IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. JOHN J. WALSH, Defendant.	))))))))	Crim. No. 2:09-cr-00403-03-6

DEFENDANT'S SENTENCING MEMORANDUM

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INTRODUCTION

John Walsh, by and through his undersigned counsel, hereby respectfully submits this Sentencing Memorandum.

Mr. Walsh fully accepts that, as a senior regulatory official at Synthes, Inc. ("Synthes"), he was in a position to have potentially detected and prevented the illegal conduct that occurred after he joined the Company in August 2003 long after most of the events at issue in the case occurred. Giving due regard to the nature of the offense, Mr. Walsh's particular circumstances, and in light of his otherwise exemplary record as a compliance professional, we respectfully submit that a sentence of probation would be appropriate. Such a sentence is within the range of the current advisory calculation pursuant to the United States Sentencing Commission, Guidelines Manual ("Sentencing Guidelines" or "U.S.S.G.") and would be fully consistent with the sentencing principles set out in 18 U.S.C. § 3553(a). It would also be proportionate to other individuals sentenced for similar strict liability misdemeanors under the responsible corporate officer doctrine pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*. As discussed below, given that Mr. Walsh only began working at Synthes long after most of the events at issue in the case occurred, and in light of his otherwise exemplary record as a compliance professional, a sentence of probation would appropriately address the sentencing principles of Section 3553(a). The parties have already stipulated and agreed that Mr. Walsh will pay a $100,000 fine, which is the statutory maximum fine permitted for a Class A misdemeanor. *See* PSR ¶ 8(e).

ARGUMENT

I. The Sentencing Guidelines Authorize a Sentence of Probation.

The Guidelines calculation as set out in the PSR, ¶¶ 60-69, is as follows:

Base Offense Level: The base offense level for violations of 21 U.S.C. §§ 331(a) and 333(a)(1) is 6. U.S.S.G. § 2N2.1(a). **6**

Specific Offense Characteristic: None. +**0**

Adjusted Offense Level: **6**

Adjustment for Acceptance of Responsibility: None. -**0**

Total Offense Level: **6**

Based on a total offense level of 6 and a criminal history category of I, the Guidelines' range for imprisonment is 0 to 6 months. U.S.S.G. Chapter 5, Part A – Sentencing Table. PSR ¶ 115.

It is clear from this calculation that the probation officer has not included in his Guidelines calculation a two-point reduction for acceptance of responsibility. At the time of his plea agreement, the government agreed and stipulated that as of the date of that agreement, Mr. Walsh "ha[d] demonstrated acceptance of responsibility for his offense making [him] eligible for a 2-level downward adjustment under U.S.S.G. § 3E1.1(a)." Guilty Plea Agreement ¶ 11(b). The Plea Agreement also set forth the facts which both parties agreed formed the basis of the offense conduct in this case. *Id.* ¶ 9. The credit for acceptance of responsibility was premised solely on Mr. Walsh's agreement to the stipulated facts that were contained in the Plea Agreement.

Since that time, Mr. Walsh has done nothing that can fairly be construed as attempting to avoid responsibility for his action. Even after he was charged and pled guilty to the strict liability offense for which he is now being sentenced, Mr. Walsh took no actions to hinder the

government's resolution of these issues. Indeed, Mr. Walsh admitted to the set of facts forming the basis for his offense conduct at his plea colloquy, *see* Tr. of Plea Hearing at 21:12 – 23:6 (July 20, 2009), and has since admitted to additional conduct beyond that stipulated set of facts. *See, e.g.*, Def.'s Obj. to PSR at 4-7. He readily accepts responsibility for the misconduct that occurred while he was a responsible corporate officer at Synthes and is openly remorseful about the wrongdoing that occurred on his watch. *See* Ex. 8, Lewandowski Letter ("[Mr. Walsh] accepted the responsibility of being an Officer of the Company and all that it entails."); Ex. 1, S. Bonnell Letter ("John has expressed to me full understanding of his role as a responsible corporate official during circumstances which, despite his most well intentioned actions, may have been outside of his direct control."); Ex. 6, Elliott Letter ("[Mr. Walsh] clearly understood the severity of the situation and even though the violation occurred many years before he joined Synthes, he did not point any fingers nor did he talk poorly about the company in general.").

Though he is silent with respect to the government's allegations of intentional misconduct, the Sentencing Guidelines require no more of him. To remain eligible for the two-level reduction for acceptance of responsibility, a defendant need only "truthfully admit[] or not falsely deny[] any additional relevant conduct for which he is accountable under § 1B1.3." U.S.S.G. § 3E1.1(a) cmt. n.3. In fact, the Guidelines specifically state that a "defendant may remain silent in respect to relevant conduct beyond the offense of conviction without affecting his ability to obtain a reduction" for acceptance of responsibility. *Id.* § 3E1.1(a) cmt. n.1(A). It undermines the very idea of a strict liability responsible corporate officer misdemeanor to require a defendant to admit to relevant conduct establishing his personal culpability in order to receive an acceptance of responsibility credit.

Based on the foregoing, the Court should grant Mr. Walsh a further two-level reduction for acceptance of responsibility under U.S.S.G. § 3E1.1, which would reduce the total offense level to four. The resulting guideline sentencing range would be 0-6 months, and a sentence of probation is authorized under U.S.S.G. § 5C1.1(b).

II. A Sentence of Probation Would be Proportionate to the Offense in this Case.

A sentence of probation, in addition to the $100,000 fine that he has already agreed to pay, would also be fair and appropriate. The strict liability nature of the offense to which Mr. Walsh pled guilty, along with his lack of intentional misconduct, counsels in favor of such a sentence.

