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

UNITED STATES OF AMERICA	:	CRIMINAL ACTION
	:	
v.	:	
	:	NO. 09-403-3-4-5-6
MICHAEL D. HUGGINS	:	
THOMAS B. HIGGINS	:	
RICHARD E. BOHNER	:	
JOHN J. WALSH	:	

ORDER

Defendants Michael D. Huggins, Thomas B. Higgins, Richard E. Bohner, and John J. Walsh each object to portions of their respective Presentence Investigation Report (PRS). The Government responded to their numerous objections. Pursuant to USSG § 6A1.3, the Court conducted an evidentiary hearing for two full days on June 6-7, 2011, giving the parties an adequate opportunity to present to the Court information regarding disputed matters that are important to sentencing. Pursuant to Federal Rule of Criminal Procedure 32(i), and having carefully considered the voluminous record, the parties' submissions and argument at the hearing, the Court resolves the Defendants' objections, the Government's requests, and matters placed in dispute, ruling as follows:

AND NOW, this 15th of November 2011, it is hereby ORDERED that the Probation Office (PO) shall modify, amend, and correct each Defendant's PSR as specifically directed below. All other objections raised by Defendants are overruled and other requests by the Government are denied.

I. DIRECTIONS TO THE PROBATION OFFICE

A. Directions to the Probation Office That Are Applicable to Each Defendant's PSR

It is ORDERED that the Probation Office shall make the following modifications to the PSR of each Defendant Huggins, Higgins, Bohner, and Walsh:

(1) The PSR for each Defendant will be corrected: The PO is directed to modify and amend PSR ¶ 28 to state as follows:

> By May 2002, **Huggins, Higgins, and Bohner were** aware of, and involved in, the process of approving the SRS test market in the spine.

(2) The PSR for each Defendant will be corrected: The PO is directed to correct PSR ¶ 40 to state:

> In late January 2003, following the first death and eight months before Norian XR was released **to** the test market . . . .

(3) The PSR for each Defendant will be corrected: The PO is directed to correct PSR ¶ 42 to reflect that:

> Eight of the 34 cases involved the treatment of VCFs.

(4) The PSR for each Defendant will be corrected: The PO is directed to correct PSR ¶ 48 by adding the sentence:

> A company has no obligation to share its draft IDE proposals with the FDA.

(5) The PSR for each Defendant will be corrected: The PO is directed to amend PSR ¶ 51 to include the following statement:

> Dr. No. 7's patient was medically frail, presenting multiple health issues, as was each of the other two patients who died.

(6) The PSR for each Defendant will be corrected: The PO is directed to correct PSR ¶ 58 as follows:

(a) The PO is directed to delete the sentence in the PSR that states: "The government, by the Park requirement, has established a prima facie case." PSR ¶ 58. The PO is directed

to add the following sentence to PSR ¶ 58: "The parties have stipulated that Defendant was a responsible corporate officer within the meaning of the applicable law. Plea Agreement ¶¶ 1, 9."

(b) The PO is directed to delete the sentence in PSR ¶ 58 that states: "Therefore, it is necessary under the Guidelines Manual for the defendant to make a greater admission to the facts of the offense, including relevant conduct, in order to qualify for the two-level reduction."

(7) The PSR for each Defendant will be corrected: The PO is directed to state in PSR ¶ 60 as follows:

> The Court rules that Guideline § 2N2.1 applies.

(8) The PSR for each Defendant will be corrected: The PO is directed to correct PSR ¶¶ 66, 67, and 69 as follows:

> The PO is directed in PSR ¶ 66 to change 0 to **2**.
> The PO is directed in PSR ¶ 67 to change 6 to **4**.
> The PO is directed in PSR ¶ 69 to change 6 to **4**.

(9) The PSR for each Defendant will be corrected: The PO is directed to correct Defendants Huggins' PSR ¶ 103, Higgins' PSR ¶ 100, Bohner's PSR ¶ 105, and Walsh's PSR ¶ 112 to include the following statements:

> Pursuant to USSG § 5E1.2(a), "[t]he court shall impose a fine in all cases, except where the defendant establishes that he is unable to pay and is not likely to become able to pay any fine." For a total offense level of 4, USSG § 5E1.2(c)(3) specifies a minimum fine of $250.00 and a maximum fine of $5,000. The Defendant has agreed to pay a fine of $100,000, the statutory maximum fine permitted for a Class A misdemeanor. Plea Agreement, ¶ 5. The Defendant has the ability to satisfy a fine within the guideline range and has agreed to satisfy the $100,000 fine to which the parties stipulated and agreed. The fine may be satisfied in a lump sum or via a monthly installment plan.

(10) The PSR for each Defendant will be corrected: The PO is directed to correct Defendants Huggins' PSR ¶ 106, Higgins' PSR ¶ 103, Bohner's PSR ¶ 108, and Walsh's PSR ¶ 115 to correct the total offense level from **6** to **4**, stating as follows:

> Pursuant to USSG Chapter 5, Part A, based on a total offense level of **4** and criminal history category of 1, the guideline range for imprisonment is 0 to 6 months.

(11) The PSR for each Defendant will be corrected: The PO is directed to correct and amend Defendants Huggins' PSR ¶ 108, Higgins' PSR ¶ 105, Bohner's PSR ¶ 110, and Walsh's PSR ¶ 117 by deleting the following sentences of sentences:

> The parties agreed to a two-level reduction to the offense, pursuant to USSG § 3E1.1(a), in the plea agreement. However, the downward adjustment, though appropriate at the time of the plea agreement, is not applied in the guideline calculations in the presentence report. The Court will need to make the final determination as to downward adjustment. Whether or not the downward adjustment is applied, there is no alteration in the guideline range.

The PO is further directed to replace the deleted sentences with the statement:

> The two-level reduction of the total offense level for acceptance of responsibility pursuant to USSG § 3E1.1(a) applies.

(12) The PSR for each Defendant will be corrected: The PO is directed to correct Defendants Huggins' PSR ¶ 118, Higgins' PSR ¶ 115, Bohner's PSR ¶ 120, and Walsh's PSR ¶ 127 by stating:

> The fine range for the instant offense is from **$250 to $5,000**, pursuant to USSG § 5E1.2(c)(3). The court shall impose a fine in all cases except where the defendant establishes that he is unable to pay and is not likely to become able to pay any fine, pursuant to USSG § 5E1.2(a).

The PO is further directed to delete footnote 21 from Huggins' PSR ¶ 118.

B. Directions to the Probation Office That Are Applicable Only to the PSR for an Individual Defendant

It is ORDERED that the Probation Office shall make the following particular modifications, amendments, and changes only to the PSR of the named individual Defendant:

1. Directions Applicable Only to the PSR for Defendant Thomas B. Higgins

(13) The PO is directed to delete Defendant Higgins' name from his PSR ¶ 42 n.13 as one of the individuals who was interviewed by the FDA investigator during the May-June 2004 inspection.

2. Directions Applicable Only to the PSR for Defendant Richard E. Bohner

(14) The PO is directed to correct the typographical errors in Defendant Bohner's PSR ¶ 6 to

correctly state the Defendant's name as follows:

> On August 13, 2009, **Richard E. Bohner**, in accordance with that written plea agreement, appeared before the Honorable Lawrence F. Stengel . . . .

(15) The PO is directed to amend Defendant Bohner's PSR ¶ 19 to correctly state:

> John Walsh reported to Huggins indirectly, through Bohner, from August 2003 until **January 2004, at which time Mr. Walsh began reporting to Fran Magee** . . . .

(16) The PO is directed to amend Defendant Bohner's PSR ¶ 78 to reflect that Mr. Bohner's mother passed away in January 2011.

3. Directions Applicable Only to the PSR for Defendant John J. Walsh

(17) The PO is directed to correct the typographical errors in Defendant Walsh's PSR ¶ 6 to correctly state the Defendant's name as follows:

> On July 20, 2009, **John J. Walsh**, in accordance with that written plea agreement, appeared before the Honorable Lawrence F. Stengel . . . .

(18) The PO is directed to correct the typographical error in Defendant Walsh's PSR ¶ 26, footnote, 6, line 8, changing the word "**factor**" to the word "**fracture**."

(19) The PO is directed to amend Defendant Walsh's PSR ¶ 49 to state that:

> At the beginning of December 2003, Mr. Walsh approved the final XR Technique Guide, and at the end of December 2003, he approved a CD-ROM document that accompanied the Technique Guide.

II. RULINGS ON EACH INDIVIDUAL DEFENDANT'S OBJECTIONS TO THE PRESENTENCE INVESTIGATION REPORT AND THE GOVERNMENT'S REQUESTS

It is further ORDERED that after careful and extensive consideration of the voluminous record, the parties' submissions and arguments, the Court pursuant to Federal Rule of Criminal Procedure 32(i), resolves and determines the Defendants' objections, the Government's requests, and all matters placed in dispute, ruling as follows:

RULINGS ON DEFENDANT MICHAEL D. HUGGINS' OBJECTIONS

Defendant Michael D. Huggins objects to portions of the Government's Presentence Report. The Court rules on each objection as follows:

(1) Defendant Huggins raises a general objection that the PSR violates the constitutional limits of the responsible corporate officer doctrine pursuant to United States v. Park, 421 U.S. 658 (1975). See Hr'g Tr. 10:4-14:24, 13:7-10 (requesting that the PSR be amended "to reflect the context in which the Park doctrine has arisen" and stating that "apart from that . . . we don't have any request"), June 6, 2011; Def. Objections, Doc. No. 138-2 at 4-5. At the hearing, Defendant withdrew the objection. Hr'g Tr. 14:13-16 ("I don't believe we have any factual disputes with respect to that aspect of the presentence report, so from that perspective we do not have an objection."), June 6, 2011.

Ruling: The objection was withdrawn at the hearing. To the extent that the objection may not have been withdrawn, it is overruled. Defendant presents legal argument, not an objection to the facts contained in the PSR. The Court makes its own determination of the applicable legal principles and the inferences to be drawn from the facts.

(2) Defendant Huggins objects that PSR ¶¶ 17-22, 23-26, 27-52 are misleading in regard to the scope of his employment duties and Synthes' operations, and his lack of motive to commit knowing misconduct. Def. Objections, Doc. No. 138-2 at 15.

Specifically, it is submitted that given the broad scope of Defendant's daily duties, the Norian product "occupied a small place in his daily work life." Def. Objections, Doc. No. 138-2 at 15. It is also submitted that the Norian product was "a tiny slice" of Synthes' products: "Sales for Synthes U.S. in 2003 totaled approximately $1 billion; the entire amount of revenue generated by sales of Norian was $469,800. That is less than .0005 of total company revenue not even taking overall revenue for other years into account." Id. It is further submitted that: "Nothing in the PSR suggests a motive for Mr. Huggins to have committed knowing misconduct. [He] did not receive additional compensation relating to Norian. Nothing in the PSR explains why [he] would risk his pristine reputation for integrity by engaging in knowing and deliberate misconduct concerning Norian." Id. Defendant submits that he was aware of the FDA filings and the contents of the label only at "a high level of generality." Hr'g Tr. 74:12, June 6, 2011.

Ruling: The objections are overruled. Defendant presents legal argument, not an objection to the facts contained in the PSR. The Court makes its own determination of the inferences to be drawn from the evidence.

(3) Defendant Huggins objects that PSR ¶¶ 17-22, 23-26, 27-52 are misleading because the PSR fails to put his conduct in the proper perspective in the context of current

developments in the pharmaceutical industry. Def. Objections, Doc. No. 138-2 at 16.

Specifically, it is submitted that the PSR "does not reflect the fact that the FDA, beginning in 2004, . . . cleared at least three bone cements for the treatment of VCFs in the spine . . . . Nor does the PSR reflect the fact that settlements by the U.S. Attorney's Office with Eli Lily & Company (for $1.415 billion, including a $515 million criminal fine, due to off-label promotion involving significant risks of the anti-psychotic drug Zyprexa), . . . and Cephalon (for $425 million, due to off-label promotion involving significant risks of three drugs, including an opioid) . . . involved no charges whatsoever against any individual officers of those companies." Def. Objections, Doc. No. 138-2 at 16.

Ruling: The objections are overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the applicable legal principles and the inferences to be drawn from the relevant facts.

(4) Defendant Huggins objects that the PSR is incomplete because it does not adequately incorporate pertinent wording of the SRS label. Def. Objections, Doc. No. 138-2 at 8-9. Defendant does not identify or object to any specific paragraphs in the PSR.

Specifically, Defendant submits that the PSR should quote the following language of the "Indications" section of the SRS label that the product was: "intended only for bony voids or defects that are not intrinsic to the stability of the bony structure. . . . [and] is intended to be placed or injected into bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process." Def. Objections, Doc. No. 138-2 at 8. It is also submitted that the PSR should quote the following language of the "Precautions" section of the SRS label: "The recommended application of Norian . . . is to fill bone defects that have been stabilized using standard orthopaedic reduction techniques and fixation protocol, i.e., external fixation pins, K-wires, plates, screws, etc." Id.

Ruling: The objections are overruled. Defendant presents argument. The SRS labels are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(5) Defendant Huggins objects that the PSR is incomplete because it does not adequately incorporate the XR label. Def. Objections, Doc. No. 138-2 at 9. Defendant does not identify or object to any specific paragraphs in the PSR.

Specifically, Defendant submits that the PSR should quote the XR label. Def. Objections, Doc. No. 138-2 at 9. It is submitted that the FDA's interpretation of the

meaning of the XR label was inconsistent with the indications stated on the XR label and the XR label was ambiguous. Id. at 9-10. Defendant submits:

> Long after the label was approved, in a January 2005 meeting with Synthes personnel, FDA officials took the position that the sole cleared indication on the Norian labels for use in the spine was in the area known as the lateral gutters. The lateral gutters, however, are not referenced on the label. The language that *is* on the label contemplates procedures and techniques that have no application to the lateral gutters. At a minimum, the FDA's reconstructed interpretation of the language shows that the labels are ambiguous, which counsels against more severe sanctions.

Id.

Ruling: The objection is overruled. Defendant presents argument. The XR labels are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(6) Defendant Huggins objects that PSR ¶¶ 23-26, and 32 are incomplete because the PSR does not state that physicians make independent medical decisions. Defendant also objects that the PSR is incomplete because it does not state that there is widespread confusion concerning the vertebroplasty procedure. Def. Objections, Doc. No. 138-2 at 9, 13.

Specifically, it is submitted that the PSR "fails to take into account . . . the different understandings among lower-level Synthes employees concerning the different procedures at issue. . . . The revised PSR continues to refer to 'vertebroplasty' as an indication instead of a procedure. PSR ¶ 32. And the PSR's response to Mr. Huggins' detailed objections [to the first draft of the PSR] concerning the different viewpoints and confusion concerning the vertebroplasty procedure is to cite definitions contained in the FDA's November 2004 'warning letter' to Synthes. PSR at 12, n.6." Def. Objections, Doc. No. 138-2 at 13.

Ruling: The objections are overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(7) Defendant Huggins objects that PSR ¶¶ 27 and 28 inaccurately suggest that there was a business plan at Synthes to treat VCFs. Defendant also objects that the PSR inaccurately draws erroneous inferences of such a plan from the occurrence of a November 15, 2001 management meeting. Hr'g Tr. 71:20-75:10, June 6, 2011.

Specifically, it is submitted that PSR ¶¶ 27 and 28 provide no factual basis to show Defendant's improper conduct or state of mind. It is also submitted that the PSR

gives a false impression that from the beginning, Synthes formed a conspiracy to promote SRS off-label to treat VCFs. Defendant argues that there is nothing wrong with making business plans, only promotion off-label is prohibited. Defendant emphasizes that there were permitted uses of SRS as a bony void filler in the spine. Hr'g Tr. 71:20-72:16, 72:17-74:1, June 6, 2011. Defendant submits that he was aware of the FDA filings and the contents of the label only at "a high level of generality." Id. at 74:8-12.

Ruling: The objections are overruled. Defendant presents argument. The objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant knowingly participated in a business plan to conduct unauthorized clinical trials of SRS, which would be mixed with barium sulphate and would be used in vertebroplasties to treat VCFs.

(8) Defendant Huggins objects to PSR ¶ 35 that is erroneously suggests Defendant engaged in improper conduct in regard to the the mixing of SRS with barium sulphate and Defendant knew that this conduct was improper. Hr'g Tr. 84:4-7, June 6, 2011; Def. Objections, Doc. No. 138-2 at 10-11.

Specifically, it is submitted that there is no evidence that Defendant knew about the"back-table mixing" of barium sulphate with SRS as part of the first "test market." Hr'g Tr. 84:4-7 ("[T]here's simply no documents before the Court that suggest that Mr. Huggins authorized any such program."), June 6, 2011. Defendant submits that PRS ¶ 35 does not evidence his improper conduct or state of mind:

> The PSR incorrectly suggests that Mr. Huggins and others engaged in improper conduct in mid-2002 with respect to Norian SRS because they were aware that doctors were using barium sulfate . . . despite the label's statement that Norian SRS was not to be mixed with any other substances. To put the matter in perspective, the FDA *itself* allowed the mixture of barium sulfate with the Norian bone cement when it approved the Norian XR label later in the same year (a fact not mentioned in the PSR).

Def. Objections, Doc. No. 138-2 at 10.

Ruling: The objections are overruled. Defendant presents legal argument. The objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant knew about the"back-table mixing" of barium sulphate with SRS and Defendant knowingly participated in unauthorized clinical trials of SRS mixed with barium sulphate, which was used in vertebroplasties to treat VCFs.

(9) Defendant Huggins objects to PSR ¶¶ 26 & n.6, 29-32, 36-37, and 41, submitting that the PSR improperly imputes the conduct of the corporations, Synthes and Norian, to the individual Defendants and considers the corporate conduct as evidence of the individual

defendants' state of mind. Hr'g Tr. 78:5-80:10, June 6, 2001; Def. Objections (objections to PSR ¶¶ 12, 29-32, 36-37, and 41), Doc. No. 138-2 at 13.

Specifically, Defendant contends that imputation of conduct based on the "collective knowledge" doctrine is impermissible: "the language, Synthes knew this or Norian knew that . . . that's where the rub is . . . the individual defendant may or may not be aware of that particular information." Hr'g Tr. 78:14-79:1, June 6, 2011. It is also submitted that "the PSR makes broad statements concerning communications between Synthes personnel and the FDA (PSR ¶¶ 29-31, 36-37, and 41), as if to suggest that the conduct is attributable to Mr. Huggins, but fails to identify the fact that Mr. Huggins did not communicate with the FDA himself during the period at issue." Def. Objections, Doc. No. 138-2 at 13.

Defendant also objects that "the PSR fails to take into account . . . the different understandings among lower-level Synthes employees concerning the different procedures at issue. . . . The revised PSR continues to refer to 'vertebroplasty' as an indication instead of a procedure. PSR ¶ 32. And the PSR's response to Mr. Huggins' detailed objections [to the first draft of the PSR] concerning the different viewpoints and confusion concerning the vertebroplasty procedure is to cite definitions contained in the FDA's November 2004 'warning letter' to Synthes. PSR at 12, n.6." Def. Objections, Doc. No. 138-2 at 13.

Ruling: The objections are overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(10) Defendant Huggins objects that PSR ¶¶ 20 & n.4 and 28 & n.7 erroneously suggest that he ran an illegal "test market" and "unauthorized clinical trials" with Norian SRS. Defendant submits that the facts contained in the PSR fail to show his knowing participation in unauthorized clinical trials of SRS. Hr'g Tr. 80:11-88:14, June 6, 2001.

Defendant objects to PSR ¶ 20 & n.4, which states in part: "The Spine Division . . . ran the Norian SRS for the spine and Norian XR test markets and unauthorized clinical trials." However, in the Plea Agreement ¶ 9(h), Defendant agreed that the training of surgeons to mix Norian SRS with barium sulphate and use the mixture in vertebroplasties for the treatment of VCFs, notwithstanding that the label stated that the product was not to be mixed with any other substance, violated 21 U.S.C. §§ 351(f)(1)(B), 352(o), and 352(f)(1). The statute was violated because the mixing made SRS a new device that required pre-market approval or clearance for this new intended use. The new device, SRS mixed with barium sulphate, also lacked adequate directions for use. Moreover, in the Plea Agreement ¶ 9(i), Defendant agreed that the training of surgeons to use Norian XR in vertebroplasties for the treatment of VCFs was unauthorized clinical testing of Norian XR in violation of the FDCA.

Defendant submits that the SRS test market was for cleared indications. He contends that there is "nothing illegitimate about a test market" for cleared/approved indications. Hr'g Tr. 81:7-9, June 6, 2011. Defendant submits that the crucial question presented is the meaning of the indication and whether the indication has been cleared or approved. Id. at 81:17-18. Defendant thus objects to the PSR, Offense Conduct section, which uses the phrase "test market" with connotations of being an illegal test market. Id. at 81:11-15. "So I think the words matter, and that the phrase 'test market' is not a clinical study. And the question, then, is was the conduct in this case somehow a clinical study under the guise of a test market." Id. at 82:6-9. Defendant submits: "[T]he question of whether a test market is something that's - - from Mr. Huggins' perspective, is something that is legal that had imperfections or was some off-label effort to deceive the FDA and conduct a clinical study is really the fundamental issue in many ways." Id. at 82:17-21.

Defendant submits that in regard to his May 30, 2002 email expressing "second thoughts" (G Ex. 8) and Dr. Lambert's 6/3/02 and 6/10-11/02 e-mails (G Ex. 32): "Mr. Huggins is saying let's take a careful look at this." Hr'g Tr. 84:13-14, June 6, 2011. Defendant submits that his e-mail (G Ex. 8) is exculpatory evidence. See, e.g., Def. Objections, Doc. No. 138-2 at 10.

Defendant submits that in regard to back-table mixing (as an unauthorized clinical trial): "there's simply no documents before the Court that suggest that Mr. Huggins authorized any such program." Hr'g Tr. 84:5-7, June 6, 2011.

Defendant disputes that he knew about off-label promotion of SRS for the treatment of VCFs. The Government asserts that based on G's Exs. 33 and 34, Defendant knew about the promotion. See Ex. 33, 6/4/2000 Throngpreda memo to Huggins re: training and education binders for test market sites, SRS with barium sulphate; Ex. 34, sales training materials. However, Defendant contends that there is no evidence G. Exs. 33 and 34 ever made their way to him. Defendant contends that the SRS test market was a lawful distribution within the scope of the label. See Hr'g Tr. 88:2-8 ("This is no different from if they used a screw and they asked a set of surgeons, how do you like this screw?").

Ruling: The objections are overruled. The objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant knowingly participated in unauthorized clinical trials of SRS, which was mixed with barium sulphate and used in vertebroplasties to treat VCFs.

(11) Defendant Huggins objects in general that the PSR inaccurately asserts his knowing participation in unauthorized clinical trials of XR. Hr'g Tr. 88:14-95:19, 95:20-97:25, June 6, 2011; see also related topics below.

Ruling: The objection is overruled. This is an objection to a broadly stated fundamental fact to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant knowingly participated in unauthorized clinical trials of XR, which was used in vertebroplasties to treat VCFs.

(12) Defendant Huggins objects to statements contained in PSR ¶ 42 concerning the July 18, 2003 safety or "risk assessment" meeting. Hr'g Tr. 89:2-95:19, June 6, 2011; Def. Objections, Doc. No. 138-2 at 11. See G's Ex. 39, minutes of safety meeting; G's Ex. 38 at DOJSYN.089.000711 (PowerPoint slide). Under this general topic, Defendant raises a number of objections, which are ruled on as follows:

(12.a.) Defendant objects that PSR ¶ 42 inaccurately states that among the topics addressed at the safety meeting, "thirty-four VCF cases to date" were discussed, when in fact only eight of the 34 cases involved decisions by surgeons to treat VCFs, and those eight cases involved SRS, the label of which cleared SRS for use in the spine and did not include the warning bullet. Hr'g Tr. 91:10-21, June 6, 2011; see also Def. Objections, Doc. No. 138-2 at 11 ("the PSR inaccurately asserts that 'thirty-four VCF cases to date' were discussed. PSR ¶ 42."). Accordingly to Defendant, the Government concedes this point and the Government did not indicate otherwise at the hearing.

