Veterinary Use*, 50 F.3d at 500; *supra* Section II.A; *see also* Shapiro Decl. ¶ 12 (attesting that there is no known case or warning letter considering design history as evidence of "intended use").

The Government's previous reliance on *United States v. Travia*, 180 F. Supp. 2d 115 (D.D.C. 2001), to provide the requisite notice is likewise misplaced. Though *Travia* allowed the

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(testimony of sales representative Bradford Ader) ("I'm getting confused here. . . . I don't know what you're asking. I don't understand [the concept of 'intended use'].").

[11] *Honey* concluded that a book for sale and a newspaper leaflet, both discussing honey's medical benefits and made available to customers in the store where the honey was sold, were promotional materials evincing the distributor's intended use of honey as a drug; it did not consider any other facts as evidence of the intended use. 218 F. Supp. at 212.

physical location of a sale as evidence that a product was intended as a drug, there was no discussion of using the product's design, truthful speech, or other internal manufacturer statements as evidence of "intended use." *See id.* Furthermore, when FDA subsequently summarized the scope of "intended use," *see* FDA Letter, *supra*, it did so without any acknowledgment of *Travia* or its broader construction. *Id.* Thus, as in *Fox*, "the Government can point to nothing that would have given [Defendants] affirmative notice that [Acclarent's actions] would be considered" unlawful. *Fox*, 132 S. Ct. at 2319.

C. The Meaning of a "Solicited" Request, Which Purportedly Could Subject a Defendant to Criminal Liability, Is Unconstitutionally Vague.

When "a law interferes with the right of free speech . . . , a more stringent vagueness test should apply." *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982). The vagueness of the meaning of a "solicited" (and thus supposedly unlawful) request for off-label conversation renders unconstitutional the consideration of Acclarent's sales representatives' use of "probing questions" as evidence in support of the adulteration and misbranding convictions.

As described by Jeffrey Shapiro in his Declaration, FDA had established a "safe harbor" that applied during the relevant period and exempted from adulteration and misbranding liability off-label discussions between a manufacturer and medical provider that were "unsolicited" by the manufacturer. Shapiro Decl. ¶ 30. FDA had summarized this policy in a 1994 Federal Register notice, explaining that "companies may . . . disseminate information on unapproved uses in response to unsolicited requests for scientific information from health care professionals." *See* Citizen Pet'n Regarding the FDA's Policy on Promotion of Unapproved Uses of Approved Drugs & Devices; Request for Cmts., 59 Fed. Reg. 59,820, 59,823 (Nov. 18, 1994) (Ex. 3); Shapiro Decl. ¶ 31.

As explained in greater detail by Mr. Shapiro, the contours of this legal safe harbor were completely unclear to industry. Shapiro Decl. ¶ 33; *see also* Citizen Pet'n (July 5, 2011) (requesting that FDA provide guidance). FDA's 1994 Notice did not define or give examples of what constitutes an "unsolicited request," and there was no case law or warning letter providing insight. Shapiro Decl. ¶ 32. FDA did not provide any meaningful guidance on this safe harbor until December 2011, which was too late to affect the conduct at issue in this case. *Id.* ¶ 34.[12]

A reasonable person was thus unable to determine that the use of probing questions, on which the Government so heavily relied at trial, would be considered violative of the Agency's guidance, let alone unlawful. Indeed, the evidence at trial was that Acclarent's experienced regulatory department believed that the use of such questions was permissible. *See, e.g.*, GX2415 (Cogan's approval of probing questions in a pre-call sales plan); GX1153 (approved Physician Discussion Guide); 10 Trial Tr. 176:20-177:1 (testimony of Barbara Logan that regulatory advised sales representatives not to initiate the conversation regarding Kenalog but that if a doctor asked a question, they could answer); *see also* 10 Trial Tr. 35:2-6 (Erik Krinsky: "[T]he goal was to allow the surgeon to be the one to make the statement, 'It would be great if I could use a steroid to -- with this device,' without me actually saying it as the sales reps, to have it come out of their mouth."). If these experts were not on notice that such questions would be considered unlawful (and the acquittal on the conspiracy counts evince this), Defendants could not have been expected to know that they were exposing themselves to criminal liability.

[12] Mr. Fabian left Acclarent prior to December 2011. Mr. Facteau left on December 31, 2011 (the day after FDA issued the draft guidance on responses to unsolicited requests). Thus, neither Defendant was in a position to respond to changes in FDA's position set forth in the 2011 FDA Draft Guidance (which in any event has never been finalized).

D. The Due Process Violations Are Exacerbated by the Strict-Liability Nature of the Challenged Convictions.

Finally, that the only counts of conviction were strict-liability offenses further compels the conclusion that the convictions violate due process. As explained in Defendants' earlier briefing (Dkt. #194 & 240), in *Colautti v. Franklin* the Supreme Court faced a statute that required physicians to observe a stated standard of care if (a) they determined that a fetus was viable or (b) "there [was] sufficient reason to believe that the fetus may be viable." 439 U.S. 379, 391 1979) (citation omitted). The Court held that this viability-determination provision was "ambiguous, and that its uncertainty is aggravated by the absence of a scienter requirement with respect to the finding of viability." *Id.* at 390. Elaborating, it pointed out that "it is unclear whether the statute imports a purely subjective standard, or whether it imposes a mixed subjective and objective standard." *Id.* at 391. *Compare supra and* Mem. Supp. MTD #2, Section II (Dkt. #185) & Mem. Supp. MTD #3, Section I (Dkt. #186-1) (discussing courts' and prosecutors' historical interpretation of the adulteration and misbranding offenses as based on the objectively determined "intended use" of a device—specifically, marketing representations—while prosecutors' most recent argument has been for use of a broader standard that includes subjective intent). The statute did not "afford broad discretion" but rather "condition[ed] potential criminal liability on confusing and ambiguous criteria." *Colautti*, 439 U.S. at 394. The statute "therefore present[ed] serious problems of notice, discriminatory application, and chilling effect on the exercise of constitutional rights." *Id.* If those flaws were not fatal, however, "[t]he vagueness of the viability-determination requirement" was, as here, "compounded by the fact that the Act subjects the [defendant] to potential criminal liability without regard to fault." *Id.*; *see id.* at 395 ("Because of the absence of a scienter requirement . . . , the statute is little more than 'a trap for those who act in good faith.'") (citation omitted). That absence of scienter

rendered the vague provision "void on its face." *Id.* at 396; *see also United Nuclear Corp. v. Cannon*, 553 F. Supp. 1220 (D.R.I. 1982).

Of particular relevance here, the evidence at trial established that Acclarent's regulatory staff (including Su-Mien Chong and Debra Cogan) clearly believed that probing questions were allowed under FDA rules.[13] There was no evidence that Defendants sought to undermine the regulatory department's directions to avoid off-label promotion of Stratus by relying on indirect probing questions believed to fall within the 1994 FDA safe harbor. Strikingly, Defendants appear to have been convicted despite having in good faith attempted to follow the strategy devised by Acclarent regulatory personnel charged with ensuring compliance with FDA regulations. *See* Jury Instrs. at 38 ("Good faith, which I will discuss in more detail shortly, is not a defense because the law does not require a defendant to know about or to have actively engaged in wrongdoing in order to be held responsible for his company's distribution of adulterated or misbranded devices."). To convict Defendants under such circumstances is anathema to this country's most fundamental principles of criminal jurisprudence.