The Supreme Court set forth the boundaries of the responsible corporate officer doctrine as it relates to the FDCA in *United States v. Dotterweich*, 320 U.S. 277 (1943), and *United States v. Park*, 421 U.S. 658 (1975). Significantly, neither defendant in these two leading cases received sentences of imprisonment. In *Dotterweich*, the president of Buffalo Pharmacal Co. was charged as a responsible corporate officer with three counts of misdemeanor violations of the FDCA for shipping misbranded and adulterated drugs in interstate commerce. 320 U.S. at 278. The defendant was sentenced to a fine of $500 and concurrent probation of 60 days on each count. *United States v. Buffalo Pharmacal Co.*, 131 F.2d 500, 501 (2d Cir. 1942), *rev'd, Dotterweich*, 320 U.S. 277. In *Park*, the defendant, president of Acme Markets, Inc., was charged with misdemeanor violations of the FDCA based upon rodent contamination in Acme's warehouses. Defendant Park was on notice of repeated failed FDA inspections, though the Court held that his liability did not turn on this awareness. *Id.* at 672-73. Nevertheless, he was sentenced only to a fine of $50 on each count. *Id.* at 666.

Since that time, the responsible corporate officer doctrine has been invoked sparingly, and typically only in a limited manner.[1] After *Dotterweich*, a number of individuals were charged as responsible corporate officers for misdemeanor violations of the FDCA, and, based on counsel's research, only one has received an incarcerative sentence. For example, in *Gel Spice*, 773 F.2d at 430-32, the president of Gel Spice was convicted of being a responsible corporate officer for a violation of 21 U.S.C. § 331(k) and was sentenced to concurrent terms of two years probation on each of 10 counts. Similarly, in *H.B. Gregory*, 502 F.2d at 701-02, the defendant was charged with a violation of 21 U.S.C. § 331(k) as a responsible corporate officer of the H.B. Gregory Company for having caused four lots of food to become adulterated while

[1] Prosecutorial reliance on the responsible corporate officer doctrine has been historically conservative. The vast majority of cases invoking the doctrine have been limited to instances where the corporate executive failed to take corrective action even after being made aware of the company's underlying violation. *See, e.g.*, *Park*, 421 U.S. at 661-62 (defendant had received notice of repeated failed FDA inspections); *United States v. Y. Hata & Co.*, 535 F.2d 508, 511 (9th Cir. 1976) (per curiam) (defendants were aware of bird infestation problem in company warehouses); *United States v. Starr*, 535 F.2d 512, 514-15 (9th Cir. 1976) (defendant was aware of mice in warehouse and failed to take corrective action, even after FDA inspection); *United States v. Gen. Nutrition, Inc.*, 638 F. Supp. 556, 558 n.2, 562 (W.D.N.Y. 1986) (defendants deliberately went "perilously close" to proscribed conduct, and there was evidence that at least one defendant intended to violate FDA regulations); *United States v. Torigian Labs., Inc.*, 577 F. Supp. 1514, 1530-31 (E.D.N.Y.), *aff'd*, 751 F.2d 373 (2d Cir. 1984) (defendant was aware of warning signs of contamination of lots of intraocular lenses); *United States v. Acri Wholesale Grocery Co.*, 409 F. Supp. 529, 532 (S.D. Iowa 1976) (defendants acknowledged awareness of rodent control problems in warehouses). Tellingly, the defendants in both *United States v. Gel Spice Co.*, 773 F.2d 427 (2d Cir. 1985), and *United States v. H.B. Gregory Co.*, 502 F.2d 700 (7th Cir. 1974), were also aware of FDCA violations, and none received a sentence of imprisonment. *See Gel Spice*, 773 F.2d at 429-32; *H.B. Gregory*, 502 F.2d at 702, 704. Likewise, the defendant in *United States v. Shapiro* was sentenced to incarceration only *after* he had violated the terms of his probationary sentence by allowing additional FDA violations to occur. 491 F.2d 335, 336 (6th Cir. 1974).

Though awareness of a violation is not a required element for finding a violation under the responsible corporate officer doctrine, the Court should consider the fact that, unlike the defendants in the cases described above, there is no evidence that Mr. Walsh was aware of Synthes' underlying violations for which he has been held strictly liable. Indeed, as already noted, Mr. Walsh joined Synthes only after the majority of the conduct at issue occurred.

stored at the Gregory warehouse. He was ordered to pay a fine of $500 on each of the four counts but received no imprisonment. *Id.* at 702, 705. The defendants in ***Shapiro***, the former co-owner and production manager of Tasty Cookie Company, were charged as responsible corporate officers under 21 U.S.C. § 331(a) & (k). 491 F.2d at 335-36. Each received a $300 fine for each count and a sentence of two years' probation.[2]

Recent prosecutions under the FDCA have resulted in similar sentences. In ***United States v. Bohrer, et al.***, No. 08-cr-40028 (D. Kan.), five responsible corporate officer of Medicis Pharmaceutical Corporation were charged with conspiracy to market Loprox and Loprox TS off-label in violation of 18 U.S.C. §§ 371-72 and 21 U.S.C. §§ 331 and 352. The off-label marketing conspiracy was alleged to have consisted of training sales representatives to promote the drug with marketing brochures and an un-reviewed study. Though the defendants pled guilty to knowingly and willfully conspiring to introduce misbranded drugs into interstate commerce, and not—like Mr. Walsh—to a strict liability responsible corporate officer misdemeanor, each was sentenced to 3 years of probation.