Ruling: The objection is sustained in part and the PSR for each Defendant will be corrected; otherwise the objection is overruled as argument. The PO is directed to correct Defendant Huggins' PSR ¶ 42 to reflect that "eight of the 34 cases involved the treatment of VCFs."

(12.b.) Defendant objects to PSR ¶ 42 as being inaccurate. PSR ¶ 42 states: "the declared purpose of the meeting was to decide whether Norian XR was safe enough to bring to market." See G. Ex. 38 at DOJSYN.089.000711(PowerPoint slide). Defendant asserts that this is inaccurate; rather the purpose was: "[T]he question is did it comport with Synthes' stringent risk concerns about the introduction of products into markets, even if they were cleared." Hr'g Tr. 90:12-16, 93:15-17, June 6, 2011.

Ruling: The objection is overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence:

(12.c.) Defendant submits that in regard to Dr. Sachs' case (patient who died on January 13, 2003) as referred to in the PSR ¶ 42, the case was an "outlier," "done off-label (SRS without rigid fixation)." Defendant continues: "But that doesn't suggest that the entire thing is some unauthorized clinical study instead of a legitimate test market." Hr'g Tr. 91:24-92:3, 93:18-20, June 6, 2011.

Ruling: The objection is overruled. Defendant presents legal argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(12.d.) Defendant objects that PSR ¶ 42 inaccurately states: "Faced with a choice whether to seek an IDE and a PMA, Synthes and Norian decided to continue the XR 'test market' for use in vertebroplasty to treat VCFs . . . ." Defendant contends that Synthes already had a 510(k) clearance for use of XR and so the "choice," as presented by the Government (whether to terminate the test market or engage in illegal conduct) is a "false dichotomy." Defendant submits that Synthes could properly choose to continue the XR test market, using XR for cleared indications in the spine within the scope of the Special 510(k) pre-market clearance, and there was nothing illegal about doing so. Hr'g Tr. 93:21-25, June 6, 2011.

Ruling: The objection is overruled. Defendant presents legal argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(12.e.) Defendant objects that: "The evidence does not reflect that [he] authorized an XR test market for use in vertebroplasty to treat VCFs in an off-label manner." Hr'g Tr. 94:4-6, June 6, 2011.

Ruling: The objection is overruled. Defendant presents argument. The objection is directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds Defendant authorized and/or failed to prevent an XR test market for use of XR in vertebroplasties to treat VCFs in an off-label manner.

(12.f.) Defendant objects to the PSR's description of the July 18, 2003 safety meeting as being inaccurate. Instead, Defendant submits that the meeting should be considered as follows: "It's an exchange between Dr. Helfet, Mr. Huggins and others about let's look at cases - - again, not cases that are deemed to be based on non-cleared uses - - let's look at cases and see - - and see whether, in fact, the company is - - wants to proceed with a product that is in a different realm from the ordinary products in which they deal, which are plates, screws, rods and so forth - - rigid fixation devices." Hr'g Tr. 92:17-24, June 6, 2011.

Ruling: The objection is overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(13) Defendant Huggins objects to statements in PSR ¶ 39 concerning the fact that no medical device report (MDR) was filed for the January 13, 2003 death of Dr. Sachs' patient. Def. Objections, Doc. No. 138-2 at 12-13.

It is uncontested that an MDR was not filed for Dr. Sachs' case. Defendant's objection is that the PSR "fails to identify facts that support the proposition that Mr.

Huggins failed to believe that Synthes was following proper MDR procedure or was not acting in good faith based on information that was presented to him." Def. Objections, Doc. No. 138-2 at 12-13. Defendant appears to be arguing that the decision not to file an MDR for this patient does not evidence Defendant's intent.

Ruling: The objection is overruled. Defendant presents legal argument. The Court makes its own determination of the inferences to be drawn from the evidence.

(14) Defendant Huggins raises no objections to PSR ¶ 40. However, Defendant Bohner raises an objection to PSR ¶ 40, Hr'g Tr. 142:6-143:2, June 6, 2011. The Court will sustain Defendant Bohner's objection in part and the PSR for each Defendant will be corrected accordingly.

Defendant Bohner objected to the phrase in PSR ¶ 40 that states: "In late January 2003, following the first death and eight months before Norian XR was released **outside** the test market, ..." Defendant Bohner submits that XR "was released **to** the test market, not outside of the test market." Hr'g Tr. 142:10-12, June 6, 2011 (emphasis added). The Government agrees: "[I]t was at the end of December 2003 that XR was released outside the test market. . . . it was approximately August of 2003, Your Honor, when it was released to the test market. So 'to' would be correct, Your Honor." Id. at 142:17-19, 23-25.

Ruling: Defendant Bohner's objection will be sustained in part and the PSR for each Defendant will be corrected. The PO is directed to correct PSR ¶ 40 to state: "In late January 2003, following the first death and eight months before Norian XR was released **to** the test market . . . ."

(15) Defendant Huggins raises two objections to PSR ¶ 43:

First, Defendant objects that PSR ¶ 43 mis-characterizes a meeting as "a strategic planning meeting on XR." Hr'g Tr. 95:20-97:25, June 6, 2011; Def. Objections, Doc. No. 138-2 at 11-12. He submits that the meeting "was a strategic planning meeting on XR and seven other different projects . . . . It was a regularly held strategic planning meeting." Id. at 95:24-96:3.

Second, Defendant objects that PSR ¶ 43 uses the term 'vertebroplasty' with a different meaning than Synthes personnel used it: "the dispute is whether a vertebroplasty . . . - - which is a procedure, is equivalent to the treatment of a VCF, which is a specific indication." Hr'g Tr. 97:17-20, June 6, 2011. See also Defendant's earlier objections that "the PSR fails to take into account . . . the different understandings among lower-level Synthes employees concerning the different procedures at issue. . . . The revised PSR continues to refer to 'vertebroplasty' as an indication instead of a procedure. PSR ¶ 32. And the PSR's response to Mr. Huggins' detailed objections [to the first draft

of the PSR] concerning the different viewpoints and confusion concerning the vertebroplasty procedure is to cite definitions contained in the FDA's November 2004 'warning letter' to Synthes. PSR at 12, n.6." Def. Objections, Doc. No. 138-2 at 13.

Ruling: The objections are overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(16) Defendant Huggins objects to statements in PSR ¶ 44 concerning his knowledge of the August 15 and 16, 2003 surgeon training meeting in Charlotte, NC. Hr'g Tr. 98:4-21, 98:23-99:16, June 6, 2011.

Specifically, Defendant objects that the contents of the training session and materials were "[n]ot within the scope of [his] knowledge . . . ." Hr'g Tr. 98:18-19, June 6, 2011. Defendant objects that there is no evidence he ever saw the XR reorder forms (G's Ex. 57): "[T]he government hasn't presented evidence that Mr. Huggins laid eyes on that document [G Ex. 57] . . . the government hasn't presented anything that Mr. Huggins knew that." Id. at 98:23-99:16.

Ruling: The objections are overruled. The objections are directed to fundamental facts to be determined by the Count. Based on the record evidence of relevant conduct, the Court finds that Defendant knew about and was aware of the XR test market. The Court also finds that Defendant was aware that Synthes trained surgeons as a means of creating an XR test market for the use of XR in vertebroplasties to treat VCFs in an off-label manner.

(17) Defendant Huggins objects to statements in PSR ¶ 45 concerning the filing of a medical device report (MDR) for the September 19, 2003 death of Dr. Nottingham's patient. Hr'g Tr. 99:18-100:13, June 6, 2011; Def. Objections, Doc. No. 138-2 at 12-13.

Specifically, Defendant submits that the contents of the MDR were not within his scope of knowledge. He disputes the Government's assertion that the MDR was vague. Hr'g Tr. 100:1-13, June 6, 2011. Defendant objects that the PSR: "fails to identify facts that support the proposition that Mr. Huggins failed to believe that Synthes was following proper MDR procedure or was not acting in good faith based on information that was presented to him." Def. Objections, Doc. No. 138-2 at 12-13. Defendant appears to be arguing that the decision not to file an MDR for this patient does not evidence his intent.

Defendant also objects to PSR ¶ 45 as giving a "misleading picture of impropriety." He submits that the PSR is not consistent with the inference of Synthes' "openness" as shown by the fact that after the Nottingham death, "the Norian product manager was given the task to contact 19 surgeons in an effort to determine the problems associated with the death." Def. Objections, Doc. No. 138-2 at 12.

Ruling: The objections are overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(18) Defendant Huggins objects to statements in PSR ¶ 46 concerning his knowledge of the September 19 and 20, 2003 surgeon training meeting in San Diego, CA. Hr'g Tr. 100:15-17, June 6, 2011. Specifically, Defendant objects that the contents of the training session and materials were not within the scope of his knowledge: "There is no dispute that that training occurred; the fact of the training. It's the content of it; the absence, again." Id.

Ruling: The objection is overruled. The objection is directed to fundamental facts to be determined by the Court as to Defendant's knowledge and awareness of the XR test market. Based on the record evidence of relevant conduct, the Court finds that Defendant knew and was aware that surgeons were being trained to use of XR in vertebroplasties to treat VCFs in an off-label manner.

(19) Defendant Huggins objects to statements in PSR¶ 47 concerning certain meetings with doctors following the September 19, 2003 death of Dr. Nottingham's patient and a decision that was made as a result of those meeting. Hr'g Tr. 100:19-101:13, June 6, 2011. Specifically, Defendant objects to the last sentence of PSR ¶ 47, which states: "The outcome of those meetings was that, despite the new death and further results from the University of Washington of the same tenor, the studies on humans with Norian XR in the test market would continue." Defendant contends that this is a legal conclusion and denies that he understood the XR test market to include "studies on humans." Id. at 100:23-101:5.

Ruling: The objections are overruled. The objections are directed to fundamental facts to be determined by the Count as to Defendant's knowledge or awareness of the XR test market. Based on the record evidence of relevant conduct, the Court finds that Defendant was aware that surgeons were being trained to use of XR in vertebroplasties to treat VCFs in an off-label manner. The Court also finds that Defendant knew and was aware that the XR test market would go forward with studies on humans being performed.

(20) Defendant Huggins objects to statements in PSR ¶ 48 concerning the November 2003 draft proposal for an investigational device exemption (IDE). Hr'g Tr. 101:14-102:24, June 6, 2011; Def. Objections, Doc. No. 138-2 at 12.

Specifically, Defendant objects to the statement in PSR ¶ 48 that the IDE was never shared with the FDA, because it implies that "there was something to share with the FDA from [his] perspective." Hr'g Tr. 102:1-2, June 6, 2011.

At the hearing, Defendants did not raise any objections to the facts contained in PSR ¶ 48. However, Defendant Huggins submits that "he believed that there were on-

label cleared indications and off-label uses, which this Nottingham surgery was a reflection of." Hr'g Tr. 102:3-5, June 6, 2011. Defendant argues that he did not know the company was engaged in off-label use: "[T]he IDE proposal flows out of the idea that . . . there was, in fact, a procedure that was not clear. The company started to become aware . . . that they're walking a line here. And so the idea is gee, a vertebroplasty without supplemental fixation, we have this warning bullet. We should - - an IDE would be a prudent, responsible thing to do here. . . . gee, doing a study for another indication that's not cleared is something that we should consider doing." Id. at 101:16-22, 102:6-7. See also Def. Objections, Doc. No. 138-2 at 12 ("when the concept of pursuing an investigational device exemption . . . for use of Norian XR in the spine was raised in 2003, Mr. Huggins considered it – not because [he] believed that the regulatory pathways already followed by the company were inappropriate, as implied by the PSR (at ¶ 48), but because it was believed that the company should assess risk factors and patient safety beyond what the law required.").

Ruling: The objection is sustained in part and the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Huggins' PSR ¶ 48 by adding the sentence:

A company has no obligation to share its draft IDE proposals with the FDA.

Otherwise, the objections are overruled. Defendant presents argument. The Court makes its own determination of the inferences to be drawn from the evidence.

(21) Defendant Huggins raises no objections to PSR ¶ 49 concerning the XR Technique Guide. Hr'g Tr. 102:24-103:1, June 6, 2011 .

Ruling: No objections to PSR ¶ 49.

(22) Defendant Huggins raises no objections to PSR ¶ 50 in regard to the January 10-11, 2004 surgeon forum. Hr'g Tr. 103:2-3, June 6, 2011.

Ruling: No objections to PSR ¶ 50.

(23) Defendant Huggins objects to the statement in PSR ¶ 51 concerning the medical device report (MDR) filed for the January 22, 2004 death of Dr. No. 7's (Dr. Ball's) patient. Hr'g Tr. 103:4-15, June 6, 2011; Def. Objections, Doc. No. 138-2 at 12-13.

Specifically, Defendant disputes the Government's assertion that the MDR was vague. Defendant also objects that the PSR "fails to identify facts that support the proposition that Mr. Huggins failed to believe that Synthes was following proper MDR procedure or was not acting in good faith based on information that was presented to him." Def. Objections, Doc. No. 138-2 at 12-13. Defendant appears to be arguing that the decision not to file an MDR for this patient does not evidence his intent.

Ruling: The objections are overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(24) Defendant Huggins raises no objection to PSR ¶ 51. However, Defendant Higgins raises an objection to PSR ¶ 51. Hr'g Tr. 121:15-122:19 (Higgins), June 6, 2011; Def. Higgins' Objections, Doc. No. 138-3 at 6.

Defendant Higgins submits that the PO previously revised PSR ¶¶ 38 and 45 to include the medical history and context for the deaths of Drs. Sachs' and Nottingham's patients. Defendant Higgins objects that the PO omitted to make similar revisions to PSR ¶ 51 to reflect the "medical context" for the death of Dr. Ball's patient. Defendant Higgins requests that PSR ¶ 51 be amended to state: "the patient's medical history, that the doctor did not attribute the death to Norian, and the autopsy's inability to draw conclusions because of the prolonged exposure to CPR." Hr'g Tr. 122:8-11, June 6, 2011.

In his written objections, Defendant Higgins objects "because [PSR ¶ 51] fails to mention, among other things, the patient's medical history (83 year old female with a history of hypertension, atypical angina, lumbar stenosis, and recent pneumonia), and that, at the time, Doctor No. 7 did not attribute the death to the use of Norian XR. Furthermore, this paragraph fails to state that the person who conducted the autopsy noted that no conclusions could be drawn from the presence of foreign material because the patient had undergone prolonged CPR." Def. Higgins' Objections, Doc. No. 138-3 at 6.

The Government did not object. Hr'g Tr. 122:15-18. The Government stated that it "certainly has no objection to the Court adding to each of the paragraphs on each of the three deaths that there was - -- each of those persons was an elderly person and each had various other medical problems. That has never been disputed." Hr'g Tr. 176:20-177:2, June 6, 2011.

Ruling: Defendant Higgins' objection will be sustained in part and the PSR for each Defendant will be corrected; otherwise the objections are overruled. The PO is directed to amend PSR ¶ 51 to include the following statement:

> Dr. No. 7's patient was medically frail, presenting multiple health issues, as was each of the other two patients who died.

(25) Defendant Huggins raises no objections to statements in PSR ¶ 52 concerning the January 22, 2004, "dear surgeon" letter and the fact that no XR product recall was made. Hr'g Tr. 103: 17-24, June 6, 2011. In his written objections, Huggins contends that PSR ¶ 52 is incomplete because it does not state that there was no legal requirement to institute a product recall of Norian XR. Def. Objections, Doc. No. 138-2 at 12.

Ruling: No objections; the written objections were withdrawn at the hearing.

(26) Defendant Huggins objects to PSR ¶ 53, Victim Impact. Hr'g Tr. 103:25-106:13, June 6, 2011; Def. Objections, Doc. No. 138-2 at 13-14.

At the hearing, Defendant offered argument, but no factual objections: "The question is the role of Mr. Huggins in that or not [the three patient deaths]. And so there's no direct or proximate showing of the product or any decisions that Mr. Huggins made, with respect to those. . . . We're not suggesting [the deaths] did not occur or that they're not extremely serious." Hr'g Tr. 104:2-8, June 6, 2011.

In Defendant's written objections, he submits that the victim impact allegations are "vague, misleading, unfairly prejudicial, and inflammatory." Def. Objections, Doc. No. 138-2 at 13. He requests that the Court decline to take the allegations of PSR ¶ 53 into account at sentencing. Id. at 14. Defendant objects to PSR ¶ 53 because there is a purported lack of evidence that the conduct of anyone at Synthes or a Norian product caused a patient death. Defendant argues that the PSR asserts only that the Norian products could not be ruled out as a cause of the first and second deaths. Defendant submits that the PSR allegations do not satisfy the standard for determining victim status at sentencing, 18 U.S.C. § 3663(a)(2), which provides: "the term 'victim' means a person directly and proximately harmed as a result of the commission of an offense" for purposes of the restitution statute. Defendant also submits that the "PSR fails to identify the advanced age, co-morbidities, and other specific characteristics of the three patients; and fails adequately to specify the independent medical judgments involved." Def. Objections, Doc. No. 138-2 at 14.

Ruling: The objections are overruled. Defendant presents argument. The Court makes its own determination of the applicable legal principles and the inferences to be drawn from the evidence. Based on the record evidence of relevant conduct, the Court finds that the patients were directly and proximately harmed by the conduct of Defendants and others at Synthes. Defendants subjected the patients to the risks of SRS and XR without the patients' full informed consent and without the FDA's authorization. Some of those patients were injured and some died. By conducting unauthorized clinical trials of SRS mixed with barium sulphate and XR on human beings, Defendants disregarded the safety of all members of society.

(27) Defendant Huggins raises no objections to PSR ¶ 54, Obstruction of Justice. Hr'g Tr. 106:15-18, June 6, 2011; Def. Objections, Doc. No. 138-2 at 14. At the hearing, Defendant stated "no objection" to the PSR's statement that no adjustment under USSG § 3C1.1 should be made for obstruction of justice. Id.

In written objections, Defendant submits that there is no factual basis for the statement in PSR ¶ 54 that he made a false statement to an FDA inspector in 2004. He submits that he was never charged with such an offense. Defendant requests that the

Court decline to take PSR ¶ 54 into account at sentencing. Def. Objections, Doc. No. 138-2 at 14-15.

Ruling: The objections to PSR ¶ 54 were withdrawn at the hearing. To the extent that the objections may not have been withdrawn, they are overruled. The FDA's 2004 inspection report is in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(28) Defendant Huggins objects to PSR ¶¶ 55-58, Acceptance of responsibility, submitting that considerations of acceptance of responsibility mandate a Total Offense Level of 4. Hr'g Tr. 15:4-18:13, 106:21-24, June 6, 2011.

Specifically, Defendant raises no objections to application of the 0-6 month base offense sentencing guideline. Hr'g Tr. 11:25-12:4, June 6, 2011. However, Defendant objects that the Government "has not recommended to Your Honor a reduction of two levels. . . . [W]e believe that the appropriate presumption, so to speak, is that the total adjusted offense level should be 4, subject to losing the two, instead of 6, subject to gaining the two. And that's, really, the nature of our objection . . . ." Id. at 16:5-7, 19-23. In regard to the standard for denying the two-level reduction for acceptance of responsibility, "falsely denied or frivolously contested what the Court deems relevant conduct," Defendant submits: "we simply don't believe that that standard has been met." Id. at 17:22-18:7. See Plea Agreement ¶ 11(b) (Government's stipulation that "as of the date of this agreement, the defendant has demonstrated acceptance of responsibility for his offense making the defendant eligible for a 2-level downward adjustment under USSG § 3E1.1(a)."); USSG § 3E1.1, Application Note (A).

Defendant also submits: "The guideline range [base offense level for imprisonment] is 0-6 months regardless of whether the total adjusted offense level is 4 or 6. The applicable guideline [for probation] does not recommend any minimum term of probation if the offense level is 4 and recommends a one-year minimum period of probation if the offense level is 6. *See* USSG § 5B1.2(a)-(b). The controlling statute contains no minimum term for a sentence of probation in a misdemeanor case. *See* 18 U.S.C. § 3561(c)(2)." Def. Objections, Doc. No. 138-2 at 6, n.2.

In the written objections, Defendant submits that the Park "prima facie case" analysis has no application here, where the parties stipulated in the plea agreements that each Defendant was a responsible corporate officer within the meaning of the applicable law. Def. Objections, Doc. No. 138-2; Plea Agreement ¶¶ 1, 9(a).

Ruling: Defendant Huggins' objections to PSR ¶ 58 are sustained in part and the PSR for each Defendant will be corrected; otherwise the objections are overruled. The PO is directed to correct the PSR as follows:

(a) The PO is directed to delete the sentence in PSR ¶ 58 that states: "The government, by the Park requirement, has established a prima facie case." The PO is directed to add the following sentence to PSR ¶ 58: "The parties have stipulated that Defendant was a responsible corporate officer within the meaning of the applicable law. Plea Agreement ¶¶ 1, 9."

(b) The PO is directed to delete the sentence in PSR ¶ 58 that states: "Therefore, it is necessary under the Guidelines Manual for the defendant to make a greater admission to the facts of the offense, including relevant conduct, in order to qualify for the two-level reduction."

(29) Defendant Huggins raises no objections to PSR ¶¶ 59, 61, 62, 63, 64, 65, and 68, Offense Level Computation.

Ruling: No objections to PSR ¶¶ PSR ¶¶ 59, 61, 62, 63, 64, 65, and 68.

(30) Defendant Huggins objects to PSR ¶ 60, Base Offense Level, in regard to the application of Guideline § 2N2.1 versus 2X5.2. Hr'g Tr. 66:25-67:11, June 6, 2011.

At the hearing, Defendant Huggins objected to the application of § 2N2.1 in PSR ¶ 60, but then expressly withdrew the objection. Hr'g Tr. 67:9-11, 66:25-67:11, June 6, 2011. Defendants Higgins, Bohner, and Walsh made no express objections to the application of § 2N2.1 as opposed to 2X5.2.

In each defendant's Plea Agreement, ¶ 11(a), it was stipulated: "The parties agree to disagree concerning whether USSG § 2N2.1(a) or § 2X5.2 applies to this case." Plea Agreements, ¶ 11(a): Def. Huggins, Doc. No. 34 at 9; Def. Higgins, Doc. No. 42 at 9; Def. Bohner, Doc. No. 64 at 9; Def. Walsh, Doc. No. 68 at 9. See also Huggins' PSR ¶ 107, Sentencing Options, Impact of the Plea Agreement, which states:

> The parties agreed to disagree as to whether USSG § 2N2.1(a) or § 2X5.2 applie[s] in this case. Appendix A of the Guidelines Manual specifies that the appropriate offense guideline section in Chapter Two applicable to the statute of conviction is found in § 2N2.1. Regardless of which guideline section applie[s], the same total offense level would be obtained. In any event, the Court may need to address this dispute at the time of sentencing.

Ruling: Defendant Huggins' objections were withdrawn at the hearing. The Court rules that Guideline § 2N2.1 applies.

(31) Defendant Huggins objects to PSR ¶ 66 (Adjustment for Acceptance of Responsibility), ¶ 67 (Adjusted Offense Level), and ¶ 69 (Total Offense Level). Def. Objections, Doc. No. 138-2 at 5-6.

Ruling: Defendant Huggins' objections to PSR ¶¶ 66, 67, and 69 are sustained and the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Huggins' PSR as follows:

> **Ruling:** The objection to PSR ¶ 66 is sustained; the PO is directed to change 0 to **2**.
> **Ruling:** The objection to PSR ¶ 67 is sustained; the PO is directed to change 6 to **4**.
> **Ruling:** The objection to PSR ¶ 69 is sustained; the PO is directed to change 6 to **4**.

(32) Defendant Huggins raises no objections to PSR ¶¶ 70-75, Defendant's Criminal History.

Ruling: No objections to PSR ¶¶ 70-75.