For all these reasons, separately and in conjunction, the Court should hold that the strict-liability misdemeanor convictions violate the Fifth Amendment's due process guarantee.

III. NO RATIONAL JURY COULD CONVICT DEFENDANTS OF THE MISBRANDING AND ADULTERATION COUNTS ON THE EVIDENCE ADDUCED BY THE GOVERNMENT.

The strict liability misdemeanor adulteration and misbranding counts—the sole counts on which Defendants were convicted—are limited to ten specific shipments of Stratus:

[13] *See, e.g.*, GX2415 (listing probing questions approved by Acclarent regulatory personnel).

Count	Stratus Shipped To	Approximate Shipment Date
9	Hospital 1, S. Weymouth	10/21/2009
10	Hospital 2, Plymouth	11/06/2009
11	Hospital 3, Lowell	11/17/2009
12	Hospital 4, Hyannis	08/11/2010
13	Hospital 5, Worcester	02/25/2011

Count	Stratus Shipped To	Approximate Shipment Date
14	Hospital 4, Hyannis	12/15/2009
15	Hospital 1, S. Weymouth	01/19/2010
16	Hospital 2, Plymouth	01/10/2010
17	Hospital 1, S. Weymouth	10/13/2010
18	Hospital 5, Worcester	05/27/2011

Indictment ¶¶ 142, 144. Yet, the Government introduced *no* evidence concerning any statements, promotional or otherwise, about Stratus that either Defendant, or anyone at Acclarent, made to customers in connection with these ten shipments. This failure of proof is critical in light of the jury's rejection of the government's conspiracy allegations. Indeed, even under the Government's novel, confusing, and counterintuitive "intended use" theory of liability (which should fail as a matter of due process, *see supra* Section II), the Government must show that the manufacturer created a new "intended use" of drug delivery for the Stratuses shipped in these specific transactions. This the Government has not done, and an acquittal on each count of conviction is required.

A. To Establish That Stratus Had a New "Intended Use" Under § 801.4, the Government Must Have Proven, at Least in Part, That Defendants Made External Marketing Claims in Connection with Each of the Ten Charged Shipments.

The misbranding and adulteration charges for which the jury returned guilty verdicts turned on the "intended use" of Stratus as a drug delivery device. The Court, over Defendants' objections, did not instruct the jury that evidence of "intended use" is limited to external marketing statements.[14] Nevertheless, there can be no dispute that there must be *some* evidence of external marketing claims sufficient to create a new "intended use." Otherwise, prosecution based on a company's or individual's internal, *subjective* intent—without any external communication to the customer—would amount to nothing more than a "thought crime," which has been roundly rejected as part of American jurisprudence. *See, e.g.*, *Powell v. Texas*, 392 U.S. 514, 543 n.4 (1968) ("[t]hat crime requires an act is invariably true if the proposition be read as meaning that a private thought is not sufficient to found responsibility") (quotation omitted) (Black, J., concurring); *Robinson v. California*, 370 U.S. 660, 678-79 (1962) (holding California statute that criminalized being addicted to narcotics unconstitutional because "addiction alone cannot reasonably be thought to amount to more than a compelling propensity to use narcotics, [and] the effect of this instruction was to authorize criminal punishment for a bare desire to commit a criminal act") (Harlan, J., concurring).

In these circumstances, the Government was required to prove that Defendants or other Acclarent personnel made external promotional statements concerning Stratus's alleged new

[14] In their Joint Proposed Jury Instructions (Dkt. #318), Defendants requested the following instruction: "Under FDA regulations, only statements the manufacturer disseminates to the public can create a new 'intended use' under the Food and Drug Act . . . . This does not include internal company documents or conversations reflecting a goal that the device be used in a certain way, nor does it include internal company communications about potential future uses or discussions of potential studies designed to gain new approval for potential future uses." *Id.* at 53.

"intended use" of drug delivery to the respective customer in connection with each of the ten shipments in Counts 9-18, such that the devices comprising the specific shipments could be—if ever—deemed misbranded or adulterated. *See Kordel v. United States*, 335 U.S. 345, 350 (1948) (to prove misbranding claim, product in question must be "accompanied by" improper promotional statements); *Veterinary Use*, 50 F.3d at 500 (to establish new intended use, FDA must demonstrate that the promotional materials are actually distributed to and relied upon by customers); *United States v. 24 Bottles*, 338 F.2d 157, 160 (2d Cir. 1964) (requiring that the claims have been "made in immediate connection with sale of the product"); *cf. Nature Food Ctrs., Inc. v. United States*, 310 F.2d 67, 70-71 (1st Cir. 1962) (rejecting defendants' argument that company documents satisfied labeling requirements in misbranding prosecution, because "[s]ome of the defendants' products were destined for sale at the stores, where the notes were not available."). Without evidence tying external promotional statements to a particular customer or account, it cannot be said that the manufacturer created a new "intended use" of Stratus for drug delivery with that customer; as above, any ruling to the contrary would expose Defendants to criminal liability for a "thought crime."

Not only is evidence of external marketing statements required to sustain a conviction, but evidence of the *order* in which those statements were purportedly made is also critical for purposes of Rule 29. As the Court instructed the jury:

> In addition, it is permissible to respond to unsolicited requests for information about FDA-regulated medical products by providing truthful, balanced, non-misleading and non-promotional scientific or medical information that is responsive to the specific request, even if responding to the request requires a manufacturer to provide information on unapproved or uncleared indications or conditions of use. Under these circumstances, such responses *may not be considered* as evidence of a new or different "intended use."

27 Trial Tr. 149:17-150:1 (emphasis added). Thus, in determining whether a new "intended use" was created in connection with that transaction, evidence of both the substance of the communications made in the course of the sales encounter at issue *and* the contextual order in which they were made are required. As to Counts 9-18, the Government failed to adduce evidence of either.

B. The Government Failed to Adduce *Any* Evidence of the Specific Marketing Claims for the Ten Charged Stratus Shipments.

The Government introduced no evidence that Defendants, or anyone else at Acclarent, made any marketing claims in connection with the shipments alleged in Counts 9-18, let alone evidence of the order or context of any such communications. Had the Indictment charged only one substantive count of either adulteration or misbranding, there would be no doubt that, to get its case to the jury, the Government would have had to call the sales representative and/or the customer involved in the single charged shipment. Here, however, rather than call percipient witnesses to testify as to what communications, if any, were had in connection with the particular sales calls underlying each of the shipments in Counts 9-18, the Government relied on its overarching conspiracy theory as the purported means of establishing the "intended use" of Stratus for drug delivery. The jury rejected this theory, leaving the Government without any record evidence sufficient to allow a rational jury to find a "new" intended use for any of the devices shipped in Counts 9-18.

