Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

John J. Walsh,
(OI File Number: 3-05-40179-9),

Petitioner,

v.

The Inspector General.

Docket No. C-13-167

Decision No. CR3478

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, John J. Walsh, from participating in Medicare, Medicaid, and all federal health care programs for a minimum period of three 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 Walsh was a consultant to and then a senior executive of Synthes Spine, a division of Synthes, Inc. (Synthes). Synthes is the American branch of a multinational medical device manufacturing corporation that specializes in "trauma products." I.G. Ex. 5 at 1, 2. The company engaged in some nefarious behavior, illegally marketing its bone cements for unapproved and dangerous uses, to the detriment of patients unfortunate enough to have been administered those products. Although he came late to the scheme, once there, Petitioner Walsh "jumped right in," becoming an active and eager participant. I.G. Ex. 18 at 54, 62.

Along with three of his colleagues at Synthes, Synthes itself, and Norian Corporation, a wholly-owned subsidiary of Synthes, Petitioner Walsh was charged in a multi-count criminal indictment. While the corporations were charged with the bulk of the offenses, Petitioner Walsh 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. 8, 13; *see* P. Joint Ex. 2 at 26-27.

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 three years. The letter explained that the I.G. took this action pursuant to section 1128(b)(1) of the Act because Petitioner Walsh 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. 3. Similar letters were sent to his colleagues/co-defendants, excluding them for periods of four 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. 1 through 27-81).[2] Petitioner submitted his individual brief (P. Br.) and, with Petitioners Higgins and Bohner, a "Joint Brief" addressing common legal issues (P. Joint Br.). Petitioner also submitted 24 exhibits for his individual case (P. Exs. 1-24), and, with Petitioners Higgins 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]

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[1] The related cases are: Thomas B. Higgins, C-13-164; Michael D. Huggins, C-13-166; 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 too many 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. 1-24, 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 20. 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 Medicare, Medicaid, and all federal health care programs; and 2) if so, does the three-year period of exclusion fall within a reasonable range.

Discussion

1. ***Petitioner Walsh 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

[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 Walsh 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 joined." He complains that the I.G.'s reply brief did not adequately respond to all of his arguments and suggests that oral argument would compel the I.G. to "address these deficiencies." I am puzzled by Petitioner's interest in affording the I.G. an additional opportunity to respond to his arguments. Moreover, deciding how to present his case is certainly within the discretion of the I.G. and his counsel. For my part, I am satisfied that the parties have presented their arguments well, exploring every nuance of this case, 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.

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).

Here, Petitioner Walsh was a consultant to Synthes from June until August 20, 2003, when he became a full-time employee. From August 2003 until January 2004, he served as Director of Regulatory and Clinical Affairs, the most senior position in that division. P. Joint Ex. 2 at 22, 23; P. Br. at 2; I.G. Ex. 15 at 64; I.G. Ex. 18 at 46: I.G. Ex. 27-79 at 25.

In a 97-count indictment, Petitioner Walsh, three other Synthes executives, Synthes itself, and Norian Corporation were charged with multiple offenses.[6] Petitioner Walsh 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 20, 2009, he pled guilty to that count, and, on November 21, 2011, the Federal District Court for the Eastern District of Pennsylvania entered judgment against him, sentenced him to five months imprisonment, and ordered him to pay the maximum fine of $100,000. I.G. Ex. 8 at 4; I.G. Ex. 13; I.G. Ex. 10 at 7, 10; P. Joint Ex. 2 at 26-27.

Petitioner concedes that he was convicted of a criminal offense but 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. P. Br. at 1, 3.

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 that 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 that statute, all I know is that

Petitioner Walsh 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 facts he admitted to, i.e., those set forth in his plea agreement or facts "proven beyond a reasonable doubt." P. Br. at 3. 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. 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. 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 well-documented level of malfeasance engaged in by the Synthes executives. 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]

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[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 a 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 relevant the extrinsic evidence of circumstances of crime); *Emem Dominic Ukpong*, DAB No. 2220 (2008) (finding no support for petitioner's claim that the scope of review should be limited to the four corners of her plea agreement).

But, in this case, 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. 13 at 1; P. Joint Ex. 9 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 or 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 he admitted only the facts set forth in his plea agreement. P. Br. at 3. Whether Petitioner Walsh can so truncate the bases for his conviction is a question I need not resolve since 1) the facts set forth in paragraph nine of the plea agreement, 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

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those findings is reliable and admissible and establishes Petitioner Walsh's active (if belated) 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. 8 at 5 (Plea Agreement ¶ 9(b)); *see* P. Joint. Ex. 2 at 16. 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. 8 at 5 (Plea Agreement ¶ 9(c)); *see* P. Joint Ex. 2 at 16. 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).

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. 8 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." Its label also warns that it is *not to be mixed with any other substance*. I.G. Ex. 8 at 5-6 (Plea Agreement ¶ 9(f)) (emphasis added); P. Ex. 1 at 5-6; *see* P. Joint Ex. 2 at 17.

