Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Thomas B. Higgins,
(OI File Number: 3-05-40179-9),

Petitioner,

v.

The Inspector General.

Docket No. C-13-164

Decision No. CR3477

Date: November 25, 2014

DECISION

Pursuant to section 1128(b)(1) of the Social Security Act (Act), the Inspector General for the Department of Health and Human Services (I.G.) has excluded Petitioner, Thomas B. Higgins, from participating in the Medicare, Medicaid, and all federal health care programs for a minimum period of five years. For the reasons discussed below, I find that the I.G. is authorized to exclude Petitioner and that the period of exclusion is not unreasonably long.

Background

Petitioner Higgins was a senior executive of Synthes, Inc. (Synthes), the American branch of a multinational medical device manufacturing corporation that specializes in "trauma products." I.G. Ex. 5 at 1, 2. With his knowledge and consent – indeed, his active encouragement – the company engaged in some nefarious behavior, illegally marketing its bone cement products for unapproved and dangerous uses, to the detriment of patients unfortunate enough to have been administered those products.

Petitioner Higgins, along with three of his colleagues at Synthes, Synthes itself, and Norian Corporation, a wholly-owned subsidiary of Synthes, were charged in a multi-count criminal indictment. While the corporations were charged with the bulk of the offenses, Petitioner Higgins was charged with introducing adulterated and misbranded medical devices into interstate commerce, a violation of the Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. §§ 331(a), 352(a), and 333(a)(1)). I.G. Ex. 5 at 54. He pled guilty, and, on November 21, 2011, the federal district court convicted him. I.G. Exs. 6, 11.

In a notice letter dated September 28, 2012, the I.G. advised Petitioner that he would be excluded from program participation for a minimum period of five years. The letter explained that the I.G. took this action pursuant to section 1128(b)(1) of the Act, because Petitioner Higgins had been convicted of a misdemeanor offense related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a healthcare item or service. I.G. Ex. 1. Similar letters were sent to Petitioner Higgins' colleagues/co-defendants, excluding them for periods of three to five years.

Petitioner and his co-defendants filed separate appeals, and the I.G. asked that their cases be consolidated.[1] Each petitioner is represented by separate counsel, and, although their appeals present common issues, the issues are not identical, and I feared that consolidating them could create an unwieldy case. In the interests of administrative efficiency, I ordered that the cases remain separate but be kept as one administrative file, and I issued the same briefing schedule for all. I allowed the I.G. to file either a single brief or four separate briefs.

The I.G. submitted a single brief (I.G. Br.) with 27 exhibits (I.G. Exs. 1through 27-81).[2] Petitioner submitted his individual brief (P. Br.) and, with Petitioners Walsh and Bohner, a "Joint Brief" addressing common legal issues (P. Joint Br.). Petitioner also submitted 32 exhibits for his individual case (P. Exs. 1-32), and, with Petitioners Walsh and Bohner, 13 joint exhibits (P. Joint Exs. 1-13). The I.G. submitted a reply brief (I.G. Reply) with six additional exhibits (I.G. Exs. 28-33).[3]

---

[1] The related cases are: Michael D. Huggins, C-13-166; John J. Walsh, C-13-167; and Richard E. Bohner, C-13-168.

[2] I.G. Exhibit 27 includes multiple parts, which are marked as I.G. Ex. 27 and I.G. Exs. 27-1, 27-1A, and 27-2 through 27-81.

[3] The parties have corrected or amended the originally-filed versions of some of these documents. I refer here to the amended documents and have disregarded the original submissions.

Petitioner objected to most of the I.G.'s proposed exhibits, and, for reasons set forth in the addendum attached, I overrule those objections. I admit into evidence I.G. Exs. 1-33, P. Exs. 1-32 and P. Joint Exs. 1-13.

The parties agree that this matter should be resolved based on their written submissions and that an in-person hearing is not required. I.G. Br. at 26; P. Br. at 28. I have therefore ruled on Petitioner's objections to exhibits (see attached as an addendum to this decision), closed the record, and issue this decision.[4]

Issues

The issues before me are: 1) has the I.G. a basis for excluding Petitioner from participating in the Medicare, Medicaid, and all federal health care programs; and 2) if so, does the five-year period of exclusion fall within a reasonable range.

Discussion

1. ***Petitioner Higgins may be excluded, because he was convicted of a misdemeanor offense related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service.***[5]

Section 1128(b)(1)(A) of the Act authorizes the Secretary of Health and Human Services to exclude from participation in all federal health care programs any individual or entity convicted of a misdemeanor offense "relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a healthcare item or service." *See* 42 C.F.R. § 1001.201(a).

[4] The petitioner in one of the related cases suggested that oral argument could be helpful. In an order dated May 1, 2014, I invited the parties to explain whether and why oral argument would be useful. I directed them to identify which, if any, arguments each would present and to explain why that argument could not adequately be presented in writing. Petitioner Higgins subsequently asked for oral argument. He identifies no specific argument that he would present but promises to ensure that the issues "are sharply delineated and fully joined" and to address any concerns or questions. I find that the parties have well presented their arguments, every nuance of this case has been explored in the parties' submissions, and that oral arguments would unnecessarily delay its resolution, without adding anything new.

[5] My findings of fact and conclusions of law are set forth, in italics and in bold, in the discussion captions of this decision.

Here, until February 2004, Petitioner Higgins was the president of Synthes Spine, a division of Synthes. He then left that position to become Senior Vice President of Global Strategy at Synthes. I.G. Ex. 5 at 1, 2; *see* P. Br. at 5; P. Joint Ex. 1 at 19. In these capacities, he was responsible for U.S. sales and was in charge of product development. I.G. Ex. 16.

In a 97-count indictment, Petitioner Higgins, three other Synthes executives, Synthes itself, and Norian Corporation were charged with multiple offenses.[6] Petitioner Higgins was charged with one count of introducing adulterated and misbranded medical devices into interstate commerce, a violation of the FDCA (21 U.S.C. §§ 331(a), 352(a), and 333(a)(1)). I.G. Ex. 5 at 54. On July 23, 2009, he pled guilty to 21 U.S.C. §§ 331(a) and 333(a)(1), and, on November 21, 2011, the Federal District Court for the Eastern District of Pennsylvania entered judgment against him, sentenced him to nine months imprisonment, and ordered him to pay a $100,000 fine, which is the statutory maximum. I.G. Ex. 6 at 4; I.G. Exs. 6, 11; I.G. Ex. 10 at 12; P. Joint Ex. 1 at 29-30. His prison sentence significantly exceeded federal sentencing guidelines for such an offense (0-6 months). I.G. Ex. 16 at 4, P. Joint. Ex. 1 at 13.

Petitioner concedes that he was convicted of a criminal offense – one count of introducing adulterated and misbranded medical devices into interstate commerce, in violation of 21 U.S.C. §§ 331(a) and 333(a)(1). P. Br. at 3. But he argues that his conviction does not justify exclusion under section 1128(b)(1), because he was not convicted of fraud or a crime "relating to" fraud. *Id.* at 2, 4.

Determining whether an offense is "related to" fraud. Petitioner argues that the I.G. may exclude under section 1128(b) only if the offender was convicted of an offense requiring "an intentional perversion of truth designed to induce action by another," which he characterizes as an element necessary to establish fraud. P. Joint Br. at 10. In Petitioner's view, I should ignore all of the facts underlying his conviction – including those he admitted – and consider only the generic criminal offense to which he pled guilty. Because conviction under sections 331(a) and 333(a)(1) does not require a finding

[6] The corporations were charged with the bulk of the offenses. Defendant Norian was charged with one count of conspiracy (18 U.S.C. § 371); seven counts of making false statements (18 U.S.C. § 1001); and 44 counts of introducing adulterated and misbranded medical devices into interstate commerce (21 U.S.C. §§ 331(a), 352(a), and 333(a) (2)). I.G. Ex. 5 at 1-49. Defendant Synthes was charged with 45 counts of introducing adulterated and misbranded medical devices into interstate commerce (21 U.S.C. §§ 331(a), 352(a), and 333(a)(1)). I.G. Ex. 5 at 50-53. The individual defendants were each charged with one count of introducing adulterated and misbranded medical devices into interstate commerce. I.G. Ex. 5 at 54.

of intent or knowledge, he reasons, his crime is not "related to" fraud, and he should not be excluded.

Petitioner's argument fails because it ignores the plain language of section 1128(b). Under that statute, the I.G. may exclude based on a conviction *relating to* fraud. It does not require a conviction for fraud itself, as Petitioner's argument suggests. In *Friedman et al. v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012), the D.C. Circuit affirmed the Departmental Appeals Board's (Board's) long-standing position on this issue and concluded that "the statute unambiguously authorizes . . . exclusion of an individual whose conviction was for conduct *factually* related to fraud." 686 F. 3d at 820 (emphasis added).

> The term "misdemeanor" [in section 1128(b)] refers to the particular circumstances of an individual's conviction, and "relating to" must denote a factual relationship between the conduct underlying the misdemeanor and the conduct underlying a "fraud."

686 F. 3d at 821.

The Board has long rejected efforts to limit section 1128 review to the bare elements of the criminal offense. *See Narendra M. Patel, M.D.*, DAB No. 1736 at 7 (2000), *aff'd, Patel v. Thompson*, 319 F.3d 1317 (11th Cir. 2003) ("We thus see nothing in section 1128(a)(2) that requires that the necessary elements of the criminal offense must mirror the elements of the exclusion authority, nor that all statutory elements required for an exclusion must be contained in the findings or record of the state criminal court."); *Timothy Wayne Hensley*, DAB No. 2044 (2006); *Scott D. Augustine*, DAB No. 2043 (2006); *Lyle Kai, R. Ph.*, DAB No. 1979 at 5 (2005) (holding that an offense is "related to" the delivery of a healthcare item or service, if there is "a nexus or common-sense connection" between the conduct giving rise to the offense and the delivery of a healthcare item or service), *aff'd, Kai v. Leavitt*, No. 05-00514 BMK (D. Haw. July 17, 2006); *Berton Siegel, D.O.*, DAB No 1467 at 5 (1994); *Carolyn Westin*, DAB No. 1381 (1993), *aff'd, Westin v. Shalala*, 845 F. Supp. 1446 (D. Kan. 1994).