The fatal gap in proof is most apparent with respect to the Stratus shipments charged in Counts 10-14, 16, and 18—to hospitals in Hyannis, Lowell, Plymouth, and Worcester—for which the Government called *no* doctors *or* sales representatives and adduced *no* documentary evidence concerning the underlying sales calls.

As for Counts 9, 15 and 17, which concerned shipments to South Shore Hospital in South Weymouth on or around October 21, 2009, January 19, 2010, and October 13, 2010, Indictment ¶¶ 142, 144, the Government called only one doctor who had worked at South Shore Hospital—at some undefined time—Dr. Cathy Chong. Dr. Chong testified to the general substance of her discussions with her sales representative, Barbara Logan, but noted that there was another sales representative, "Susan," with whom she also spoke about Acclarent products at various other times. 8 Trial Tr. 124:3-5. Dr. Chong was not asked about, and did not testify regarding, the content of any communications with "Susan."

The Government also called Ms. Logan, who testified that another sales representative, "Susan Fallon," took over a portion of Ms. Logan's territory after she (Ms. Fallon) joined the company. 10 Trial Tr. 130:5-7. As Ms. Logan described it, Ms. Fallon assumed responsibility for "half of the downtown Boston hospitals and out to Worcester and south, and I also had Rhode Island. So, she [Ms. Fallon] was receiving Rhode Island, Cape Cod." *Id.* at 130:12-17. The territory Ms. Fallon assumed thus included South Shore Hospital in South Weymouth. Acclarent hired Ms. Fallon as of October 5, 2009, GX1573, before any of the charged shipments to South Shore Hospital occurred. Thus, Susan Fallon—*not* Barbara Logan—was the sales representative assigned to South Shore Hospital at or around the time of the alleged adulterated or misbranded shipments referenced in Counts 9, 15 and 17.

Further, while there was some testimony about how Ms. Logan presented the Stratus to Dr. Chong, there was no evidence that any of the interactions between Dr. Chong and Ms. Logan were connected to the shipments to South Shore Hospital charged in Counts 9, 15, and 17. As discussed above, at the time of these three shipments, Ms. Fallon (whom the Government inexplicably failed to call as a witness) was the sales representative assigned to South Shore

Hospital. In addition, Dr. Chong testified she worked at various points in time at Carney Hospital, Milton Hospital, out of her own office in Weymouth, and at Tufts Medical Center. 8 Trial Tr. 123:1-12. Ms. Logan testified that there were multiple (albeit unidentified) doctors at South Shore Hospital to whom she sold Stratus. 10 Trial Tr. 130:18-131:2. In sum, the government failed to adduce any evidence that Barbara Logan was the sales representative, or Dr. Chong the customer, involved in Counts 9, 15, and 17, let alone that Ms. Logan's or Dr. Chong's testimony concerned any of those shipments.

What is more, the actual evidence adduced at trial was inconsistent and insufficient to permit an inference that the intended use of the devices in the ten charged shipments was for drug delivery. For example, one doctor testified that his Acclarent sales representatives never promoted Stratus for drug delivery in his presence. *See* 22 Trial Tr. 174:7-9 (Dr. Hoisington: "Q. So you're confident that Acclarent never recommended to any physician that they use this [Stratus] for drug delivery? A. In my presence they never did."). Another testified that he thought of using Stratus for drug delivery on his own, without any input from anyone at Acclarent. 24 Trial Tr. 41:16-19 (Dr. Catalano: "Q. What was the most interesting aspect of the device to you? A. As soon as I saw it when it was presented to us, the first thing that went into my head was I'm going to put a drug in this thing because it's perfect for that."). Still another was not even asked about what, if anything, Acclarent sales representatives told him about using Stratus for drug delivery, let alone the context of those conversations. *See, e.g.*, 18 Trial Tr. 173:3-205:22 (direct examination of Dr. Citardi).[15]

[15] While Dr. Citardi discussed what he learned about Stratus at "the meeting where that data was first presented," 18 Trial Tr. 183:13-19, the Government introduced no evidence concerning whether the doctors involved in Counts 9-18 attended that meeting.

Likewise, of the seven sales representatives the Government called, at least one testified affirmatively that he did *not* promote Stratus as a drug delivery device, or at all. *See, e.g.*, 10 Trial Tr. 37:2-7 (Eric Krinsky: "I never, myself, actively sold or pitched the device to any surgeons that I called on."). Another was asked how he was *instructed* to position Stratus, but the Government never asked him how he *actually* positioned Stratus or whether he promoted Stratus consistent with that instruction. 7 Trial Tr. 115:20-116:2 (Ben Steffen). Because there were so few instances where the Government elicited testimony about what a sales representative said to a specific customer, and the record evidence is inconsistent on what was said (or in what order) in each sales interaction, it is not permissible, let alone plausible, for a jury to draw the inference that the manufacturer created a "drug delivery" intended use for any of the devices included in the ten charged shipments.[16]

Proof beyond a reasonable doubt of each and every element of the substantive misdemeanor counts requires more than what the Government adduced at trial. *See Kordel*, 335 U.S. at 348; *Veterinary Use*, 50 F.3d at 500. In particular, evidence of the alleged external promotional statements and the order in which the alleged communications unfolded is required to establish the manufacturer created the requisite "new" intended use. Otherwise, evidence of a promotional frolic and detour of a single sales representative regarding isolated sales calls in

[16] Indeed, even when the Government did ask sales representative witnesses about their sales interactions, the questions were often asked in a hypothetical, generic sense—*what would you have said?*—rather than based on what the witness actually said or did in specific sales calls. *See, e.g.*, 4 Trial Tr. 199:4-200:10 (Mollie Vanderkarr: "Q. What *would* you say *if* a physician asked you, 'Why would I want to use it with saline?' A. *In general*, I *would* say something along the lines of . . . Q. *Would* you say anything else about how -- on that topic or in response to that question? Are there other things that you would reference? . . . *if* you walked into a physician and wanted to introduce the physician to the Stratus, how *would* you do it? A. So *assuming* we've kind of already gotten through the niceties and he knows me -- or she knows me, I *would* say . . . And so I *would generally* lead them through several questions, and then I *might* ask them . . . And *typically* they *would* say . . . Or *sometimes* they *may* ask me . . . And I *would* say . . . .") (emphasis added).

Indiana at some unknown point could permit a jury to conclude that Stratus devices were correspondingly adulterated or misbranded in Massachusetts in 2009 and 2010, or that a statement by a single sales representative to a single doctor about off-label use—made years before the charged shipment occurs—somehow deems all future shipments to that account, or other customer accounts, adulterated or misbranded.

On this record, therefore, no rational jury could find, with respect to any of the charged shipments, that the manufacturer had created a new drug delivery intended use for any of the devices thus shipped. Accordingly, Rule 29 requires that a judgment of acquittal be entered on each of the substantive misdemeanor misbranding and adulteration counts.