In ***United States v. Purdue Frederick Co., et al.***, No. 07-cr-00029 (W.D. Va.), three former officers of Purdue all pled guilty, as responsible corporate officers, to the misdemeanor charge of misbranding under 21 U.S.C. § 331(a)(1). Between 1996 and 2001, Purdue employees marketed OxyContin misleadingly as less addictive, less subject to abuse, and less likely to cause tolerance and withdrawal than other pain medications. Despite the magnitude of the alleged harm caused by the resultant abuse of OxyContin, the three officers each were sentenced to three years' probation.

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[2] Probation was revoked and a 6-month jail sentence was imposed on the co-owner after a subsequent inspection revealed that the premises were again infested with vermin, in violation of the terms of probation. *Id.* at 336.

Of those individuals who have been sentenced for responsible corporate officer misdemeanors under the FDCA, counsel's research has revealed only a single instance resulting in a sentence of imprisonment. In *United States v. Hermelin*, 11-cr-00085 (E.D. Mo.), the former CEO and Chairman of the Board of KV Pharmaceutical ("KV"), pled guilty to two misdemeanor violations of the FDCA, in violation of 21 U.S.C. §§ 331 and 352(a). KV had shipped oversized morphine tablets to retailers, resulting in incorrect labeling stating that the drugs were of uniform strength. In addition to being held responsible for his company's conduct, Hermelin was also alleged to have personally engaged in intentional misconduct by instructing employees to minimize written communications about the company's manufacturing problems and preventing KV's Quality Insurance personnel from being involved in the company's internal investigation. Hermelin received a prison term of 30 days, which was later amended to 17 days.

As has been discussed at length in prior briefing and at the June 6-7 hearing, Mr. Walsh is situated far differently than Hermelin. Mr. Walsh joined Synthes long after the main events at issue—including the regulatory clearances for Norian XR and the initiation of the surgeon training fora. The government has not demonstrated that Mr. Walsh engaged in personal wrongdoing, as his actions were informed by his good faith view of the Norian XR label and his understanding of applicable principles, including the *Washington Legal Foundation* cases, as discussed below. *See* Def.'s Bench Memorandum Regarding Issues Presented at June 6, 2011 Hearing at 9-11 [Dkt. 153] ("Bench Memorandum"). Imposing an incarcerative sentence on Mr. Walsh would be disproportionate to sentences and penalties in other cases relying upon the responsible corporate officer doctrine, particularly those involving the FDCA.

III. Mr. Walsh Has Not Engaged in Intentional Misconduct.

As discussed above, Mr. Walsh pled guilty to a stipulated set of facts comprising the offense conduct in this case. In particular, Mr. Walsh acknowledged that he served as a

responsible corporate officer of Synthes during part of the period of time in which Synthes engaged in the off-label marketing and promotion of its medical devices Norian SRS and Norian XR. *See* Guilty Plea Agreement ¶ 1. Mr. Walsh takes full responsibility for all such illegal activities that occurred during the period in which he was charged with preventing such violations. Had Mr. Walsh fully appreciated the conduct taking place at Synthes during the period in which he was a responsible corporate officer, he would have done his utmost to prevent it from occurring. Indeed, Mr. Walsh acknowledges that, in retrospect, he would have made some decisions differently had he been aware of the extent of the conduct that occurred—decisions such as the manner in which he drafted parts of Synthes' FDA 483 responses and the "dear surgeon" letters. *See* Bench Memorandum at 24-27.

All of his actions, however, were premised on his thoughtful and good faith view of the Norian XR label, which he reached long before the FDA's inspection preceding the issuance of the warning letter. The decisions that he made were consistent with his view that the Norian XR label permitted use of the product in the spine as long as it was not load-bearing. If the product was used with supplemental fixation (such as screws or brackets), even to treat a vertebral compression fracture ("VCF"), Mr. Walsh honestly believed that such use was on-label—a belief that is corroborated by significant contemporaneous documentation. *See* Bench Memorandum at 4-8.

What Mr. Walsh has not pled guilty to, however, is intentional misconduct or wrongdoing in furtherance of the company's off-label marketing or promotion of its medical devices. In its Sentencing Memorandum and at the June 6-7 hearing before this Court, the government argued that the Court should consider certain unproven, government-asserted facts constituting intentional misconduct on the part of Mr. Walsh. The government, however, has

presented no evidence of intentional wrongdoing, nor any evidence that Mr. Walsh knew about Synthes' off-label promotion of Norian XR. *See* Bench Memorandum at 9-11.

The majority of the personal culpability that the government asserts with respect to Mr. Walsh relates to his approval of the Norian XR Technique Guide and CD-ROM. The inclusion of case studies in the Technique Guide depicting the off-label treatment of vertebral compression fractures was a regrettable, yet inadvertent, oversight. *See* Bench Memorandum at 21 & n.17. After this oversight was brought to his attention, however, Mr. Walsh's decisions to permit further distribution of the Technique Guide and to approve the CD-ROM were taken in good faith. Numerous witnesses recall Mr. Walsh's thoughtful consideration of the materials in light of the then-recent *Washington Legal Foundation* cases. *See* Bench Memorandum at 23 & n.22. Indeed, the Supreme Court's recent decision in *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) vindicates Mr. Walsh's good-faith belief, at the time he approved the CD-ROM, that including off-label cases was protected First Amendment activity. *See also Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000).