I also note that, by regulation, "evidence of crimes, wrongs or acts other than those at issue in the instant case is admissible . . . ." 42 C.F.R. § 1005.17(g). If I were limited to considering the generic elements of the criminal offense to which Petitioner pled guilty, this regulation would serve no purpose.

Moreover, ignoring the conduct underlying the conviction would defeat the purpose of the statute, which is to protect program beneficiaries and program integrity from those who have shown themselves to be untrustworthy. If I relied solely on the language of 21 U.S.C. §§ 331(a) and 333(a)(1), I would not know the extent of Petitioner's involvement in the illegal activity. Based solely on the language of the statute, all I know

is that he introduced adulterated and misbranded medical devices into interstate commerce. Nothing in those provisions refers to conviction as a "responsible corporate officer." Unless I look at the indictment, the guilty plea, or other of the court documents, I would not know whether Petitioner pled guilty as a responsible corporate officer, or because he admitted that he personally willed the violation. Indeed, under Petitioner's theory, the I.G. could not exclude *anyone* convicted under sections 331(a) and 333(a)(1), even the defendant who admitted that he knowingly and deliberately introduced a dangerous product into interstate commerce. Congress plainly did not intend such a result. *See Narendra M. Patel, M.D.*, DAB No. 1736.[7]

The guilty plea. In the alternative, Petitioner argues that I may consider only the contents of his plea agreement. Because he pled guilty as a "responsible corporate officer," without admitting any knowledge of or involvement in the crime, he reasons that his crime is not "related to" fraud. Further, he points out that his plea agreement does not describe any fraudulent conduct by him, Synthes, or any other individual or company. P. Br. at 3, 5-6; P. Joint Br. at 3-7, 19-21. In Petitioner's view, no admissible evidence establishes that any person or corporation was guilty of anything, but for the strict liability imposed by the FDCA. P. Br. at 23-24; P. Joint Br. at 28-29.

Petitioner's argument suggests that no one at Synthes did anything wrong, but somehow the company – through no intentional fault of its own, its managers, or its employees – stumbled into introducing adulterated and misbranded devices into interstate commerce. Such a scenario, on its face, strains credulity. Moreover, I find Petitioner's argument ironic, given the almost-unimaginable – but well-documented – level of malfeasance engaged in by Petitioner Higgins and his colleagues. In the words of the sentencing judge, Legrome D. Davis:

> The scope of their scheme is without parallel, the risks created for an unsuspecting public were grave, and the scale of the deception of the Food and Drug Administration can only be characterized as extreme.

I.G. Ex. 21 at 1.[8]

---

[7] The I.G. does not argue that Petitioner's conviction is related to breach of fiduciary responsibility; however, a responsible corporate officer has such a duty to shareholders and to the business itself. Arguably, a responsible corporate officer breaches that responsibility if he fails to prevent or correct illegal activity, such as introducing adulterated and misbranded medical devices into interstate commerce.

[8] In my ruling on Petitioner's objections to the I.G.'s exhibits (attached), I explain why Judge Davis's conclusions are admissible and why I consider his findings reliable. Moreover, without regard to the judge's findings, the evidence upon which he based

Limiting my review to the facts of the plea agreement could effectively restrict me to the basic elements of the crime, without allowing me to consider the full context of the underlying criminal activity. So, for the same reasons my review is not limited to the elements of the offense, it is not limited to the facts admitted in the plea agreement. *See Narendra M. Patel, M.D.*, DAB No. 1736 (finding extrinsic evidence of circumstance of crime relevant.); *Emem Dominic Ukpong*, DAB No. 2220 (2008) (finding no support for the petitioner's claim that the scope of review should be limited to the four corners of her plea agreement).

But even if I relied solely on Petitioner's plea agreement, ignoring all the evidence to which he objects, the facts he admitted would, by themselves, establish the necessary connection between his crime and fraud.

I note, as a threshold matter, that Petitioner pled guilty to Count 97 of the indictment (which was apparently not prepared until after the plea agreement was executed and, unlike the plea agreement, accurately refers to the charge to which he pled). Count 97 incorporates paragraphs one through 93 of Count One of the indictment. Those paragraphs describe the crime in some detail. I.G. Ex. 5 at 1-28, 54; I.G. Ex. 11 at 1; P. Joint Ex. 1 at 26, 29. In their joint brief, the petitioners seem to recognize that those facts describe the offenses to which they pled guilty, because they argue that I must disregard all of the allegations of the indictment *except* those described in Count 97 – which necessarily includes paragraphs one through 93 of Count One. P. Joint Br. at 28-29 ("To the extent the Indictment alleges facts that go beyond what is admitted in the Plea Agreement of wrongful acts other than those described in Count 97, they are simply not relevant to the actual basis for the conviction of Petitioners and must be disregarded."). Notwithstanding this apparent admission in the joint brief, as well as the judgment itself, Petitioner, in his individual brief insists that he pled guilty and was convicted based solely on the facts set forth in paragraph nine of his plea agreement. P. Br. at 18. Whether Petitioner Higgins can so truncate the bases for his conviction is a question I need not resolve, since 1) the facts set forth in paragraph nine, by themselves, justify the exclusion; and 2) in the alternative, other admissible and compelling evidence establishes his personal participation in introducing adulterated and misbranded devices into interstate commerce.

The crime involves two Synthes products: the calcium phosphate bone cements Norian Skeletal Repair System (Norian SRS) and its successor, Norian XR (made up of Norian SRS to which barium sulfate is added). I.G. Ex. 5 at 2, 11 (Indictment ¶¶ 1b., 35, 36). The Food and Drug Administration (FDA), which regulates such products, has

---

those findings is reliable and admissible and establishes Petitioner Higgins' active participation in the misconduct. *See Narendra M. Patel, M.D.*, DAB No. 1736.

categorized Norian SRS and Norian XR as "significant risk devices." A "significant risk device" presents the potential for serious risk to patient health and safety. 21 C.F.R. § 812.3(m); I.G. Ex. 6 at 5; P. Ex. 1 at 5 (Plea Agreement ¶ 9(B)); *see* I.G. Ex. 20 at 2; P. Joint. Ex. 1 at 20. Its manufacturer may not undertake any clinical trial or investigation without FDA approval and review by an "Institutional Review Board," which is a group of scientists, physicians, experts in bioethics, and others. I.G. Ex. 5 at 4 (Indictment ¶ 10); I.G. Ex. 6 at 5; P. Ex. 1 at 5 (Plea Agreement ¶ 9(C)); *see* P. Joint Ex. 1 at 20. The process may be long and expensive, but it is necessary to ensure that the clinical trial is properly monitored and that human subjects are protected. *See* I.G. Ex. 5 at 4 (Indictment ¶ 10); P. Ex. 19 at 2 (describing the time and resources required to obtain FDA approval).

A manufacturer cannot legally market a device for a new use unless it notifies the FDA of its plans to do so. I.G. Ex. 6 at 5; P. Ex. 1 at 5 (Plea Agreement ¶ 9(E)).

In December 2001, the FDA approved Norian SRS for use as a "bone void filler." It is approved to fill bone voids that are "*not* intrinsic to the stability of the bony structure in the extremities, spine, and pelvis."[9] Its label also warns that it is *not to be mixed with any other substance*. I.G. Ex. 6 at 5-6; P. Ex. 1 at 5-6 (Plea Agreement ¶ 9(F)) (emphasis added); *see* P. Joint Ex. 1 at 20-21.

The FDA became concerned that some surgeons were nevertheless using bone void fillers in the spine for load-bearing indications. I.G. Ex. 6 at 6; P. Ex. 1 at 6 (Plea Agreement ¶ 9(G)); P. Joint Ex. 1 at 21. When Synthes sought FDA approval for Norian XR – made up of calcium phosphate and barium sulfate – the FDA directed Synthes and Norian to specify, in the product's label, that the cement was not intended for "load-bearing indications" such as vertebroplasty. I.G. Ex. 6 at 6-7; P. Ex. 1 at 6-7 (Plea Agreement ¶ 9(G)); *see* P. Joint Ex. 1 at 21-22. Vertebroplasty is a procedure for treating compression fractures of the spine. Bone cement is injected into the cracked or broken vertebrae. It hardens, stabilizes the bone, and supports the spine. I.G. Ex. 5 at 9. To ensure patient safety, the cement used must be approved for that use. Among other problems, cement can leak, causing soft tissue damage, or, because so many blood vessels are near the spine, it can leak into the venous system, causing pulmonary embolism and death. I.G. Ex. 5 at 9-10 (Indictment ¶ 31); *see* I.G. Ex. 27-31 at 11; I.G. Exs. 27-62, 27-65, 27-66, 28; P. Joint Ex. 7 at 1; P. Joint Ex. 8 at 1.

---

[9] In describing his plea agreement, Petitioner writes that the FDA cleared Norian SRS "as a general bone filler in the extremities, spine and pelvis," but omits the critical modifying phrase "*not intrinsic to the stability of the bony structure* in the extremities, spine and pelvis." P. Br. at 6 (emphasis added).

Synthes and Norian promised that they would not promote Norian XR for vertebroplasty or other load-bearing indications, unless they obtained FDA approval. In December 2002, the FDA approved Norian XR, but required an indication statement identical to that of Norian SRS *plus* the explicit warning that it is "*not intended for treatment of vertebral compression fractures*." I.G. Ex. 6 at 6-7; P. Ex. 1 at 6-7 (Plea Agreement ¶ 9(G)) (emphasis added).

As it happened, the FDA's concerns were well-founded. Physicians were, in fact, misusing the Norian cements. But the FDA did not learn until much later that *the companies themselves* had been encouraging the misuse, supplying the product and training the surgeons in its unapproved use. As Petitioner concedes in his plea agreement, between August and December 2002 (before the FDA approved Norian XR for any purpose), the companies trained surgeons to mix Norian SRS with barium sulfate and to use the resulting medical device in vertebroplasty surgeries to treat vertebral compression fractures. These actions violated the FDCA, 21 U.S.C. §§ 351(f)(1)(B), 352(o), and 352(f)(1), because the mixing created a new device that required premarket approval for the new intended use. I.G. Ex. 6 at 7; P. Ex. 1 at 7 (Plea Agreement ¶ 9(H)).