IV. THE CONVICTIONS ON COUNTS 9-13 AND COUNTS 14-18 ARE MUTUALLY EXCLUSIVE AND CANNOT STAND.

Defendants' convictions on Counts 9-18 should be vacated and judgment of acquittal entered for the reasons set forth above. Even assuming, *arguendo*, that the Court concludes the Government adduced sufficient evidence for a rational jury to find that the new "intended use" of the Stratus devices in the ten charged shipments was for drug delivery, the convictions should nonetheless be vacated, and a new trial ordered, for the separate reason that the jury's misbranding and adulteration verdicts are mutually exclusive: The (identical) devices and the (identical) relevant facts and circumstances surrounding them on which the substantive misdemeanor misbranding and adulteration counts are based cannot—as the verdicts unequivocally demonstrate—be deemed both Class I (requiring a 510(k) premarket notification, or "510(k)") *and* Class III (requiring a premarket approval or "PMA"). In short, the misbranding (failure to file a 510(k)) convictions necessarily preclude the adulteration (failure to file a PMA) convictions, and vice versa.

A. Mutually Exclusive Verdicts Require a New Trial.

Generally, consistency in a verdict is "'not necessary'"; inconsistent verdicts may be the product of "'mistake, compromise, or lenity.'" *United States v. Randolph*, 794 F.3d 602, 609-10 (6th Cir. 2015) (quoting *Dunn v. United States*, 284 U.S. 390, 393 (1932), and *United States v. Powell*, 469 U.S. 57, 65 (1984)). Two exceptions to this general rule exist, however: (1) "where jury verdicts 'are marked by such inconsistency as to indicate arbitrariness or irrationality'"; and (2) "'where a guilty verdict on one count necessarily excludes a finding of guilt on another,' i.e. a 'mutually exclusive' verdict." *Id.* at 610-11 (quoting *United States v. Lawrence*, 555 F.3d 254, 263 (6th Cir. 2009), and *United States v. Ruiz*, 386 F. App'x 530, 533 (6th Cir. 2010)).

The First Circuit applied this latter exception in *Villarreal Corro v. United States*, 516 F.2d 137 (1st Cir. 1975). There, the defendant was convicted of several charges, including illegal importation of cocaine under 21 U.S.C. § 174 and tax violations related to the purchase of cocaine under 26 U.S.C. § 4704. *Id.* at 139. The First Circuit *sua sponte* reversed defendant's conviction under 26 U.S.C. § 4704 after concluding that,

> [s]ince the jury found appellant guilty on the illegal importation count, the only reasonable and consistent basis on which they could also have found him guilty of purchase not in or from the original stamped package was to conclude that the purchase was made outside of the United States. We do not see how the purchase of a drug outside the United States by a foreign national can be deemed a violation of 26 U.S.C. § 4704, a revenue provision. Appellant failed to raise this point, but we consider it a plain error and thus reverse as to the purchase count.

Id. at 141; *cf. United States v. Sturm*, 671 F. Supp. 79, 91 (D. Mass. 1987) (declining to reverse inconsistent, but not mutually exclusive, verdicts because "[t]his is not a circumstance in which conviction on one count necessarily precludes conviction on another count"), *aff'd in part, vacated in part on other grounds*, 870 F.2d 769 (1st Cir. 1989).

The mutually exclusive verdict exception has been widely recognized outside the First Circuit as well. *See, e.g., United States v. Gross*, 961 F.2d 1097, 1107 (3d Cir. 1992) ("The

exception only operates in those situations where a jury has convicted a defendant of two crimes and those *convictions* are mutually exclusive. Such a result would be patently unjust because a defendant would be convicted of two crimes, at least one of which he could not have committed."); *United States v. Bethea*, 483 F.2d 1024, 1030-31 (4th Cir. 1973) (reversing contradictory convictions and remanding for new trial where the defendant's "guilt or innocence on all counts depended upon the jury's resolution of one factual question . . . . [and] conviction on all . . . counts was not logically possible"); *Thomas v. United States*, 314 F.2d 936, 938 (5th Cir. 1963) (finding "obvious inconsistency between the guilty judgments on both counts" and, in light of conclusive trial record, dismissing Count II while affirming Count I); *Randolph*, 794 F.3d at 610-11; *Masoner v. Thurman*, 996 F.2d 1003, 1005 (9th Cir. 1993) (holding that inconsistent jury verdicts are not reviewable unless "the challenged verdicts are necessarily logically inconsistent"); *United States v. Shippley*, 690 F.3d 1192, 1195 (10th Cir. 2012) (reviewing "metaphysically impossible" verdict involving an inconsistency on the same count with the same defendant); *United States v. Daigle*, 149 F. Supp. 409, 413 (D.D.C. 1957) ("where a guilty verdict on one count negatives some fact essential to a finding of guilty on a second count, two guilty verdicts may not stand"), *aff'd per curiam*, 248 F.2d 608 (D.C. Cir. 1957), *cert. denied*, 355 U.S. 913 (1958).

In *Bethea*, the defendant was convicted of both (1) failing to keep his local draft board advised of his address, and (2) failing to report for induction into the military service and for an armed forces physical examination. *Id.* at 1025-26. The charges centered on "one factual question": whether the orders to report were sent to a "good" address. *Id.* at 1030. To be guilty of failing to report, the draft board had to have sent the notices to a "good" address, but the board could not have sent the notices to a "good" address if the defendant failed to advise the board of

his address. *Id*. Accordingly, the Fourth Circuit concluded that the convictions on all counts were "not logically possible," and reversed and remanded to the district court with an instruction to the jury that "conviction on one count will bar conviction on the other." *Id.* at 1030-31.

A similar situation arose in *Thomas v. United States*. There, the defendant was convicted of (1) smuggling marijuana into the United States (Count I), and (2) transporting and concealing the marijuana without having paid the transfer tax (Count II). 314 F.2d at 937. The Fifth Circuit noted that Count I was predicated on a finding that the defendant acquired the marijuana in Mexico and attempted to smuggle it into the United States, whereas Count II was predicated on a finding that the defendant acquired the marijuana within the United States. *Id.* at 939. The appellate court affirmed the conviction on Count I and reversed the conviction on Count II "[i]n view of the obvious inconsistency between the guilty judgments on both counts, and since the record conclusively demonstrate[d] that the marihuana was acquired in Mexico." *Id.*

B. The Verdicts on Counts 9-13 and 14-18 Are Mutually Exclusive.

The same principle of preclusion applies here. The jury convicted Defendants of two different substantive offenses: (1) adulteration based on failure to file a PMA for the new intended use of drug delivery (Counts 9-13); and (2) misbranding based on failure to submit a 510(k) for the new intended use of drug delivery (Counts 14-18). But, under the FDCA and accompanying FDA regulations and guidance, a device is required to have *either* a PMA *or* a 510(k) for a particular intended use, not both. Yet the Government chose to charge both misbranding and adulteration, relying in both sets of counts on a single "drug delivery" intended use theory, and is thus responsible for the "metaphysically impossible" outcome: The only way the jury could have found Defendants guilty of adulteration on Counts 9-13 (based on failure to file a PMA) was to conclude that Stratus for the intended use of drug delivery was required to have a PMA, and *not* a 510(k). In contrast, the only way the jury could have found Defendants

guilty of misbranding on Counts 14-18 (based on failure to file a 510(k)) was to conclude that Stratus for the intended use of drug delivery was required to have a 510(k), and *not* a PMA. The convictions on *both* Counts 9-13 *and* 14-18 are thus "patently unjust"; a guilty verdict on Counts 9-13 negates a fact essential to a finding of guilty on Counts 14-18, and vice versa. Accordingly, the verdicts cannot stand and a new trial is necessary.