A. Increasing Mr. Walsh's Sentence Based on His Approval of Marketing Materials Would Violate the First Amendment.

This Court should reject the government's invitation to increase Mr. Walsh's sentence based on his approval of the XR Technique Guide and Norian XR CD-ROM. *See* PSR ¶ 49. In light of the Supreme Court's June 2011 decision in *Sorrell* striking down a State-law restriction on pharmaceutical manufacturers' promotional speech, it would be unlawful to enhance Mr. Walsh's sentence based on what is protected First Amendment expression. The Supreme Court long ago "extend[ed] the protection of the First Amendment to evidence introduced at a sentencing hearing." *Dawson v. Delaware*, 503 U.S. 159, 168 (1992). And the Supreme Court has repeatedly held that the First Amendment "protects commercial speech from unwarranted

governmental regulation." *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 561 (1980). Following this Court's June 6-7, 2011 hearing, the Supreme Court in *Sorrell* struck down under the First Amendment a Vermont law prohibiting pharmaceutical manufacturers from using "prescriber-identifying" information for marketing and promoting their drugs to doctors, concluding that the statute imposed impermissible content-, speaker-, and viewpoint-based restriction on speech. *Sorrell* provides additional grounds, not available at the June 6-7 hearing or previously, to contest the government's attempt to punish Mr. Walsh's approval of the Technique Guide and CD-ROM, which included depictions of a concededly off-label use of Norian XR to treat vertebral compression fractures resulting from osteoporosis without the use of supplemental fixation.

The Technique Guide and CD-ROM both represent quintessential commercial speech under *Central Hudson* and *Sorrell*, and Mr. Walsh's role in approving those documents is protected by the First Amendment. Just as in *Sorrell*, the government's speech restrictions here plainly discriminate based on the speaker's identity, the speech's content, and even the speaker's viewpoint. In particular, a doctor could make or publish precisely the same statements about off-label use as are contained in the Technique Guide and CD-ROM without fear of penalty or prosecution. Indeed, even a pharmaceutical manufacturer may discuss off-label uses so long as it *discourages* such uses rather than *promoting* them. *Sorrell* stands for the proposition that, absent compelling circumstances not present here, the government may not impose such speaker-, content-, and viewpoint-based criminal penalties for truthful and non-misleading speech about lawful conduct, particularly when that conduct concerns a physician's lawful use of a device outside of its FDA-approved indications. Indeed, three Justices in *Sorrell* explicitly recognized that the Court's opinion all but sounded a death knell for the FDA's ban on truthful, non-

misleading off-label marketing activity. *Id.* at 2678 (Breyer, J., dissenting).[3] This Court should decline the government's invitation to rely on protected First Amendment expression to increase Mr. Walsh's sentence.

1. Under *Sorrell*, Content-, Speaker-, and Viewpoint-based Restrictions on a Pharmaceutical Manufacturer's Marketing and Promotion Efforts Are Subject to "Heightened Scrutiny" Under the First Amendment and Are Presumptively Invalid.

The Vermont statute in *Sorrell*, "Act 80," restricted the sale, disclosure, and use of pharmacy records that reveal the prescribing practices of individual doctors. The statute targeted a process, known as "detailing," by which pharmaceutical manufacturers promote their products to doctors. "Detailers" employed by pharmaceutical manufacturers typically visit a doctor's office to persuade the doctor to prescribe a particular pharmaceutical. Unsurprisingly, if such salespersons know in advance about a physician's prescription practices (so-called "prescriber-identifying information") they can more accurately predict which doctors will be interested in a particular drug and how best to tailor their sales pitch. 131 S. Ct. at 2659-60. Pharmacies routinely receive such prescriber-identifying information when processing prescriptions. *See*

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[3] Courts and commentators alike have recognized *Sorrell*'s direct significance for the FDA's off-label marketing restrictions. *See, e.g.*, Order, *United States v. Caronia*, No. 09-cr-5006 (2d Cir. July 14, 2011) (directing parties to file supplemental briefs addressing relevance of *Sorrell* in appeal from misbranding conviction); Lisa Blatt et al., *Does* Sorrell v. IMS Health *Mark the End of Off-Label Promotion Prosecution?*, Pharmaceutical L. & Indus. Rep. (BNA) (July 15, 2011), *available at* http://www.arnoldporter.com/resources/documents/ArnoldPorterLLP_BNAPharmaceuticalLawIndustryReport_7152011.pdf.

Although defense counsel indicated at a June 6-7, 2011 hearing that Mr. Walsh was not making a direct First Amendment challenge, *Sorrell* serves as an intervening, on-point binding authority (decided 16 days *after* that hearing) and thus provides ample justification for Mr. Walsh to press a First Amendment challenge now. *See* Tr. of Hearing at 197, *United States v. Norian Corp.*, No. 2:09-cr-403 (June 7, 2011); *Beazer East, Inc. v. Mead Corp.*, 525 F.3d 255, 263 (3d Cir. 2008) ("An exception to normal law of the case and waiver rules is recognized when an intervening decision from a superior court changes the controlling law."). Whatever the state of the law on or before June 7, *Sorrell* is now binding precedent that removes any possible doubt that a pharmaceutical manufacturer's truthful and non-misleading promotion and marketing activity is protected First Amendment speech.

21 U.S.C. § 353(b). Many pharmacies sell this information to "data mining" firms that analyze it and lease their reports to pharmaceutical manufacturers, whose detailers use the reports to refine their marketing tactics and boost sales.