(33) Defendant Huggins raises no objections to PSR ¶¶ 76-102, and 104, Offender Characteristics. Counsel stated at the hearing that Defendant had no objections to PSR ¶¶ 76-104. Hr'g Tr. 107:6-18.

Ruling: No objections to PSR ¶¶ 76-102, and 104; the objections were withdrawn at the hearing.

(34) Defendant Huggins objected to PSR ¶ 103, Offender Characteristics, Applicable Guideline Range for Fine. Defendant raised this objection only in written objections, Doc. No. 138-2 at 7, n.6, but withdrew the objection at the hearing, Hr'g Tr. 107:6-18.

> In written objections, Defendant submits: "Although [he] has agreed to pay the maximum statutory fine of $100,000, the PSR nonetheless should, but does not, state the applicable fine range under USSG § 5E1.2(c)(3). PSR ¶ 103. That guideline recommends a minimum fine of $250.00 and a maximum fine of $5,000. The fact that Mr. Huggins has agreed to pay a fine 400 times greater than the minimum fine recommended by the guideline and 20 times greater than the maximum is material to the Court's overall sentencing determination." Doc. No. 138-2 at 7, n.6.
>
> Although Defendant Huggins objects that the guideline range for a fine has been omitted, Defendants Higgins, Bohner, and Walsh did not object to the omission. The amendment of the total offense level from 6 to 4 changes the guideline range for the fine from $500.00-$5,000.00 to $250.00-$5,000.00. Thus, the PSR for each defendant will be amended to reflect the correct guideline range for a fine.

Ruling: Defendant Huggins' objection is sustained in part and the PSR for each Defendant will be corrected; otherwise the objections are overruled. The PO is directed to correct Defendant Huggins' PSR ¶ 103 to include the following statements:

> Pursuant to USSG § 5E1.2(a), "[t]he court shall impose a fine in all cases, except where the defendant establishes that he is unable to pay and is not likely to become

able to pay any fine." For a total offense level of 4, USSG § 5E1.2(c)(3) specifies a minimum fine of $250.00 and a maximum fine of $5,000. The Defendant has agreed to pay a fine of $100,000, the statutory maximum fine permitted for a Class A misdemeanor. Plea Agreement, ¶ 5. The Defendant has the ability to satisfy a fine within the guideline range and has agreed to satisfy the $100,000 fine to which the parties stipulated and agreed. The fine may be satisfied in a lump sum or via a monthly installment plan.

(35) Defendant Huggins raises no objections to PSR ¶¶ 105, 107, 109-117, 119, Sentencing Options.

Ruling: No objections to to PSR ¶¶ 105, 107, 109-117, 119.

(36) Defendant Huggins objects to PSR ¶ 106, Sentencing Options, Guideline Provisions, which states:

> Pursuant to USSG Chapter 5, Part A, based on a total offense level of 6 and criminal history category of 1, the guideline range for imprisonment is 0 to 6 months.

Defendant objects to PSR ¶ 106 based on considerations of acceptance of responsibility. Def. Objections, Doc. No. 138-2 at 5-6. In this case, those considerations do not affect the base offense level guideline range of 0 to 6 months for imprisonment. At the hearing, Defendant stated that he does not contest that the guideline range for imprisonment is 0 to 6 months. Hr'g Tr. 11:25-12:4, June 6, 2011. However, Defendants Huggins and Bohner object to the statement in their respective PSRs of the total offense level as "6," instead of "4." Defendants Higgins and Walsh did not object.

Ruling: Defendant Huggins' objection is sustained in part and Defendant Bohner's objection will be sustained in part, and the PSR for each Defendant will be corrected; otherwise the objections are overruled. The PO is directed to amend the total offense level in Defendant Huggins' PSR ¶ 106 from **6** to **4.**

(37) Defendant Huggins does not object to PSR ¶ 108, Sentencing Options, Impact of the Plea Agreement, which states:

> The parties agreed to a two-level reduction to the offense, pursuant to USSG § 3E1.1(a), in the plea agreement. However, the downward adjustment, though appropriate at the time of the plea agreement, is not applied in the guideline calculations in the presentence report. The Court will need to make the final determination as to downward adjustment. Whether or not the downward adjustment is applied, there is no alteration in the guideline range.

Ruling: Although Defendant Huggins does not object to PSR ¶ 108, the PSR for each Defendant will be corrected. The PO is directed to correct and amend the PSR by deleting the sentences of PSR ¶ 108 quoted above and stating instead:

> The two-level reduction of the total offense level for acceptance of responsibility pursuant to USSG § 3E1.1(a) applies.

(38) Defendant Huggins does not object to PSR ¶ 118, Sentencing Options, Fines, Guideline Provisions, which states:

> The fine range for the instant offense is from $500 to $5,000, pursuant to USSG § 5E1.2(c)(3). The court shall impose a fine in all cases except where the defendant establishes that he is unable to pay and is not likely to become able to pay any fine, pursuant to USSG § 5E1.2(a).[21]

Footnote 21 (which appears only in Defendant Huggins' PSR) states:

> If the Court would find that the total offense level is 4 instead of 6 due to the application of the two-level downward adjustment, pursuant to USSG § 3E1.1(a), then the minimum fine, pursuant to the Fine Table found in USSG § 5E1.2(c)(3), would be $250.00 instead of $500.00. Nevertheless, the defendant has already agreed to pay a $100,000 fine as part of the plea agreement.

Ruling: Although Defendant Huggins does not object to PSR ¶ 118, the PSR for each Defendant will be corrected. The PO is directed to correct and amend Defendant Huggins' PSR ¶ 118 by deleting footnote 21 and stating:

> The fine range for the instant offense is from **$250 to $5,000**, pursuant to USSG § 5E1.2(c)(3). The court shall impose a fine in all cases except where the defendant establishes that he is unable to pay and is not likely to become able to pay any fine, pursuant to USSG § 5E1.2(a).

(39) Defendant Huggins raises no objections to PSR ¶ 120, Factors That May Warrant Departure.

Ruling: No objections to PSR ¶ 120.

(40) Defendant Huggins objects to PSR ¶ 121, Factors That May Warrant a Sentence Outside of the Guideline System, and Addendum, Grounds for Alternative Sentence. In pertinent part, PSR ¶ 121 states:

> The probation officer has not identified possible grounds for a sentence outside of the advisory guidelines system other than the nature of the defendant's guilty plea in this case. The defendant agrees with this position. . . .

The Addendum states: "Pursuant to Rule 32(i)(3), Fed. R. Crim. P., and USSG § 6A1.3, the Court will resolve any objection in its written decision before the time of sentencing." PSR Addendum at 48.

At the hearing, Defendant Huggins did not object to PSR ¶ 121. After the Court reviewed with counsel "the pure issues of legal structure, analytical structure" and asked counsel if there were "any basic framework issues" that had not been discussed, that someone might want to raise, counsel did not raise any issues concerning PSR ¶ 121 or the Addendum. Hr'g Tr. 67:12-19, June 6, 2011.

Defendant objects only in written objections, Def. Objections, Doc. No. 138-2 at 6-7. Defendant submits that the "PSR is incomplete . . . because it fails to identify the fact that the Court is not legally required to resolve factual disputes concerning the offense conduct" under Fed. R. Crim. P. 31(i)(3)(B) and USSG § 6A1.3. Id. at 3, 6-7. Defendant continues: "The Court has the discretion to conclude that (1) Mr. Huggins should receive a sentence of probation even if the PSR's description of offense conduct is deemed correct; and (2) the Court does not need to resolve the outstanding factual disputes under Fed. R. Crim. P. 32(i)(3)(B) because they 'will not affect sentencing.'" Id. at 7.

Ruling: The objections are overruled. Defendant presents argument. Defendant raises questions of law and questions concerning the application of law to the relevant facts, which are functions within the Court's discretion at sentencing. The Court makes its own determination of the sentence to be imposed.

At the hearing, Defendant Huggins stated that he has nothing further, no more factual objections. Hr'g Tr. 107:21-23, 108:13.

RULINGS ON DEFENDANT THOMAS B. HIGGINS' OBJECTIONS

Defendant Thomas B. Higgins objects to portions of the Government's Presentence Report. The Court rules on each objection as follows:

(1) Defendant Higgins objects to PSR ¶ 7, Charges and Convictions. Def. Objections, Doc. No. 138-3 at 2.

Specifically, Defendant objects to the first sentence of PSR ¶ 7, which states in part: "The instant offense occurred between in or about May 2002 and in or about July 2004 . . . ." Defendant submits that as of February 2004, he was Senior Vice President of Global Strategy, Synthes and he was no longer President of the Spine Division (see PSR ¶ 20) and therefore, he cannot be a responsible corporate officer for any of the conduct after February 2004. Def. Objections, Doc. No. 138-3 at 2.

Ruling: The objection is overruled. Defendant presents argument. The Court makes its own determination of the applicable legal principles and the inferences to be drawn from the evidence.

(2) Defendant Higgins raises no objections to PSR ¶ 17, Offense Conduct, Defendant Synthes. Hr'g Tr. 114:3-8, June 6, 2011.

Ruling: No objections to PSR ¶ 17.

(3) Defendant Higgins raises no objections to PSR ¶ 18, Offense Conduct, Defendant Norian. Hr'g Tr. 114:9-10, June 6, 2011.

Ruling: No objections to PSR ¶ 18.

(4) Defendant Higgins raises no objections to PSR ¶ 19, Offense Conduct, Defendant Huggins. Hr'g Tr. 114:11-12, June 6, 2011.

Ruling: No objections to PSR ¶ 19.

(5) Defendant Higgins objects to PSR ¶ 20 & n.4, Offense Conduct, Defendant Higgins. Hr'g Tr. 114:13-19, June 6, 2011; Def. Objections, Doc. No. 138-3 at 2-3. PSR ¶ 20 states in part:

> From 1999 through 2005, the time period covered by the indictment, Higgins held the positions of President of Synthes' Spine Division from 1999 through January 2004, Senior Vice President of Global Strategy, Synthes from February 2004 through May 2005 . . . . The Spine Division at Synthes ran the Norian SRS for the spine and Norian XR test markets and unauthorized clinical trials.[4]
> Footnote 4 states in part:
>
> In paragraph 9(I) of each of the defendant's plea agreement, each defendant agreed that the training of spine surgeons to use Norian XR in vertebroplasty-type surgeries to treat VCFs, a part of the so-called 'test market' for Norian XR, was unauthorized clinical testing of Norian XR for the treatment of VCFs which violated the FDCA.

Specifically, Defendant objects that based on his status as a responsible corporate officer, he had no intent to violate the law. Defendant stated that he has no objections to

the facts contained in PSR ¶ 20, but "will argue inferences about mens rea as to knowledge of unauthorized clinical trials." Hr'g Tr. 114:13-19, 114:14-16, June 6, 2011. It is submitted that: "Consistent with the unique nature of the responsible corporate officer doctrine, Mr. Higgins accepted responsibility for his company's conduct and pled guilty, even though he had no intent to violate the law." Def. Objections, Doc. No. 138-3 at 2-3. In regard to PSR ¶ 20 n.4, Defendant submits that he had no intent to violate the law: "[H]e did not believe *at the time* that the activities of the Spine Division constituted what the government later alleged to be 'unauthorized clinical trials' and he never intended for the Spine Division to conduct activities that could violate the FDCA." Id. at 3.

Ruling: The objections are overruled. Defendant presents argument, not an objection to the facts contained in the PSR. The Court makes its own determination of the applicable legal principles and the inferences to be drawn from the facts. The objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant knew and was aware that the Spine Division was conducting unauthorized clinical trials of SRS and XR in violation of the FDCA, and Defendant participated in conducting those clinical trials. The Court finds that at the time the clinical trials were planned and were conducted, Defendant knew that the trials violated the FDCA.

(6) Defendant Higgins raises no objections to PSR ¶ 21, Offense Conduct, Defendant Bohner. Hr'g Tr. 114:20-21, June 6, 2011. In written objections, Defendant objected "with respect to 'unauthorized clinical trials,'" citing to his objection to PSR ¶ 20. However, the written objection appears to have been withdrawn at the hearing. To the extent the objection was not withdrawn, it is ruled on by the Court's ruling on PSR ¶ 20.

Ruling: No objections to PSR ¶ 21; objections withdrawn.

(7) Defendant Higgins raises no objections to PSR ¶ 22, Offense Conduct, Defendant Walsh. Hr'g Tr. 114:22-23, June 6, 2011.

Ruling: No objections to PSR ¶ 22.

(8) Defendant Higgins raises no objections to PSR ¶ 23, Medical Context. Hr'g Tr. 114:24-25, June 6, 2011.

Ruling: No objections to PSR ¶ 23.

(9) Defendant Higgins raises no objections to PSR ¶ 24, Medical Context. Hr'g Tr. 115:1-2, June 6, 2011.

Ruling: No objections to PSR ¶ 24.

(10) Defendant Higgins raises no objections to PSR ¶ 25, Medical Context. Hr'g Tr. 115:3-4, June 6, 2011.

Ruling: No objections to PSR ¶ 25.

(11) Defendant Higgins raises no objections to PSR ¶ 26, Medical Context. Hr'g Tr. 115:5-6, June 6, 2011.

Ruling: No objections to PSR ¶ 26.

(12) Defendant Higgins objects to statements in PSR ¶ 27 concerning the creation of test markets for use of SRS in vertebroplasty and kyphoplasty surgeries for the treatment of VCFs. Hr'g Tr. 115:7-15, June 6, 2011.

Specifically, Defendant objects to the sentence in PSR ¶ 27 that states: "The purpose of these interviews [of doctors in the spring 2000 about their use of SRS and PMMA] was to create a market for the use of a version of SRS with radiopaque barium sulfate in vertebroplasty and kyphoplasty surgeries to treat VCFs." Id. at 115:7-12. In written objections, Defendant disputes that "the purpose of Synthes' market research was to 'create a market' for the use of SRS to treat VCFs. To the contrary, the evidence shows that Synthes performed permissible market research to understand physicians' needs." Def. Objections, Doc. No. 138-3 at 3.

Ruling: The objections to PSR ¶ 27 are overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(13) Defendant Higgins raises no objections to the facts contained in PSR ¶ 28. Hr'g Tr. 115:16-18, June 6, 2011; Def. Objections, Doc. No. 138-3 at 4.

Specifically, Defendant Higgins stated that he has no factual objections, "our objection is in the nature of inferences, so therefore, none." Hr'g Tr. 115:16-18, June 6, 2011.

In written objections, Defendant submits a number of points: He objects that PSR ¶ 28 suggests there is something improper about a test market involving "a limited release of an approved product, which physicians, utilizing medical judgment, can choose to use on or off label as they see fit." Def. Objections, Doc. No. 138-3 at 4. He disputes that he knew at the time the conduct amounted to unauthorized clinical trials. Id. He submits the he accepts that conduct in violation of FDCA took place, but maintains that he lacked intent to violate the law. Id.

Ruling: No objections to PSR ¶ 28; the written objections were withdrawn at the hearing. The relevant facts are in evidence. The Court makes its own determination of the inferences to be

drawn from the evidence. As to Defendant's intent, the objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant knew and was aware that the Spine Division was conducting unauthorized clinical trials of SRS and XR in violation of the FDCA, and Defendant participated in conducting those clinical trials. The Court finds that at the time the clinical trials were planned and were conducted, Defendant knew the trials violated the FDCA.

(14) Defendant Higgins objects to inferences to be drawn from facts contained in PSR ¶ 29 regarding a December 20, 2001 510(k) pre-marekt clearance for SRS as a general bone void filler. Hr'g Tr. 115:22-25, June 6, 2011; Def. Objections, Doc. No. 138-3 at 4. PSR ¶ 29 states in part: "Synthes never told the FDA that it intended to market SRS for load-bearing spine use such as treating VCFs."

Specifically, Defendant states that he has no factual objections, but "as far as inferences and individual defendants' knowledge, we'd leave that to later. The answer is none [no objections]." Hr'g Tr. 115:22-25, June 6, 2011. In written objections, Defendant objects to PSR ¶ 29 because "it wrongly suggests he intended to mislead the FDA, or that he was aware that any other Synthes employee had such intent." Def. Objections, Doc. No. 138-3 at 4.

Ruling: No objections to PSR ¶ 29; the written objections withdrawn at the hearing. To the extent that the objections may not have been withdrawn, they are overruled. The Court makes its own determination of the inferences to be drawn from the evidence. As to Defendant's intent, the objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant intended to mislead the FDA.

(15) Defendant Higgins raises no objections to PSR ¶ 30. Hr'g Tr. 116:2-1, June 6, 2011.

Ruling: No objections to PSR ¶ 30.

(16) Defendant Higgins raises no objections to the facts contained in PSR ¶ 31. Hr'g Tr. 116:3-14, June 6, 2011. However, at the hearing, Defendant requested and was granted a general exception:

Counsel: "[S]o for all of these where I answer none [no factual objections], can I have a general caveat that with respect to inferences and individual defendants' knowledge that we'll leave it for later?"

The Court: "Yes. I thought that was understood."

Id. at 116:4-13.

Ruling: No objections to PSR ¶ 31; a general exception to inferences to be drawn from the facts with respect to Defendants' knowledge was granted.

(17) Defendant Higgins raises no objections to PSR ¶ 32. Hr'g Tr. 116:12-17, June 6, 2011.

Ruling: No objections to PSR ¶ 32.

(18) Defendant Higgins raises no objections to PSR ¶ 33. Hr'g Tr. 116:12-17, June 6, 2011.

Ruling: No objections to PSR ¶ 33.

(19) Defendant Higgins raises no objections to PSR ¶ 34 & n.8. Hr'g Tr. 116:12-17, June 6, 2011.

Ruling: No objections to PSR ¶ 34.

(20) Defendant Higgins raises no objections to PSR ¶ 35. Hr'g Tr. 116:18-117:2, June 6, 2011; Higgins Doc. No. 138-3 at 4-5.

Defendant initially objected to PSR ¶ 35 n.10 in regard to the allegations that Synthes promoted the mixing of SRS with barium sulphate, which resulted in a "self-created dilemma," but after the Court acknowledged the statements were not factual, Defendant stated he had no factual objections. Hr'g Tr. 116:18-25, June 6, 2011.

PSR ¶ 35 n.10 states the dilemma as follows: "[T]he defense informed . . . that the company was faced with a dilemma: . . . The company could let the surgeons mix Norian with barium sulfate on their own, with the high risk that they would do it incorrectly . . . and of poor outcomes for patients. Or, the company could advise surgeons how to mix it properly, thereby increasing the likelihood of successful outcomes for patients. In the interest of patient safety, the company chose to take the second approach. . . . [The Government contends that Synthes] having created the market for the off-label use of a more radiopaque version of SRS for use in such surgeries in the first place, and having done so in spite of knowledge of the patient risk involved, it seems inaccurate and misleading to say that the companies now faced a 'dilemma' and had to teach surgeons how to perform the off-label procedure 'in the interest of patient safety.'"

In written objections, Defendant disputes that the dilemma was self-created and instead, submits that doctors created the need for Synthes' participation in advising doctors how to mix SRS: "[I]t is in fact a situation that arises because doctors are permitted by law to prescribe drugs and devices for off-label uses as they see fit, and regularly do so." Def. Objections, Doc. No. 138-3 at 5.

Ruling: No objections to PSR ¶ 35; the written objections were withdrawn at the hearing. To the extent the objections were not withdrawn at the hearing, the objections are overruled. The Court makes its own determination of the inferences to be drawn from the evidence.

(21) Defendant Higgins objects to PSR ¶ 36 in regard to the Fall 2002 and December 2002 510(k) pre-market notifications for XR, which granted clearance for XR as a general bone void filler. Hr'g Tr. 117:5-119:1, June 6, 2011; Def. Objections, Doc. No. 138-3 at 5.

Specifically, Defendant objects to the sentence of PSR ¶ 36 that states: "Synthes never told the FDA that its true intended use for XR was to market it for load-bearing spine use such as treating VCFs." Defendant submits that this statement is a "conclusion . . . In some ways it's the heart of what we're doing here, to determine what people intended and knew." Otherwise, Defendant has no factual objections. Hr'g Tr. 117:5-16, June 6, 2011. In written objections, Defendant "objects to the innuendo that Synthes hid 'its true intended use' for Norian XR from the FDA. Mr. Higgins had no intent to hide anything from the FDA." Def. Objections, Doc. No. 138-3 at 5.

Ruling: The objections to PSR ¶ 36 are overruled. As to Defendant's intent, the objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant intended to hide from the FDA the use of XR in vertebroplasties for the treatment of VCFs.

(22) Defendant Higgins raises no objections to PSR ¶ 37. Hr'g Tr. 119:1-3, June 6, 2011.

Ruling: No objections to PSR ¶ 37.

(23) Defendant Higgins objects to PSR ¶ 38 in regard to the January 13, 2003 death of Dr. Sachs' patient. Hr'g Tr. 119:4-14, June 6, 2011; Def. Objections, Doc. No. 138-3 at 5.

Specifically, Defendant objects to the sentence of PSR ¶ 38 that states: "Doctor 4 [Sachs] did not rule out the mixed SRS as a cause of the death." Defendant submits that the statement is incomplete in that: "It was not ruled out - - . . . but it was not ruled in." Hr'g Tr. 119:7-10, June 6, 2011. In written objections, Defendant makes the same argument, stating that he "objects to the innuendo that Doctor No. 4 did not 'rule out' Norian SRS as a cause of death because it implies a connection between Norian and the death. Doctor No. 4 did not 'rule in' Norian SRS as a cause of death either . . . not one of the doctors . . . could say that Norian was the cause of his patient's death." Def. Objections, Doc. No. 138-3 at 5.

Ruling: The objections to PSR ¶ 38 are overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence. Based on the record evidence of relevant conduct, the Court finds that the patients were directly and proximately harmed by the conduct of Defendants and others at Synthes. Defendants subjected the patients to the risks of SRS and XR without the patients' full informed consent and without the FDA's authorization. Some of those patients were injured and some died. By conducting unauthorized clinical trials of SRS mixed with barium sulphate and XR on human beings, Defendants disregarded the safety of all members of society.

(24) Defendant Higgins objects to PSR ¶ 39 concerning the fact that no medical device report (MDR) was filed for the January 13, 2003 death of Dr. Sachs' patient. Hr'g Tr. 119:15-16, June 6, 2011; Higgins Doc. No. 138-3 at 5.

At the hearing, Defendant stated that he has no objections to PSR ¶ 39. Hr'g Tr. 119:15-16, June 6, 2011. In written objections to PSR ¶ 39, however, Defendant makes the same argument that he made in regard to PSR ¶ 38, stating that he "objects to the innuendo that Doctor No. 4 did not 'rule out' Norian SRS as a cause of death because it implies a connection between Norian and the death. Doctor No. 4 did not 'rule in' Norian SRS as a cause of death either . . . not one of the doctors . . . could say that Norian was the cause of his patient's death." Def. Objections, Doc. No. 138-3 at 5.

Also in written objections, Defendant states that he was not involved in the MDR process and cannot speak to the regulatory requirements of that process." Def. Objections, Doc. No. 138-3 at 5.

Ruling: No objections to PSR ¶ 39; the objections were withdrawn at the hearing. To the extent the objections may not have been withdrawn, they are overruled. Defendant presents argument seeking to establish an inference from the evidence: Defendant's lack of intent to violate the regulations requiring the filing of an MDR. The Court makes its own determination of the inferences to be drawn from the evidence.

(25) Defendant Higgins raises no objections to PSR ¶ 40. Hr'g Tr. 119:17-18, June 6, 2011. However, Defendant Bohner raises an objection to PSR ¶ 40, Hr'g Tr. 142:6-143:2, June 6, 2011. The Court will sustain Defendant Bohner's objection in part and the PSR for each Defendant will be corrected accordingly.