Notwithstanding their assurances to the FDA, the product's label, and federal law, between August 2003 and January 2004, the companies trained spine surgeons to use Norian XR in vertebroplasty surgeries to treat vertebral compression fractures. They did so as part of a "test market," gathering clinical data about the surgeries performed by these Synthes-trained physicians in order to assess the risks posed by using Norian XR this way. Because the companies were testing a significant risk device without the required FDA approval, they violated the FDCA, 21 U.S.C. § 351(f)(1). I.G. Ex. 6 at 8; P. Ex. 1 at 8 (Plea Agreement ¶ 9(I)).

Throughout this time (December 2002 until January 2004), the companies were promoting the off-label use of Norian XR – in vertebroplasty surgeries to treat vertebral compression fractures – in violation of the FDCA, 21 U.S.C. § 351(f)(1). I.G. Ex. 6 at 8-9; P. Ex. 1 at 8-9 (Plea Agreement ¶ 9(J)); P. Joint Ex. 1 at 23.

Although he did not mention his own involvement in the illegal activity, Petitioner Higgins acknowledged that, as a corporate officer, he was responsible for preventing such violations. I.G. Ex. 6 at 1, 5; P. Ex. 1 at 1, 5 (Plea Agreement ¶¶ 1, 9(A)).

Petitioner admits that the companies illegally test marketed and promoted their cements. I.G. Ex. 6 at 1; P. Ex. 1 at 1 (Plea Agreement ¶ 1); *see* P. Joint Ex. 1 at 16-17 (describing the elements necessary to establish the crimes of misdemeanor adulteration and misdemeanor misbranding). They promised the FDA that they would not promote their cements for unapproved purposes; they did it anyway; and they did not tell the FDA what they were doing. From these admitted facts, I can reasonably infer – indeed, I find no other inference reasonable – that company employees acted intentionally and

deliberately. I consider such conduct "related to" fraud, if not actual fraud. Thus, without regard to Petitioner Higgins' personal involvement in such illegal activities, these facts, *which he conceded as part of his plea agreement*, establish that his offense is related to fraud.

Petitioner Higgins' knowledge of and participation in the underlying fraud. Just because prosecutors don't *need* to establish actual knowledge to sustain a conviction under the FDCA does not mean that the corporate officer didn't *have* actual knowledge. The biggest difference between this and the *Friedman* case is that, in *Friedman*, no compelling evidence established that the corporate officials were aware of their company's illegal activity. *See Paul D. Goldenheim et al.*, DAB No. 2268 (2009) at 13-14 n.9; *aff'd in part sub nom. Friedman v. Sebelius*, 686 F.3d 813. In contrast, when he sentenced Petitioner Higgins, Judge Davis concluded:

> Higgins betrayed the trust of his office and his position of leadership. Over the course of several years, he personally compromised and undermined the FDA's largely voluntary system for regulation of medical devices. He misled and manipulated surgeons by failing to provide accurate and complete information as to the significant risks associated with the use of Synthes bone cements in vertebral compression fracture surgeries. Sadly, he exploited and harmed vulnerable patients who necessarily relied on the integrity of professional judgments, which they had insufficient information to question.

I.G. Ex. 20 at 23.

Petitioner Higgins' direct involvement in the crime is established by overwhelming evidence. Judge Davis concluded that the "facts" of his involvement were "*true beyond all reasonable question*." I.G. Ex. 20 at 4 (Judge's Memorandum) (emphasis added). Among the many examples cited by Judge Davis (and supported by compelling documentary evidence) are the following:

- As early as February 2000, Petitioner Higgins sent a memorandum to the CEO of Synthes proposing a clinical trial of Norian SRS without FDA approval. He wanted to identify willing surgeons, select test sites, provide the cement, train the surgeons, and compile and review the data. The test market was to be completed in 90 days. I.G. Ex. 20 at 4 (Judge's Memorandum ¶ 1); I.G. Ex. 27-3; *see* I.G. Ex. 27-2 (notes regarding employee conversations with physicians about potential Norian study).

- Other Synthes employees repeatedly warned Petitioner Higgins that it would be illegal to conduct such a clinical trial of Norian SRS. In 2000, the then-group manager for Synthes's Regulatory and Clinical Spine Division, Barry Sands, told

him that the company could not initiate a study without an approved "Investigational Device Exemption" from the FDA. I.G. Ex. 20 at 4 (Judge's Memorandum ¶ 2); I.G. Ex. 29 at 2, 5.

- In a memorandum dated March 19, 2001, Michael Sharp, another employee in the regulatory department at Synthes, explained that he "made it clear [to Tom Higgins that] we absolutely could not do anything [that] could be considered promotion of SRS for use in the spine. . . . [Synthes staff] could not ask surgeons if they had used SRS, how SRS had performed in this indication, possible problems or ways to improve the use of SRS for this procedure, how often they might use SRS for such a procedure, etc." Mr. Sharp also "made it clear that the spine company should not be providing SRS to any account . . . that there is absolutely no reason[ ] that a spine consultant should ever be discussing SRS with a surgeon or providing the product." I.G. Ex. 20 at 5 (Judge's Memorandum ¶ 4); I.G. Ex. 27-18; P. Ex. 21 at 10.

  Petitioner criticizes the sentencing judge for relying on the Sharp warnings, suggesting that, because Regulatory Employee Sharp issued them before Norian SRS was approved for use in the spine, they no longer applied after the product was so approved. P. Br. at 21. But these warnings leave no room for misunderstanding as to what constitutes the "promotion" of a medical device. *See* P. Br. at 14-16. That the FDA approved Norian cements' limited use in the spine did not give the company carte blanche to promote it for all spinal surgeries, as Petitioner well knew. After all, the FDA insisted on language emphasizing that the product was *not* approved for vertebroplasty surgeries. I therefore find no merit to Petitioner Higgins' claim that he reasonably thought that Synthes's "test marketing" of Norian XR was legitimate. *See* P. Br. at 8-12.[10] Judge Davis characterized the company executives' (including Petitioner Higgins') actions in obtaining FDA approval for Norian XR: "They deliberately circumvented the premarket approval and [Investigational Device Exemption] processes for the novel use of their bone cements (thereby avoiding required careful study, scientific testing and explicit approval by the FDA), and instead surreptitiously sought and obtained a 510(k) exception, intentionally deceiving the FDA by failing to disclose their intended, and previously agreed upon, purposes." I.G. Ex. 20 at 13 (Judge's Memorandum).

[10] To support this proposition that Petitioner Higgins reasonably believed that the marketing was legal, Petitioner submits highly edited exerts from the grand jury testimony of various individuals who were involved in promoting the cements. P. Exs. 4-11, 13-18; P. Br. at 23-24. I find these scraps of testimony unreliable and unpersuasive.

- In March 2001, Petitioner Higgins learned that two patients, undergoing spine surgeries using an unapproved Norian cement with the same chemical formulation as Norian SRS, **suffered hypotensive events**.[11] Petitioner Higgins also knew that a Synthes sales representative was present at the off-label surgeries. I.G. Ex. 20 at 4 (Judge's Memorandum ¶ 3); I.G. Ex. 27-37 at 20.

- At a November 15, 2001 meeting, Petitioner Higgins participated in the company's decision not to pursue a clinical study aimed at obtaining FDA approval for using Norian SRS mixed with barium sulfate in vertebroplasty surgeries to treat vertebral compression fractures. The company officials instead decided "to get a few sites to perform 60-80 procedures and help them publish their clinical results." They rejected the safer and lawful approach because of the cost (about three years and a million dollars plus loss of Synthes's competitive advantage in the bone cement market). I.G. Ex. 20 at 5 (Judge's Memorandum ¶ 5); I.G. Ex. 27-5 at 2-3.

- In April 2002, researchers at the University of Washington began Synthes-commissioned pilot studies on Norian SRS. In e-mails beginning May 4, 2002, those researchers described the "alarming effect" the cement had on a pig:

> At 2 cc's the pig went into fulminant cardiopulmonary arrest. Autopsy showed Norian as a grisel like substance in right ventricle. More concerning was that the entire pulmonary artery system had clotted off. This could represent an uncontrolled activation of the coagulation cascade.
>
> The bothersome thing about the event from 4/30 was that it happened with only 2cc's in a full-sized pig. It led to a disproportionate and massive clot . . . all within a minute. *We were expecting to kill the pig* with the full 10cc load in a slow and progressive fashion – *but not suddenly and with a relatively small dose*. We also need to worry about a coagulogenic effect of the substance itself.

I.G. Ex. 28 at 1, 2 (emphasis added); I.G. Ex. 20 at 6 (Judge's Memorandum ¶ 7).

- Petitioner Higgins knew the alarming results of the pig studies. He knew that the chemical composition of Norian SRS posed lethal risks when used in the spine in vertebroplasties. He also "knew, or should have known, that the planned development of a cement to treat vertebral compression fractures was potentially

[11] I have highlighted in bold evidence that the Norian products' (mis)use had an adverse impact on individuals. *See* the following discussion of adverse impact.

suspect, and caution and strict adherence to regulatory procedure [were] required. Importantly, Higgins knew, or should have known, of the need for further testing before the product could be safely used on humans." I.G. Ex. 20 at 6-7 (Judge's Memorandum ¶ 7); I.G. Ex. 27-31 at 1-2.

Petitioner criticizes Judge Davis for referring to the pig studies without considering that, over a year later, the University of Washington researcher attended a Synthes Strategic Planning Meeting, where he purportedly opined that "it [presumably Norian XR] is the safest material to use, especially with low pressure system." P. Br. at 22 (citing P. Ex. 31 at 1); I.G. Ex. 27-55 at 1. Judge Davis considered the minutes of this meeting, although he did not point to that particular entry. I.G. Ex. 20 at 9 (Judge's Memorandum ¶ 16).[12] However, in April 2002, no one had suggested that Norian XR was "safest." In any event, I find that this cryptic reference to an ambiguous passing remark, made 16 months after-the-fact, hardly justifies Petitioner Higgins' disregard of the pig study's dramatic results.