In an attempt to discourage these practices, Vermont enacted Act 80, which imposes civil penalties on the sale, disclosure, and use of pharmacy records that reveal individual doctors' prescribing practices. In addition to prohibiting pharmacies from ***selling*** prescriber-identifiable information, the Act prohibited drug manufacturers from ***using*** prescriber-identifiable information to "market[] or promot[e]" prescription drugs. 131 S. Ct. at 2660.

Pharmaceutical manufacturers challenged Act 80 under the First Amendment, and the Supreme Court struck down the law. The Court held that Act 80 was subject to "heightened judicial scrutiny" under the First Amendment because it imposed speaker-, content-, and viewpoint-based restrictions on protected speech, prohibiting drug manufacturers from "communicating with physicians in an effective and informative manner." *Id.* at 2663-64. The statute selectively burdened the ability of certain speakers (i.e., drug manufacturers) to disseminate truthful and non-misleading information about their products, while allowing others (e.g., the State, insurers, and researchers) freely to disseminate such information. *Id.* And the statute not only "disfavor[ed] marketing, that is, speech with a particular content," it implemented Vermont's preference for generic drugs, rather than the brand-name versions advanced by manufacturers' marketing efforts, crossing into "actual viewpoint discrimination." *Id.* The Court rejected Vermont's contention that the law validly regulated access to information and conduct, rather than speech, saying that "the creation and dissemination of information are speech within the meaning of the First Amendment." *Id.* at 2667.

Emphasizing that "[c]ontent-based regulations are presumptively invalid," the Court found Act 80 did not satisfy even the "commercial speech inquiry" under cases like *Central Hudson*, much less heightened scrutiny. The Court concluded the statute did not "directly advance[] a substantial governmental interest" and was not "drawn to achieve that interest." 131 S. Ct. at 2667-68. *Sorrell* rejected Vermont's asserted interest in "protect[ing] medical privacy," observing that the law allowed pharmacies to share prescriber-identifiable information "with anyone for any reason save one: . . . marketing," and allowed "insurers, researchers, journalists, [and] the State itself," but not marketers, to use the information. *Id.* at 2668. The Court also rejected the idea that Act 80 protected doctors against harassment by salesmen, noting less-restrictive remedies such as doctors simply declining to meet with representatives. *Id.* at 2669. Nor was Act 80 justified to mitigate the effects of marketing on physicians' treatment decisions, because the "fear that speech might persuade provides no lawful basis for quieting it." *Id.* at 2670. Finally, the Court held that Vermont could not seek to reduce public health costs by promoting the use of generic drugs "through the indirect means of restraining certain speech by certain speakers." *Id.*

2. *Sorrell* Prohibits Criminalizing a Pharmaceutical Manufacturer's Marketing and Promotion of Off-label Uses.

As in *Sorrell*, the government seeks to penalize Mr. Walsh based on speaker-, content-, and viewpoint-based restrictions on speech. The FDA's off-label regulations single out certain disfavored speakers for restrictions and penalties based on First Amended expression.[4]

[4] Although the manner in which the relevant statutes and FDA regulations fit together to restrict speech is somewhat intricate, the net effect of those regulations is simple: criminalizing First Amendment protected expression. Mr. Walsh pleaded guilty to a single violation of 21 USC § 331(a), which prohibits the introduction into interstate commerce of any medical device that is "adulterated or misbranded." A device is misbranded unless its labeling bears "adequate directions for use," *id.* § 352(f), defined in FDA regulations to mean "directions under which the layman can use a device safely and for the purposes for which it is intended," 21

Manufacturers (and others with labeling responsibility) face criminal penalties when the government relies on statements promoting or marketing a device for an unapproved use as part of a misbranding prosecution. By contrast, doctors, academics, and others without labeling responsibilities may freely discuss and promote off-label uses of FDA-approved drugs or devices without fear of penalty or prosecution. *See Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the FDA*, 37 Fed. Reg. 16,503, 16,504 (Aug. 15, 1972). Indeed, the FDA has expressly acknowledged that off-label use by doctors is widespread and "may even constitute a medically recognized standard of care" given that the pace of medical discovery often outstrips the FDA's regulatory processes. FDA, *Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009), *available at* http://www.fda.gov/regulatoryinformation/guidances/ucm125126.htm; *see also* 21 U.S.C. § 396 (Food, Drug, and Cosmetic Act does not "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship"). On their face, the FDA's off-label rules also regulate both the content and viewpoint of speech, allowing speech about *on-label* uses, but prohibiting even truthful, non-misleading speech promoting *off*-label uses, and permitting manufacturers to transmit information *discouraging* off-label uses, but banning *promotion*.

C.F.R. § 801.5(a) (2011). The FDA has defined "intended use" to mean the "objective intent of the persons legally responsible for the labeling of devices," determined by "such persons' expressions" and circumstances surrounding the product's distribution, including "advertising matter" or other "oral or written statements." *Id.* § 801.4. The FDA looks to promotional and marketing statements as evidence of an intent that an approved product be used for an unapproved (off-label) use.

Like in *Sorrell*, the government here seeks to prohibit pharmaceutical manufacturers "from communicating with physicians in an effective and informative manner," 131 S. Ct. at 2663. Act 80 impermissibly sought to prohibit pharmaceutical manufacturers from including certain truthful and non-misleading content (there, prescriber-identifying information) in marketing products to physicians; here, the FDA's off-label regulations attempt to restrict the same kinds of communications between the same parties. Indeed, that *Sorrell* struck down Act 80, which had only *civil* penalties, makes clear the same result follows *a fortiori* when the government seeks to enhance a *criminal* sentence based on essentially the same protected First Amendment activity. If anything, the FDA marketing restrictions are more offensive. Whereas Act 80 only prohibited pharmaceutical manufacturers from accessing information other parties had collected, the FDA's off-label prohibition bars manufacturers from "conveying information *that [they] already possess*[]." 131 S. Ct. at 2665-66 (emphasis added).