Defendant Bohner objects to the phrase in PSR ¶ 40 that states: "In late January 2003, following the first death and eight months before Norian XR was released **outside** the test market, ..." Defendant Bohner submits that XR "was released **to** the test market, not outside of the test market." Hr'g Tr. 142:10-12, June 6, 2011 (emphasis added). The Government agrees: "[I]t was at the end of December 2003 that XR was released outside the test market. . . . it was approximately August of 2003, Your Honor, when it was released to the test market. So 'to' would be correct, Your Honor." Id. at 142:17-19, 23-25.

Ruling: Defendant Bohner's objection to PSR ¶ 40 will be sustained in part and the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Higgins' PSR ¶ 40 to state: "In late January 2003, following the first death and eight months before Norian XR was released **to** the test
market . . . ."

(26) Defendant Higgins objects to PSR ¶ 41 in regard to a February 2003 e-mail from a Synthes employee to the FDA regarding the use of XR with pedicle screws. Hr'g Tr. 119:19-23, June 6, 2011; Def. Objections, Doc. No. 138-3 at 5.

Specifically, Defendant objects that there is no evidence that he ever saw the e-mail and the Government agrees. Hr'g Tr. 119:20-23, June 6, 2011. In written objections, Defendant submits that he "was not involved in the communications reflected in this paragraph [PSR ¶ 41]." Def. Objections, Doc. No. 138-3 at 5. Even assuming this to be true, Defendant does not submit there anything factually inaccurate in PSR ¶ 41.

Ruling: The objection to PSR ¶ 41 is overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(27) Defendant Higgins objects to PSR ¶ 42 & n.13 concerning the July 18, 2003 safety meeting, the FDA inspection in 2004, and the decision by Synthes personnel to proceed with the XR test markets and test sites. Hr'g Tr. 119:24-120:7, June 6, 2011; Def. Objections, Doc. No. 138-3 at 5. Under this general topic, Defendant raises a number of objections, which are ruled on as follows:

(27.a.) Defendant objects to PSR ¶ 42 n.13, because it inaccurately states that he was interviewed during the FDA's inspection, when he was not interviewed. The Government concedes that he was not interviewed. Hr'g Tr. 119:25-120:7, June 6, 2011. In written objections, Defendant makes the same objection. Def. Objections, Doc. No. 138-3 at 5.

Ruling: The objection to PSR ¶ 42 n.13 is sustained. The PO is directed to delete Defendant Higgins' name from PSR ¶ 42 n.13 as one of the individuals interviewed by the FDA investigator during the May-June 2004 inspection.

(27.b.) Although Defendant Higgins does not object, Defendant Huggins objects that PSR ¶ 42 inaccurately states that among the topics addressed at the safety meeting, "thirty-four VCF cases to date" were discussed, when in fact only eight of the 34 cases involved decisions by surgeons to treat VCFs, and those eight cases involved SRS, the label of which cleared SRS for use in the spine and did not include the warning bullet. Hr'g Tr. 91:10-21, June 6, 2011; see also Def. Huggins' Objections, Doc. No. 138-2 at 11 ("the PSR inaccurately asserts that 'thirty-four VCF cases to date' were discussed. PSR ¶ 42."). Accordingly to Huggins, the Government concedes this point and the G never said otherwise at the hearing.

Ruling: Defendant Huggins' objection will be sustained in part and the PSR for each Defendant will be corrected accordingly. The PO is directed to correct Defendant Higgins' PSR ¶ 42 to reflect that "eight of the 34 cases involved the treatment of VCFs."

(27.c.) Defendant Higgins objects that PSR ¶ 42 inaccurately suggests there something improper about test markets. Specifically, he objects to the statement that after the July 18, 2003 safety meeting: "Faced with the choice whether to seek an IDE and a PMA, Synthes and Norian decided to continue the XR 'test market' for use in vertebroplasty to treat VCFs that had begun in the summer of 2002 with SRS, with the goal of having 'test sites' publish results of surgeries." In written objections, Defendant makes the same objection to PSR ¶ 28 in regard to the PSR's characterization of "test markets" and "test sites." Defendant submits that PSR ¶¶ 28 and 42 inaccurately suggest there is something improper about a test market involving "a limited release of an approved product, which physicians, utilizing medical judgment, can choose to use on or off label as they see fit." Def. Objections, Doc. No. 138-3 at 4, 5. Defendant disputes he knew at the time that the conduct amounted to unauthorized clinical trials. Id. He submits that he accepts that violative conduct took place but maintains that he lacked intent to violate the law. Id. See also Defendants similar objections to PSR ¶ 49.

Ruling: The objections to PSR ¶ 42 are overruled. Defendant presents argument seeking to establish an inference from the evidence: Defendant's lack of knowledge that his conduct and the conduct of others at Synthes amounted to unauthorized clinical trials of SRS and XR on human beings in violation of the FDCA. The Court makes its own determination of the inferences to be drawn from the evidence. Based on the record evidence of relevant conduct, the Court finds that Defendant knew and was aware that the Spine Division was conducting unauthorized clinical trials of SRS and XR in violation of the FDCA, and Defendant participated in conducting those unauthorized clinical trials. The Court finds that at the time the clinical trials were planned and were conducted, Defendant knew the trials violated the FDCA.

(28) Defendant Higgins raises no objections to PSR ¶ 43. Hr'g Tr. 120:9, June 6, 2011.

Ruling: No objections to PSR ¶ 43.

(29) Defendant Higgins objects to PSR ¶ 44 in regard to the August 15 and 16, 2003 surgeon training meeting in Charlotte, NC. Hr'g Tr. 120:10-14, June 6, 2011; Def. Objections, Doc. No. 138-3 at 5-6.

Specifically, Defendant objects that PSR ¶ 44 is incomplete: "[O]ur objection is in the nature of completeness, including the failure to indicate the very material fact that the [XR] warning bullet was read word-for-word at these training sessions." Hr'g Tr. 120:10-14, June 6, 2011. In written objections, Defendant submits that PSR ¶ 44 is incomplete because "the materials distributed at the August 2003 training included copies of the FDA approval letter for Norian XR (which reproduced the indication statement) and the Norian XR label (which included the warning 'not intended for treatment of vertebral compression fractures')." Def. Objections, Doc. No. 138-3 at 5-6.

Ruling: The objections to PSR ¶ 44 are overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the record.

(30) Defendant Higgins raises no objections to PSR ¶ 45. Hr'g Tr. 120:16-17, June 6, 2011.

Ruling: No objections to PSR ¶ 45.

(31) Defendant Higgins raises no objections to PSR ¶ 46. Hr'g Tr. 120:18-19, June 6, 2011.

Ruling: No objections to PSR ¶ 46.

(32) Defendant Higgins raises no objections to PSR ¶ 47. Hr'g Tr. 120:20-21, June 6, 2011.

Ruling: No objections to PSR ¶ 47.

(33) Defendant Higgins objects to statements in PSR ¶ 48 concerning the November 2003 draft proposal for an investigational device exemption (IDE). Hr'g Tr. 120:22-121:5, June 6, 2011; Def. Objections, Doc. No. 138-3 at 6.

At the hearing, Defendants did not raise any objections to the facts contained in PSR ¶ 48. However, Defendant Higgins objects that PSR ¶ 48 is incomplete and should be amended to "indicate that there was no obligation for a company to submit its internal consideration about whether or not to do an IDE . . . ." The Government agrees: "There's no obligation to share draft IDE proposals with the FDA." Hr'g Tr. 120:22-121:5, June 6, 2011. In written objections, Defendant raises the same objection: "There is no requirement for a company to tell the FDA that it is merely considering or discussing preparing an IDE proposal." Def. Objections, Doc. No. 138-3 at 6.

Ruling: The objection to PSR ¶ 48 will be sustained in part and the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Higgins' PSR ¶ 48 by adding the sentence:

A company has no obligation to share its draft IDE proposals with the FDA.

Otherwise, the objections are overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(34) Defendant Higgins objects to PSR ¶ 49. Hr'g Tr. 121:6-7, June 6, 2011; Def. Objections, Doc. No. 138-3 at 6.

Specifically, PSR ¶ 49 states that "at the end of December 2003, Synthes released XR for sale beyond the original 'test market'." Defendant did not object to PSR ¶ 49 at

the hearing. However, in written objections to PSR ¶ 49, Defendant makes the same objections to PSR ¶ 49 that he makes to PSR ¶¶ 28 and 42 in regard to the PSR's characterization of "test markets' and "test sites." Defendant submits that PSR ¶¶ 28, 42, and 49 suggest there is something improper about a test market involving "a limited release of an approved product, which physicians, utilizing medical judgment, can choose to use on or off label as they see fit." Def. Objections, Doc. No. 138-3 at 4, 6. Defendant disputes he knew at the time that the conduct amounted to unauthorized clinical trials. Id. He submits the he accepts that conduct in violation of the FDCA took place but maintains he lacked intent to violate the law. Id.

Ruling: No objections to PSR ¶ 49; the written objections were withdrawn at the hearing. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence. As to Defendant's intent, the objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant knew and was aware that the Spine Division was conducting unauthorized clinical trials of SRS and XR in violation of the FDCA, and Defendant participated in conducting those unauthorized clinical trials. The Court finds that Defendant knew, at the time the clinical trials were planned and were conducted, that the trials violated the FDCA.

(35) Defendant Higgins objects to PSR ¶ 50 in regard to the January 10 and 11, 2004 surgeon forum. Hr'g Tr. 121:8-14, June 6, 2011; Def. Objections, Doc. No. 138-3 at 6.

Specifically, Defendant objects that PSR ¶ 50 inaccurately states: "Synthes and Norian representatives did nothing to dispel any confusion that Dr. 4's presentation [explaining to the doctors and rewording the warning on the XR label] may have caused." Defendant submits that: "the evidence shows that the XR warning bullet was read word-for-word at each training session." Hr'g Tr. 121:9-14, 121:8-14, June 6, 2011. See also Defendant's objection to PSR ¶ 44, concerning the August 15 and 16, 2003 surgeon training meeting in Charlotte, NC: "[O]ur objection is in the nature of completeness, including the failure to indicate the very material fact that the [XR] warning bullet was read word-for-word at these training sessions." Hr'g Tr. 120:10-14, June 6, 2011.

In written objections, Defendant objects "because he did not attend the January 2004 surgeon training forum." Def. Objections, Doc. No. 138-3 at 6.

Ruling: The objections to PSR ¶ 50 are overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence. As to Defendant's intent, the objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that at the time that the surgeon forums and physician training sessions were planned and conducted, Defendant knew and was aware that the surgeon forums and physician training sessions were integral parts of clinical trials that violated the FDCA.

(36) Defendant Higgins objects that PSR ¶ 51 is incomplete in regard to the January 22, 2004 death of Dr. No. 7's (Dr. Ball's) patient. Hr'g Tr. 121:15-122:19, June 6, 2011; Def. Objections, Doc. No. 138-3 at 6.

Defendant submits that the PO previously revised PSR ¶¶ 38 and 45 to include the medical history and context for the deaths of Drs. Sachs' and Nottingham's patients. Defendant objects that the PO omitted to make similar revisions to PSR ¶ 51 to reflect the "medical context" for the patient's death. Higgins requests that PSR ¶ 51 be amended to state: "the patient's medical history, that the doctor did not attribute the death to Norian, and the autopsy's inability to draw conclusions because of the prolonged exposure to CPR." Hr'g Tr. 122:8-11, June 6, 2011.

In written objections, Higgins objects "because [PSR ¶ 51] fails to mention, among other things, the patient's medical history (83 year old female with a history of hypertension, atypical angina, lumbar stenosis, and recent pneumonia), and that, at the time, Doctor No. 7 did not attribute the death to the use of Norian XR. Furthermore, this paragraph fails to state that the person who conducted the autopsy noted that no conclusions could be drawn from the presence of foreign material because the patient had undergone prolonged CPR." Def. Objections, Doc. No. 138-3 at 6.

The Government did not object. Hr'g Tr. 122:15-18. The Government stated that it: "certainly has no objection to the Court adding to each of the paragraphs on each of the three deaths that there was - -- each of those persons was an elderly person and each had various other medical problems. That has never been disputed." Hr'g Tr. 176:20-177:2, June 6, 2011.

Ruling: Defendant Higgins' objection to PSR ¶ 51 is sustained in part and the PSR for each Defendant will be corrected; otherwise the objections are overruled. The PO is directed to amend PSR ¶ 51 to include the following statement:

> Dr. No. 7's patient was medically frail, presenting multiple health issues, as was each of the other two patients who died.

(37) Defendant Higgins objects to PSR ¶ 52 as incomplete in regard to the February 2004 "dear surgeon" letter and the fact that he was no longer the President of Synthes Spine Division after January 2004. Hr'g Tr. 122:21-123:11, June 6, 2011; Def. Objections, Doc. No. 138-3 at 6.

Specifically, Defendant objects that PSR ¶ 52 does not reflect that as of the date of the "dear surgeon" letter in February 2004 [see G Ex. 76, "Dear Surgeon" letter dated 2/10/04], he was no longer President of Synthes' Spine Division: "[h]is position starting in February of 2004 was president of global strategies, where his responsibilities were different." Hr'g Tr. 122:21-123:11, June 6, 2011. See also PSR ¶ 20, which Defendant

accepts as true: "From 1999 through 2005, the time period covered by the indictment, Higgins held the positions of President of Synthes' Spine Division from 1999 through January 2004, Senior Vice President of Global Strategy, Synthes from February 2004 through May 2005 . . . ." Defendant does not contend that there are any factual inaccuracies in PSR ¶ 52. In written objections, Defendant raises the same objection that he "was not involved in the dissemination of the letter" and "[t]o the extent the PSR suggests otherwise, Mr. Higgins objects." Def. Objections, Doc. No. 138-3 at 6.

Ruling: The objections to PSR ¶ 52 are overruled. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(38) Defendant Higgins raises no objections to PSR ¶ 53, Victim Impact. Hr'g Tr. 123:12-14, June 6, 2011; Def. Objections, Doc. No. 138-3 at 6-7.

At the hearing, Defendant stated he has no objections. Hr'g Tr. 123:12-14, June 6, 2011. In written objections, Defendant strenuously objects: "[A]s the PSR plainly states elsewhere, there are no victims in this offense. *See* PSR at ¶¶ 62 (Victim-Related Adjustment), and 116 (Restitution). As the PSR itself concludes, 'no independent medical expert has concluded to a reasonable degree of medical certainty that the [Norian] products are a cause of any of the deaths.' PSR at ¶ 53. Accordingly, this portion of the PSR should read: 'None.'" Def. Objections, Doc. No. 138-3 at 6-7.

Ruling: No objections to PSR ¶ 53; the written objections were withdrawn at the hearing. To the extent that any objections may not have been withdrawn, they are overruled. Defendant presents argument. The Court makes its own determination of the inferences to be drawn from the evidence. Based on the record evidence of relevant conduct, the Court finds that the patients were directly and proximately harmed by the conduct of Defendants and others at Synthes. Defendants subjected the patients to the risks of SRS and XR without the patients' full informed consent and without the FDA's authorization. Some of the patients were injured and some died. By conducting unauthorized clinical trials of SRS mixed with barium sulphate and XR on human beings, Defendants disregarded the safety of all members of society.

(39) Defendant Higgins does not raise any objections to PSR ¶ 54, Obstruction of Justice. Hr'g Tr. 123:15-18, June 6, 2011.

Ruling: No objections to PSR ¶ 54.

(40) Defendant Higgins objects to PSR ¶¶ 55-58, Acceptance of Responsibility, submitting that considerations of acceptance of responsibility mandate a Total Offense Level of 4. Hr'g Tr. 23:11-16, 123:15-18, June 6, 2011; Def. Objections, Doc. No. 138-3 at 7-10.

At the hearing, Defendant Higgins did not state any objections based on acceptance of responsibility, appearing to rely on the Court's earlier discussion of the

issues with Defendant Huggins. Defendant Higgins: "That's been covered in the morning, so." Hr'g Tr. 123:15-18, June 6, 2011. In written objections, Defendant Higgins raises the same objections as Defendant Huggins. Def. Objections, Doc. No. 138-3 at 7-10.

At the hearing, Defendant Higgins focused his objections on whether the Court should consider intent in its analysis of relevant conduct, when the offense is a strict liability misdemeanor that does not require proof of mens rea. However, Defendant Higgins unequivocally concedes that under the responsible corporate officer doctrine, a no-intent strict liability misdemeanor offense, the Court may consider relevant conduct and intent. Hr'g Tr. 23:11-16, June 6, 2011.

Ruling: Defendant Higgins' objection to PSR ¶ 58 is sustained in part and the PSR for each Defendant will be corrected; otherwise the objections are overruled. The PO is directed to correct the PSR as follows:

(a) The PO is directed to delete the sentence in the PSR that states: "The government, by the Park requirement, has established a prima facie case." PSR ¶ 58. The PO is directed to add the following sentence to PSR ¶ 58: "The parties have stipulated that Defendant was a responsible corporate officer within the meaning of the applicable law. Plea Agreement ¶¶ 1, 9."

(b) The PO is directed to delete the sentence in PSR ¶ 58 that states: "Therefore, it is necessary under the Guidelines Manual for the defendant to make a greater admission to the facts of the offense, including relevant conduct, in order to qualify for the two-level reduction."

(41) Defendant Higgins raises no objections to PSR ¶¶ 59, 61, 62, 63, 64, 65, and 68, Offense Level Computation.

Ruling: No objections to PSR ¶¶ PSR ¶¶ 59, 61, 62, 63, 64, 65, and 68.

(42) Defendant Higgins raises no objections to PSR ¶ 60, Base Offense Level, Application of Guideline § 2N2.1 vs. 2X5.2. However, Defendant Huggins raised an objection but then withdrew the objection.

At the hearing, Defendant Huggins objected to the application of § 2N2.1 in PSR ¶ 60, but then expressly withdrew the objection. See Hr'g Tr. 67:9-11, 66:25-67:11, June 6, 2011. Defendants Higgins, Bohner, and Walsh made no express objections to the application of § 2N2.1 as opposed to 2X5.2.

In each defendant's Plea Agreement, ¶ 11(a), it was stipulated: "The parties agree to disagree concerning whether USSG § 2N2.1(a) or § 2X5.2 applies to this case." Plea

Agreements, ¶ 11(a): Def. Huggins, Doc. No. 34 at 9; Def. Higgins, Doc. No. 42 at 9; Def. Bohner, Doc. No. 64 at 9; Def. Walsh, Doc. No. 68 at 9. See also Higgins' PSR ¶ 104, Sentencing Options, Impact of the Plea Agreement, which states:

> The parties agreed to disagree as to whether USSG § 2N2.1(a) or § 2X5.2 applie[s] in this case. Appendix A of the Guidelines Manual specifies that the appropriate offense guideline section in Chapter Two applicable to the statute of conviction is found in § 2N2.1. Regardless of which guideline section applie[s], the same total offense level would be obtained. In any event, the Court may need to address this dispute at the time of sentencing.

Ruling: The Court rules that Guideline § 2N2.1 applies.

(43) Defendant Higgins raises no objections to PSR ¶¶ 66, 67, and 69. However, Defendant Huggins raises objections to PSR ¶ 66 (Adjustment for Acceptance of Responsibility), ¶ 67 (Adjusted Offense Level), and ¶ 69 (Total Offense Level), which the Court will sustain and the PSR for each Defendant will be corrected accordingly.

Ruling: Defendant Huggins' objections to PSR ¶¶ 66, 67, and 69 will be sustained and the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Higgins' PSR as follows:

Ruling: The objection to PSR ¶ 66 is sustained; the PO is directed to change 0 to **2**.
Ruling: The objection to PSR ¶ 67 is sustained; the PO is directed to change 6 to **4**.
Ruling: The objection to PSR ¶ 69 is sustained; the PO is directed to change 6 to **4**.

(44) Defendant Higgins raises no objections to PSR ¶¶ 70-75, Defendant's Criminal History.

Ruling: No objections to PSR ¶¶ 70-75.

(45) Defendant Higgins raises no objections to PSR ¶¶ 76-99, and 101, Offender Characteristics.

Ruling: No objections to PSR ¶¶ 76-99, and 101.

(46) Defendant Higgins raises no objections to PSR ¶ 100, Offender Characteristics, Applicable Guideline Range for Fine. However, Defendant Huggins objects to his PSR ¶ 103, Offender Characteristics, Applicable Guideline Range for Fine, which the Court will sustain in part and the PSR for each Defendant will be corrected accordingly.

In written objections, Defendant Huggins submits: "Although [he] has agreed to pay the maximum statutory fine of $100,000, the PSR nonetheless should, but does not, state the applicable fine range under USSG § 5E1.2(c)(3). . . . That guideline recommends

a minimum fine of $250.00 and a maximum fine of $5,000. The fact that [Defendant] has agreed to pay a fine 400 times greater than the minimum fine recommended by the guideline and 20 times greater than the maximum is material to the Court's overall sentencing determination." Def. Objections, Doc. No. 138-2 at 7, n.6.

Although Defendant Huggins objects that the guideline range for a fine was omitted, Defendants Higgins, Bohner, and Walsh do not object to the omission. The amendment of the total offense level from 6 to 4 changes the guideline range for the fine from $500.00-$5,000.00 to $250.00-$5,000.00. Thus, the PSR for each defendant will be amended to reflect the correct guideline range for a fine.

Ruling: The PO is directed to correct Defendant Higgins' PSR ¶ 100 to include the following statements:

> Pursuant to USSG § 5E1.2(a), "[t]he court shall impose a fine in all cases, except where the defendant establishes that he is unable to pay and is not likely to become able to pay any fine." For a total offense level of 4, USSG § 5E1.2(c)(3) specifies a minimum fine of $250.00 and a maximum fine of $5,000. The Defendant has agreed to pay a fine of $100,000, the statutory maximum fine permitted for a Class A misdemeanor. Plea Agreement, ¶ 5. The Defendant has the ability to satisfy a fine within the guideline range and has agreed to satisfy the $100,000 fine to which the parties stipulated and agreed. The fine may be satisfied in a lump sum or via a monthly installment plan.

(47) Defendant Higgins raises no objections to PSR ¶¶ 102, 104, 106-114, 116-117, Sentencing Options.

Ruling: No objections to PSR ¶¶ 102, 104, 106-114, 116-117.

(48) Defendant Higgins raises no objections to PSR ¶ 103, Sentencing Options, Guideline Provisions, which states:

> Pursuant to USSG Chapter 5, Part A, based on a total offense level of 6 and criminal history category of 1, the guideline range for imprisonment is 0 to 6 months.

Although Defendant Higgins does not object, Defendant Huggins objects to the same statement in his PSR ¶ 106, Sentencing Options, Guideline Provisions based on considerations of acceptance of responsibility. Def. Huggins' Objections, Doc. No. 138-2 at 5-6. Defendant Bohner also objects to the same statement in his PSR ¶ 108. Def. Bohner's Objections, Doc. No. 138-4 at 13. In this case, considerations of acceptance of responsibility do not affect the base offense level guideline range of 0 to 6 months for imprisonment. However, Defendants Huggins and Bohner object to the statement of the

total offense level as being "6," instead of "4." Defendants Higgins and Walsh do not object. Because the Court will sustain in part Huggins' objection to his PSR ¶ 106 and Bohner's objection to his PSR ¶ 108, the PSR for each Defendant will be corrected accordingly.

Ruling: The objections will be sustained in part; otherwise the objections will be overruled as argument. The Court makes its own determination of the applicable legal principles. The PO is directed to amend Higgins' PSR ¶ 103 to correct the total offense level from **6** to **4**, stating as follows:

> Pursuant to USSG Chapter 5, Part A, based on a total offense level of **4** and criminal history category of 1, the guideline range for imprisonment is 0 to 6 months.

(49) Defendant Higgins raises no objections to PSR ¶ 105, Sentencing Options, Impact of the Plea Agreement, which states in part:

> The parties agreed to a two-level reduction to the offense, pursuant to USSG § 3E1.1(a), in the plea agreement. However, the downward adjustment, though appropriate at the time of the plea agreement, is not applied in the guideline calculations in the presentence report. The Court will need to make the final determination as to downward adjustment. Whether or not the downward adjustment is applied, there is no alteration in the guideline range.