The FDA became concerned that some surgeons were nevertheless using bone void fillers in the spine for load-bearing indications. I.G. Ex. 8 at 6 (Plea Agreement ¶ 9(g)); P. Joint Ex. 2 at 18. 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. 8 at 6-7 (Plea Agreement ¶ 9(g)); *see* P. Joint Ex. 2 at 17-18. 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 should 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; P. Joint Ex. 7 at 1; P. Joint Ex. 8 at 1.

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. 8 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. 8 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 – thus during Petitioner Walsh's tenure as Director of Regulatory and Clinical Affairs at Synthes Spine – 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. 8 at 7-8 (Plea Agreement ¶ 9(i)); P. Joint Ex. 2 at 19.

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. 8 at 8-9 (Plea Agreement ¶ 9(j)); P. Joint Ex. 2 at 20.

Petitioner Walsh acknowledged that – at least during the time he served as a corporate officer – he was responsible for preventing such violations. I.G. Ex. 8 at 1, 5 (Plea Agreement ¶¶ 1, 9(a)); I.G. Ex. 18 at 9-12; P. Joint Ex. 2 at 16, 21-23.

Petitioner admits that the companies illegally test marketed and promoted their cements. I.G. Ex. 8 at 1 (Plea Agreement ¶ 1); *see* P. Joint Ex. 2 at 16-21 (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 Walsh's 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 Walsh's 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, here, the corporate officers planned and executed the fraud.

For his part, Petitioner Walsh was not involved in the initial decisions to test market the Norian cements (i.e., to identify willing surgeons, select test sites, provide the product, train surgeons, and assess the results), but, as Judge Davis observed, he became an active participant in the fraud shortly after his arrival at Synthes Spine. He "knowingly participated" in the unauthorized clinical trials and participated in Synthes's training of surgeons. I.G. Ex. 8 at 7-8 (Plea Agreement ¶¶ 9 (h)(i)); I.G. Ex. 15 at 64, 67-68, 70-72; I.G. Ex. 18 at 11-12, 19, 54-55, 60-61, 70. The evidence supports Judge Davis's conclusions:

- On September 19, 2003, a patient died during spinal surgery performed by Dr. Paul Nottingham using Norian XR. This was the second patient death related to the off-label use of the product. 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).[9] As Director of Regulatory Affairs, Petitioner Walsh had some responsibility for the contents of that report. I.G. Ex. 18 at 19, 23.

  Petitioner Walsh met with Synthes Product Manager Josi Hamilton and other Synthes Spine executives on September 23, 2003, to discuss the death and the company's ongoing involvement with the Norian XR test market. 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. Dr. Nottingham reported that "[d]uring cement delivery . . . a drastic drop in blood pressure was noted. . . ."; he also reported 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. Exs. 27-62, 27-65, 27-66. These comments should have triggered alarm bells for the Director of Regulatory Affairs.

- In an e-mail, dated October 1, 2003, Product Manager Hamilton summarized her interview with Dr. Joe Lane. She wrote that Dr. Lane thought that "Norian XR is potentially dewatering and causing episodes of hypotension. . . . With our system,

[9] "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).

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')." Michael Huggins, President of Synthes North America, forwarded a copy of the e-mail to Petitioner Walsh. I.G. Ex. 27-68. Again, this is the type of information that called for immediate action by the Director of Regulatory Affairs.

- On October 16, 2003, Product Manager Hamilton forwarded to Petitioner Walsh question-and-answer e-mails between a Synthes regulatory affairs employee and FDA personnel. In an e-mail dated February 25, 2003, the Synthes employee wrote that several Synthes engineers returned from a meeting of the American Academy of Orthopedic Surgeons with literature showing injectable calcium phosphate used for compression fractures. She asked if Synthes could "indicate [Norian XR] for compression fractures in the spine," so long as they told the surgeons that it "must be used with supplemental fixation (i.e., pedicle screws)." FDA personnel responded the following day: "Use in treating compression fractures of the spine *is not a cleared use* for any of the bone void fillers. . . . This indication is considered a new intended use and requires [premarket approval] and clinical data." She suggested that Synthes "may want to forward the apparently misbranded labeling to the appropriate persons in compliance." I.G. Ex. 27-53; *see* I.G. Ex. 8 at 5-8 (Plea Agreement ¶¶ 9(f), (g),(h),(i),(j)); I.G. Exs. 27-46 at 1; I.G. Ex. 27-69 (emphasis added).

  Months later, during the FDA investigation (discussed below), Petitioner and his staff apparently generated an internal memorandum declaring the "use of void bone fillers in the augmentation of pedicle screws . . . is not intrinsic to the stability of the bony structure" and therefore permissible. P. Ex. 4 at 1; P. Ex. 5. To the extent that this was even debatable, Petitioner Walsh should have challenged the FDA's position when it first came to his attention. He should also have told the FDA that Synthes intended to continue marketing the bone void fillers for this purpose. That Petitioner Walsh withheld this information from the FDA supports the finding that his later actions were intentionally misleading.