The government's attempt to increase Mr. Walsh's criminal sentence based on activity it asserts violated (plainly content-, speaker-, and viewpoint-restrictive) off-label regulations is subject to "heightened judicial scrutiny" and "'presumptively invalid'" under *Sorrell*. *Id.* at 2666-67 (quoting ***R.A.V. v. St. Paul***, 505 U.S. 377, 382 (1992)). The government seeks to punish Walsh for expressing a particular viewpoint—i.e., presenting a use of Norian XR outside of its labeled indications in materials to be provided to physicians. It purports to penalize conduct that, if engaged in by physicians, would be wholly lawful, and, even then, selects between particular viewpoints in dictating which cases can be presented in such materials (i.e., allowing discussion of the product's use in treating a non-VCF but prohibiting discussion of treating a VCF). Under

Sorrell, the Court should reject the government's invitation to sentence Mr. Walsh based on constitutionally protected expression.[5]

But even assuming a "commercial speech inquiry" is the relevant standard of review, the government cannot show the underlying prohibitions "directly advance[] a substantial governmental interest" and are "drawn to achieve" that interest. *Id.* In other cases, the government has attempted to justify the FDA's off-label rules as creating an incentive for manufacturers to submit new uses of approved products to the FDA's rigorous approval process—on the theory that unrestricted off-label marketing might persuade doctors to adopt off-label uses without the need for regulatory approval. But the government may not "burden the speech of [manufacturers] in order to tilt public debate in a preferred direction," particularly where the speech in question is directed to sophisticated listeners (i.e., physicians), not lay persons or the general public. *Id.* at 2671. Nor may the government justify off-label restrictions as controlling false or misleading speech. The Training Manual and CD-ROM described lawful off-label use of Norian XR by doctors. "[T]he fear that people would make bad decisions if given truthful information cannot justify content-based burdens on speech." *Id.* at 2670-71 (internal quotation marks omitted). The government may also assert an interest in providing consumers "reliable information" about medical devices. *See* Supplemental Br. for the United States at 9, *United States v. Caronia*, No. 09-5006 (2d Cir. Aug. 29, 2011) ("Gov't *Caronia* Br."), *available at* http://www.hpm.com/pdf/blog/US%20Caronia%20Supp%20Brief.pdf. But

[5] Indeed, given that Mr. Walsh has been convicted of a strict liability offense, the Court need not and should not reach this constitutional question in this case. The Court may simply decline to sentence Mr. Walsh based on this purported "relevant conduct" by invoking the doctrine of constitutional avoidance. *Cf. Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council*, 485 U.S. 568, 575 (1988).

that interest would be more directly served by requiring manufacturers to disclose that a particular promoted use is off-label.

Penalizing First Amendment-protected activity while sentencing a defendant for a strict liability "responsible corporate officer" offense would impose "more than an incidental burden on protected expression." 131 S. Ct. at 2665. The FDA itself has emphasized doctors' need for "objective, balanced, and accurate information on important unapproved uses of approved products." *Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices*, 63 Fed. Reg. 64,556, 64,579 (Nov. 20, 1998). And manufacturers are uniquely positioned to provide physicians with such information, as they have "superior access to information about their [devices]." *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009). The FDA rules chill manufacturers from providing doctors with truthful information they can lawfully use in treating patients.

The government may, as it has in other cases, attempt to avoid *Sorrell* by suggesting that off-label marketing and promotion are not themselves unlawful, but rather relevant as evidence of a product's intended use. *See* Gov't *Caronia* Br. at 6-7. But *Sorrell* rejected Vermont's similar attempt to recharacterize Act 80 as merely a regulation of conduct. 131 S. Ct. at 2666-67. And there can be little doubt that a Technique Guide and CD-ROM communicating information about a manufacturer's product are quintessential speech under the First Amendment. *See id.* at 2667 ("[T]he creation and dissemination of information are speech within the meaning of the First Amendment."). [6]

[6] Under *Sorrell*, it is also irrelevant whether the government directly criminalizes First Amendment-protected activity or burdens it indirectly by treating certain types of speech as conclusive "evidence" that a manufacturer's product is "intended" for off-label use and thus misbranded. *See* 131 S. Ct. at 2664. Although the First Amendment "does not prohibit evidentiary use of speech to establish the elements of a crime or to prove motive or intent,"

The government may also argue that the expression here was false or misleading and thus not protected under *Central Hudson*. *See* 131 S. Ct. at 2672. As it has before, the government is likely to make the patently unfair assertion that the Technique Guide and CD-ROM were false and misleading as they failed to indicate that one of the patients depicted had died. The government well knows, however, that there is absolutely *no evidence* that Mr. Walsh knew or should have known this fact at the time he approved the Technique Guide or CD-ROM. *Compare* Bench Memorandum at 20-24, *with In re Orthopedic Bone Screw Prods. Liability Litig.*, 193 F.3d 781, 793 (3d Cir. 1999) (addressing argument that commercial speech was misleading and not truthful where medical device defendants "knowingly withheld material facts at [] seminars"), *and United States v. Bell*, 414 F.3d 474, 485 (3d Cir. 2005) (government may regulate commercial speech "to prevent *deception* of customers" (emphasis added)). The government has not shown the case study here would have been misleading to the company's highly sophisticated audience of surgeons and other physicians. The government also points to the omission of a warning bullet from the Technique Guide that the product is not intended for the treatment of VCFs. But again there is no evidence that this omission was intentional or knowing. To the contrary, Mr. Walsh understood that the Technique Guide would be distributed together with other materials that would include the warning bullet, including the package insert, and the CD-ROM itself undisputedly *did* incorporate the warning language.