Ruling: Although Defendant Higgins does not object to PSR ¶ 105, the PSR for each Defendant will be corrected. The PO is directed to correct and amend the PSR by deleting the sentences of PSR ¶ 105 quoted above and stating instead:

> The two-level reduction of the total offense level for acceptance of responsibility pursuant to USSG § 3E1.1(a) applies.

(50) Defendant Higgins raises no objections to PSR ¶ 115, Sentencing Options, Fines, Guideline Provisions, which states:

> The fine range for the instant offense is from $500 to $5,000, pursuant to USSG § 5E1.2(c)(3). The court shall impose a fine in all cases except where the defendant establishes that he is unable to pay and is not likely to become able to pay any fine, pursuant to USSG § 5E1.2(a).

Ruling: Although Defendant Higgins does not object to PSR ¶ 115, the PSR for each Defendant will be corrected. The PO is directed to correct PSR ¶ 115 by stating:

> The fine range for the instant offense is from **$250 to $5,000**, pursuant to USSG § 5E1.2(c)(3). The court shall impose a fine in all cases except where the defendant establishes that he is unable to pay and is not likely to become able to pay any fine, pursuant to USSG § 5E1.2(a).

At the hearing, Defendant Higgins stated that he has no other objections to the PSR. Hr'g Tr. 123:20-21, June 6, 2011.

RULINGS ON DEFENDANT RICHARD E. BOHNER'S OBJECTIONS

Defendant Richard E. Bohner objects to portions of the Government's Presentence Report. The Court rules on each objection as follows:

(1) Defendant Bohner objects to typographical errors in PSR ¶ 6, Charges and Convictions. Hr'g Tr. 150:8-16, June 6, 2011; Def. Objections, Doc. No. 138-4 at 3.

Ruling: The objection to PSR ¶ 6 is sustained. The PO is directed to correct the typographical errors in PSR ¶ 6 to correctly state the Defendant's name:

> On August 13, 2009, **Richard E. Bohner**, in accordance with that written plea agreement, appeared before the Honorable Lawrence F. Stengel . . . .

(2) Defendant Bohner raises no objections to PSR ¶¶ 17, 18, 20, 22, Offense Conduct. Hr'g Tr. 124:14-126:5.

Ruling: No objections to PSR ¶¶ 17, 18, 20, 22.

(3) Defendant Bohner objects to PSR ¶ 19, Offense Conduct. Hr'g Tr. 124:25-125:10, June 6, 2011; Def. Objections, Doc. No. 138-4 at 3.

> Specifically, Defendant objects to PSR ¶ 19, which in part states: "John Walsh reported to Huggins indirectly, through Bohner, from August 2003 until February 2004 . . . ." Defendant contends that Defendant Walsh reported to him until January 2004, at which time Walsh began reporting to Fran Magee. The Government agrees. Hr'g Tr. 124:25-125:4, 125:8, June 6, 2011.

Ruling: The objection to PSR ¶ 19 is sustained. The PO is directed to amend PSR ¶ 19 to correctly state:

> John Walsh reported to Huggins indirectly, through Bohner, from August 2003 until **January 2004, at which time Mr. Walsh began reporting to Fran Magee** . . . .

(4) Defendant Bohner objects to PSR ¶ 21, Offense Conduct. Hr'g Tr. 125:12-126:3, June 6, 2011.

Specifically, Defendant objects that PSR ¶ 21 inaccurately implies that he "was involved in the management and oversight of the spine division," and "suggests that he was more involved in the spine division than any of his other numerous responsibilities, because as is pointed out in the paragraph itself, he was responsible for overseeing many parts of the company . . . ." Hr'g Tr. 125:14-22, June 6, 2011. In written objections, Defendant raises the same objection that PSR ¶ 21 improperly suggests that he led or managed the Spine Division. Defendant contends that he: "never held a position in the Spine Division, nor did he lead or manage the Spine Division. As Vice President of Operations, Mr. Bohner was not involved in the Spine Division more than any other product division of the company." Def. Objections, Doc. No. 138-4 at 3. However, at the hearing, Defendant stated that in regard to PSR ¶ 21, "the words as written are accurate." Hr'g Tr. 125:25, June 6, 2011.

Ruling: The objection to PSR ¶ 21 is overruled. Defendant concedes that there is nothing factually inaccurate in PSR ¶ 21. The Court makes its own determination of the inferences to be drawn from the evidence.

(5) Defendant Bohner raises no objections to PSR ¶¶ 23 through 26, Medical Context. Hr'g Tr. 126:6-9, June 6, 2011.

Ruling: No objections to PSR ¶¶ 23, 24, 25, 26.

(6) Defendant Bohner objects to PSR ¶ 27 in regard to the market research and interviews of doctors about the use of SRS to treat VCFs. Hr'g Tr. 126:10-127:10, June 6, 2011.

Specifically, Defendant objects that he "was not involved at all in the market research" described in PSR ¶ 27. Defendant's counsel stated: "Now, the paragraph doesn't say he was involved but . . . . So I feel betwixt and between about whether I should object to every paragraph where it doesn't refer to him, because I'm worried he'll be lumped in with everybody else, or not object, because it's accurate as written, but leaves the Court with the wrong impression that somehow he's involved." Hr'g Tr. 126:11-127:2, June 6, 2011. In written objections, Defendant states: "[he] did not approve, direct or participate in the surgeon interviews. The market research was carried out by the Spine Division. . . . [He] never held a position in or managed the Spine Division." Def. Objections, Doc. No. 138-4 at 3.

Ruling: The objections to PSR ¶ 27 are overruled. Defendant concedes there is nothing factually inaccurate in PSR ¶ 27. The Court makes its own determination of the inferences to be drawn from the evidence.

(7) Defendant Bohner objects to PSR ¶ 28 & n.7. Hr'g Tr. 127:11-133:3, June 6, 2011.

Specifically, Defendant refers to PSR ¶ 28, which states in part that there was a November 2001 management meeting attended by Huggins, Higgins, and other top Synthes officials. Defendant objects that PSR ¶ 28 might be mistakenly read to imply that Defendant Bohner attended the meeting, when he did not. Hr'g Tr. 127:12-18, June 6, 2011. Defendant raises the same concern in his written objections: "Mr. Bohner did not attend the November 2001 management meeting that is discussed in this paragraph, as is corroborated by the minutes of the meeting." Def. Objections, Doc. No. 138-4 at 3.

In regard to PSR ¶ 28, n.7, concerning the term "test market," Defendant disputes: that the purpose of the market research was to create a market; that he knew at the time that the test markets were illegal; and that he approved, directed or participated in the surgeon interviews that are referred to in footnote 7. Hr'g Tr. 128:7-17, 132:18-20, June 6, 2011. In written objections, Defendant raises a similar objection. Def. Objections, Doc. No. 138-4 at 4.

Defendant also objects to PSR ¶ 28, n.7, which states in part: "The defendants were reportedly unaware that the test market of a FDA approved product would be considered a violation of law or that the FDA would require the company to pursue an IDE before conducting such a test market. This argument here, again, seems to contradict the stipulations made by the parties in the plea agreement." Defendant submits that his lack of awareness does not contradict the stipulations in his plea agreement. Hr'g Tr. 132:22-25, June 6, 2011. In written objections, Defendant raises a similar objection. Def. Objections, Doc. No. 138-4 at 4. Defendant contends: "[He] did not attend a test market training session; did not supervise the employees who organized and conducted the test market sessions; and we are not aware of any evidence that [he] reviewed or approved the test market presentations or the evaluation forms used for them." Id.

Ruling: The objections to PSR ¶ 28 are overruled. Defendant concedes that there is nothing factually inaccurate in PSR ¶ 28. The Court makes its own determination of the inferences to be drawn from the evidence. As to Defendant's knowledge and intent, the objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant knew and was aware that the Spine Division was conducting "test markets" that amounted to unauthorized clinical trials of SRS and XR in violation of the FDCA, and Defendant participated in conducting those trials. The Court finds Defendant knew at the time the clinical trials were planned and were conducted that the trials violated the FDCA.

(8) Defendant Bohner objects to PSR ¶ 29. Hr'g Tr. 133:12-134:4, June 6, 2011; Def. Objections, Doc. No. 138-4 at 4.

Specifically, Defendant objects that PSR ¶ 29 is incomplete: "It fails to explain that it was lawful to seek a general regulatory clearance from the FDA and later apply for

a specific indication. The paragraph fails to explain . . . that in Synthes' 510(k) application, Synthes' proposed labeling described the intended use of SRS in general terms. And it specifically included use in the spine. . . . At this time, December of 2001, Synthes filed for a clearance for SRS as a general bone void filler for use in the spine." Hr'g Tr. 133:14-134:2, June 6, 2011. Defendant raises the same objection in his written objections. Def. Objections, Doc. No. 138-4 at 4.

Ruling: The objections to PSR ¶ 29 are overruled. Defendant presents argument. The SRS labels are in evidence. The Court makes its own determination of the applicable legal principles and the inferences to be drawn from the evidence.

(9) Defendant Bohner raises no objections to PSR ¶ 30. Hr'g Tr. 134:6, June 6, 2011.

Ruling: No objections to PSR ¶ 30.

(10) Defendant Bohner objects to PSR ¶ 31. Hr'g Tr. 134:9-19, June 6, 2011; Def. Objections, Doc. No. 138-4 at 5.

Specifically, as referenced in PSR ¶ 31, Defendant objects that he did not participate in the May 8, 2002 telephone conference with the FDA, during which the mixing of SRS with barium sulphate was discussed. However, Defendant concedes that his name is not mentioned in PSR ¶ 31, and he has no objections to the facts contained in PSR ¶ 31 as written. Hr'g Tr. 134:9-18, June 6, 2011. Defendant raises the same objection in written objections. Def. Objections, Doc. No. 138-4 at 5.

Ruling: The objections to PSR ¶ 31 are overruled. The Court makes its own determination of the inferences to be drawn from the evidence.

(11) Defendant Bohner objects to PSR ¶ 32. Hr'g Tr. 134:9-19, June 6, 2011; Doc. No. 138-4 at 5.

Specifically, Defendant objects to the statement in PSR ¶ 32 about a December 2002 meeting of Synthes employees. Defendant objects that he did not participate in the meeting. Defendant concedes that his name is not mentioned in PSR ¶ 32, and he has no objections to the facts contained in PSR ¶ 32 as written. Hr'g Tr. 134:9-18, June 6, 2011. In written objections, Defendant raises the same objection. Def. Objections, Doc. No. 138-4 at 5.

In written objections, Defendant objects that PSR ¶ 32 is incomplete: "It omits the evidence showing confusion about the SRS label. A surgeon testified before the grand jury that "it's easy to Monday morning quarterback," but reading the label it's reasonable to interpret it to mean that "if you don't believe that you need bony stability, you could still use this Norian or PMMA or any other cement to fill a bone void in the

entire skeleton from the neck all the way down to the toes." Def. Objections, Doc. No. 138-4 at 5.

Ruling: The objections to PSR ¶ 32 are overruled. The SRS labels are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(12) Defendant Bohner raises no objections to PSR ¶ 33. Hr'g Tr. 134:21, June 6, 2011.

Ruling: No objections to PSR ¶ 33.

(13) Defendant Bohner objects to PSR ¶ 34 & n.8. Hr'g Tr. 134:22-138:6, June 6, 2011; Def. Objections, Doc. No. 138-4 at 5.

Specifically, Defendant concedes that in PSR ¶ 34(A) "[n]o affirmative statements are incorrect," but objects that additional facts should have been stated. Hr'g Tr. 135:5-10, June 6, 2011. In regard to PSR ¶ 34(A), Defendant states he had no advance knowledge of Dr. Delamarter's surgeries in February 2001 that resulted in the two hypotensive events; and following those events, the company sent "a strongly worded message to the sales force that Synthes cannot promote and does not support off-label use of these products." Defendants submits that he participated in that email. Id. at 135:23-136:6. In written objections, Defendant raises the same objection. Def. Objections, Doc. No. 138-4 at 5 (*e.g.*, "The message instructed sales consultants not to be present during cases involving off-label uses of Norian products, and warned that disciplinary action might be imposed if consultants failed to comply with this instruction."). See also Defendant's objections to PSR ¶¶ 38 and 40 below.

In regard to PSR ¶ 34(B), Defendant objects that the paragraph "does not state that the surgeons and doctors that attended the meeting could not determine the cause of Dr. Number 1's hypotensive events." Hr'g Tr. 137:5-8, June 6, 2011. In written objections, Defendant raises the same objection. Def. Objections, Doc. No. 138-4 at 5.

In regard to PSR ¶ 34(C) and (D), Defendant states that he has no objections. Hr'g Tr. 137:22-23, June 6, 2011. In written objections, Defendant did not object to PSR ¶ 34 (C) and (D). Def. Objections, Doc. No. 138-4 at 5.

In regard to PSR ¶ 34(E), Defendant objects that the paragraph fails to state that "the XR product manager informed Synthes employees in July 2003, that per her discussions with Dr. Number 3, the University of Washington studies were not intended for drawing conclusion[s] regarding human clinical experience." Hr'g Tr. 137:25-138:4, June 6, 2011. In written objections, Defendant raises the same objection. Def. Objections, Doc. No. 138-4 at 5.

Ruling: The objections to PSR ¶ 34 & n.8 are overruled. Defendant presents argument. Defendant does not object to any facts contained in PSR ¶ 34(A) through (E). The additional facts that Defendant suggests should be included in PSR ¶ 34 are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(14) Defendant Bohner objects to PSR ¶ 35 & n.10. Hr'g Tr. 138:7-139:8, June 6, 2011; Def. Objections, Doc. No. 138-4 at 5-6.

Specifically, Defendant objects to the statement in PSR ¶ 35: "Synthes and Norian approved the SRS test market in the spine, in which the companies taught spine surgeons how to mix SRS with barium sulfate and use it in surgeries to treat VCFs." Defendant objects to the extent that this statement suggests he approved this, even though his name is not mentioned. Hr'g Tr. 138:8-17, June 6, 2011. In written objections, Defendant objects to PSR ¶ 35 "insofar as it suggests that he engaged in intentional wrongdoing." Def. Objections, Doc. No. 138-4 at 6.

Defendant objects to the allegation in PSR ¶ 35 n.10 of a "self-created dilemma": "[T]he defense informed . . . that the company was faced with a dilemma: . . . The company could let the surgeons mix Norian with barium sulfate on their own, with the high risk that they would do it incorrectly . . . and of poor outcomes for patients. Or, the company could advise surgeons how to mix it properly, thereby increasing the likelihood of successful outcomes for patients. In the interest of patient safety, the company chose to take the second approach. . . . [The Government contends that] having created the market for the off-label use of a more radiopaque version of SRS for use in such surgeries in the first place, and having done so in spite of knowledge of the patient risk involved, it seems inaccurate and misleading to say that the companies now faced a 'dilemma' and had to teach surgeons how to perform the off-label procedure 'in the interest of patient safety.'" Defendant Bohner objects to this statement for the same reasons that Defendant Higgins objects. Hr'g Tr. 139:4-5, June 6, 2011. However, earlier at the hearing, Defendant Higgins initially objected to PSR ¶ 35 n.10 in regard to allegations of Synthes' "self-created dilemma," but after the Court acknowledged the statements were not factual, Higgins stated he had no factual objections. Hr'g Tr. 116:18-25, June 6, 2011. In written objections, Defendant Bohner objects that he never made the "inaccurate and misleading argument" about a "dilemma," as ascribed in PSR ¶ 35 n.10 to "the defense." Def. Objections, Doc. No. 138-4 at 6. He also objects that he did not approve, direct or participate in the surgeon interviews or other aspects of this market research that allegedly led to the "self-created dilemma" as referenced in PSR ¶ 35 n.10. Id.

Ruling: The objections to PSR ¶ 35 & n.10 are overruled. Defendant presents argument. Defendant concedes that his name is not mentioned in PSR ¶ 35. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(15) Defendant Bohner objects to PSR ¶ 36. Hr'g Tr. 139:9-12, June 6, 2011; Def. Objections, Doc. No. 138-4 at 6.

Specifically, Defendant objects to PSR ¶ 36, stating that he "did not draft or review the company's 510(k), but it does not specifically state that he did." Hr'g Tr. 139:10-12, June 6, 2011. In written objections, Defendant raises the same objection. Def. Objections, Doc. No. 138-4 at 6.

Ruling: The objections to PSR ¶ 36 are overruled. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(16) Defendant Bohner raises no objections to PSR ¶ 37. Hr'g Tr. 139:13-14, June 6. 2011. In written objections, Defendant did not object to PSR ¶ 37.

Ruling: No objections to PSR ¶ 37.

(17) Defendant Bohner objects to PSR ¶ 38 in regard to the January 13, 2003 death of Dr. Sachs' patient. Hr'g Tr. 139:15-18, June 6, 2011; Def. Objections, Doc. No. 138-4 at 7.

At the hearing, Defendant stated: "Our only objection here is that Mr. Bohner had no advance knowledge of this surgery, but this paragraph doesn't say that he did." Hr'g Tr. 139:16-18, June 6, 2011. In written objections, Defendant makes the same objection and further states that "[t]he consultant's presence during procedures involving off-label use of the CRS and SRS products was against company instructions to the sales force in March 2001." Def. Objections, Doc. No. 138-4 at 7. See also Defendant's objections to PSR ¶¶ 34(A) and 40.

Ruling: The objections to PSR ¶ 38 are overruled. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(18) Defendant Bohner objects to PSR ¶ 39 & n.12 in regard to the fact that no medical device report (MDR) was filed for the January 13, 2003 death of Dr. Sachs' patient. Hr'g Tr. 139:19-142:6, June 6, 2011; Def. Objections, Doc. No. 138-4 at 7-8.

Specifically, Defendant objects: "This paragraph omits evidence that when Mr. Bohner first learned of the death of [Dr. Sachs'] patient, [he] expressed concern that when a death occurs, a manufacturer only has a given number of days to report the incident to the FDA." Hr'g Tr. 139:20-25, 140:7-11, June 6, 2011. In written objections, Defendant raises the same objection. Def. Objections, Doc. No. 138-4 at 7. The Government responds: "[T]he Government would not object to the addition that [Defendant Bohner] is suggesting. We believe that that information was given by Mr. Bohner to other people at the MIP [market introduction plan for XR] meeting in late January of 2003. . . . And that he did express that concern . . . ." Hr'g Tr. 141:9-18, June 6, 2011.

Defendant also objects that PSR ¶ 39 "fails to state that company documents show an MDR was not filed for the death of this patient, because the death did not meet the definition of an MDR reportable event. Medical professionals did not believe the product caused or contributed to the patient's death." Hr'g Tr. 141:20-142:6, June 6, 2011. In written objections, Defendant raised a similar argument. Def. Objections, Doc. No. 138-4 at 7.

Defendant objects to PSR ¶ 39 n.12, which states in part: "A MDR is filed in cases where the product cannot be ruled out as a cause of death. This would have been the case for any of the three patients deaths, regardless of their state of health before the surgeries." Defendant contends that the decision not to file the MDR was reasonable and lawful. Defendant asserts that PSR ¶ 39 n.12 is incomplete because it "fails to state that, per the applicable regulation, manufacturers 'do not have to report adverse events for which there is information that would cause a person who is qualified to make a medical judgment (e.g. a physician, nurse, risk manager, or biomedical engineer) to reach a reasonable conclusion that a device did not cause or contribute to a death or serious injury . . . .' 21 C.F.R. § 803.20(c)(2) (2003). Contrary to the implication of footnote 12, the state of a patient's health before surgery is highly relevant to this determination." Def. Objections, Doc. No. 138-4 at 7-8.

Ruling: The objections PSR ¶ 39 & n.12 are overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the applicable legal principles and the inferences to be drawn from the evidence.

(19) Defendant Bohner objects to PSR ¶ 40. Hr'g Tr. 142:6-143:2, June 6, 2011. Defendant raises a number of objections to PSR ¶ 40, which are ruled on as follows:

(19.a.) Defendant Bohner objects to the phrase in PSR ¶ 40 that states: "In late January 2003, following the first death and eight months before Norian XR was released **outside** the test market, ..." Defendant Bohner submits that XR "was released **to** the test market, not outside of the test market." Hr'g Tr. 142:10-12, June 6, 2011 (emphasis added). The Government agrees: "[I]t was at the end of December 2003 that XR was released outside the test market. . . . it was approximately August of 2003, Your Honor, when it was released to the test market. So 'to' would be correct, Your Honor." Id. at 142:17-19, 23-25.

Ruling: Defendant Bohner's objection is sustained in part and the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Bohner's PSR ¶ 40 to state: "In late January 2003, following the first death and eight months before Norian XR was released **to** the test market . . . ."

(19.b.) Defendant also objects to PSR ¶ 40 for the same reasons he objects to PSR ¶¶ 34(A) and 38, that these paragraphs omit certain facts concerning an e-mail that he

forwarded to management notifying the sales force that Norian should not be promoted for off-label uses. Defendant also submits that PSR ¶¶ 34(A), 38, and 40 should be revised to include a statement that the FDA does not regulate the practice of medicine and therefore, doctors can choose what products to use as they see fit. Defendant objects that PSR ¶ 40 "incorrectly states that [he] included the VCF warning in his proposed e-mail to the sales force as an example of what off-label uses were forbidden, and that [he] understood the treatment of VCFs was forbidden." Hr'g Tr. 143:3-25, June 6, 2011.

Counsel for Defendant Bohner did not identify the exhibit numbers for the e-mails he referenced. Apparently, counsel was referring to e-mails discussed in regard to PSR ¶¶ 34(A) and 38. See G. Ex. 26 (Huggins 3/16/01 e-mail to Bohner and others, stating "You need to real [sic, 'reel in'] the sales force"); G. Ex. 52 (e-mail chain: Huggins 3/29/01 e-mail to sales force about company's position on off-label uses of SRS or CRS; Bohner 1/28/03 e-mail forwarding Huggins 3/29/01 e-mail to Huggins and Higgins.) Counsel also submits that Defendant Bohner sent a February 17, 2003 e-mail, which was copied to Spine Division employees, "which made very clear that he did not support Spine's proposed revisions to the message to the sales force, and he warned that supporting off-label usage is a violation of federal law." Defendant Bohner stated in that e-mail: "Supporting off-label usage is a violation of federal law." Hr'g Tr. 144:1-7, June 6, 2011; Def. Objections, Doc. No. 138-4 at 9, 8-9.

Ruling: The objections to PSR ¶¶ 34(A), 38, and 40 are overruled. The relevant communications and facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(20) Defendant Bohner objects to PSR ¶ 41 in regard to a February 2003 email from a Synthes employee to the FDA concerning the use of XR with pedicle screws. Hr'g Tr. 144:16-23, June 6, 2011; Def. Objections, Doc. No. 138-4 at 9.

Specifically, Defendant objects that "he never received this communication that's described in paragraph 41. But the paragraph doesn't say that he did . . . . So it's not affirmatively inaccurate." Hr'g Tr. 144:19-22, June 6, 2011. In written objections, Defendant objects insofar as PSR ¶ 41 suggests "he either received or was aware of this email exchange. The Synthes employee who sent this email to the FDA did not report directly to Mr. Bohner at that time. (Moreover, under the applicable regulation, an informal email from a FDA representative does not constitute official FDA guidance.)" Def. Objections, Doc. No. 138-4 at 9.

Ruling: The objection to PSR ¶ 41 is overruled. The relevant facts are in evidence. The Court makes its own determination of the applicable legal principles and the inferences to be drawn from the evidence.

(21) Defendant Bohner raises a number of objections to PSR ¶ 42 in regard to a July 18, 2003 "safety meeting" of Synthes personnel. Hr'g Tr. 144:23-145:8, June 6, 2011. The Court rules on the objections as follows:

(21.a.) Although Defendant Bohner does not raise the objection, Defendant Huggins raises an objection to PSR ¶ 42 that the Court will sustain in part.