The FDCA, FDA regulations, and FDA guidance make clear that medical devices require *either* a PMA *or* a 510(k) for a particular intended use, not both. Section 360e of Title 21 of the Code directs when a PMA is required for a particular intended use. FDA regulations, codified at 21 C.F.R. § 807, govern the § 510(k) process and provide that a 510(k) is *not* required "for a device for which a premarket approval application . . . is pending before the [FDA]." 21 C.F.R. § 807.81(b)(1). In other words, a 510(k) is *not* required if a PMA is so required.

Agency guidance also makes clear that a 510(k) is required *only* where a PMA is *not* required. *See, e.g.*, FDA, "Premarket Notification 510(k)" (last updated Sept. 16, 2015), *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ (Ex. 14) ("Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, *for which a Premarket Approval (PMA) is not required, must submit a 510(k)* to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act . . . ") (emphasis added); FDA, "Classify Your Medical Device" (last updated July 29, 2014), *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm (Ex. 15) ("The class to which your device is assigned determines, among other things, the type of premarketing submission/application required for FDA clearance to market. If your device is classified as Class I or II, and if it is not exempt, a 510k will be required for

marketing. . . . For Class III devices, a premarket approval application (PMA) will be required unless [certain exceptions not applicable here apply]. In that case, a 510k will be the route to market.").[17] All of these sources make clear that the PMA/510(k) requirement is an "either/or" scenario: where there is a singular device with a singular "intended use" for drug delivery, it cannot simultaneously require *both* a 510(k) *and* a PMA (nor can it simultaneously be both Class I and Class III—a necessary predicate of the finding that a singular device requires both a 510(k) and a PMA).

Consistent with this dichotomy between Class I/Class III classification and 510(k)/PMA requirements, the Court instructed the jury as follows:

> A device classified as a Class III device must be approved by the FDA before it can be distributed in interstate commerce. This is generally accomplished through the *Premarket Approval*, also called the PMA, process, which involves the manufacturer of the device submitting a premarket approval application to the FDA. . . . A device can be removed from the automatic Class III designation, *bypass the PMA process*, and be assigned to either Class I or Class II *if the manufacturer obtains a Section 510(k) determination* or order of 'substantial equivalence' from the FDA for the device's intended use. . . .

27 Trial Tr. 144:7-23 (emphasis added). The Court went on to instruct the jury that a "medical device is adulterated if it is a Class III device that is required to have, but does not have, an FDA approved premarket approval or 'PMA' application for [a] particular intended use and is not otherwise exempt from such approval." *Id.* at 164:24-165:3. In response to a question from the jury during deliberation, the Court further instructed that:

[17] The Court may take judicial notice of guidance published on the FDA's website. *Gent v. CUNA Mut. Ins. Soc'y*, 611 F.3d 79, 84 n.5 (1st Cir. 2010) (taking judicial notice of the "relevant facts" found on the CDC website that were "not subject to reasonable dispute"); *Denius v. Dunlap*, 330 F.3d 919, 926-27 (7th Cir. 2003) (citing examples of courts taking judicial notice of information from agency websites); *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 33 (D.D.C. 2014) (taking judicial notice of FDA's "Frequently Asked Questions" section).

> [i]f the device doesn't have an FDA approved PMA for a particular intended use and isn't exempt, then it is a class three device for that intended use, but if the FDA has classified it as a class one or class two device for a particular use, then it is not a class three device for that intended use *and no PMA is required* for that use.

30 Trial Tr. 11:20-25 (emphasis added).[18] Each of these instructions makes clear that the jury's finding that the Stratus was adulterated was predicated on a finding that it required a PMA. If Stratus was required to have a PMA, however, then—as a matter of law—it was not required to have a 510(k). Thus, the jury's verdict convicting Defendants on *both* adulteration based on failure to file a PMA for the intended use of drug delivery (Counts 9-13) *and* misbranding based on failure to file a 510(k) for the intended use of drug delivery (Counts 14-18) are mutually exclusive. Accordingly, the convictions on Counts 9-18 must be vacated and a new trial ordered.

V. THE GOVERNMENT'S REPEATED USE OF IMPROPER EVIDENCE WARRANTS A NEW TRIAL.

In addition to—and perhaps because of—the legal and factual deficiencies that undermined its core charging theories, the Government repeatedly put before the jury irrelevant and prejudicial evidence and arguments. Such conduct not only misled the jury but also sought to inflame its passions and prejudices. Considered cumulatively, the Government's improprieties compromised Defendants' right to a fair trial. For this reason as well, the Court should vacate the jury's verdict and grant a new trial.

A. The Government Repeatedly Sought to Inflame the Jury with Misleading, Unsupported, and Prejudicial Arguments Concerning Stratus's Safety.

Despite the Court's admonition that the trial would not be about the safety of the Stratus device, *e.g.*, 5/26/16 Mot. Hr'g Tr. 131:18-19, the Government repeatedly endeavored to do just

[18] The jury's question that prompted the additional instruction was: "'On Page 33 for adulteration elements: States a device is class three for any uncleared or unapproved intended use. The charge requires the device be both class three and not have an FDA-approved PMA for a particular intended use and is not exempt. Does the latter requirement fulfill the former requirement?'" 30 Trial Tr. 3:8-13.

that—through misleading, unsupported, and inflammatory assertions that Defendants' alleged deception of the FDA and physicians had placed patients at risk of traumatic injury from an allegedly untested and unsafe device.

Defendants repeatedly sought to prevent the Government from introducing irrelevant and prejudicial safety claims. Defendants' Motion *in Limine* #1 (Dkt. #288) reflects Defendants' initial attempt to preclude such evidence. In response to the Court's comments on that motion, the Government represented that it would not over-emphasize the limited safety issues that it believed were relevant.[19] Based on that representation, the Court deferred a definitive ruling.[20]

Once trial commenced, however, the Government reversed course and repeatedly asserted through its arguments and through its often-leading questions of witnesses that Stratus was dangerous and that Defendants had concealed these purported dangers from FDA, from physicians, and, by implication, from patients. The Government began sounding this theme in its opening, where it graphically described Stratus as an untested device that physicians implanted with a "super-sharp needle," which they used to "stick a hole" through a patient's ethmoid sinus "in between your eyes, right next to your brain," separated by only a "paper-thin barrier." 2 Trial Tr. 28:10-15, 29:20. The Government then followed up its opening by eliciting equally graphic testimony from Dr. Armstrong, its first witness, who described Stratus as implanted with a "spike," 3 Trial Tr. 47:1, which posed the risk of piercing a patient's optic nerve or carotid artery, resulting in blindness, a stroke, or "life-threatening bleeding." *Id.* at 152:5-10. With successive witnesses, the Government then proceeded to roll out a series of other supposedly undisclosed dangers associated with Stratus, including but not limited to the alleged risk of wing

[19] 5/26/16 Mot. Hr'g Tr. 141:19-142:4.