Wisconsin v. Mitchell, 508 U.S. 476, 489 (1993), Mr. Walsh pleaded guilty to a *strict liability* offense as to which questions of his "intent" are irrelevant. Thus even if marketing and promotion bear on whether off-label uses were "intended," such activities "have no [legitimate] bearing," *Dawson*, 503 U.S. at 168, on the issues at this sentencing proceeding. The Government does not rely on the Technique Guide and CD-ROM to prove an "element[]" of the crime or Mr. Walsh's "intent." Rather, the Government seeks to rely on marketing materials—i.e., protected speech—for the sole and impermissible purpose of establishing relevant conduct to enhance Mr. Walsh's sentence.

At the end of the day, *Sorrell*'s implications for the FDA's off-label regulatory regime were sufficiently plain that Justice Breyer, joined by Justices Ginsburg and Kagan, observed explicitly that "the same First Amendment standards that apply to Vermont here would apply to similar regulatory actions [in] . . . [FDA] regulation[s]." *Id.* at 2675-76 (Breyer, J., dissenting). Thus, *Sorrell* has immediate implications for the FDA's efforts to "control in detail just what a pharmaceutical firm can, and cannot, tell potential purchasers about its products." *Id.* at 2678. The government's reliance here on evidence of marketing and promotional activity for a strict-liability offense is an impermissible attempt to "burden[] disfavored speech by disfavored speakers." *Id.* at 2663 (majority op.). This Court should reject that approach and decline to consider that evidence in determining Mr. Walsh's sentence. It would be unlawful to enhance Mr. Walsh's sentence to penalize protected First Amendment speech.

IV. Mr. Walsh's Background and Personal Characteristics Demonstrate Him to be a Dedicated Professional of High Integrity.

Mr. Walsh deeply regrets his involvement in the misconduct that occurred at Synthes while he was an executive at the company. Yet, Mr. Walsh's conduct for those few short months cannot be considered in isolation. Rather, it should be viewed in the context of his entire career—one that was marked by a dedication to professionalism and integrity. *See* Exs. 1, 2, 3, 4, 6, 7, 9, 10, 11, 12, 13, 14. Despite that dedication, Mr. Walsh's career in the regulatory field is effectively over, forever marred by this case. The past three years have had a devastating impact on Mr. Walsh and his family, both emotionally and financially, and the effects of this case will have a lasting effect on his life.

Mr. Walsh was born and raised in Wilkes-Barre, Pennsylvania. After his mother left when he was only 13 years old, Mr. Walsh supported himself by working his way through high school and college. Nevertheless, he distinguished himself at Wilkes University, where he

served as Governor for Pennsylvania Circle K, as President for Omicron Delta Epsilon, and on the Student Disciplinary Committee. During his senior year, he was encouraged to attend law school by the late Honorable Max Rosen of the United States Court of Appeals for the Third Circuit, who also served on the Board of Trustees for Wilkes University, after hearing Mr. Walsh speak at a university event.

Though Mr. Walsh worked his way through law school, he did not take a bar examination and has never practiced law. Rather, immediately upon graduation from law school, he joined Coulter Corporation (later Beckman Coulter), where he worked as a Senior Regulatory Specialist and helped lead the regulatory and manufacturing efforts to bring a critical HIV/AIDS blood screening test to the United States. He was promoted in 1998 to Regulatory Affairs Manager for the Immunodiagnostics Division, where he worked with the FDA to gain approval for the first blood screening test for prostate cancer. In 2001, he moved to Centerpulse to serve as a director of Regulatory Affairs and Qualify Systems in the Spine and Cardiovascular Divisions. He was promoted to Vice President for Regulatory Affairs. After leaving Centerpulse, Mr. Walsh started his own consulting service, which was his sole employment for a short time before he joined Synthes. *See* PSR ¶¶ 103-04.

At Synthes, Mr. Walsh was charged with developing and building the regulatory and clinical affairs program, almost single-handedly, from the ground up—a task which he took very seriously. One of his first projects at Synthes was to obtain regulatory approval for a device called VEPTR—Vertical Expandable Prosthetic Titanium Rib—a life-saving device intended to dynamically straighten the spines of infants and toddlers with severe deformity and create room for normal lung development. Mr. Walsh convinced Synthes to forego all profits on the device in exchange for a limited Humanitarian Device Exemption approval. It was projects like

VEPTR, intended to improve the lives of patients who used them, that drew Mr. Walsh to join Synthes in the first place.