- In June 2002 e-mails to Petitioner Higgins and other Synthes executives, Dr. Kenneth Lambert, a physician consultant characterized as "necessary and proper" the company's earlier decision to declare a moratorium on the use of Norian SRS in the spine "because of **several cases . . . that caused serious concerns about the safety of its use**." The consultant expressed concern that controlled studies had begun and asked, rhetorically, what had changed, answering that nothing had changed except a journal article describing a death involving the use of SRS. He warned that giving SRS to a surgeon for his use without any protocol "amounts to human experimentation whose only defense seems to be that it will be a small study." He opined that the company should be "uncomfortable" with any surgeon who is "comfortable" using SRS. He specifically warned Petitioner Higgins "that the company could suffer serious consequences if [the studies] are not done properly. Having the FDA take approval away may not be the worst consequence." I.G. Ex. 27-32 at 4, 6 (emphasis added); I.G. Ex. 20 at 7 (Judge's Memorandum ¶ 9).

- Petitioner Higgins received other explicit warnings of the life-threatening risks posed by using Norian SRS in vertebroplasties. He was copied on correspondence to Synthes, dated June 28, 2002, from University of Washington researchers. They warned "that vertebroplasty presents a unique risk of Norian's entry into the venous system with subsequent transport to the lung and a consequent risk of

[12] The researcher is also quoted as saying "need to better define timing of surgery in these studies" and recommending an FDA study to gain approval for the product's use in vertebroplasty. P. Ex. 31 at 1.

serious morbidity or mortality." I.G. Ex. 20 at 7 (Judge's Memorandum ¶ 10) (Judge's emphasis); I.G. Ex. 27-31 at 11.

- Petitioner Higgins attended a Management Review Board Meeting on September 17, 2002. Attendees discussed vertebroplasty, and Synthes CEO Hansjörg Wyss asked "about the test market set up and how surgeons, who are interested in the product, were to be trained." I.G. Ex. 27-35 at 4, 5; I.G. Ex. 20 at 7 (Judge's Memorandum ¶ 11).

- On May 8, 2002, representatives from the FDA met with Synthes personnel. At that meeting, the FDA representatives "expressed concerns" about " imprecise indications for use of bone void fillers" in the spine. They said that they "understood that surgeons were using [the fillers] in the spine for load bearing indications" and asked for additional labeling to specify that "load bearing indications, such as vertebroplasty" were not included in the indication for use. The Synthes representatives promised that they would not promote the material "for such indications as vertebroplasty or other load bearing indications without the appropriate regulatory clearances." Petitioner Higgins received a copy of the meeting minutes, and therefore knew about the FDA concerns and the company's assurances. I.G. Ex. 27-13 at 2; I.G. Ex. 29 at 3-4; *see* I.G. Ex. 6 at 6-7; P. Ex. 1 at 6-7 (Plea Agreement ¶ 9(G)); P. Ex. 19 at 1 (advising Synthes Spine employees that "FDA . . . still pushing for specific wording with regards to no vertebroplasty and non load bearing only. . . .").

- On January 13, 2003, **a patient of Dr. Barton Sachs died** during a vertebroplasty/kyphoplasty[13] procedure, for which the surgeon had used SRS mixed with barium sulphate (the combination that became Norian XR). No autopsy was performed and no one filed a medical device report. I.G. Ex. 20 at 7 (Judge's Memorandum ¶ 12); I.G. Ex 27-37 at 8; I.G. Exs. 27-49 through 27-51.[14]

  Synthes's failure to report or follow-up on this, and other adverse events, seriously undermines its claim to have been conducting a legitimate test market in order to determine the "level of risk" associated with the procedure. How does one assess the "level of risk" without adequately investigating the negative outcomes?

---

[13] "Kyphoplasty" is a variation on vertebroplasty surgery, in which a surgical instrument and balloon are inserted into the compressed vertebral body to create a cavity into which the bone cement can be filled. I.G. Ex. 5 at 9 (Indictment ¶ 29).

[14] These documents are handwritten notes taken by Synthes employees Nisra Thongpreda, Josi Hamilton, and Stuart Weikel of a telephone conference call they had with Dr. Sachs on January 16, 2003.

- On February 10, 2003, Petitioner Higgins approved and signed the "Final Market Introduction Plan for [Norian] XR," predicting after-tax profits of 35 times the cost of raw materials. I.G. Ex. 20 at 8, 14 (Judge's Memorandum ¶ 14); I.G. Ex. 27-37. The plan includes a "Release to Market Strategy" that describes the "back table mixing" of Norian SRS with barium sulfate (which became Norian XR, but was not then approved). It says that "this part of the test market began in September 2002, and that two sites were selected to participate in Phase I" (which included Dr. Sachs). I.G. Ex. 27-37 at 77; *see* I.G. Ex. 6 at 7; P. Ex. 1 at 7 (Plea Agreement ¶ 9(H). For Phase II, which would begin in August 2003, eight additional test sites had been selected, based on, among other factors, "*affiliation with treating vertebral compression fractures*." Phase III would begin in September 2003 and would add eight additional sites. I.G. Ex. 27-37 at 77 (emphasis added).

- At the company's July 18, 2003 Safety Meeting, the participants – including Petitioner Higgins – considered their options: 1) maintain the current plan; 2) postpone the test market and re-evaluate later; or 3) cancel the project as "too unsafe." I.G. Ex. 20 at 8 (Judge's Memorandum ¶ 15); I.G. Ex. 27-38 at 22. They decided to proceed with the market plan, obtaining a larger case base, at multiple sites, which, they said, would allow them better to estimate the rate of complications. "*This will help us determine our associated level of risk and decide what level is too high.*" I.G. Ex. 20 at 8-9 (Judge's Memorandum ¶ 15) (Judge's emphasis); I.G. Ex. 27-39 at 2; I.G. Ex. 27-40. Not only did Petitioner Higgins attend the meeting, one of the attendees sent him a copy of the meeting minutes. I.G. Ex. 27-40. Moreover, as Judge Davis observed: "These determinations, of course, can be made properly only in accordance with FDA regulatory protocol. A test market cannot lawfully be used to determine the safety and efficacy of a significant risk medical device." I.G. Ex. 20 at 9 (Judge's Memorandum ¶ 15).

- At an August 14, 2003 Strategic Planning Meeting, Petitioner Higgins was among the participants who decided to proceed with the unauthorized clinical trials of Norian XR, to "prove safety of the technique" on human beings. I.G. Ex. 20 at 9 (Judge's Memorandum ¶ 16); I.G. Ex. 27-55.

- When Norian XR was "officially released to Test Market," Josi Hamilton, the Synthes Product Manager, sent an e-mail, dated August 28, 2003, announcing the release, advising that Synthes "shipped to 13 Spine sites Wednesday afternoon, and have 4 cases scheduled for Friday!!" She thanked everyone for their continued support. She sent a copy of this e-mail to Petitioner Higgins. I.G. Ex. 20 at 9 (Judge's Memorandum ¶ 16); I.G. Exs. 27-58, 27-59.

- On September 19, 2003, **a second patient died** during spinal surgery performed by Dr. Paul Nottingham using Norian XR. Again, no autopsy was performed. I.G. Exs. 27-62, 27-66. Although a medical device report was filed, it *did not mention that the procedure was a vertebroplasty/kyphoplasty using Norian XR.* I.G. Ex. 20 at 9 (Judge's Memorandum ¶ 17) (emphasis added).

- On September 19 and 20, 2003, Petitioner Higgins participated in the "Norian XR Test Market Kick-Off" session. Its purpose was to train surgeons to use Norian XR in vertebroplasties to treat vertebral compression fractures. I.G. Ex. 20 at 9 (Judge's Memorandum ¶ 18); I.G. Exs. 27-63 and 27-64.

- Petitioner Higgins met with Product Manager Hamilton and others on September 23, 2003. At that meeting and in a follow-up memorandum, dated October 15, 2003, Product Manager Hamilton summarized her interviews with two of the 19 surgeons participating in the Norian XR clinical trials. One physician, Dr. Paul Nottingham, reported that "**[d]uring cement delivery . . . a drastic drop in blood pressure was noted**. . . ." ; he noted a **cement leak during injection** "and feels this was the cause of the incident." He characterized the Synthes "system" as "guesswork as to how much material to inject" and opined that "a clinical trial is necessary before releasing" Norian XR. He also complained that "the sales consultant pushed this 'product' on him and was unclear as to its status on the market." I.G. Ex. 20 at 9-10 (Judge's Memorandum ¶ 19); I.G. Exs. 27-62, 27-65, 27-66.

- In another e-mail, dated October 1, 2003, Product Manager Hamilton advised Petitioner Higgins and others of her interview with Dr. Joe Lane. She wrote that Dr. Lane thought that "Norian XR is **potentially de-watering and causing episodes of hypotension**. . . . With our system, he says there is no egress hole, so the pressure can be too high . . . with an old fracture, the cement might not have a place to go, so a **venous leak can happen**. . . . He believes Norian XR should have gone to the [Institutional Review Boards] of every participating hospital [because] of the information we're collecting. . . . Lane thinks we should go to the FDA ASAP to understand what is necessary in order to change our labeling (Remove 'Not for use in Vertebral Compression Fractures')." I.G. Ex. 20 at 10 (Judge's Memorandum ¶ 19); I.G. Ex. 27-68.

- Petitioner Higgins and others met on October 31, 2003, to consider the serious questions surrounding the use of Norian XR in unauthorized clinical trials (e.g., the death of Dr. Nottinham's patient, the University of Washington pig studies).

They also considered their "competitors' status."[15] Notwithstanding the second death and aware of the risks, the participants opted to "continue the experimental use of [Norian] XR on humans." I.G. Ex. 20 at 10 (Judge's Memorandum ¶ 20); I.G. Ex. 27-67.

- In a memorandum dated November 19, 2003, Product Manager Hamilton updated Petitioner Higgins on the University of Washington's ongoing Norian XR studies, concluding that "[t]here is not enough information yet for the surgeons to draw any conclusions regarding the clinical use of [Norian] XR." I.G. Ex. 20 at 10 (Judge's Memorandum ¶ 21); I.G. Ex. 27-61.