[20] *See, e.g., id.* at 144:5-9, 145:24-25.

detachments,[21] infections (which the Government claimed occurred, but were not disclosed, during the SPACER study),[22] and Kenalog-induced adverse effects (including blindness).[23]

In fact, the Government's safety arguments were baseless, as the prosecutors well knew. Records showed that Stratus had a very low rate of adverse effects and no serious injuries or deaths[24]—information that the Government elected not to present to the jury. The lead FDA reviewer of Stratus (Dr. Mann, whom the Government listed as a witness but did not call) informed the Government prior to trial that there no significant adverse events associated with Stratus.[25] And the FDA itself concluded in 2010-11—five years before trial—that a safety limitation for the 510(k) clearance was not warranted because there was no basis for concluding that the extensive off-label use of Stratus with drugs was causing harm.[26]

As the irrelevant and prejudicial nature of the Government's presentation became clearer at trial, the Court increasingly limited the safety issues that the Government was permitted to mention before the jury, in response to Defendants' continuing objections.[27] But by then, it was too late. The Government had prejudiced the jury with inflammatory assertions of grave safety

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[21] *See* 6 Trial Tr. 34:1-6 & 7 Trial Tr. 46:7-47:2 (Vanderkarr direct: suggesting there were issues with wing detachment); 8 Trial Tr. 148:18-149:21 (Chong direct: suggesting there were issues with wing detachment); 16 Trial Tr. 55:1, 59:3-10, 75:21-22, 77:5-7 (Khan direct: discussing wing detachment).

[22] *See* 2 Trial Tr. 24:3-13 (Gov't's opening: suggesting that there was no approval for the SPACER study); 19 Trial Tr. 48:9-12 (Michele direct: testifying that there were unreported adverse events in the Spacer study); *cf.* 18 Trial Tr. 67:14-17 (Khan cross: testifying that the Spacer study received approval to commence).

[23] *E.g.*, 3 Trial Tr. 152:5-10 (Armstrong direct: suggesting risk of blindness).

[24] *See, e.g.*, DX0874-0024 ("There were no study device, study drug, or study procedure related serious adverse events reported in the DELIVER study.").

[25] Mem. of Interview of Dr. Eric Mann at 3 (July 29, 2014) (Ex. 16).

[26] GX2586-137, -138.

[27] 7 Trial Tr. 119:23-121:22; 24 Tr. 42:6-43:8, 47:18-25.

risks, even though such assertions were neither relevant nor real. And although the Government prior to trial had represented to the Court that its limited safety allegations would not create a need for "mini-trials,"[28] that is effectively what happened, to the detriment of Defendants. Defendants were forced repeatedly to address claims regarding the trocar (whose use FDA cleared, and whose alleged risk did not depend on whether the device was used with saline or steroids); the potential for blindness (which Dr. Armstrong and others admitted was vanishingly small);[29] wing detachments (which had nothing to do with the use of steroids, happened in only a tiny percentage of procedures, and which FDA was satisfied were fully addressed by Acclarent in 2009);[30] and the small number of supposed "adverse" events from the SPACER study, whose innocuous nature was explained by Dr. Levine.[31] In sum, the Government's repeated efforts to interject inflammatory safety issues into the trial constituted a bell that no amount of countervailing evidence from Defendants, or admonition from the Court, could unring.

Further, it was a theme that the Government, undeterred, continued to hammer—in highly prejudicial terms—right through the end of trial. Among the final words in its closing, the Government insinuated that Defendants had treated the "American population" as "guinea pigs." 26 Trial Tr. 130:4-5. Then, in its rebuttal, the Government pointedly noted that Defendants should not be absolved "just because this time no one died." 27 Trial Tr. 132:14-15.

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[28] *See* Gov't's Combined Response to Defs.' Mots. *in Limine* Nos. 1 Through 6, at 3 (Dkt. #330).

[29] 4 Trial Tr. 64:19-64:5 (Armstrong cross: acknowledging he had no concern that Stratus's drug delivery function would cause blindness).

[30] GX1653-0003 to -0020 (November 2009 submission re July 2009 root cause analysis); GX2437_001 (November 2009 510(k) submission for modified device); GX2437_004 (March 2010 clearance of November 2009 510(k) submission).

[31] *See* 23 Trial Tr. 190:14-195:3.

No justification excuses the Government's inappropriate efforts to inflame the passions and prejudices of the jury. The likely impact of the Government's conduct on the jury, coupled with the additional improprieties summarized below, warrants the relief requested herein.

B. Defendants Were Further Unfairly Prejudiced by the Refusal of the Government to Immunize Debra Cogan, and the Suggestion That Defendants Could Have Called Her to Testify.

Defendants moved prior to trial to immunize Debra Cogan, who was a senior regulatory employee with Acclarent. The Government refused, based on arguments provided to the Court under seal, and with which the Court is by now familiar.

In retrospect, it is clear that Ms. Cogan's testimony would have been critical to the misdemeanor counts on which convictions were returned, all of which related to whether Stratus's intended use fell within its FDA clearance. Ms. Cogan's testimony would have directly addressed this issue: how Acclarent regulatory employees structured marketing to comply with FDA rules, including the "unsolicited requests" safe harbor as it existed through 2011.

Ms. Cogan, for example, participated actively in discussions that generated the exhibits introduced during Mr. Barrigar's testimony, which the Government argued showed that Stratus required additional clearances. Mr. Barrigar was incapable of explaining the regulatory department's advice regarding whether additional clearances were necessary. Ms. Cogan would have been able to do so. Similarly, Ms. Cogan approved numerous regulatory submissions that advised sales representatives to rely on the FDA "unsolicited request" safe harbor, and was the author of GX1172, which she believed outlined the legal sale of Stratus using probing questions.[32] She was uniquely qualified to explain why she and other regulatory personnel advised Mr. Facteau and Mr. Fabian (and others) to handle Stratus as they did.

[32] *See* GX1172-0021 to -0027; *see also* GX2415.

By refusing to immunize Ms. Cogan, the Government seriously hampered Defendants' ability to present this critical exculpatory evidence to the jury. Lest any doubt existed before, the prejudicial impact of the Government's intransigence became clear with the return of the verdict.

To the extent the Court directs that a new trial is required, it appears likely Ms. Cogan would be available to testify: It would be difficult to defer to any renewed refusal by the Government to immunize her, in light of the jury's acquittal of Defendants on all felony charges relating to fraud and false statements. Ms. Cogan's availability at any retrial of the misdemeanor counts would serve the interests of justice, and constitutes another reason to allow a retrial.