Specifically, Defendant Huggins objects that PSR ¶ 42 inaccurately states that among the topics addressed at the safety meeting, "thirty-four VCF cases to date" were discussed, when in fact only eight of the 34 cases involved decisions by surgeons to treat VCFs, and those eight cases involved SRS, the label of which cleared SRS for use in the spine and did not include the warning bullet. Hr'g Tr. 91:10-21, June 6, 2011; see also Def. Huggins' Objections, Doc. No. 138-2 at 11 ("the PSR inaccurately asserts that 'thirty-four VCF cases to date' were discussed. PSR ¶ 42."). Accordingly to Huggins, the Government concedes this point and the G never said otherwise at the hearing.

Ruling: Defendant Huggins' objection to PSR ¶ 42 will be sustained in part and the PSR for each Defendant will be corrected; otherwise the objection is overruled as argument. The PO is directed to correct Defendant Bohner's PSR ¶ 42 to reflect that "eight of the 34 cases involved the treatment of VCFs."

(21.b.) Defendant Bohner objects that PSR ¶ 42 "fails to state that the XR product manager informed the attendees that [Dr. Sachs] did not attribute the death of his patient to Norian's product. The product manager informed the attendees that the death of [Dr. Sachs'] patient was a non-reportable event, and . . . the attendees were informed that the University of Washington studies were not to be used in making conclusions in human clinical experience." Hr'g Tr. 144:25-145:8, June 6, 2011. In written objections, Defendant makes the same objection. Def. Objections, Doc. No. 138-4 at 9.

In written objections, Defendant also objects that at the time of the July 18, 2003 safety meeting, he did not believe that proceeding with the test market plan was illegal. Def. Objections, Doc. No. 138-4 at 9.

Ruling: The objections to PSR ¶ 42 are overruled. Defendant presents argument not an objection to the facts contained in PSR ¶ 42. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(22) Defendant Bohner raises no objections to PSR ¶ 43. Hr'g Tr. 145:10, June 6, 2011; Def. Objections, Doc. No. 138-4 at 9.

Ruling: No objections to PSR ¶ 43.

(23) Defendant Bohner objects to PSR ¶ 44 in regard to the August 15 and 16, 2003 surgeon training meeting in Charlotte, NC. Hr'g Tr. 145:10-22, June 6, 2011; Def. Objections, Doc. No. 138-4 at 10.

Specifically, Defendant objects that he "didn't supervise the employees who organized and conducted the test market session. We're not aware of any evidence that he reviewed or approved the test market presentations or the evaluation form . . . at the time the test market was occurring." Hr'g Tr. 145:13-19, June 6, 2011. Defendant concedes that the paragraph does not say that he did any of those things. Id. at 145:20-22. In written objections, Defendant raises the same objection, adding that he "did not attend a test market training session." Def. Objections, Doc. No. 138-4 at 10.

Ruling: The objections to PSR ¶ 44 are overruled. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(24) Defendant Bohner objects to PSR ¶ 45 in regard to the September 19, 2003 death of Dr. Nottingham's patient. Hr'g Tr. 145:23-146:10, June 6, 2011; Def. Objections, Doc. No. 138-4 at 10.

Specifically, Defendant objects that he "had no advance knowledge of this surgery or that a sales consultant would be present during the surgery," but concedes that the paragraph does not say that "any of those circumstances existed." Hr'g Tr. 145:25-146:6, June 6, 2011. Defendant disputes the characterization in PSR ¶ 45 of the MDR as vague: "the MDR was not vague as to the fact that a patient had died during use of Norian XR in a spinal procedure." Id. at 146:8-10. In written objections, Defendant raises the same objection. Def. Objections, Doc. No. 138-4 at 10.

Ruling: The objections to PSR ¶ 45 are overruled. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(25) Defendant Bohner raises no objections to PSR ¶ 46. Hr'g Tr. 146:15-20, June 6, 2011; Def. Objections, Doc. No. 138-4 at 10.

Ruling: No objections to PSR ¶ 46.

(26) Defendant Bohner raises no objections to PSR ¶ 47. Hr'g Tr. 146:15-20, June 6, 2011; Def. Objections, Doc. No. 138-4 at 10.

Ruling: No objections to PSR ¶ 47.

(27) Defendant Bohner objects to PSR ¶ 48 in regard to the November 2003 draft proposal for an investigational device exemption (IDE). Hr'g Tr. 146:21-147:8, June 6, 2011; Def. Objections, Def. Objections, Doc. No. 138-4 at 10-11.

Specifically, Defendant Bohner objects to PSR ¶ 48 because it improperly suggests the company concealed from the FDA its intention to pursue an IDE. Hr'g Tr. 146:22-24, June 6, 2011. In written objections, Defendant Bohner submits: "Shortly after the IDE proposal was circulated internally, a decision was made to pursue an IDE study, and shortly after that, the company initiated discussion with the FDA about an IDE." Def. Objections, Doc. No. 138-4 at 10.

PSR ¶ 48 quotes a portion of the draft IDE proposal that states in part: "Currently, Norian is being used off-label to treat VCFs." In written objections, Defendant Bohner objects to the extent that the quotation inaccurately suggests the company was conceding it had engaged in off-label promotion. Defendant contends that the quotation refers to doctors using products off-label and there is nothing illegal about that. Def. Objections, Doc. No. 138-4 at 10-11.

Defendant Higgins also objects that PSR ¶ 48 is incomplete and should be amended to "indicate that there was no obligation for a company to submit its internal consideration about whether or not to do an IDE . . . ." The Government agrees: "There's no obligation to share draft IDE proposals with the FDA." Hr'g Tr. 120:22-121:5, June 6, 2011. In written objections, Defendant Higgins raises the same objection: "There is no requirement for a company to tell the FDA that it is merely considering or discussing preparing an IDE proposal." Def. Higgins' Objections, Doc. No. 138-3 at 6.

Ruling: The objections to PSR ¶ 48 are sustained in part and the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Bohner's PSR ¶ 48 by adding the sentence:

A company has no obligation to share its draft IDE proposals with the FDA.

Otherwise, the objections are overruled. Defendant Bohner presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(28) Defendant Bohner raises no objections to PSR ¶ 49 in regard to Technique Guide, which Defendant Walsh approved for for release to the Spine Division sales force. Hr'g Tr. 147:9-12, June 6, 2011; Def. Objections, Doc. No. 138-4 at 11.

Defendant Bohner raised no objections to PSR ¶ 49 at the hearing. However, in written objections, he raises the following two objections.

First, Defendant submits that he did not review or approve the Technique Guide and there is no evidence that Defendant Walsh consulted with him on the decision to approve the Technique Guide.

Secondly, Defendant Bohner objects to the statement in PSR ¶ 49: "Also at the end of December 2003, Synthes released XR for sale beyond the original 'test market.'" Defendant objects to this statement being incomplete. Defendant suggests that PSR ¶ 49 should be amended to state: "At the end of December 2003, Norian XR became 'available for sale on a limited basis' and was only released 'to those accounts with surgeons who have participated in the test market and those who have been trained at a Synthes Spine sponsored Norian XR forum.'" Def. Objections, Doc. No. 138-4 at 11 (Defendant Bohner relies on an e-mail from Karen Caron, Project Manager, to Spine All Sales Consultants & Mgrs, et al. (Dec. 31, 2003, 2:45 pm)).

Ruling: No objections to PSR ¶ 49; the written objections were withdrawn at the hearing. To the extent that any objections may not have been withdrawn at the hearing, the objections are overruled. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(29) Defendant Bohner raises no objections to PSR ¶ 50 in regard to the January 10 and 11, 2004 surgeon forum. Hr'g Tr. 147:13-14, June 6, 2011; Def. Objections, Doc. No. 138-4 at 11.

At the hearing, Defendant Bohner raised no objections to PSR ¶ 50. Hr'g Tr. 147:13-14, June 6, 2011. In written objections, he stated only that he "did not attend the surgeon forum." Def. Objections, Doc. No. 138-4 at 11.

Ruling: No objections to PSR ¶ 50; the written objections were withdrawn at the hearing. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(30) Defendant Bohner objects to statements contained in PSR ¶ 51 regarding to the medical device report (MDR) filed for the January 22, 2004 death of Dr. No. 7's (Dr. Ball's) patient. Hr'g Tr. 147:15-148:6, June 6, 2011; Def. Objections, Doc. No. 138-4 at 11. A number of objections are raised to PSR ¶ 42, which the Court rules on as follows:

(30.a.) Defendant concedes that there is: "Nothing affirmatively inaccurate . . .." in PSR ¶ 51. Hr'g Tr. 147:16-17, June 6, 2011. However, Defendant objects that "he had no advance knowledge or involvement in this. . . . but the paragraph's not affirmatively inaccurate with respect to that." Id. at 147:20-22.

Defendant also objects to the use of the word "vague" in PSR ¶ 51: "Although Synthes and Norian filed an MDR on the third death, that MDR was vague as to the surgery and its details." Hr'g Tr. 147:24-148:3, June 6, 2011. Defendant submits "vague" is inaccurate. In written objections, Defendant raises the same objections. Def. Objections, Doc. No. 138-4 at 11.

Ruling: The objections to PSR ¶ 51 are overruled. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(30.b.) In addition, Defendant Higgins objects that PSR ¶ 51 is incomplete in regard to the January 22, 2004 death of Dr. No. 7's (Dr. Ball's) patient. Hr'g Tr. 121:15-122:19, June 6, 2011; Def. Objections, Doc. No. 138-3 at 6.

Defendant Higgins submits that the PO previously revised PSR ¶¶ 38 and 45 to include the medical history and context for the deaths of Drs. Sachs' and Nottingham's patients. Defendant objects that the PO omitted to make similar revisions to PSR ¶ 51 to reflect the "medical context" for the patient's death. Higgins requests that PSR ¶ 51 be amended to state: "the patient's medical history, that the doctor did not attribute the death to Norian, and the autopsy's inability to draw conclusions because of the prolonged exposure to CPR." Hr'g Tr. 122:8-11, June 6, 2011.

In written objections, Higgins objects "because [PSR ¶ 51] fails to mention, among other things, the patient's medical history (83 year old female with a history of hypertension, atypical angina, lumbar stenosis, and recent pneumonia), and that, at the time, Doctor No. 7 did not attribute the death to the use of Norian XR. Furthermore, this paragraph fails to state that the person who conducted the autopsy noted that no conclusions could be drawn from the presence of foreign material because the patient had undergone prolonged CPR." Def. Objections, Doc. No. 138-3 at 6.

The Government did not object. Hr'g Tr. 122:15-18. The Government stated that it: "certainly has no objection to the Court adding to each of the paragraphs on each of the three deaths that there was - -- each of those persons was an elderly person and each had various other medical problems. That has never been disputed." Hr'g Tr. 176:20-177:2, June 6, 2011.

Ruling: Defendant Higgins' objections to PSR ¶ 51 are sustained in part and the PSR for each Defendant will be corrected; otherwise the objections are overruled. The PO is directed to amend PSR 51 to include the following statement:

> Dr. No. 7's patient was medically frail, presenting multiple health issues, as was each of the other two patients who died.

(31) Defendant Bohner objects to PSR ¶ 52 in regard to the February 2004 "dear surgeon" letter and the fact that no XR product recall was made. Hr'g Tr. 148:7-149:5, June 6, 2011; Def. Objections, Doc. No. 138-4 at 11.

Specifically, Defendant objects that PSR ¶ 52 is incomplete: "[I]t does not state that the companies had informed the FDA of the second and third deaths by filing MDR reports. This paragraph also fails to state that following the third death, the company

canceled the scheduled training fora and stopped actively marketing the product." Hr'g Tr. 148:8-13, June 6, 2011. Defendant suggests that PSR ¶ 52 should be amended to include statements of fact to this effect. Id. at 148:14-25.

In written objections, Defendant raises the same objections, stating in addition that "the company determined that no MDR was required for the first death." Def. Objections, Doc. No. 138-4 at 11. In addition, Defendant submits that the "dear surgeon" letter "was a voluntary letter that urged surgeons to seriously consider whether use of any bone void filler is appropriate in treating VCFs." Id.

Ruling: The objections to PSR ¶ 52 are overruled. Defendant presents argument. The facts that Defendant suggests should be added to PSR ¶ 52 are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(32) Defendant Bohner raises no objections to PSR ¶ 53, Victim Impact. Hr'g Tr. 149:6-7, June 6, 2011; Def. Objections, Doc. No. 138-4 at 12.

Ruling: No objections to PSR ¶ 53.

(33) Defendant Bohner objects to PSR ¶ 54, Obstruction of Justice. Hr'g Tr. 149:8-11, June 6, 2011; Def. Objections, Doc. No. 138-4 at 12.

Although Defendant raised no objections at the hearing, in his written objections, Defendant "objects to the application of any enhancement under USSG § 3C1.1." Def. Objections, Doc. No. 138-4 at 12. Defendant submits that any allegedly false statements made to the FDA during the FDA's 2004 inspection at Synthes do not warrant an enhancement under USSG § 3C1.1. Id.

Although PSR ¶ 54 attributes false statements to Defendant Bohner, the PO has not recommended any enhancement based on obstruction of justice.

Ruling: The objections to PSR ¶ 54 are overruled. The Court makes its own determination of the applicable legal principles and the inferences to be drawn from the evidence.

(34) Defendant Bohner objects to PSR ¶¶ 55-58, Acceptance of Responsibility, submitting that considerations of acceptance of responsibility mandate a Total Offense Level of 4. Hr'g Tr. 15:4-8, 25:9-29:11, 149:12-14, June 6, 2011; Def. Objections, Doc. No. 138-4 at 12-13.

Specifically, Defendant Bohner objects to statements in the PSR to the effect that defendants must admit to facts of relevant conduct in order to qualify for the two-level reduction in the offense level. Defendant submits that these statements in the PSR are incorrect on two grounds: (1) "the relevant facts of this offense are bounded by the

written, carefully negotiated, stipulated facts in paragraph 9 of the plea agreement, and as to that Mr. Bohner has acknowledged responsibility," and (2) "under 3E1.1 it is simply wrong to state that one has an affirmative obligation to acknowledge further facts." Hr'g Tr. 26:5-27:3. Defendant objects that PSR ¶ 58 incorrectly states that he must "make a greater admission to the facts of the offense, including relevant conduct, in order to qualify for the two-level reduction." Def. Objections, Doc. No. 138-4 at 12. Defendant submits: "This is incorrect; Mr. Bohner has admitted all 'offense conduct' – which is the conduct comprising the elements of the offense." Id.

Ruling: Defendant Bohner's objections to PSR ¶ 58 are sustained in part and the PSR for each Defendant will be corrected; otherwise the objections are overruled. The PO is directed to correct the PSR as follows:

(a) The PO is directed to delete the sentence in the PSR that states: "The government, by the Park requirement, has established a prima facie case." PSR ¶ 58. The PO is directed to add the following sentence to PSR ¶ 58: "The parties have stipulated that Defendant was a responsible corporate officer within the meaning of the applicable law. Plea Agreement ¶¶ 1, 9."

(b) The PO is directed to delete the sentence in PSR ¶ 58 that states: "Therefore, it is necessary under the Guidelines Manual for the defendant to make a greater admission to the facts of the offense, including relevant conduct, in order to qualify for the two-level reduction."

(35) Defendant Bohner raises no objections to PSR ¶¶ 59, 61, 62, 63, 64, 65, and 68, Offense Level Computation.

Ruling: No objections to PSR ¶¶ 59, 61, 62, 63, 64, 65, and 68.

(36) Defendant Bohner raises no objections to PSR ¶ 60, Base Offense Level, Application of Guideline § 2N2.1 vs. 2X5.2. However, Defendant Huggins raised an objection but then withdrew the objection.

At the hearing, Defendant Huggins objected to the application of § 2N2.1 in PSR ¶ 60, but then expressly withdrew the objection. See Hr'g Tr. 67:9-11, 66:25-67:11, June 6, 2011. Defendants Higgins, Bohner, and Walsh made no express objections to the application of § 2N2.1 as opposed to 2X5.2.

In each defendant's Plea Agreement, ¶ 11(a), it was stipulated: "The parties agree to disagree concerning whether USSG. § 2N2.1(a) or § 2X5.2 applies to this case." Plea Agreements, ¶ 11(a): Def. Huggins, Doc. No. 34 at 9; Def. Higgins, Doc. No. 42 at 9; Def. Bohner, Doc. No. 64 at 9; Def. Walsh, Doc. No. 68 at 9. See also Bohner's PSR ¶ 109, Sentencing Options, Impact of the Plea Agreement, which states:

> The parties agreed to disagree as to whether USSG. § 2N2.1(a) or § 2X5.2 applie[s] in this case. Appendix A of the Guidelines Manual specifies that the appropriate offense guideline section in Chapter Two applicable to the statute of conviction is found in § 2N2.1. Regardless of which guideline section applie[s], the same total offense level would be obtained. In any event, the Court may need to address this dispute at the time of sentencing.

Ruling: The Court rules that Guideline § 2N2.1 applies.

(37) Defendant Bohner raises no objections to PSR ¶¶ 66, 67, and 69. However, Defendant Huggins raises objections to PSR ¶ 66 (Adjustment for Acceptance of Responsibility), ¶ 67 (Adjusted Offense Level), and ¶ 69 (Total Offense Level), which the Court will sustain and the PSR for each Defendant will be corrected accordingly. Defendant Walsh also objects to PSR ¶¶ 58 and 66.

Ruling: Defendant Huggins' objections to PSR ¶¶ 66, 67, and 69 will be sustained and Defendant Walsh's objection to PSR ¶ 66 will be sustained, and the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Bohner's PSR as follows:

> **Ruling:** The objection to PSR ¶ 66 is sustained and the PO is directed to change 0 to **2**.
> **Ruling:** The objection to PSR ¶ 67 is sustained and the PO is directed to change 6 to **4**.
> **Ruling:** The objection to PSR ¶ 69 is sustained and the PO is directed to change 6 to **4**.

(38) Defendant Bohner raises no objections to PSR ¶¶ 70-75, Defendant's Criminal History.

Ruling: No objections to PSR ¶¶ 70-75.

(39) Defendant Bohner raises no objections to PSR ¶¶ 76-77, 79-104, and 106, Offender Characteristics.

Ruling: No objections to PSR ¶¶ 76-77, 79-104, and 106.

(40) Defendant Bohner objects that PSR ¶ 78, Offender Characteristics, Personal and Family Data, requires correction. Hr'g Tr. 149:23-150:6, June 6, 2011; Def. Objections, Doc. No. 138-4 at 13.

> Defendant submitted: "[O]n paragraph 78 there is a reference at the end of the paragraph to Mr. Bohner's mother stating that she is elderly, sick and frail. She has, in fact, passed away." Hr'g Tr. 149:23-150:1, June 6, 2011. Defendant makes the same objection in his written objections. Def. Objections, Doc. No. 138-4 at 13.

Ruling: The objection to PSR ¶ 78 is sustained. The PO is directed to amend the PSR ¶ 78 to reflect that Mr. Bohner's mother passed away in January 2011.

(41) Defendant Bohner raises no objections to PSR ¶ 105, Offender Characteristics, Applicable Guideline Range for Fine. However, Defendant Huggins objects to his PSR ¶ 103, Offender Characteristics, Applicable Guideline Range for Fine, which the Court will sustain in part and the PSR for each Defendant's will be corrected accordingly.

In written objections, Defendant Huggins submits: "Although [he] has agreed to pay the maximum statutory fine of $100,000, the PSR nonetheless should, but does not, state the applicable fine range under USSG § 5E1.2(c)(3). . . . That guideline recommends a minimum fine of $250.00 and a maximum fine of $5,000. The fact that [Defendant] has agreed to pay a fine 400 times greater than the minimum fine recommended by the guideline and 20 times greater than the maximum is material to the Court's overall sentencing determination." Def. Objections, Doc. No. 138-2 at 7, n.6.

Although Defendant Huggins objects that the guideline range for a fine was omitted, Defendants Higgins, Bohner, and Walsh do not object to the omission. The amendment of the total offense level from 6 to 4 changes the guideline range for the fine from $500.00-$5,000.00 to $250.00-$5,000.00. Thus, the PSR for each defendant will be amended to reflect the correct guideline range for a fine.

Ruling: Defendant Huggins' objection will be sustained and the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Bohner's PSR ¶ 105 to include the following statements:

> Pursuant to USSG § 5E1.2(a), "[t]he court shall impose a fine in all cases, except where the defendant establishes that he is unable to pay and is not likely to become able to pay any fine." For a total offense level of 4, USSG § 5E1.2(c)(3) specifies a minimum fine of $250.00 and a maximum fine of $5,000. The Defendant has agreed to pay a fine of $100,000, the statutory maximum fine permitted for a Class A misdemeanor. Plea Agreement, ¶ 5. The Defendant has the ability to satisfy a fine within the guideline range and has agreed to satisfy the $100,000 fine to which the parties stipulated and agreed. The fine may be satisfied in a lump sum or via a monthly installment plan.

(42) Defendant Bohner raises no objections to PSR ¶¶ 107, 109, 111-114, 116-119, and 121, Sentencing Options.

Ruling: No objections to PSR ¶¶ 107, 109, 111-114, 116-119, and 121.

(43) Defendant Bohner objects to PSR ¶ 108, Sentencing Options, Guideline Provisions based on consideration of acceptance of responsibility. Def. Objections, Doc. No. 138-4 at 13. In pertinent part, PSR ¶ 108 states:

> Pursuant to USSG Chapter 5, Part A, based on a total offense level of 6 and criminal history category of 1, the guideline range for imprisonment is 0 to 6 months.

Specifically, Defendant Bohner suggests that PSR ¶ 108 should be amended to include the following:

> (1) under the Guidelines if the applicable guideline range is in Zone A, a sentence of imprisonment is not required, unless the applicable Chapter Two guidelines expressly mandate one, USSG § 5C1.1(b); and (2) neither of the potentially applicable Chapter Two provisions expressly require a term of imprisonment, see USSG §§ 2N2.1; 2X5.2.

Def. Objections, Doc. No. 138-4 at 13-14.

In addition, Defendant Huggins objects to the same statement in his PSR ¶ 106, Sentencing Options, Guideline Provisions based on considerations of acceptance of responsibility. Def. Huggins' Objections, Doc. No. 138-2 at 5-6. In this case, considerations of acceptance of responsibility do not affect the base offense level guideline range of 0 to 6 months for imprisonment. However, Defendants Huggins and Bohner object to the statement of the total offense level as being "6," instead of "4." Although Defendants Huggins and Bohner object, Defendants Higgins and Walsh do not object to this statement of the total offense level. The Court sustains in part Huggins' objection to his PSR ¶ 106 and Bohner's objection to his PSR ¶ 108, and the PSR for each Defendant's will be corrected accordingly.

Ruling: The objections are sustained in part; otherwise the objections are overruled as argument. The Court makes its own determination of the applicable legal principles. The PO is directed to correct the total offense level from **6** to **4** and amend Defendant Bohner's PSR ¶ 108 to state as follows:

> Pursuant to USSG Chapter 5, Part A, based on a total offense level of **4** and criminal history category of 1, the guideline range for imprisonment is 0 to 6 months.

(44) Defendant Bohner objects to PSR ¶ 110, Sentencing Options, Impact of the Plea Agreement. Def. Objections, Doc. No. 138-4 at 14. In pertinent part, PSR ¶ 110 states:

> The parties agreed to a two-level reduction to the offense, pursuant to USSG § 3E1.1(a), in the plea agreement. However, the downward adjustment, though appropriate at the time of the plea agreement, is not applied in the guideline calculations in the presentence report. The Court will need to make the final determination as to downward adjustment. Whether or not the downward adjustment is applied, there is no alteration in the guideline range.

Ruling: Defendant Bohner's objection to PSR ¶ 110 is sustained and the PSR for each Defendant will be corrected. The PO is directed to correct and amend Defendant Bohner's PSR by deleting the sentences of PSR ¶ 110 quoted above and stating instead:

> The two-level reduction of the total offense level for acceptance of responsibility pursuant to USSG § 3E1.1(a) applies.