- On January 22, 2004, **a third patient died** while undergoing kyphoplasty surgery to treat a vertebral compression fracture. Dr. Hieu Ball performed the surgery. An autopsy report was preformed, and a medical device report filed. I.G. Ex. 20 at 10 (Judge's Memorandum ¶ 22); I.G. Exs. 27-74; 27-75.[16]

- The FDA investigated Synthes from May 11 through June 18, 2004, and issued a warning letter to Synthes on November 5, 2004. I.G. Ex. 20 at 11 (Judge's Memorandum ¶ 23); I.G. Ex. 33; *see* I.G. Ex. 27-79. The letter advised Synthes that, during its investigation, it learned that Synthes was "marketing the Norian XR for new intended uses without approval or clearance from FDA[,] in violation of the Act." The letter also advised the company that the FDA found violations of the Medical Device Reporting regulation (21 C.F.R. Part 803) and the Current Good Manufacturing Practice of the Quality System regulation (21 C.F.R. Part 820). I.G. Ex. 20 at 11 (Judge's Memorandum ¶ 23); I.G. Ex. 33 at 1.

- Petitioner Higgins was involved in preparing the Synthes response to the FDA. In that response, the company (falsely) claimed that no clinical trials had occurred; and that the test market was conducted for cleared indications only, not to test the

---

[15] Apparently, one of Synthes's competitors was also developing a bone cement at about this time, and the FDA had approved a "second pilot human clinical study," using the competitor's cement in vertebral compression fracture repair. P. Ex. 19 at 3.

[16] I note that Dr. Ball was among the physicians who criticized Dr. Nottingham and his purportedly "aggressive surgical tactics." Dr. Ball also opined that "it is necessary to focus on proper patient selection." I.G. Ex. 27-62 at 1-2; P. Joint Ex. 9 at 1. But four months after the death of Dr. Nottingham's patient, Dr. Ball's own patient died while undergoing the procedure. I.G. Ex. 27-74. She was 83-years-old and a smoker, suffering from hypertension, atypical angina, diabetes, and asthma. P. Joint Ex. 11 at 2-3. So I don't know what Dr. Ball meant by "proper patient selection."

> safety and efficacy of the bone cements. It denied training surgeons to use the cements. I.G. Ex. 20 at 11 (Judge's Memorandum ¶ 24); I.G. Ex. 16 at 70-71.

The court concluded that Petitioner Higgins' case "stands apart" from all other cases involving convictions of responsible corporate officers "because the criminal conduct at issue is his own." I.G. Ex. 20 at 15-16.

> To summarize thousands of pages of documents reviewed before the imposition of sentence, Thomas Higgins, as President of the Spine Division, planned and participated in the unlawful clinical trials. He is fairly described as having been the "hands on manager of the unlawful clinical trials." [*citing* Sentencing Transcript, I. G. Ex. 16 at 55, 77] He was the actual leader of the Spine Division from whom his subordinate corporate-actors received direction. He received contemporaneous reports from his managers and lower level employees on the conduct and results of the trials. He was in front, up close, and in person on product development and all important decisions involving bone cements. He was fully aware that patients in the clinical trials were being subjected to untested and unapproved medical devices and were being placed at risk without their knowledge or consent. Indeed, when Defendant and persons under his control conducted training sessions, the surgeons were not advised of the deaths or adverse events, even though one of the deaths had occurred on the first day of the September 19-20 forum. Moreover, as he acknowledged to Barry Sands and Michael Sharp in 2000, Higgins fully understood that the 510(k) process was not an appropriate approval route for the devices at issue. Thus, all subsequent events occurred . . . against the backdrop of Higgins' acknowledged awareness that the Synthes test market was outside the boundaries of the law.

I.G. Ex. 20 at 12-13; *see also* I.G. Ex. 16 at 19-20 ("[A]cting in concert [with his colleagues, Petitioner Higgins] affirmatively decided to proceed, to ignore the risk, to ignore the concerns, to ignore the evidence that had been presented by a host . . . of different medical consultants . . . . [T]hey crafted an approach [that] circumvented the regulatory authority and included lying on multiple occasions to the regulatory authority. . . .").

Petitioner characterizes as "simply not true" Judge Davis's conclusion that Petitioner Higgins and his employees did not tell the physicians attending the September 19-20 training forum about the first two patient deaths (which occurred on January 13, 2003 and September 19, 2003), claiming that Product Manager Hamilton personally "called surgeons to inform them about the death" of Dr. Nottingham's patient. In support, Petitioner cites what appears to be a memorandum containing the notes of Ms. Hamilton's conversations with physicians. P. Br. at 17 (citing P. Ex. 25). Nothing

indicates when she had these conversations, but the memorandum is dated October 18, 2005, more than two years after the death of Dr. Nottingham's patient and almost three years after the death of the first patient. Thus, neither this document nor any other cited evidence contradicts the judge's finding that Synthes employees conducted the September 2003 training sessions without telling the participating physicians about the two deaths or other adverse consequences.

Petitioner plainly knew about and participated in the illegal test marketing that ultimately led to his conviction. His conviction was thus factually related to fraud, and the I.G. appropriately excluded him from program participation under section 1128(b).

Financial Misconduct. Petitioner Higgins (along with Petitioners Walsh and Boehner) argues that he should not be excluded, because his conviction is not "related to" financial misconduct. There are two problems with this argument. First, as Judge Davis found, Petitioner and his cohorts were, in fact, motivated by financial gain. They wanted to avoid the expense associated with seeking FDA approval, and they hoped that their actions would engender enormous profits. I.G. Ex. 20 at 5, 8, 14; I.G. Ex. 27-5 at 2-3; I.G. Ex. 29 at 2-3. In that sense, the illegal activity was "related to" financial misconduct. *Breton Lee Morgan, M.D.*, DAB No. 2264 at 13 (2009) (finding that the petitioner, who obtained, for his own use, hydrocodone samples from pharmaceutical representatives by claiming he would give them to patients for medical purposes, "derived some unquantifiable measure of pecuniary value by illegally diverting the controlled substances.")

Second, and even more compelling, the Board has rejected soundly Petitioner's "narrow interpretation" of the statutory language, finding it "not compatible with the structure and context of the statutory language as a whole." That decision was ultimately affirmed by the Fourth Circuit Court of Appeals. *Breton Lee Morgan, M.D.*, DAB No. 2264, *aff'd*, *Morgan v. Sebelius*, 694 F.3d 535.[17] In affirming the Board's decision, the Court of Appeals found that the statutory language "makes clear" that, to warrant exclusion, the offense "need only to relate to at least one of [the] five categories[.]" 694 F.3d at 538. (emphasis added). The Court explicitly rejected as "simply not correct" Morgan's argument that the presence of the word "other" would be superfluous but for this narrowing effect. To the contrary, the presence of the word "other" reflects the fact that the other categories can also relate to financial misconduct. Had Congress intended that an offense must relate to financial misconduct, it could have omitted all of the other

[17] The exclusion in *Breton Lee Morgan* was brought under section 1128(a)(3) of the Act, but the reasoning applies here, because the relevant language of section 1128(a)(3) is identical to that in section 1128(b)(1) ("relating to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct").

terms, and "simply required the exclusion for offenses 'relating to financial misconduct.'" *Id.*

The Court also noted that Morgan's interpretation would defeat the statute's purposes, which are to protect federal programs from untrustworthy individuals and to "provide a clear and strong deterrent against the commission of criminal acts." *Id*. at 538 (citing S. Rep. 100-109 at 5 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682, 686). In the court's view, and I agree, Congress was targeting fraud generally, not simply fraud relating to financial misconduct. Its purposes would not be served by narrowing the scope of the statute.

2. A five-year exclusion is not unreasonably long.

Having found a basis for the exclusion, I now consider whether a five-year exclusion falls within a reasonable range. The statute provides that the period of exclusion under section 1128(b)(1) "shall be 3 years, unless the Secretary determines in accordance with published regulations that a shorter period is appropriate because of mitigating circumstances or that a longer period is appropriate because of aggravating circumstances." Act § 1128(c)(3)(D); 42 C.F.R. § 1001.201(b)(1). So long as the period of exclusion is within a reasonable range, based on demonstrated criteria, I have no authority to change it. *Joann Fletcher Cash*, DAB No. 1725 at 16-17 (2000) (citing 57 Fed. Reg. 3298, 3321 (1992)).

Among the factors that may serve as bases for lengthening the period of exclusion are two relied on by the I.G.: 1) the acts resulting in the conviction, or similar acts, had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals; and 2) the sentence imposed by the court included incarceration. 42 C.F.R. § 1001.201(b)(2) (iii) and (iv).[18]

Incarceration. The court sentenced Petitioner Higgins to nine months in jail, a sentence that is significantly longer than called for by federal sentencing guidelines (a minimum of no jail time and a maximum of six months). I.G. Ex. 11 at 2; I.G. Ex. 16 at 77. When he accepted Petitioner's guilty plea, Judge Lawrence F. Stengel pointed out that Petitioner Higgins' case would ordinarily have fallen into the "zero to six-month" guideline range, based on the "offense level" and his criminal history score. However, although "very important," the guidelines are not mandatory. Other factors, such as the nature and circumstances of the offense, the defendant's history, and his character go into the determination. P. Joint Ex. 1 at 13.

[18] Although, arguably, "the acts that resulted in the conviction, or similar acts, were committed over a period of one year or more," the I.G. here did not cite this aggravating factor as a basis for increasing the period of exclusion. *See* 42 C.F.R. § 1001.201(b)(2)(ii); *see, e.g.*, I.G. Ex. 16 at 46 ("[I]t's a [deliberate] choice that is made over a two, two and a half year period.").