Finally, a new trial at which Ms. Cogan would appear would remove any taint associated with the Government's improper argument in closing that Defendants could have called Ms. Cogan to testify if they had chosen to do so.[33]

C. The Government Repeatedly Asked Improper Questions That Implied That No Doctor Used Stratus with Saline and That Stratus Did Not Function as a Spacer, Contrary to the Actual Facts Known to the Government.[34]

The Government repeatedly elicited testimony at trial that suggested to jurors that no doctor ever used Stratus with saline rather than steroids, and that the device could not function as a spacer (independent of its use to deliver Kenalog). The Government was aware, however, well before trial that Dr. Hoisington *did* use Stratus with saline repeatedly, and that he and other doctors who believed in the value of stents legitimately perceived utility in the use of Stratus as a

[33] *See* 27 Trial Tr. 124-9:11 (Gov't's rebuttal: "If there was a witness that the defense wanted to call because they thought that would totally contradict what you heard, they had that right."); 27 Trial Tr. 161:20-162:2 (Court's resulting instruction).

[34] *See* 2 Trial Tr. 40:22-24 (Gov't's opening statement: suggesting that the device did not function as a spacer); 26 Trial Tr. 43:14-24 (Gov't's closing: arguing that the Stratus did not function as a spacer); 27 Trial Tr. 119:3-10, 125:3-5, 136:23-25 (Gov't's rebuttal: arguing that the saline leaked right out and that the Stratus did not function as a spacer).

spacer.[35] In fact, as both Dr. Hoisington and Dr. Levine testified at trial, Stratus's spacing function did not depend on saline elution, FDA repeatedly cleared Stratus as a spacer without requesting data from Acclarent concerning the device's saline elution rate, and the Government in any event lacked a valid basis for its elution claims.[36]

The Government nonetheless elicited testimony from witness after witness that suggested Stratus never was used with saline.[37] While it might have been fair for the Government to assert that a significant majority of doctors elected to use Stratus with Kenalog, it was improper for the Government repeatedly to suggest—given what it knew from Dr. Hoisington—that absolutely no doctors ever used saline and that the device was useless as a spacer. The inappropriateness of these assertions was made more egregious by the fact that the testimony the Government elicited from its FDA witnesses on this point (the value of Stratus as a spacer) was not based on the

[35] *See* Mem. of Interview of Dr. Douglas Hoisington at 6 (Oct. 25, 2013) (Ex. 17) (stating that Dr. Hoisington estimated that he used the device with saline approximately 15% of the time).

[36] *See* 22 Trial Tr. 75:8, 103:19, 104:2-8 (Hoisington direct: testifying that saline "promoted the Spacer effect," that there was a "huge difference" between the bench and an actual human being, and that he was unaware of any results showing saline leaked); 23 Trial Tr. 130:1-23 (Levine direct: testifying to Stratus's use as a spacer); 24 Trial Tr. 107:21 (Catalano redirect: testifying that Stratus "worked well" as a spacer regardless).

[37] *See, e.g.*, 5 Trial Tr. 98:7-99:24 (asking Mollie Vanderkarr whether she heard of any physician using Stratus with saline); 7 Trial Tr. 105:20-106:5 (asking Ben Steffen the same); 9 Trial Tr. 58:25-59:4 (asking Kevin Convery whether he ever saw Stratus being used with saline); 10 Trial Tr. 31:12-13 (asking Erik Krinsky whether he heard of any physician using Stratus with saline); 10 Trial Tr. 66:24-67:2 (asking Barbara Logan the same); 11 Trial Tr. 28:25-29:4 (asking Brad Ader the same); 23 Trial Tr. 85:14-16 (asking Hank Plain whether he "underst[oo]d that 100 percent of the use of the product was with Kenalog-40"); *see also* Trial Tr. 40:22-23 (Gov't's opening: "Doctors weren't willing to use it as a spacer with saline."); 7 Trial Tr. 121:3-5 (AUSA Weinreb: "[T]he only thing a surgeon was ever going to use the Stratus for was drug delivery. I don't think that's being disputed anymore.").

witnesses' personal knowledge but rather on the Government's feeding the FDA incomplete information during the investigation, thus planting this misperception in the witnesses' minds.[38]

D. The Convictions Resulted in Part from Untrue Testimony Elicited by the Government and Which It Failed to Correct as Required by *Napue v. Illinois*.

On Trial Day 7 (June 14, 2016), Benjamin Steffen testified that another sales representative, Kevin Convery, had made a presentation to Steffen's April 2010 "new hire" training class using a document dated June 2009 (GX1364).[39] The Government emphasized in its questioning of Steffen that the presentation discussed promotion of Stratus even though the training occurred after J&J's no-promotion ("Catalog Only") policy was in effect.[40]

The inaccuracy of Steffen's answers to the prosecutor's questions became apparent on Trial Day 9 (June 16, 2016), when Convery testified. Convery stated under oath that the presentation he gave in 2010 was DX2314, which did not contain references to promotion of Stratus.[41] Taken as a whole, Convery's testimony conclusively showed that Steffen's testimony that Convery had delivered a presentation to new sales representatives encouraging them to promote Stratus in 2010—when six of the ten shipments for which Defendants were subsequently convicted of misbranding/adulteration occurred—was untrue and misleading.

The Supreme Court has made clear that where a government witness has offered untrue testimony, a prosecutor is required to take corrective action, or any subsequent conviction will be dismissed. This is so even if the false testimony is not solicited intentionally: "The same result [dismissal of a conviction] obtains when the State, although not soliciting false evidence, allows

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[38] *See* 17 Trial Tr. 29:23-30-30:21) (Khan cross: testifying that her understanding that Stratus did not work as a spacer with saline "came from the prosecutor").

[39] 7 Trial Tr. 88:11-95-17 (Steffen direct: confirming he saw GX1364, dated June 2009, during his 2010 training because "it's a presentation, quite frankly, you're not going to forget").

[40] 7 Trial Tr. 94:8-99:8, 108:1-19.

[41] 9 Trial Tr. 171:21-178:21.

it to go uncorrected when it appears." *Napue v. Illinois*, 360 U.S. 264, 269 (1959); *see also* Mass. Rules of Prof'l Conduct R. 3.3(a)(4) ("If a lawyer has offered, or the lawyer's client or witnesses testifying on behalf of the client have given, material evidence and the lawyer comes to know of its falsity, the lawyer shall take reasonable remedial measures."); *cf.* Model Rules of Prof'l Conduct R. 3.3 (Am. Bar Ass'n).[42]

Here, however, the prosecutors did not take corrective action and never informed the jury that the Government no longer contended that Convery had made a presentation to Steffen and his fellow new hire trainees to promote Stratus in 2010. To the contrary, during closing, the prosecutor argued that Convery's statements either were made in 2010 or, if not, were still probative if made at other times, notwithstanding the Government's prior (inaccurate) emphasis on the timing of the statements.[43] In making this argument, the prosecutor failed to renounce and correct the inaccurate testimony elicited from Steffen, and therefore failed to meet the standard set forth in *Napue*.

[42] Defendants do not know the circumstances that led to the Government's eliciting Steffen's untrue testimony to the jury. Although Defendants do not have information indicating that the prosecutors were aware, prior to putting Steffen on the stand, that his anticipated testimony on this point was incorrect, Government attorneys met repeatedly with Steffen and Convery prior to their testifying, and in any event certainly became aware of the inaccuracy as of Convery's cross-examination.