(45) Defendant Bohner objects to PSR ¶ 115, Sentencing Options, Possible Special Conditions. Def. Objections, Doc. No. 138-4 at 14. In pertinent part, PSR ¶ 115:

> Due to the defendant's history and/or nature of the instant offense(s), including his agreement to pay a $100,000 fine, the following special conditions of community supervision, not specifically authorized by statute, should be considered at sentencing: financial disclosure, no new debt.

Specifically, Defendant objects:

> [He] should not be required to submit to financial disclosure or be barred from taking on new debt. The PSR provides no explanation of the potential need for such conditions, which would needlessly burden both the Court and its Probation Office on the one hand, and Mr. Bohner and his family on the other. These suggested conditions are not supported by the other information in the PSR, most notably the statement of Mr. Bohner's Net Worth in paragraph 98 [$4,780,348.00].

Def. Objections, Doc. No. 138-4 at 14.

Ruling: The objection to PSR ¶ 115 is overruled. The Court makes its own determination of the applicable legal principles and the sentence to be imposed.

(46) Defendant Bohner objects to PSR ¶ 120, Sentencing Options, Fines, Guideline Provisions. Def. Objections, Doc. No. 138-4 at 14. In pertinent part, PSR ¶ 120 states:

> The fine range for the instant offense is from $500 to $5,000, pursuant to USSG § 5E1.2(c)(3). The court shall impose a fine in all cases except where the defendant establishes that he is unable to pay and is not likely to become able to pay any fine, pursuant to USSG § 5E1.2(a).

Specifically, Defendant suggests that PSR ¶ 120 should be modified to include the following statements: "In some cases [involving a guideline range in Zone A], a fine appropriately may be imposed as the sole sanction. USSG § 5C1.1, cmt. n.2. Mr. Bohner already has agreed to pay the maximum fine punishable for this offense." Def. Objections, Doc. No. 138-4 at 14.

Ruling: The objection to Defendant Bohner's PSR ¶ 120 is sustained in part and the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Bohner's PSR ¶ 120 by stating:

> The fine range for the instant offense is from **$250 to $5,000**, pursuant to USSG § 5E1.2(c)(3). The court shall impose a fine in all cases except where the defendant establishes that he is unable to pay and is not likely to become able to pay any fine, pursuant to USSG § 5E1.2(a).

Otherwise, the objection is overruled. The suggested modifications to the PSR amount to legal argument as to the sentence to be imposed, which is within the Court's discretion.

(47) Defendant Bohner objects to PSR ¶ 123, Factors That May Warrant a Sentence Outside of the Guidelines System. Def. Objections, Doc. No. 138-4 at 15. In pertinent part, PSR ¶ 123 states:

> The probation officer has not identified possible grounds for a sentence outside of the advisory guidelines system other than the statement from the defense, as presented in the footnote to paragraph 94, that []any period of confinement "would be particularly harmful to his efforts to get back on his feet following his termination from Synthes" as it would "prevent him from pursuing the productive opportunities described above precisely at the time he is beginning to have some success and effectively terminate him from gainful employment for the second time."

Specifically, Defendant suggests that PSR ¶ 123 should be modified to include the following statements:

> Mr. Bohner's productive activities since his plea may, just like those of someone post-conviction, "be taken as the most accurate indicator of his present purposes and tendencies and significantly to suggest the period of restraint and the kind of discipline that ought to be imposed upon him." *Pepper v. United States*, 131 S. Ct. 1229, 1242-43 (2011) . . . (holding that post-sentencing conduct must be considered by a court on re-sentencing).

Ruling: The objection to PSR ¶ 123 is overruled. The modifications to PSR ¶ 123 that Defendant Bohner suggests amount to legal argument on the sentence to be imposed. The Court makes its own determination of the sentence to be imposed.

At the hearing, Bohner stated that he has no other objections to the PSR: "That's all I have, Your Honor." Hr'g Tr.150:20, June 6, 2011.

RULINGS ON DEFENDANT JOHN J. WALSH'S OBJECTIONS

Defendant John J. Walsh objects to portions of the Government's Presentence Report.

The Court rules on each objection as follows:

(1) Defendant Walsh raises a general objection that the PSR improperly imputes to him conduct of the other Defendants. Defendant also raises this objection in regard to PSR ¶¶ 22, 27-47, 49-51, 53, and 54, among other unspecified allegations in the PSR. Def. Objections, Doc. No. 137 at 1-3.

Specifically, Defendant grounds his objection on the period of time he was employed with Synthes Spine Division. It is undisputed that Defendant was hired as a part-time regulatory consultant for the Spine Division in June 2003, and he became a full-time regulatory employee in August of 2003. On that basis, Defendant objects to PSR ¶ 54, which in part states that he made knowingly false statements to the FDA inspector in 2004. Defendant submits that the statements attributed to him are based on conduct of other Defendants of which he has no personal knowledge. Defendant submits that he has no personal knowledge of the events and allegations contained in PSR ¶¶ 27-47, 50-51, and therefore, he does not have a basis to admit or deny the accuracy of those events and allegations. Def. Objections, Doc. No. 137 at 1-3.

Ruling: The objections are overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the applicable legal principles and the inferences to be drawn from the evidence. As to Defendant's knowledge and intent, the objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant knew about Synthes' prior use of SRS mixed with barium sulphate to treat VCFs. The Court also finds that Defendant knowingly participated in clinical trials of XR in vertebroplasties to treat VCFs without the FDA's approval. The Court finds that Defendant knew of and participated in Synthes' training of surgeons as a means of creating an XR test market for the use of XR in vertebroplasties to treat VCFs in an off-label manner.

(2) Defendant raises no objections to PSR ¶¶ 1-5, and 7, The Offense, Charges and Convictions.

Ruling: No objections to PSR ¶¶ 1-5, and 7.

(3) Defendant Walsh objects to typographical errors in PSR ¶ 6, The Offense, Charges and Convictions. Hr'g Tr. 151:10-25, June 6, 2011.

Ruling: The objection to PSR ¶ 6 is sustained. The PO is directed to correct the typographical errors in PSR ¶ 6 to correctly state the Defendant's name as follows:

> On July 20, 2009, John J. Walsh, in accordance with that written plea agreement, appeared before the Honorable Lawrence F. Stengel . . . .

(4) Defendant Walsh raises no objections to PSR ¶¶ 8-16, The Offense, Plea Agreement Information. Hr'g Tr. 152:14-17, June 6, 2011.

Ruling: No objections to PSR ¶¶ 8-16. Hr'g Tr. 152:16-17, June 6, 2011.

(5) Defendant Walsh raises no objection to PSR ¶¶ 17-21, The Offense, The Offense Conduct. Hr'g Tr. 152:18-25, June 6, 2011.

Ruling: No objections to PSR ¶¶ 17-21.

(6) Defendant Walsh objects to PSR ¶ 22, The Offense, The Offense Conduct. Hr'g Tr. 152:18-22, 153:1-14, June 6, 2011; Def. Objections, Doc. No. 137 at 1-2.

> Specifically, Defendant objects: "While . . . paragraph 22 states accurately that Mr. Walsh was hired as a regulatory consultant for the Spine Division in June 2003, we believe that his tenure as a responsible corporate officer would have begun at the time that he became a full-time employee in August of 2003. So, again, we're not stating . . . that that's actually inaccurate but there's no evidence that Mr. Walsh had any responsibility or duty as a consultant relating to Norian from the time of June 2003 through August 2003." Hr'g Tr. 153:1-14, June 6, 2011. In written objections, Defendant raises the same objections. Def. Objections, Doc. No. 137 at 1-2.

Ruling: The objections to PSR ¶ 22 are overruled. The relevant facts are in evidence. The Court makes its own determination of the applicable legal principles and inferences to be drawn from the evidence.

(7) Defendant Walsh raises no objections to PSR ¶ 25, Medical Context.

> Defendant submits that the entire section of PSR, Medical Context ¶¶ 23-26, "accurately describe[s] his understanding that the terms 'vertebroplasty' and 'vertebral compression fracture' ('VCF') are separate and distinct in that a 'vertebroplasty' is a surgical technique, while a VCF is a medical condition resulting primarily from osteoporosis." Def. Objections, Doc. No. 137 at 3.

Ruling: No objections to PSR ¶ 25.

(8) Defendant Walsh objects to PSR ¶¶ 23, 24, and 26, Medical Context. Hr'g Tr. 154:1-21, June 6, 2011; Def. Objections, Doc. No. 137 at 3.

> Specifically, Defendant submits that certain definitions are relevant to what he understood the terms to mean when he worked at Synthes. Defendant objects to PSR

¶ 23, which defines 'vertebral compression fractures' as: "fractures of the spine, most of which result from osteoporosis." Defendant submits the phrase "most of which" is inaccurate because his "understanding [of] a VCF [vertebral compression fracture] is . . . a type of compression fracture that results from the condition of osteoporosis." Hr'g Tr. 154:6-21, June 6, 2011.

Defendant submits that certain definitions show that he understood "the use of Norian XR in a vertebroplasty procedure was not outside of the labeled indication for the product unless used to treat a VCF resulting from osteoporosis." Hr'g Tr. 154:6-21, June 6, 2011. Defendant continues: "a 'vertebroplasty' is a surgical technique" and "a VCF is a medical condition resulting primarily from osteoporosis." Id. Defendant submits that vertebroplasty may also be used to treat other conditions of the spine, for example, vertebral hemangioma and other tumors of the spine. Id. & n. 1, Ex. A, 5/20/04, Def. Mem (discussing his understanding of the meaning of 'vertebroplasty' and 'kyphoplasty').

Ruling: The objections to PSR ¶¶ 23, 24, and 26 are overruled. Defendant presents argument. The Court makes its own determination of the inferences to be drawn from the evidence. As to Defendant's knowledge and intent, the objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant knew the use of XR in a vertebroplasty procedure was outside of the labeled indications for the product regardless of whether XR was used to treat a VCF resulting from osteoporosis or another condition.

(9) Defendant Walsh objects to PSR ¶ 24, Medical Context. Hr'g Tr. 154:22-155:13, June 6, 2011; Def. Objections, Doc. No. 137 at 3.

Specifically, Defendant submits that certain definitions are relevant to what he understood the terms to mean when he worked at Synthes. Defendant disputes the accuracy of the statement contained in PSR ¶ 24: "In the 1980s, a surgery called vertebroplasty was developed to treat VCFs." Defendant draws the Court's attention to a 5/20/2004 memorandum that he prepared concerning the meaning and usage of the terms 'vertebroplasty' and 'kyphoplasty." Def. Objections, Doc. No. 137, Ex. A at 15. Defendant submits this memorandum shows that he understood vertebroplasty surgery was pioneered to treat a vertebral lesion, hemangioma. Defendant submits that "based on his review of the label and his understanding of these procedures, he would have understood that there would have been . . . multiple on-label . . . indications for this product besides the treatment of VCF." Hr'g Tr. 154:22-155:12, June 6, 2011.

Defendant also submits that his understanding of certain definitions show that he understood "the use of Norian XR in a vertebroplasty procedure was not outside of the labeled indication for the product unless used to treat a VCF resulting from osteoporosis." Def. Objections, Doc. No. 137 at 3. Defendant submits that "a 'vertebroplasty' is a

surgical technique" and "a VCF is a medical condition resulting primarily from osteoporosis." Id. Def. submits that vertebroplasty may also be used to treat other conditions of the spine, for example, vertebral hemangioma and other tumors of the spine. Id. & n. 1, Ex. A, 5/20/04 Def. Mem. (discussing his understanding of the meaning of 'vertebroplasty' and 'kyphoplasty').

Ruling: The objections to PSR ¶ 24 are overruled. Defendant presents argument. The Court makes its own determination of the inferences to be drawn from the evidence. As to Defendant's knowledge and intent, the objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant knew the use of XR in a vertebroplasty procedure was outside of the labeled indications for the product regardless of whether XR was used to treat a VCF resulting from osteoporosis or another condition.

(10) Defendant Walsh objects to PSR ¶ 26 & n.6, Medical Context. Hr'g Tr. 155:16-157:8, June 6, 2011; Def. Objections, Doc. No. 137 at 3. Defendant raises a number of objections, which are ruled on as follows:

(10.a.) Defendant objects to typographical errors in PSR ¶ 26, footnote 6, line 8, requesting that the errors be corrected. Hr'g Tr. 155:15-156:18, June 6, 2011.

Ruling: The objection to PSR ¶ 26 n.6 is sustained. The PO is directed to correct the typographical error in PSR ¶ 26, footnote, 6, line 8, changing the word "**factor**" to the word "**fracture**."

(10.b.) Defendant objects to PSR ¶ 26 n.6, lines 12-15 as being "imprecise." Hr'g Tr. 157:5-7, 156:19-157:8, June 6, 2011; Def. Objections, Doc. No. 137 at 3. Specifically, Defendant objects to the following statement in the PSR:

> Since the voids being filled are intrinsic to the stability of the bony structure, vertebroplasty, as well as kyphoplasty, as represented in the November 5, 2004, warning letter, for the treatment of such conditions (e.g. VCFs) is "not within the cleared intended uses for which Norian XR was cleared."

Defendant submits that "the only off-label indication for that product would have been the use of the product to treat a VCF without supplemental fixation." Id.

Defendant submits that his understanding of certain definitions show that he understood "the use of Norian XR in a vertebroplasty procedure was not outside of the labeled indication for the product unless used to treat a VCF resulting from osteoporosis." Def. Objections, Doc. No. 137 at 3. Defendant submits that "a 'vertebroplasty' is a surgical technique" and "a VCF is a medical condition resulting primarily from osteoporosis." Id. Defendant submits that vertebroplasty may also be used to treat other

conditions of the spine, for example, vertebral hemangioma and other tumors of the spine. Id. & n. 1, Ex. A, 5/20/04, Def. Mem. (discussing his understanding of the meaning of the terms 'vertebroplasty' and 'kyphoplasty').

Ruling: The objections to PSR ¶ 26 n.6 are overruled. Defendant presents argument. The Court makes its own determination of the inferences to be drawn from the evidence. As to Defendant's knowledge and intent, the objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant knew the use of XR in a vertebroplasty procedure was outside of the labeled indications for the product, regardless of whether XR was used to treat a VCF resulting from osteoporosis or another condition and regardless of whether supplemental fixation was used.

(11) Other than Defendant Walsh's general objection discussed above in paragraph (1), Defendant raises no specific objections to PSR ¶¶ 27, 29-47, 50-51, Synthes and Norian's Development and Marketing of Norian SRS and XR for Treatment of Vertebral Compression Fractures.

Ruling: No objections to PSR ¶¶ 27, 29-41, 50-51, except as set forth in paragraph (1) above.

(12) Defendant Walsh objects to PSR ¶ 28 & n.7. Hr'g Tr. 157:9-24, June 6, 2011.

> Specifically, Defendant objects to the statement contained in PSR ¶ 28 n.7:
>
> The defendants disagree that the purpose of Synthes' market research was to 'create a market' for the use of SRS to treat VCFs, noting that it is common business practice to use market research to determine, qualify, and quantify needs, which then leads to the development of products to address those needs.

Defendant submits that he "isn't in the position to disagree or agree with that statement. [He] did not make a objection one way or another as to what the purpose of Synthes' market research was. This was all - - the planning for the conducting the test market all happened before he got there." Hr'g Tr. 157:18-23, June 6, 2011.

Ruling: The objection to PSR ¶ 28 & n.7 is overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the applicable legal principles and inferences to be drawn from the evidence.

(13) Defendant Walsh raises no objections to PSR ¶ 40. However, Defendant Bohner raises an objection to PSR ¶ 40. Hr'g Tr. 142:6-143:2, June 6, 2011. The Court will sustain Defendants Bohner's objection in part and the PSR for each Defendant will be corrected accordingly.

Ruling: Defendant Bohner's objection to PSR ¶ 40 will be sustained in part and the PSR for each Defendants will be corrected. The PO is directed to correct Defendant Walsh's PSR ¶ 40 to state: "In late January 2003, following the first death and eight months before Norian XR was released **to** the test market, ..."

(14) Defendant Walsh raises no objections to PSR ¶ 42. However, Defendant Huggins raises an objection to PSR ¶ 42. Hr'g Tr. 91:10-21, June 6, 2011; Def. Huggins' Objections, Doc. No. 138-2 at 11. Defendant Huggins objects that PSR ¶ 42 inaccurately states that among the topics addressed at the July 18, 2003 safety meeting, "thirty-four VCF cases to date" were discussed, when in fact only eight of the 34 cases iinvolved decisions by surgeons to treat VCFs. Id. Defendant Bohner objects to PSR ¶ 42 for similar reasons. Hr'g Tr. 142:6-143:2, June 6, 2011. Defendant Huggins submits that the Government concedes this point and the Government never said otherwise at the hearing. The Court will sustain Defendants Huggins' and Bohner's objections in part and the PSR for each Defendant will be corrected accordingly.

Ruling: Defendants Huggins' and Bohner's objections to PSR ¶ 42 will be sustained in part and the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Walsh's PSR ¶ 42 to reflect that "eight of the 34 cases involved the treatment of VCFs."

(15) Defendant Walsh objects to PSR ¶ 48 in regard to the November 2003 draft proposal for an investigational device exemption (IDE). Hr'g Tr. 157:24-159:13, June 6, 2011; Def. Objections, Doc. No. 137 at 4-5. Under this general topic, Defendant raises a number of objections which the Court rules on as follows:

(15.a.) Specifically, Defendant Walsh objects to the accuracy of the statement contained in PSR ¶ 48: "This proposal was never shared with the FDA." Hr'g Tr. 159:2-4, 12-13, June 6, 2011. Defendant also objects to the statement as being incomplete. Hr'g Tr. 159:2-4, 12-13, June 6, 2011.

Defendant submits that he "did not consider that document to be an IDE proposal, the draft. . . . [He] actually had discussions with FDA officials with respect to the company's intention to potentially seek an IDE for VCF at least the part to treat VCF and specifically a Barbara Zimmerman and a Ted Stevens from the FDA." Hr'g Tr. 158:10-17, June 6, 2011. Defendant directs the Court's attention to exhibits submitted at the hearing and exhibits attached to his written objections. Id. at 158:22-159:13; Def. Objections, Doc. No. 137 at 15-41. In written objections, Defendant raises similar objections. Def. Objections, Doc. No. 137 at 4-5; see also G Ex. 70 (11/10-11/03 email chain regarding the IDE proposal).

At the hearing, Defendants did not raise any objections to the accuracy of the facts contained in PSR ¶ 48. However, Defendant Huggins objects to the statement in PSR ¶ 48: "This proposal was never shared with the FDA." Hr'g Tr. 101:14-102:24, June 6,

2011; Def. Objections, Doc. No. 138-2 at 12. Defendant Higgins also objects that PSR ¶ 48 is incomplete and should be amended to "indicate that there was no obligation for a company to submit its internal consideration about whether or not to do an IDE . . . ." Hr'g Tr. 120:22-121:5, June 6, 2011; Def. Objections, Doc. No. 138-3 at 6. The Government agrees: "There's no obligation to share draft IDE proposals with the FDA." Hr'g Tr. 120:22-121:5, June 6, 2011. The Court will sustain Defendants Huggins', Higgins' and Walsh's objections in part and the PSR for each Defendant will be corrected accordingly.

Ruling: The objections to PSR ¶ 48 will be sustained in part and the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Walsh's PSR ¶ 48 by adding the sentence:

A company has no obligation to share its draft IDE proposals with the FDA.

Otherwise, Defendant Walsh's objections are overruled. Defendant presents argument. The facts that Defendant suggests should be included in PSR ¶ 48 are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence.

(15.b.) In regard to PSR ¶ 48 concerning the November 2003 draft IDE proposal, Defendant Walsh admits that he "was involved in the drafting [of] the proposal." Hr'g Tr. 159:3-4, June 6, 2011. However, Defendant disputes that the draft IDE proposal evidences his intent to violate the FDCA: "[He] was aware that Synthes was interested in seeking a new indication for Norian XR to treat VCFs based on the fact that physicians were using the product off-label for that purpose. However, [he] as not aware that Synthes was, in fact, promoting Norian XR off-label for that purpose." Def. Objections, Doc. No. 137 at 5.

Ruling: The objection to PSR ¶ 48 is overruled. Defendant presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence. As to Defendant's knowledge and intent, the objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant knowingly participated in promoting XR off-label for use in vertebroplasties to treat VCFs without the FDA's approval.

(16) Defendant Walsh objects to statements contained in PSR ¶ 49 concerning his December 2003 approval of the Technique Guide for release to the Synthes Spine Division sales force. Hr'g Tr. 159:14-162:1, June 6, 2011; Def. Objections, Doc. No. 137 at 6-8. Under this general topic, Defendant raises a number of objections, which are ruled on as follows:

(16.a.) Specifically, Defendant Walsh objects to the statement contained in PSR ¶ 49: "At the end of December 2003, John Walsh approved the XR Technique Guide for

release to the Spine sales force . . . ." Defendant objects that this statement is inaccurate: "after several prior approvals, including one by his predecessor in regulatory [John Gilbert], . . . [Defendant Walsh] approved of the final XR technique guide at the beginning of December 2003. He approved a subsequent document, a CD-ROM document at the end of December 2003." Hr'g Tr. 159:19-23, June 6, 2011; Def. Objections, Doc. No. 137 at 6-7.

Ruling: The objection to PSR ¶ 49 is sustained in part; otherwise the objection is overruled. The PO is directed to amend PSR ¶ 49 to state that:

> At the beginning of December 2003, Mr. Walsh approved the final XR Technique Guide, and at the end of December 2003, he approved a CD-ROM document that accompanied the Technique Guide.

(16.b.) Defendant Walsh objects to the statement contained in PSR ¶ 49: "[T]he Technique Guide did not disclose or otherwise state the specific warning on XR's label, 'not intended for treatment of [VCFs]'. . . ." Defendant submits that the omission of the warning bullet from the Technique Guide was necessitated by the Guide's format and that the CD-ROM specifically included the warning bullet. Defendant submits that the Technique Guide does not support an inference that the omission of the XR warning bullet was intentionally made. Hr'g Tr. 160:3-161:8, June 6, 2011; Def. Objections, Doc. No. 137 at 7.

Ruling: The objection to PSR ¶ 49 is overruled. Defendant Walsh presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence. As to Defendant's knowledge and intent, the objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds it more likely than not that Defendant intended to omit the XR warning bullet from the Technique Guide.

(16.c.) Defendant Walsh objects to the statement contained in PSR ¶ 49 that "the Technique Guide contained x-rays of VCFs, some of which were x-rays of the spine of Doctor No. 4's [Dr. Sachs'] patient who had died on the operating table in January 2003 during a surgery to treat VCFs." Defendant submits that "[t]here's absolutely no evidence that [he] was aware of that fact. And, indeed, that adverse event took place before [he] joined the company." Walsh submits that this evidence does not support an inference that he knew the x-rays depicted an off-label use of the product or depicted a patient who had "suffered an adverse event." Hr'g Tr. 161:8-12, June 6, 2011; Def. Objections, Doc. No. 137 at 6-7.

Defendant Walsh expressly concedes that he "accepts responsibility for the fact that both documents [Technique Guide and CD-ROM] did include depiction of the off-label use of the product." Hr'g Tr. 159:24-160:1, June 6, 2011.

Defendant continues: "And he made a judgment, we believe in good faith, to keep the face [sic] in the CD-ROM based on his understanding of what was then a very well publicized set of decisions called the *Washington Legal Foundation* line of cases." Hr'g Tr. 161:22-162:1, June 6, 2011; Def. Objections, Doc. No. 137 at 7-8. Defendant submits that he: "considered the documents [Technique Guide and CD-ROM] to be educational materials, rather than promotional tools. . . . At the time of his approval of the Technique Guide and CD-ROM, [he] believed that inclusion of the case studies containing x-rays of VCFs was protected speech under the First Amendment after the precedent set by the *Washington Legal Foundation* cases. *See Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000), *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.C. Cir. 1998)
. . . . [H]e did not consider the inclusion of the materials to constitute the promotion of Norian XR outside of its labeled indications." Def. Objections, Doc. No. 137 at 7-8.