Judge Davis did not take the sentencing guidelines lightly. He also recognized that, under the terms of his plea agreement, Petitioner waived his right to appeal the sentence, so long as it was no longer than six months. "But the fact of the matter is that [nine months] is the minimal sentence that I think is appropriate to protect the societal interest in this matter." I.G. Ex. 16 at 78; *see* I.G. Ex. 6 at 11 (Plea Agreement ¶ 13b(2) and (3)). Judge Davis explained that he departed from the guidelines, because the crime was much worse than any other case brought against a responsible corporate officer. Alluding to the facts underlying the Supreme Court's decision in *United States v. Park*, 421 U.S. 658 (1975), he noted that:

> [t]his matter does not involve holding an unaware corporate executive accountable for vermin in a warehouse. The sentencing considerations with Higgins are far more stark and compelling. We have not been able to locate a single case that involves such carefully constructed, meticulously implemented, and patently illegal, clinical trials. It is axiomatic that it is improper to use test markets to assess the safety of Class III devices. Nor can we find a reported case evincing such a pattern of deception with the FDA. And we cannot find a case where the decision-makers ignored such clear warnings of the potentially fatal nature of the product for such an extended period. We certainly cannot find a case where the corporate actors disregarded two deaths, even failing to provide notice of the first as required by law. Finally, and most importantly, Higgins' case stands apart from other *Park* doctrine cases because the criminal conduct at issue is his own.

I.G. Ex. 20 at 15-16.

Further, although he described Petitioner Higgins as "an accomplished and decent man," the judge questioned how such a man "came to participate in this extended course of callous and illegal behavior." In the judge's view, that behavior "speaks to the character of the offender and the nature and circumstances of the offense." He also noted that Petitioner Higgins' written statement (he did not testify) "provided no insight and no true answers for he acknowledged the wrongfulness of his conduct only through the lens of hindsight." I.G. Ex. 20 at 16-17 (Judge's Memorandum).

Any period of incarceration, no matter how short, justifies increasing the period of exclusion. Nine months is, in fact, a relatively substantial period of incarceration. *Jason Hollady, M.D.*, DAB No. 1855 at 12 (2002); *Stacy Ann Battle, D.D.S.*, DAB No. 1843 at 7 (2002) (finding that four months in a halfway house, followed by four months home confinement justifies lengthening the period of exclusion); *Brenda Mills, M.D.*, DAB CR1461 at 4 (2006) (finding that six months home confinement justifies increase in length of exclusion), *aff'd*, DAB No. 2061 (2007).

I consider Petitioner's incarceration, by itself, sufficient to justify the relatively modest increase in his period of exclusion, particularly in light of the judge's significant and well-supported upward departure from the sentencing guidelines.[19]

Adverse impact. Unquestionably, Petitioner Higgins and his colleagues at Synthes subjected unsuspecting patients to "illegal and dangerous human experimentation." I.G. Ex. 20 at 14 (Judge's Memorandum). Even without a showing of additional harm, I find that promoting unauthorized experimentation on human subjects, particularly without their informed consent, by itself, establishes a significant adverse impact on the individuals who are subjected to it. *See* I.G. Ex. 27-32 at 4, 6; I.G. Ex. 20 at 7.

Unfortunately, in this case, the adverse impact on individuals went beyond subjecting them to unauthorized experimentation. Judge Davis found that "patients were directly and proximately harmed by the conduct of the Defendants and others at Synthes." They were subjected to the risks of Norian SRS and Norian XR without their full informed consent and without the FDA's authorization. Some were injured and some died. By conducting the unauthorized trials of these cements, the judge found, Synthes employees "disregarded the safety of all members of society." I.G. Ex. 15 at 19, 31; I.G. Ex. 20 at 14 (Judge's Memorandum) ("Ultimately, three unsuspecting persons died during the Synthes clinical trials."); I.G. Ex. 27-37 at 20.

In his findings, listed above, Judge Davis included examples of the adverse effects Petitioner's crime had on individuals. I have highlighted those examples, any one of which, by itself, justifies increasing the period of exclusion. Notably:

---

[19] I recognize the dangers inherent in comparing periods of exclusion. Comparisons can be of limited value, at best, and misleading, at worst. Not only is the universe of cases we review extremely limited, comparisons rarely consider the entire circumstances of the particular cases. Nevertheless, some proportionality is desirable, in order to assure the integrity of the exclusion process. Five-year exclusions are regularly imposed for offenses that seem trivial when compared to Petitioner Higgins' actions. *See, e.g., Nabil Elhadidy, M.D.*, DAB CR2000 (2009) (five-year exclusion based on one misdemeanor count of offering a false instrument, with conviction discharged after petitioner completed community service and paid a $160 fine); *Andrew D. Goddard*, DAB No. 2032 (2006) (five-year exclusion for appropriating one Lasix tablet, valued at $0.20, from pharmacy and, as a prank, placing it in the employee coffee pot). And much longer periods of exclusion have been imposed for offenses having less impact than Petitioner's. *See Doantrang Thi Nguyen*, DAB CR2191 (2010) (13-year exclusion imposed based on one misdemeanor count of introducing misbranded drug (Lipitor that was not approved for sale in the U.S. into interstate commerce)).

- Prior to March 2001, two patients suffered hypotensive events while undergoing surgery, using an unapproved Norian cement with the same chemical formulation as Norian SRS, and with a Synthes sales representative present. I.G. Ex. 20 at 4; I.G. Ex. 27-37 at 20. Petitioner has not denied these events. Nor does he deny that such sudden drops in blood pressure were associated with the use of the Norian cements in vertebroplasties.

- On January 13, 2003, Dr. Sach's patient died while undergoing the unapproved surgery. Synthes employees knew about it. No one reported the death and no autopsy was performed. I.G. Ex. 20 at 7; I.G. Ex. 27-37 at 8; I.G. Exs. 27-49 – 27-51.

  Petitioner complains that the I.G. has not proven that the Norian cement directly caused this (and the other) deaths. But Petitioner Higgins and his colleagues were in a position to learn the role the cement played in the death of Dr. Sach's patient – indeed the ostensible purpose of their "test market" was to determine the risks associated with the procedure. To the extent that the causes of the patient deaths were never fully determined, they bear significant responsibility and should not now benefit from their failure to investigate adequately and their failure to disclose the findings so that others could investigate. As Judge Davis recognized, failing to report and investigate such a death is a dangerous practice and puts all future patients at risk.

  Moreover, no one doubts that the patients died as a direct result of the surgeries – surgeries that were undertaken because Petitioner, his company, and his colleagues, illegally promoted the misuse of the Norian cements.

- On September 19, 2003, Dr. Nottingham's patient died while undergoing the unapproved surgery. Again, no autopsy was performed, and, although a medical device report was filed, it did not accurately describe the procedure (vertebroplasty using Norian XR). I.G. Ex. 20 at 9. During the surgery, the patient experienced what the surgeon described as a "drastic drop in blood pressure." He also noted a "cement leak." I.G. Ex. 20 at 9-10; I.G. Exs. 27-62, 27-65, 27-66. At least one other physician opined that "Norian XR is potentially de-watering and causing episodes of hypotension." I.G. Ex. 20 at 10; I.G. Ex. 27-68. Even if Dr. Nottingham's patient had survived, a hypotensive event is an "adverse impact."

- On January 22, 2004, Dr. Ball's patient died while undergoing surgery to treat a vertebral compression fracture using Norian XR. I.G. Ex. 20 at 10; I.G. Exs. 27-74, 27-75.

  Only Dr. Ball's patient underwent an autopsy. As with the experimental pig, this patient died within a minute or two of the surgeon's introducing the cement.

> According to the autopsy report, "[i]mmediately following the installation of [the Norian XR] cement bilaterally . . . her blood pressure decreased and [she] was unresponsive to CPR." P. Joint Ex. 11 at 3. Similar to the findings in the pig studies, the autopsy examiners also found "foreign material" inside what they presumed were capillaries, and "clumps" of this material inside larger blood vessels of the lungs. P. Joint Ex. 11 at 4; I.G. Ex. 27-31 at 11. Except for the amount, this material was "indistinguishable" from the clumps they found in her spine. P. Joint Ex. 11 at 5. Petitioner does not explain the presence of the same "foreign material" in both the lungs and the spine. There may be other explanations; however these findings are consistent with the risks described by the many researchers who warned that Norian XR could enter the venous system and travel to the lungs. I consider this compelling evidence that the unapproved use of the Norian cement "had a significant adverse physical . . . impact on Dr. Ball's patient."

Petitioner Higgins concedes that three patients undergoing surgeries using the Norian cements "experienced hypotensive events and died," but points out that all were elderly; all suffered serious underlying health problems and multiple co-morbidities, including significant coronary problems. In Petitioner's view, the patients were not harmed by the procedure, because they likely died from their underlying conditions. P. Joint Br. at 36-37.

But Petitioner does not explain why these extraordinarily vulnerable patients – with serious underlying cardiac conditions – would undergo an experimental procedure that was associated with negative cardiac events. As Judge Davis recognized, the patients did so *because they did not know about those negative events*! *See* P. Ex. 28 at 5 (referring to one of the victims, Judge Davis described him as "a scientist, a physicist" who was unable "to make a choice about whether he would undergo an optional procedure because information wasn't shared to him or his doctor, and you and your co-defandants did it."); I.G. Ex. 16 at 7-9 ("[U]nfortunately, he didn't have the information that we now know prior to his surgery.").

According to Petitioner, at one least one of these patients (Dr. Sachs') needed and obtained "cardiologist clearance to undergo procedure with general anesthesia." The patient herself signed a "special form" acknowledging the heightened risk. P. Joint Br. at 37. Petitioner does not provide copies of the patient consent nor the cardiologist's clearance, but relies on Product Manager Hamilton's notes of her telephone conversation with Dr. Sachs. P. Joint Ex. 6. This hearsay-on-hearsay comes from individuals with a vested interest in avoiding responsibility for the negative outcome, and I do not consider it very reliable. Nevertheless, accepting Ms. Hamilton's version of Dr. Sachs' version, I see no claim that the cardiologist cleared the patient for anything more drastic than an approved surgical procedure involving general anesthesia. I see no evidence that either the cardiologist or the patient realized that she would undergo an unapproved and highly

experimental procedure, known to cause hypotensive events, a procedure that presented the "unique risk" of the cement's entry into the venous system and transport to the lungs. I.G. Ex. 27-31 at 11.