[43] *See* 27 Trial Tr. 130:23-131:4 (Gov't's closing: "There was a long discussion from Mr. Libby about Kevin Convery's slides, but what he didn't mention was that Kevin Convery told you that he gave the slides with the off-label Stratus messages with the big steroid picture four to six times at new-hire training before catalog-only. Ben Steffen remembered seeing them at some point.").

The prosecution thus tried to rehabilitate Steffen's testimony, rather than acknowledge that the testimony was untrue, despite undisputed evidence that Steffen attended training in April 2010 and Convery had updated his slides to remove Stratus references by that point. Following Convery's testimony, there is no reason to believe that Steffen in fact remembered seeing the particular slides shown him by the Government. Pursuant to *Napue*, the prosecution should have corrected Steffen's testimony, not engaged in speculation to try to rehabilitate it.

The effect of Steffen's uncorrected testimony was to invite the jury to conclude that Defendants intentionally violated J&J's no-promotion policy—a claim that (according to the prosecutors) showed a willingness to violate FDA rules regarding intended use, which were the underpinnings of the convictions in this case. Given the distinct possibility that the jury accepted this invitation—and that it did so based on Steffen's inaccurate testimony[44]—*Napue* supports dismissal of the convictions.

E. The Government Improperly Sought to Incriminate Mr. Fabian by Seeking to Induce Witnesses to Place Him at Meetings the Government Knew He Did Not Attend or Could Not Have Attended.

The Government also improperly attempted to suggest through its questioning of Fred Barrigar that Mr. Fabian may have attended meetings that the Government knew Mr. Fabian either did not attend, or could not have attended.[45]

F. The Government Presented Evidence Suggesting That the Use of "OUS" Booths at a Trade Show Violated FDA Rules, Even Though FDA Itself Says That Use of Such Booths Is Permissible.

On June 14, 2016, the Government, in questioning Wendy Oakes, introduced testimony that at the 2008 AAO meeting, Acclarent promoted Stratus for off-label use, at a booth specially designated for sales in other countries ("OUS") where Stratus was cleared for that use. 7 Trial Tr. 216:24-219:17. The clear point of the Government's questioning was to suggest that use of a

[44] For example, with respect to Defendant Fabian the Government sought to convince the jury that he may have been personally present at the training in 2010, and thus had to know that Convery was encouraging sales representatives to violate the J&J policy. There was no comparable evidence regarding Fabian's attendance at earlier training sessions in 2009 where Convery may have actually presented GX1364. Thus, the prosecution's argument in closing that it did not matter whether the presentation was given in 2009 or 2010 was untrue and misleading.

[45] *See* 12 Trial Tr. 20:25-21:16 (Barrigar direct: suggesting attendance by Mr. Fabian at 8/14/2007 meeting of senior management); 21 Trial Tr. 21-220:19-24 (stipulating that Mr. Fabian was employed at Acclarent from August 20, 2007 to November 11, 2011); 13 Trial Tr. 31:11-25, 166:19-170:15 (testimony by Barrigar suggesting Mr. Fabian attended project update meetings when Government knew from Barrigar's prior sworn testimony that Mr. Fabian was likely the only one *not* to attend these meetings).

foreign sales booth for this purpose was not permissible and would be relevant to establishing that the intended use of Stratus in the United States was for use with steroids.

This line of questioning was clearly improper in light of the fact that FDA itself has long taken the position that promotion of devices for use outside the United States is permissible under FDA regulations. *See* Shapiro Decl. ¶¶ 27-29. The Government, when informed by counsel of FDA's position, nevertheless made no attempt to correct the record to reflect that the use about which Oakes testified was, in fact, completely permissible under FDA practice.[46]

G. A New Trial Is Warranted in Light of the Government's Pervasive Misconduct.

As set forth above, the Government's misconduct was pervasive and consistent. It began with the Government's opening statement and continued through rebuttal. The First Circuit has recognized that this type of continued misconduct, even if not "conscience-shocking," is sufficient to warrant a new trial. *See United States v. Manning*, 23 F.3d 570, 575 (1st Cir. 1994).

Moreover, the most severe of the Government's misconduct occurred during key inflection points at trial—opening and closing. The Government bookended an evidentiary case predicated in large part on its irrelevant, unsupported, and misleading statements concerning the safety and efficacy of the Stratus with opening, closing, and rebuttal arguments in which the Government made a wholly improper appeal to the jury to protect public safety. *See id.* (recognizing that "closing arguments—the last words spoken to the jury by the trial attorneys" are particularly potent); *United States v. Hardy*, 37 F.3d 753, 758–59 (1st Cir. 1994) (recognizing that appeals to emotion are improper). The Government's misconduct at rebuttal

[46] *Compare United States v. Carpenter*, Crim. Action No. 04-10029-GAO, 2011 U.S. Dist. LEXIS 98626 (D. Mass. Sept. 1, 2011) (government disclosing information to facilitate correction of the record).

was particularly galling as the Government had already been warned by the Court, following its initial summation, that this type of appeal was improper.[47]

Furthermore, the Government's misconduct occurred on top of a case that was already fraught with unfair danger for Defendants. The trial was factually complex, involved a confusing and contradictory regulatory regime, and required application of complex jury instructions. In addition, the Government's requested charges permitted conviction on an attenuated lesser-included misdemeanor theory of strict liability. In these circumstances, it was paramount that the Government present a clean case that permitted the jury to dispassionately assess the facts that mattered. *Arrieta-Agressot v. United States*, 3 F.3d 525, 529-30 (1st Cir. 1993). The Government failed to do so.

Finally, Defendants made efforts to address the Government's misconduct through vigorous cross-examination, direct examination of defense witness, and through seeking curative instructions when appropriate, but were unable to vindicate Defendants' rights with these steps. Most significantly, the Court issued a curative instruction following the Government's closing in an effort to address the Government's appeal to safety. The Court stated:

> At the close of her closing, Ms. Bloom made some comments about incentivizing the behaviors of others and generalizing as to why following the FDA process is important. I want to caution you that you must decide this case solely based on the facts presented to you in this courtroom and based on the conduct of these defendants. You're not to be fueled by any considerations of the system, device testing or the mission of the FDA. Okay?[48]

The First Circuit has recognized, however, that curative instructions may be insufficient to avoid prejudice. *Hardy*, 37 F.3d at 759. In the full context of this case, no curative instructions could undo the damage of the Government's repeated efforts to present misleading evidence and

[47] *See* 26 Trial Tr. 138:14-16 ("THE COURT: You can't suggest that these people need to be convicted to make sure that other people don't also imperil the American people.").

[48] 26 Trial Tr. 141:10-17.

argument as to safety and efficacy and otherwise distort the fact finding process, efforts which culminated in its improper summation.

At bottom, the Government's misconduct compromised Defendants' right to a fair trial, and a new trial is warranted.

CONCLUSION

For the reasons set forth above, the Court should grant Defendants' motion and enter a judgment of acquittal on Counts Nine through Eighteen or, alternatively, a new trial.

Respectfully submitted,

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Dated: August 31, 2016

CERTIFICATE OF SERVICE

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) and paper copies will be sent to those indicated as non-participants on August 31, 2016.

/s/ William T. Hassler
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