Indeed, many former colleagues wrote to this Court to express their surprise and dismay upon hearing of the charges leveled against Mr. Walsh. The majority of those colleagues indicated that they considered Mr. Walsh both a guidepost and a mentor in the field of regulatory affairs. One Regulatory Affairs Specialist at Synthes, Jason Lipman, who previously worked as an FDA reviewer, describes how "whenever a complicated question arose, the regulatory team [at Synthes] employed [its] favorite acronym, WWJD, to guide [them] in [their] decision-making process. WWJD stood for 'What would John do' and was synonymous with a high standard of excellence and integrity." Ex. 9, Lipman Letter. Another former colleague, Stacey Bonnell, MBA, writes about how Mr. Walsh "quickly became [her] mentor, imparting upon [her] the importance of compliance equal only to patient safety." Ex. 1, S. Bonnell Letter. She goes on to describe how Mr. Walsh "created teaching opportunities to advance [her] professional development on a daily basis, often challenging [her] to think critically and always with complete reverence for the government regulations." *Id.* She credits Mr. Walsh for her successful professional career. A third colleague, Susan Lewandowski, who holds a Masters in Regulatory Affairs and Quality Assurance, stated: "One of the things I liked best about reporting to John was that he gave me the opportunity to figure things out on my own. I quickly learned that when I went to him with a question, I should already have a possible answer that we could discuss and critique. One of his favorite activities was walking over to the [Regulatory Affairs] group and posing a regulatory or quality based question and then discussing the answer." Ex. 8, Lewandowski Letter. These letters demonstrate the Mr. Walsh was a dedicated regulatory professional whose career, in all likelihood, has been permanently derailed as a result of this

offense. Further punishment through incarceration is unnecessary to serve the goals of Section 3553(a).

Mr. Walsh dedicated his career to the field of regulatory affairs and achieved great success in that discipline. He was known by many as a "consummate professional" and a strident enforcer of both legal and ethical principles. At the time he left Synthes in February 2010, he served as the Global Vice President for Regulatory Affairs for Spine. Yet, this case has quickly made Mr. Walsh unemployed, and likely unemployable. He faces almost certain exclusion from any future work in the field of regulatory affairs.

Through the extensive media coverage of the case, much of which has unfairly failed to note the strict liability nature of the offense, has Mr. Walsh's reputation has been irrevocably tarnished, both professionally and personally. His close friends understand that the stigma associated with the case has had a devastating effect on Mr. Walsh. *See* Ex. 11, Sheriff Letter; Ex. 6, Elliott Letter. Mr. Walsh worries deeply about his ability to provide for his family, and about the impact that his sentence will have on his children and their opinion of him. *See* Ex. 4, Culp Letter.

Fourteen people who have known Mr. Walsh personally and professional for many years have submitted support letters on his behalf. Support for Mr. Walsh comes from personal friends and family, all of whom describe Mr. Walsh as a generous and devoted husband and father. Each of them paint Mr. Walsh as unfailingly honest in his personal and professional pursuits. One friend of over 20 years, Stephen Sheriff, relates how Mr. Walsh's integrity extends even onto the golf course with his refusal to "bend those rules to his advantage or to the advantage of a playing partner or opponent." Ex. 11, Sheriff Letter; *see also* Ex. 6, Elliott Letter. Mr. Walsh is also described as generous, quick to lend a hand to friends in need and to other worthy causes.

Ex. 4, Culp Letter; Ex. 10, O'Donnell Letter; Ex. 2, W. Bonnell Letter; Ex. 5, Dehmer Letter; Ex. 3, Buch Letter.

Tellingly, despite this investigation and the associated negative publicity that he and Synthes garnered as a result, Mr. Walsh continues to receive support from professional colleagues who worked both with and for Mr. Walsh throughout his career in regulatory affairs. One former colleague at Synthes describes him as "one of [her] favorite former managers and genuinely a good man." Ex. 8, Lewandowski Letter. Another "immensely admire[d] his ability to make difficult (and oft-times unpopular) decisions in a constant effort to remain compliant with governing law." Ex. 1, S. Bonnell Letter. A former FDA employee, who later worked with Mr. Walsh at Synthes, reports that he "was never put in a position where [he] felt uncomfortable with a regulatory decision or strategy under John's leadership." Ex. 9, Lipman Letter. These family, friends, and colleagues now ask this Court to consider, in imposing a sentence, the full life and character of Mr. Walsh.

V. Mr. Walsh Respectfully Submits that a Non-Custodial Sentence Will Meet the Goals of Section § 3553(a).

Section 3553(a)(2) instructs that a sentence imposed should be "sufficient, but not greater than necessary, to comply with the [following] purposes:" the need for the sentence imposed

> (A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense; (B) to afford adequate deterrence to criminal conduct; (C) to protect the public from further crimes of the defendant; and (D) to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner.

18 U.S.C. § 3553(a) & (a)(2). Mr. Walsh is no longer employed, and he is likely unemployable in the regulatory field. He is therefore incapable of any repeated offense, and the public needs no additional protection. He has suffered greatly, both emotionally and financially. He has lost his only source of income, thereby jeopardizing his ability to provide financially for his family.

Mr. Walsh has also already agreed to pay a $100,000 fine, reflecting his acknowledgement of the seriousness of his offense. Furthermore, his reputation is irrevocably tarnished both professionally and in the community. The charges against him have been widely publicized in the media so as to deter both Mr. Walsh and others from the type of conduct at issue here. Further punishment in the form of an incarcerative sentence would be unnecessary to satisfy these sentencing principles.

CONCLUSION

For the foregoing reasons, Mr. Walsh respectfully requests that the Court consider that a sentence of probation, along with the $100,000 fine that Mr. Walsh has already agreed to pay, would provide just punishment for the admitted offense.

Respectfully submitted,

s/ Craig D. Margolis
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CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of November, 2011, a true and correct copy of this DEFENDANT'S MEMORANDUM IN AID OF SENTENCING was filed electronically with the Clerk of Court using the CM/ECF system, which will then send notification of such filing to the following:

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Dated: November 14, 2011

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Craig D. Margolis