Petitioner disavows any responsibility for the surgeries, pointing out that physicians often use medical devices in unapproved ways and suggesting that the physicians themselves are accountable for any adverse outcome. P. Joint Br. at 39. I recognize that physicians may use medical devices in unapproved ways. As happened with the Norian cements, using a device in ways that are not approved can endanger patient safety. It is therefore vitally important that manufacturers not promote their products' use in such unapproved – and potentially dangerous – ways. *See, e.g.* I.G. Ex. 27-18. No doubt the physicians should be held responsible for their own actions, but that does not relieve Petitioner of his responsibility. The physicians may have pulled the trigger, but Petitioner, his colleagues, and his employees supplied the guns and ammunition, and enlisted and trained gunmen they knew to be willing.

Moreover, Judge Davis found that the Synthes executives misled physicians into "believing the products could be used safely. To say that the physicians were 'sophisticated and experienced' does not mean that they were not misled. . . . The reading of the [Norian] XR label word-for-word during the training sessions did not cure the lack of critical information about the product's dangers." I.G. Ex. 20 at 19-20.

In light of the substantial amount of human experimentation, putting patients at significant risk of hypotensive events and even death, the question is not so much whether a five-year exclusion is reasonable, but why the period of exclusion is so low.

Mitigating factors. The regulations consider mitigating just three factors: 1) a petitioner was convicted of three or fewer misdemeanor offenses, and the resulting financial loss to the program was less than $1,500; 2) the record in the criminal proceedings demonstrates that a petitioner had a mental, physical, or emotional condition that reduced his culpability; and 3) a petitioner's cooperation with federal or state officials resulted in others being convicted or excluded, or additional cases being investigated, or a civil money penalty being imposed. 42 C.F.R. § 1001.201(b)(3). Characterizing a mitigating factor as "in the nature of an affirmative defense," the Board has ruled that a petitioner has the burden of proving any mitigating factor by a preponderance of the evidence. *Barry D. Garfinkel, M.D.*, DAB No. 1572 at 8 (1996), *aff'd*, *Garfinkel v. Shalala*, No. 3-96-604 (D. Minn. 1997).

Here, Petitioner Higgins was convicted of one misdemeanor offense, and the I.G. does not allege that his crime caused program financial losses. His relatively short period of exclusion reflects that factor.

Petitioner claims that he cooperated with law enforcement and is therefore entitled to additional consideration under section 1001.102(c)(3). In support of this claim, he points to the timing of his guilty plea relative to the timing of his company's guilty plea and suggests a relationship between his taking "responsibility for whatever it is that [Synthes] may have done that violated the FDCA" and the company's guilty plea. P. Br. at 26. Even among unsuccessful arguments of "cooperation with law enforcement," this one is exceptionally weak. At sentencing, Petitioner's own attorney characterized as "speculation" the notion that his plea agreement led to other guilty pleas, and Petitioner has added no additional support for his claim. I.G. Ex. 16 at 18.

"It is entirely Petitioner's burden" to show that his cooperation resulted in others being convicted or excluded, or additional cases being investigated or excluded, or a civil money penalty being imposed. *Stacey R. Gale*, DAB No. 1941 at 9 (2004). Section 1001.102(c)(3) "should be viewed narrowly (i.e., that it is designed to accommodate 'only significant cooperation')." *Marcia C. Smith*, DAB No. 2046 at 10 (2006). The regulation is "designed to authorize mitigation for significant or valuable cooperation that yielded positive results for the state or federal government in the form of a *new case* actually being opened for investigation. . . ." *Smith*, DAB No. 2046at 9 (citing *Stacey R. Gale*, DAB No. 1941 at 11) (emphasis in original). The regulation contemplates a situation in which the target of the original investigation, i.e., the person who later claims that the mitigating factor applies, gives information that results in an investigation of a new target or targets. Expanding an existing investigation does not qualify. *Smith*, DAB No. 2046 at 9-10.

The investigations of the Norian and Synthes companies and their corporate executives were all parts of one whole. Petitioner is not entitled to special consideration simply because he was among the first to plead guilty to a crime that he and his company committed.

Petitioner raises other factors, which, he argues, should be considered in assessing his trustworthiness. He complains that the regulations are too narrow, because they omit factors that, is his view, should be considered mitigating. P. Joint Br. at 40. But the statute provides that any deviation from the prescribed three-year exclusion must be made "in accordance with published regulations." I thus may not consider any factor not set forth in the regulations. *See* 42 C.F.R. § 1005.4(c)(1).

Finally, Petitioner points out that during the sentencing hearing, Judge Davis mentioned that he was not worried about the defendant committing another crime. P. Br. at 18 (citing P. Ex. 28 at 6). Judge Davis made this remark in the context of explaining that he ordered supervised release following incarceration mainly to make sure that Petitioner paid the fine, rather than to deter additional criminal activity. The observation did not find its way into the judge's written memorandum. In fact, throughout the sentencing phase, Judge Davis struggled to understand why such a purportedly upstanding citizen

would engage in such reprehensible behavior. He gave the defendant every opportunity to explain himself, which the defendant declined to do. *See* I.G. Ex. 20 at 16-17 (Judge's Memorandum). Indeed, as Petitioner Higgins' submissions here establish, to this day, he denies any culpability other than occupying his corporate officer position at Synthes.

In any event, the Board has repeatedly observed that the exclusion remedy serves two purposes: to protect program beneficiaries and program integrity from those who have shown themselves to be untrustworthy; and to deter others from engaging in similar misconduct. *Breton Lee Morgan, M.D.*, DAB No. 2264 at 9 (citing *Jeremy Robinson* DAB No. 1905 at 3 (2004)); S. Rep. No. 109, 100th Cong., 1st Sess. (1987) ("clear and strong deterrent"); *Joann Fletcher Cash*, DAB No. 1725 at 15, 18 (discussing trustworthiness and deterrence). In imposing an expanded jail sentence, Judge Davis emphasized that he considered the penalty necessary to deter similar wrong-doing. Introducing adulterated and misbranded products into interstate commerce significantly endangers the public. *United States v. Park*, 421 U.S. 658. Yet the temptations to engage in such conduct are substantial, promising potentially enormous profits with relatively little risk to the individuals involved. Judge Davis recognized that imposing significant jail time is one of the few effective deterrents. So too is exclusion.

Conclusion

Petitioner's crime demonstrates that he presents a significant risk to the integrity of health care programs and the safety of program beneficiaries. With others, he callously disregarded the FDA requirements, the repeated warnings from his regulatory department, and the truly frightening findings of his researchers. He withheld from the FDA and participating physicians alarming evidence of dangers associated with his company's cements when used in vertebroplasties. His crime merited significant jail time, and it cries out for a significant period of exclusion. Based on all of the circumstances described above, I find that a five-year exclusion is not unreasonably long.

/s/
Carolyn Cozad Hughes
Administrative Law Judge

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Thomas B. Higgins,
(OI File Number: 3-05-40179-9),

Petitioner,

v.

The Inspector General

Docket No. C-13-164

Date: November 25, 2014

ADDENDUM TO DECISION CR3477: RULING ON OBJECTIONS TO EXHIBITS

The Inspector General for the Department of Health and Human Services (I.G.) has excluded Petitioner, Thomas B. Higgins, from participating in all federal health care programs for a minimum period of five years, pursuant to section 1128(b)(1) of the Social Security Act. Petitioner Higgins appealed the exclusion. The parties have submitted their written arguments and proposed exhibits. The I.G. submitted 33 exhibits (I.G. Exs. 1-33). Of these, I.G. Ex. 27 includes multiple parts: I.G. Ex. 27, I.G. Ex. 27-1 and I.G. Ex. 27-1A; I.G. Ex. 27-2 through I.G. Ex. 27-81.

Petitioner objects to my admitting many of the I.G.'s proposed exhibits. For the reasons discussed below, I overrule Petitioner's objections and admit I.G. Exs. 1-33.

As a threshold matter, I note that I am not bound by the Federal Rules of Evidence and may admit evidence that would not ordinarily be admitted under them. 42 C.F.R. § 1005.17(b). With limited exceptions, I admit all evidence that is relevant and material. *See* 42 C.F.R. § 1005.17(c), (d), (e) and (f). By regulation, evidence of crimes, wrongs or acts other than those at issue in the case before me is also admissible, in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. 42 C.F.R. § 1005.17(g).

I.G. Ex. 5 – Criminal Indictment.

Petitioner objects to I.G. Ex. 5, which is his criminal indictment. He argues that, because he was named only in Count 97 of the 97-count indictment, "most of the document has nothing to do with him." As to Count 97 itself, he characterizes it as "merely a set of allegations" with "no evidentiary value" and claims that he did not, in fact, plead guilty to those allegations, but limited his guilty plea to the facts set forth in his plea agreement, I.G. Ex. 6. He claims that he did not even see the indictment before he pled guilty. Petitioner Thomas B. Higgins' Responses and Objections to I.G.'s Informal Exhibit List (P. Objections) at 2.

Petitioner executed his plea agreement on May 22, 2009. The indictment must have been drafted shortly thereafter, because, according to the district court's docket sheet, it was filed on June 16, 2009. I.G. Exs. 5, 6; I.G. Ex. 10 at 9. Petitioner pled guilty more than two years later, on November 21, 2011, and the district court entered judgment on November 22, 2011. I.G. Ex. 10 at 24; I.G. Ex. 11 at 1. It seems odd that Petitioner Higgins would not have reviewed the indictment before he pled guilty to one of its counts.

The guilty plea and judgment refer to Count 97 of the indictment, which, by itself, makes the indictment relevant. I.G. Ex. 11. Moreover, Count 97 incorporates paragraphs one through 93 of Count One, which represent a substantial portion of the indictment, so the notion that the indictment has very little to do with Petitioner Higgins is plainly wrong. I.G. Ex. 5 at 1-28, 54. Further, Petitioner Higgins pled guilty as a responsible corporate officer. At a minimum, he is guilty because the company and its employees engaged in criminal behavior. The indictment describes that conduct and is thus inextricably intertwined with Petitioner's own conviction. Even Petitioner's plea agreement refers to the indictment; it says that the defendant "agrees to plead guilty to Count One. . . ."[1] I.G. Ex. 6 at 1 (Plea Agreement ¶ 1). The indictment is thus relevant and admissible. *See* 42 C.F.R. § 1005.17(g); *Emem Dominic Ukpong*, DAB No. 2220 at 3 (2008) (finding that the ALJ properly admitted the criminal indictment, conditions of probation, and other documents beyond the petitioner's plea agreement); *W. Scott Harkonen, M.D.*, DAB No. 2485 at 18-20 (2012) (finding that the ALJ properly relied on all the factual allegations set forth in count one of the indictment, where Petitioner was convicted under that count), *aff'd, Harkonen v. Sebellius*, No. C13-0071 PJH, 2013 WL 5734918 (N.D. Cal. 2013).