Ruling: The objections to PSR ¶ 49 are overruled. Defendant Walsh presents argument. The relevant facts are in evidence. The Court makes its own determination of the inferences to be drawn from the evidence. As to Defendant's state of mind and motives, the Court finds based on the record evidence of relevant conduct that Defendant knowingly promoted the use of XR in vertebroplasties to treat VCFs without the FDA's approval. The Court finds that Defendant knew of and participated in Synthes' training of surgeons as a means of creating an XR test market for the use of XR in vertebroplasties to treat VCFs in an off-label manner.

(17) Defendant Walsh raises no objections to PSR ¶ 51. However, Defendant Higgins objects that PSR ¶ 51 is incomplete in regard to the January 22, 2004 death of Dr. No. 7's (Dr. Ball's) patient. Hr'g Tr. 121:15-122:19, June 6, 2011; Def. Higgins' Objections, Doc. No. 138-3 at 6. The Government did not oppose Defendant Higgins' objection. Hr'g Tr. 122:15-18, 176:20-177:2, June 6, 2011. The Court will sustain in part Defendant Higgins' objection in part and the PSR for each Defendant will be corrected accordingly.

Ruling: The Court will sustain in part Defendant Higgins' objection to PSR ¶ 51 and the PSR for each Defendant will be corrected. The PO is directed to amend Defendant Walsh's PSR ¶ 51 to include the following statement:

> Dr. No. 7's patient was medically frail, presenting multiple health issues, as was each of the other two patients who died.

(18) Defendant Walsh objects to a number of statements contained in PSR ¶ 52 as being mis-characterizations of the February 2004 "dear surgeon" letter. Hr'g Tr. 168:4-172:22, June 6, 2011; Def. Objections, Doc. No. 137 at 8-9.

Specifically, Defendant Walsh concedes that he participated in drafting the "dear surgeon" letter. Hr'g Tr. 169:12-13, June 6, 2011. However, he objects to PSR ¶ 52 as being a mis-characterization of the letter. Id. at 168:17-169:8; Def. Objections, Doc. No.

137 at 8; G Ex. 76 (2/10/04 "dear surgeon" letter). Defendant objects to the following statement in PSR ¶ 52: "Synthes and Norian left XR on the market, and sent surgeons a misleading 'dear surgeon' letter . . . . The letter was silent about the warning bullet . . . ." Defendant submits that the letter was not silent about the warning bullet ("not intended for the treatment of vertebral compression fractures") because the letter stated the substance of the warning in other words. Hr'g Tr. 168:17-169:8, June 6, 2011. The "dear surgeon" letter stated:

> Norian XR, Norian SRS, and Norian CRS are calcium phosphate bone void fillers. These products are intended for the treatment of bony voids or defects that are not intrinsic to the stability of the bony structure. The use of cements or bone void fillers in the treatment of vertebral compression fractures is intrinsic to the stability of the vertebral body. Accordingly, **Norian XR, Norian SRS, and Norian CRS should not be used in the treatment of vertebral compression fractures.** Additionally, any such use of these products is not consistent with their FDA cleared labeling and therefore is considered 'off-label' use.

G Ex. 76, 2/10/04 "Dear Surgeon" Letter.

Defendant Walsh also objects to the statement contained in PSR ¶ 52: "[The 'dear surgeon' letter] further omitted to state that (1) Synthes had conducted a 'test market' in which it had trained surgeons to use XR to treat VCFs . . . ." Defendant disputes that he intended to mislead by omitting any mention of the test markets in the "dear surgeon" letter. Hr'g Tr. 169:9-170:3, June 6, 2011. However, Defendant concedes that "[h]e did have knowledge of . . . the test markets." Id. at 169:16-17.

Defendant Walsh also objects to the statement contained in PSR ¶ 52: "[The 'dear surgeon' letter] further omitted to state that . . . (2) the pilot studies indicated that Norian appeared to be a thrombogenic agent . . . ." Defendant submits that he had limited knowledge about the pilot studies and therefore, disputes that he intended to mislead by omitting mention of the pilot studies in the "dear surgeon" letter. Hr'g Tr. 170:5-171:15, June 6, 2011.

Defendant Walsh also objects to the statement contained in PSR ¶ 52: "[The 'dear surgeon' letter] further omitted to state that . . . (3) three patients had died on the operating table when spine surgeons had used Norian XR or its predecessor, SRS, off-label to treat VCFs." Defendant submits that the "dear surgeon" letter was addressed to a sophisticated audience of physicians and "clearly states that there have been adverse events involving deaths." Defendant disputes that the letter is evidence of his intent to mislead or hide anything. Hr'g Tr. 171:16-172:22, June 6, 2011. See G Ex. 76, 2/10/04 "dear surgeon" letter ("[F]or some patients, surgical treatment of vertebral compression fractures can result in catastrophic consequences. . . . deaths have been reported in cases

involving the use of calcium phosphate bone void fillers in the treatment of vertebral compression fractures.").

In written objections, Defendant submits: "At the time of the "dear surgeon" letter, [he] was not aware that surgeons had been trained relating to the use of Norian XR to treat VCFs." Def. Objections, Doc. No. 137 at 8. Defendant submits that the letter was "not misleading, but was a responsible measure taken to ensure that medical providers and Synthes personnel were warned against the potential adverse consequences of the off-label use of Norian XR and that Synthes should not promote the use of the product for that purpose." Def. Objections, Doc. No. 137 at 8-9.

Ruling: The objections to PSR ¶ 52 are overruled. The February 2004 "dear surgeon" letter is in evidence. The Court makes its own determination of the inferences to be drawn from the evidence. As to Defendant's knowledge and intent, the objections are directed to fundamental facts to be determined by the Court. Based on the record evidence of relevant conduct, the Court finds that Defendant participated in drafting a letter than was designed, first and foremost, to protect the business interests of Synthes and its officers rather than the safety of all members of society who might come into contact with the dangers created by the XR device. While the letter was a step in the right direction, the letter should have been more forthright and plain in the statement of the dangers posed by use of XR in vertebroplasties to treat VCFs.

(19) Defendant Walsh objects to PSR ¶ 53, Victim Impact. Hr'g Tr. 172:6-12, June 6, 2011.

Specifically, Defendant objects to the statement contained in PSR ¶ 53: "Three patients were treated in the test markets off-label with Norian XR and/or Norian SRS-R . . . for VCFs and died . . . ." Defendant submits that he is a responsible corporate officer for only two of the deaths and "there's never been a conclusive causal link drawn between the use of the products and the deaths." Hr'g Tr. 173:6-10, June 6, 2011.

Ruling: The objection to PSR ¶ 53 is overruled. Defendant presents argument. The Court makes its own determination of the applicable legal principles and the inferences to be drawn from the evidence. Based on the record evidence of relevant conduct, the Court finds that the patients were directly and proximately harmed by the conduct of Defendants and others at Synthes. Defendants subjected the patients to the risks of SRS and XR without the patients' full informed consent and without the FDA's authorization. Some of the patients were injured and some died. By participating in the promotion and unauthorized clinical trial XR on human beings, Defendant Walsh disregarded the safety of all members of society.

(20) Defendant Walsh objects to PSR ¶ 54, Obstruction of Justice. Hr'g Tr. 173:16-175:9, June 6, 2011; Def. Objections, Doc. No. 137 at 9-10.

Specifically, the PO has not recommended any enhancement based on obstruction of justice. Defendant agrees that an obstruction of justice enhancement is not warranted.

Defendant concedes that he made statements to the FDA inspector in 2004 as set forth in PSR ¶ 54: "We're not contending here today that those statements may not be inaccurate." Hr'g Tr. 174:22-23, June 6, 2011. However, Defendant disputes that he intentionally or knowingly made a false statement to the FDA inspector. Hr'g Tr. 174:25-175:9, June 6, 2011; Def. Objections, Doc. No. 137 at 9-10 ("Mr. Walsh's statements to the FDA . . . during the course of the FDA's investigation . . . reflect his personal knowledge and understanding of the events which led to the investigation, many of which occurred in the years before his arrival at Synthes."). In written objections, Defendant objects to the inclusion of the false statements in the revised PSR, which statements had not been included in the original PSR. Defendant contends the revisions are untimely and prejudicial. Def. Objections, Doc. No. 137 at 9.

Ruling: The objections to PSR ¶ 54 are overruled. The Court makes its own determination of the inferences to be drawn from the evidence. At to Defendant's knowledge and intent, the Court finds that Defendant intentionally or knowingly made false statements to the FDA inspector in 2004.

(21) Defendant Walsh objects to PSR ¶¶ 55-58, Acceptance of Responsibility, submitting that considerations of acceptance of responsibility mandate a Total Offense Level of 4. Hr'g Tr. 15:4-8, 29:13-36:25, June 6, 2011; Def. Objections, Doc. No. 137 at 10-12.

Specifically, Defendant objects to PSR ¶¶ 58 and 66 as being incorrect and requests that the PRS be amended. Defendant submits that he is entitled to a two-level reduction for acceptance of responsibility as of the time the plea agreement was signed, the PSR was written, and the hearing was held on June 6-7, 2011. In other words, he submits that the "baseline" [or total offense level after an adjustment for acceptance of responsibility] should reflect a credit for the two-level reduction. Defendant draws the Court's attention to the comments to USSG § 3E1.1: "a defendant may remain silent in respect to relevant conduct beyond the offense of conviction without affecting his ability to obtain a reduction." Hr'g Tr. 29:20-30:1, 30:5-10, June 6, 2011; Def. Objections, Doc. No. 137 at 10, 12. Defendant submits that the PSR is incorrect "in contravention to the comment" because the PSR states that "the defendants had some type of affirmative obligation to admit further evidence or facts beyond what was stipulated in the plea agreement in order to be entitled for acceptance of responsibility credit." Hr'g Tr. 30:15-19, June 6, 2011; Def. Objections, Doc. No. 137 at 12.

Defendant requests that the PSR be amended to set forth the correct "baseline" [or total offense level after an adjustment for acceptance of responsibility] subject to the Court's further analysis of relevant conduct. Defendant submits: "[W]e don't believe that the baseline would be that he has falsely contested or frivolously denied, certainly at the time that the presentence investigation report was written, relevant conduct, and, therefore, he would be, as a baseline, entitled to a two-level reduction for acceptance of responsibility." Hr'g Tr. 36:17-22, June 6, 2011.

On similar grounds, each Defendant objects to PSR ¶ 58. Defendant Huggins objects: Hr'g Tr. 15:4-18:13, 106:21-24, June 6, 2011; Def. Huggins' Objections, Doc. No. 138-2. Defendant Higgins objects: Hr'g Tr. 123:15-18, June 6, 2011; Def. Higgins' Objections, Doc. No. 138-3 at 7-10. Defendant Bohner objects: Hr'g Tr. 15:4-8, 25:9-29:11, 149:12-14, June 6, 2011, Def. Bohner's Objections, Doc. No. 138-4 at 12-13. The Court will sustain the objections in part and the PSR for each Defendant will be corrected accordingly.

Ruling: Defendant Walsh's objections to PSR ¶58 are sustained in part and the PSR for each Defendant will be corrected; otherwise the objections are overruled. The PO is directed to correct the Defendant Walsh's PSR ¶ 58 as follows:

(a) The PO is directed to delete the sentence in the PSR that states: "The government, by the Park requirement, has established a prima facie case." PSR ¶ 58. The PO is directed to add the following sentence to PSR ¶ 58: "The parties have stipulated that Defendant was a responsible corporate officer within the meaning of the applicable law. Plea Agreement ¶¶ 1, 9."

(b) The PO is directed to delete the sentence in PSR ¶ 58 that states: "Therefore, it is necessary under the Guidelines Manual for the defendant to make a greater admission to the facts of the offense, including relevant conduct, in order to qualify for the two-level reduction."

(22) Defendant Walsh raises no objections to PSR ¶¶ 59, 61-65, and 68, Offense Level Computation.

Ruling: No objections to PSR ¶¶ 59, 61-65, and 68.

(23) Defendant Walsh does not object to PSR ¶ 60, Base Offense Level, Application of Guideline § 2N2.1 vs. 2X5.2. However, Defendant Huggins raised an objection and then withdrew the objection.

At the hearing, Defendant Huggins objected to the application of § 2N2.1 in PSR ¶ 60, but then expressly withdrew the objection. See Hr'g Tr. 67:9-11, 66:25-67:11, June 6, 2011. Defendants Higgins, Bohner, and Walsh made no express objections to the application of § 2N2.1 as opposed to 2X5.2.

In each defendant's Plea Agreement, ¶ 11(a), it was stipulated: "The parties agree to disagree concerning whether USSG § 2N2.1(a) or § 2X5.2 applies to this case." Plea Agreements, ¶ 11(a): Def. Huggins, Doc. No. 34 at 9; Def. Higgins, Doc. No. 42 at 9; Def. Bohner, Doc. No. 64 at 9; Def. Walsh, Doc. No. 68 at 9. See also Walsh's PSR ¶ 116, Sentencing Options, Impact of the Plea Agreement, which states:

> The parties agreed to disagree as to whether USSG § 2N2.1(a) or § 2X5.2 applie[s] in this case. Appendix A of the Guidelines Manual specifies that the appropriate offense guideline section in Chapter Two applicable to the statute of conviction is found in § 2N2.1. Regardless of which guideline section applie[s], the same total offense level would be obtained. In any event, the Court may need to address this dispute at the time of sentencing.

Ruling: The Court rules that Guideline § 2N2.1 applies.

(24) Defendant Walsh objects to PSR ¶ 66, Offense Level Computation. See paragraph (21) above. Defendant Walsh raises no objections to PSR ¶¶ 67 and 69. However, Defendant Huggins objects to PSR ¶ 66 (Adjustment for Acceptance of Responsibility), ¶ 67 (Adjusted Offense Level), and ¶ 69 (Total Offense Level), which objections the Court will sustain and the PSR for each Defendant will be corrected accordingly.

Ruling: Defendant Huggins' objections to PSR ¶¶ 66, 67, and 69 will be sustained, and Defendant Walsh's objection to PSR ¶ 66 is sustained, and the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Walsh's PSR as follows:

Ruling: The objection to PSR ¶ 66 is sustained; the PO is directed to change 0 to **2**.
Ruling: The objection to PSR ¶ 67 is sustained; the PO is directed to change 6 to **4**.
Ruling: The objection to PSR ¶ 69 is sustained; the PO is directed to change 6 to **4**.

(25) Defendant Walsh raises no objections to PSR ¶¶ 70-83, Defendant's Criminal History.

Ruling: No objections to PSR ¶¶ 70-83.

(26) Defendant Walsh raises not objections to PSR ¶¶ 84-111, and 113, Offender Characteristics.

Ruling: No objections to PSR ¶¶ 84-111, and 113.

(27) Defendant Walsh raises no objections to PSR ¶ 112, Offender Characteristics, Applicable Guideline Range for Fine. However, Defendant Huggins raises an objection to his PSR ¶ 103, Offender Characteristics, Applicable Guideline Range for Fine, which the Court will sustain in part, and the PSR for each Defendant will be corrected accordingly.

> In written objections, Defendant Huggins submits: "Although [he] has agreed to pay the maximum statutory fine of $100,000, the PSR nonetheless should, but does not, state the applicable fine range under USSG § 5E1.2(c)(3). . . . That guideline recommends a minimum fine of $250.00 and a maximum fine of $5,000. The fact that [Defendant] has agreed to pay a fine 400 times greater than the minimum fine recommended by the

guideline and 20 times greater than the maximum is material to the Court's overall sentencing determination." Def. Objections, Doc. No. 138-2 at 7, n.6.

Although Defendant Huggins objects that the guideline range for a fine was omitted, Defendants Higgins, Bohner, and Walsh do not object to the omission. The amendment of the total offense level from 6 to 4 changes the guideline range for the fine from $500.00-$5,000.00 to $250.00-$5,000.00. Thus, the PSR for each defendant will be amended to reflect the correct guideline range for a fine.

Ruling: The PO is directed to correct Defendant Walsh's PSR ¶ 112 to include the following statements:

> Pursuant to USSG § 5E1.2(a), "[t]he court shall impose a fine in all cases, except where the defendant establishes that he is unable to pay and is not likely to become able to pay any fine." For a total offense level of 4, USSG § 5E1.2(c)(3) specifies a minimum fine of $250.00 and a maximum fine of $5,000. The Defendant has agreed to pay a fine of $100,000, the statutory maximum fine permitted for a Class A misdemeanor. Plea Agreement, ¶ 5. The Defendant has the ability to satisfy a fine within the guideline range and has agreed to satisfy the $100,000 fine to which the parties stipulated and agreed. The fine may be satisfied in a lump sum or via a monthly installment plan.

(28) Defendant Walsh raises no objections to PSR ¶¶ 114, 116, 118-126, and 128, Sentencing Options.

Ruling: No objections to PSR ¶¶ 114, 116, 118-126, and 128.

(29) Defendant Walsh raises no objections to PSR ¶ 115, Sentencing Options, Guideline Provisions, which states:

> Pursuant to USSG Chapter 5, Part A, based on a total offense level of 6 and criminal history category of 1, the guideline range for imprisonment is 0 to 6 months.

Although Defendant Walsh does not object, Defendant Huggins objects to the same statement in his PSR ¶ 106, Sentencing Options, Guideline Provisions based on considerations of acceptance of responsibility. Def. Huggins' Objections, Doc. No. 138-2 at 5-6. Defendant Bohner also objects to the same statement in his PSR ¶ 108. Def. Bohner's Objections, Doc. No. 138-4 at 13. In this case, considerations of acceptance of responsibility do not affect the base offense level guideline range of 0 to 6 months for imprisonment. However, Defendants Huggins and Bohner object to the statement of the total offense level as being "6," instead of "4." Defendants Walsh and Higgins do not object. Because the Court sustains in part Huggins' objection to his PSR ¶ 106 and

Bohner's objection to his PSR ¶ 108, the PSR for each Defendant will be corrected accordingly.

Ruling: The objections will be sustained in part; otherwise the objections will be overruled as argument. The Court makes its own determination of the applicable legal principles. The PO is directed to amend Walsh's PSR ¶ 115 to correct the total offense level from **6** to **4**, stating as follows:

> Pursuant to USSG Chapter 5, Part A, based on a total offense level of **4** and criminal history category of 1, the guideline range for imprisonment is 0 to 6 months.

(30) Defendant Walsh raises no objections to PSR ¶ 117, Sentencing Options, Impact of the Plea Agreement, which states in part:

> The parties agreed to a two-level reduction to the offense, pursuant to USSG § 3E1.1(a), in the plea agreement. However, the downward adjustment, though appropriate at the time of the plea agreement, is not applied in the guideline calculations in the presentence report. The Court will need to make the final determination as to downward adjustment. Whether or not the downward adjustment is applied, there is no alteration in the guideline range.

Ruling: Although Defendant Walsh does not object to PSR ¶ 117, the PSR for each Defendant will be corrected. The PO is directed to correct and amend Defendant Walsh's PSR ¶ 117 by deleting the sentences of PSR ¶ 117 quoted above and stating instead:

> The two-level reduction of the total offense level for acceptance of responsibility pursuant to USSG § 3E1.1(a) applies.

(31) Defendant Walsh raises no objections to PSR ¶ 127, Sentencing Options, Fines, Guideline Provisions, which states:

> The fine range for the instant offense is from $500 to $5,000, pursuant to USSG § 5E1.2(c)(3). The court shall impose a fine in all cases except where the defendant establishes that he is unable to pay and is not likely to become able to pay any fine, pursuant to USSG § 5E1.2(a).

Ruling: Although Defendant Walsh does not object to PSR ¶ 127, the PSR for each Defendant will be corrected. The PO is directed to correct Defendant Walsh's PSR ¶ 127 by stating:

> The fine range for the instant offense is from **$250 to $5,000**, pursuant to USSG § 5E1.2(c)(3). The court shall impose a fine in all cases except where the defendant establishes that he is unable to pay and is not likely to become able to pay any fine, pursuant to USSG § 5E1.2(a).

At the hearing, Defendant Walsh stated that he has no other objections to the PSR.: "I don't believe we have any objections, Your Honor, to the remainder of the presentence investigation report." Hr'g Tr. 175:19-21, June 6, 2011.

RULINGS ON THE GOVERNMENT'S RESPONSES TO DEFENDANTS' OBJECTIONS

At the hearing on June 6-7, 2011, the Government responded to the Defendants' objections. Hr'g Tr. 37:1-40:20, 175:24-183:25, June 6, 2011; Hr'g Tr. 218:22-280:5, June 7, 2011. The Government requests one modification to each Defendant's PSR ¶ 28, which the Court rules on as follows:

(1) The Government requests that Defendants Huggins, Higgins, and Bohner be named in PSR ¶ 28 as individuals who, as of May 2002, had knowledge of and participated in the test markets using SRS mixed with barium sulphate. Hr'g Tr. 178:1-182:24, June 6, 2011. For each Defendant, PSR ¶ 28 currently states:

> In November 2001, at a management meeting attended by Huggins, Higgins, and other top Synthes officials, the Spine Division made a presentation on how Synthes could obtain the FDA's approval for use of Norian to treat VCFs. The Spine Division reported that the IDE and PMA process would take 36 months and cost Synthes at least $1 million. After this meeting, the CEO and major shareholder of Synthes directed that Synthes would not pursue FDA approval of Norian via an IDE and a PMA but instead would press on with a "test market" for use of an extra-radiopaque version of Norian in the spine, with the aim of trying to persuade surgeons to publish on the results of their surgeries. Higgins followed this directive, approving an SRS test market in the spine ("Phase I"), meaning a test market for SRS mixed with barium sulphate to treat VCFs, which began in late summer 2002. By May 2002, Huggins was aware of, and involved in, the process of approving the SRS test market in the spine. (emphasis added)

The Government requests that the under-lined text in PSR ¶ 28 quoted above be modified to state the names of Huggins, Higgins, and Bohner. Hr'g Tr. 178:14-18, 179:8-13, June 6, 2011 ("and we would request that the names Higgins and Bohner be added here"). As modified, PSR ¶ 28 would state:

> By May 2002, **Huggins, Higgins, and Bohner were** aware of, and involved in, the process of approving the SRS test market in the spine.

The Government bases the request on the following record:

- G Ex.35, September 17, 2002 Management Review Board meeting minutes showing that the SRS test market in the spine was discussed and a PowerPoint, G Ex. 36, containing a number of slides on that test market.

- G Ex. 8, Defendant Huggins 5/30/02 e-mail to Defendants Higgins, Bohner, and others expressing his "second thoughts" about the SRS test market in the spine.

- G Ex. 9, Josi Hamilton's 5/31/02 time-line for the SRS test market in the spine.

- G Ex. 10, 5/22/02 e-mail exchange between Defendant Bohner and Hamilton about "forecasting" SRS inventory.

- G Ex.33, 6/4/02 Throngpreda memo to Defendants Huggins, Higgins, and Bohner concerning the SRS training; and G Ex. 34, PowerPoint presentation for the SRS training.

- G Ex. 35, 9/17/02 "Spine Business Plan Review" and Management Review Board meeting agenda and minutes (taken by David Paul) show that Defendants Huggins, Higgins, and Bohner were present; and G Ex. 36, PowerPoint presentation that was given at that 9/17/02 meeting.

- G Ex. 80, Page 1DOJSYN.020.009079: Excerpts from Bohner's diary for 5/22/02, "Presidents Meeting," noting there was a presidents' meeting on that date.

See Hr'g Tr. 180:9-182:24, June 6, 2011.

Ruling: The Government's request is granted. For each Defendant's PSR, the PO is directed to amend PSR ¶ 28 to state as follows:

> By May 2002, **Huggins, Higgins, and Bohner were** aware of, and involved in, the process of approving the SRS test market in the spine.

III. CONCLUSION

Based on the record and the parties' submissions and argument at the June 6-7, 2011 evidentiary hearing, the rulings set forth above are so ORDERED.

BY THE COURT:

/s/ Legrome D. Davis

Legrome D. Davis, J.