The indictment would be admissible in any event, both as part of the case's procedural background and because I am allowed to consider "extrinsic evidence of the underlying

[1] Except for those provisions of Count One that are incorporated by reference into Count 97, no one argues that Petitioner pled guilty to Count One. The language of his actual conviction trumps the language of the plea agreement.

circumstances of the offense." *Ukpong*, DAB No. 2220 at 2; *Gena C. Randolph*, DAB No. 2526 at 4-6 (2013) (finding the indictment and sentence sheet admissible); *see* 42 C.F.R. § 1005.17(g) (making admissible "evidence of crimes, wrongs, or acts other than those at issue in the instant case. . . ."). Of course, if unsupported, the allegations of the complaint would be entitled to little, if any, weight.

I.G. Ex. 10 – District Court Docket Sheet for Criminal Proceedings.

Petitioner Higgins does not so much object to the admission of the district court's docket sheet, as express concern that it will be misused. P. Objections at 3. This is a matter for argument. His concerns do not make the document inadmissible.

I.G. Exs. 15 through 21 – District Court's Sentencing Documents.

Petitioner Higgins objects to my admitting any of the district court's sentencing documents, arguing that they are "not entitled to collateral estoppel effect, have no independent evidentiary value, and should not, therefore, be considered in this exclusion proceeding." P. Objections at 3-5; P. Joint Brief (Br.) at 23-28. In support, he cites the Second Circuit decision in *SEC v. Monarch*, 192 F.3d 295 (2d Cir. 1999).

First, the I.G. has not suggested that I afford collateral estoppel effect to the sentencing documents. Rather, the I.G. argues that the district court's findings merit considerable deference. I.G. Reply at 27 (citing *Upkong*, DAB No. 2220; *Harkonen, M.D.*, DAB No. 2485 at 17-18). I agree. I am not persuaded that the Second Circuit's decision in *SEC v. Monarch* compels my disregard of Judge Davis's well-supported findings and other documents from the sentencing proceeding. Indeed, the appeals court's reasoning suggests the opposite: I may fairly consider the sentencing findings.

The *Monarch* court addressed whether findings made in a criminal sentencing proceeding should preclude relitigating an issue in a subsequent civil case. There, a jury acquitted Defendant Bertoli on RICO (Racketeer Influenced and Corrupt Organizations Act) charges but convicted him on related charges of obstructing justice. The district judge enhanced his sentence, finding that he had, in fact, committed securities fraud and conspired to cover it up – the very charges on which he had been acquitted. In subsequent civil proceedings, the Securities and Exchange Commission argued that, based on the sentencing findings, Mr. Bertoli was collaterally estopped from denying his securities fraud liability.[2]

[2] In contrast to these proceedings, which derive from Petitioner's criminal conviction, the SEC sued Defendant Bertoli in a civil proceeding "parallel" to the criminal case, based on the same alleged violations of federal securities laws.

The Second Circuit deemed it "unfair" to preclude Defendant Bertoli from relitigating the securities fraud issue in a subsequent civil action. However, the court would not adopt a sweeping *per se* prohibition against extending the doctrine of "offensive collateral estoppel" (also referred to as "issue preclusion"), concluding that the doctrine could be applied "in those circumstances where it is clearly fair and efficient to do so." *Id*. at 306. The court enumerated the reasons why applying the doctrine might be unfair: 1) applying the doctrine deprives a party of "procedural opportunities" that are available to the civil litigant, particularly the opportunity to take discovery, which may be limited in sentencing proceedings; 2) applying the doctrine could deny a party the opportunity to present witnesses or receive a full-blown evidentiary hearing; 3) the sentencing court may consider evidence that has "sufficient indicia of reliability," whereas, in civil litigation, the evidence must be admissible under the Federal Rules of Evidence; 4) a criminal defendant might not challenge sensitive issues or evidence, for fear that doing so could enhance his sentence; and 5) the criminal defendant might be reluctant to testify during sentencing. *Id*. at 305.

Here, Petitioner Higgins may not challenge his conviction nor attack collaterally any facts adjudicated as part of that conviction. 42 C.F.R. § 1001.2007(d). However, no one has suggested that he is precluded from challenging issues or evidence extrinsic to his conviction, including Judge Davis's findings. In fact, he has done so. *See, e.g.*, P. Br. 6-17, 19-24.

But, even assuming that the *Monarch* decision has any relevance to this case, nothing in that decision compels me to reject the sentencing documents. The indicia of unfairness do not apply for the following reasons:

1) In contrast to civil court actions, the regulations governing these proceedings afford Petitioner very limited procedural opportunities, such as discovery. *See* 42 C.F.R. § 1005.7 (discovery is limited to requests for production of relevant and material documents);

2) The sentencing court conducted an evidentiary hearing for two full days, "giving the parties an adequate opportunity to present to the Court information regarding disputed matters that are important to sentencing." I.G. Ex. 15 at 1; I.G. Ex. 16 at 3, 47. In contrast, here, Petitioner Higgins waived his right to a hearing. P. Br. at 28.

3) The Federal Rules of Evidence do not apply in these proceedings (42 C.F.R. § 1005.17);

4) Petitioner does not point to any "sensitive issue or evidence" that he declined to challenge during sentencing. Indeed, the court's docket sheet attests to the ample opportunities Petitioner Higgins had to challenge the government's

evidence and argument before the sentencing judge. I.G. Ex. 10 at 20-27. Although he did not testify at the sentencing hearing, he opted to have his statement read into the record; in effect, he "testified" without subjecting himself to any questioning. I.G. Ex. 16 at 22-25. He has declined to testify during these proceedings.

5) Although Judge Davis characterized his findings as "true beyond all reasonable question," the standard of proof in sentencing enhancement is "preponderance of the evidence." I.G. Ex. 20 at 4, 12 (citing *United States v. Fisher*, 502 F.3d 293, 307 (3d Cir. 2007)). In these proceedings, the "burden of persuasion" is judged by the same standard, "preponderance of the evidence." 42 C.F.R. § 1005.15(d).

See U.S. ex rel. Lamberts v. Stokes, 640 F. Supp.2d 927, 930-33 (W.D. Mich. 2009) (finding issue preclusion appropriate where the sentencing hearing afforded the parties the opportunity to present witness testimony and argument, the parties had significant incentives to litigate the issue at sentencing, and the burden of proof was the same in both sentencing and subsequent civil proceedings).

Petitioner also complains that, at sentencing, the court is not limited to the conduct of the underlying offense, but may consider all of the defendant's "relevant conduct." P. Joint Br. at 16. This argument does not help Petitioner for two reasons: 1) in fact, Judge Davis relied on the facts underlying Petitioner's criminal conduct, and his findings are supported by reliable, admissible evidence. If anything, Petitioner Higgins benefitted from the judge's considering conduct beyond that underlying the criminal offense, because he considered most of the defendant's own "characterizations of his background and character." I.G. Ex. 20 at 11-12; 2) by regulation, I, like the sentencing court, may consider "evidence of crimes, wrongs or acts other than those at issue in the instant case . . . ." 42 C.F.R. § 1005.17(g).

I thus find the sentencing documents admissible. Whether or not the sentencing judge's findings are entitled to collateral estoppel effect, they are certainly entitled to deference, particularly where, as here, they were arrived at following a full-blown adjudicative proceeding and are well-supported.

I.G. Exs. 22 through 26 – Court documents relating to the convictions of Petitioner's co-defendants.

Petitioner objects to my admitting court documents relating to the convictions of his co-defendants, because he is not named in them and played no part in their creation. P. Objections at 6-7. As noted above, Petitioner pled guilty as a responsible corporate officer. At a minimum, he is guilty, because the company and its employees engaged in criminal behavior. These documents describe that conduct and are thus inextricably

intertwined with Petitioner's own conviction. They are therefore relevant and material and admissible.

I.G. Ex. 27 – Government's presentence memorandum and exhibit list.

Petitioner objects to my admitting the government's presentence memorandum, characterizing it as "merely argument," and arguing that it serves no legitimate purpose. The I.G. included the document because it incorporates the underlying exhibits (I.G. Exs. 27-1 through 27-81) upon which the sentencing judge relied; to "give context" to the district court's order and memorandum; and "for completeness." I.G. Reply at 27-28.

The presentence memorandum itself may not be entitled to much weight, but I find it admissible as part of the criminal court record. Moreover, the document summarizes the voluminous documents relied on by the court and may be considered admissible as a "summary of voluminous records." *See* Civil Remedies Division Procedures ¶ 10; Fed. R. Evid. 1006.

I.G. Exs. 27-1 through 27-81.

After objecting to the admission of Judge Davis's careful analysis of the evidence as having "no independent evidentiary value," Petitioner Higgins objects to my admitting the underlying evidence upon which Judge Davis based his opinion. P. Objections at 7-19. These documents include company e-mails, memoranda, reports, minutes of meetings, and other documents describing the conduct underlying Petitioner's (and his colleagues') criminal offense.

Petitioner apparently objects to these documents because they go beyond the limited facts to which he admitted in his plea agreement. In Petitioner's view, I may consider only those facts proven beyond a reasonable doubt in the criminal case.[3] P. Joint Br. at 22. As explained more fully in my decision, the issue before me is whether Petitioner's offense "relates to" fraud. All evidence of his underlying conduct – which would include I.G. Exs. 27-1 through 27-81 – is therefore relevant, material and admissible.

/s/
Carolyn Cozad Hughes
Administrative Law Judge

[3] Moreover, as discussed above, the I.G. here need only establish facts supporting the exclusion "by a preponderance of the evidence." 42 C.F.R. § 1005.15(d).