- Petitioner Walsh and others met on October 31, 2003, to consider serious questions surrounding the use of Norian XR in unauthorized clinical trials (e.g., the death of Dr. Nottinham's patient, some alarming pig studies conducted by University of Washington researchers).[10] They also considered their "competitors'

[10] 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

status."[11] 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. 18 at 26-27; I.G. Ex. 27-67.

- In December 2003, Petitioner Walsh approved the final Norian XR "Technique Guide" and accompanying CD-ROM for release to the Synthes Spine sales force. I.G. Ex. 15 at 5; I.G. Ex. 27-73; I.G. Ex. 27-79 at 25; P. Br. at 2. Significantly, the Technique Guide did not mention the required warning label ("not intended for treatment of vertebral compression fractures"). Judge Davis concluded that the omission, "more likely than not," was intentional. I.G. Ex. 15 at 70-71; I.G. Ex. 18 at 61. Both the guide and the CD included pictures showing the off-label use of the product. I.G. Ex. 15 at 71-72. Remarkably, the guide *includes spinal x-rays of the first patient to die during surgery* for vertebral compression fractures using Norian SRS mixed with barium sulphate. I.G. Ex. 27-73 at 9; *see* I.G. Ex. 27-38 at 8; I.G. Ex. 27-39 at 1; I.G. Ex. 27-72.

  In his brief, Petitioner Walsh admits that he approved the final draft of the guide but claims that some unnamed person switched case studies without his knowledge. He characterizes his approving the version as a "regrettable oversight," but argues that no evidence suggests "that [he] played a role in selecting the case studies or that he was aware at the time of the inadvertent inclusion of an off-label case study in the final Technique Guide." P. Br. at 10.

  But Petitioner Walsh has proffered no actual evidence to support his contention. He did not testify; he submitted no affidavit. Because he unquestionably approved the guide – off-label case study and all – I can reasonably infer that he was aware of its contents, particularly in the absence of any evidence to the contrary. As an attorney and regulatory specialist, he must have understood how important it was to issue an accurate and legal guide. He was responsible for the materials he

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researchers described the "alarming" effect the cement had on a pig, who "went into fulminant cardiopulmonary arrest." An autopsy showed "Norian as a grisel like substance in right ventricle." Researchers were even more concerned that "the entire pulmonary artery system had clotted off." Researchers were most troubled that a very small amount (2cc's of the cement) led to "a disproportionate and massive clot" within just one 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*." I.G. Ex. 28 (emphasis added).

[11] 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. *See* I.G. Ex. 18 at 25-27.

approved. Whether he approved the guide negligently or deliberately, he is accountable for its contents.

Moreover, Petitioner acknowledges that "a few weeks after" he approved the Guide, he learned that it and the CD-ROM included case studies of the off-label uses of Norian XR. P. Br. at 11. He claims that he nevertheless approved the training materials, considering them protected by the First Amendment. I note that Judge Davis rejected this argument, and so do I. The First Amendment does not protect misleading speech. I.G. Ex. 15 at 72; I.G. Ex. 18 at 52.[12]

- 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 performed, and a medical device report filed. I.G. Exs. 27-74; 27-75.[13]

- Thus, by the end of January 2004, three patients had died while undergoing surgeries using Norian XR to treat vertebral compression fractures. I.G. Exs. 27-74, 27-75. Thereafter, Petitioner Walsh revised a "Dear Surgeon" letter, which Synthes sent to physicians participating in the unauthorized trials. I.G. Ex. 15 at 72-73; I.G. Ex. 27-76; I.G. Ex. 30; P. Br. at 2-3. In Judge Davis's view, the initial draft "gave fair notice," but Petitioner Walsh altered it "to a degree that made it less clear what the issue was." I.G. Ex. 18 at 15. The revised version should have been "more forthright and plain" in stating the dangers posed by misusing Norian XR in vetebroplasties to treat vertebral compression fractures. Judge Davis found that the letter "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 [Norian XR]." I.G. Ex. 15 at 72-74; I.G. Ex. 18 at 14, 61.

  Judge Davis's conclusions are well-founded, as shown by comparing the initial draft of the letter with Petitioner Walsh's altered version. The initial draft reported

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[12] The regulations bar Petitioner from collaterally attacking his criminal conviction in this forum. 42 C.F.R. § 1001.2007(d); *Joann Fletcher Cash*, DAB No. 1725 (2000). When he pled guilty, he waived all potential defenses to the criminal charges, including the First Amendment claims.

[13] 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 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. So I don't know what Dr. Ball meant by "proper patient selection."

that "one of our surgeons experienced a complication while using Norian XR during a kyphoplasty procedure" and that Synthes would stop distributing the product until it understood the "chemical and physiologic interactions of calcium phosphate cements as they apply to the spine." I.G. Ex. 30.

The revised version begins with general language about vertebral compression fractures and points out that, in response to reported deaths, the FDA has warned against using certain products (its competitor's as well as the Norian cements) to treat vertebral compression fractures. The letter repeats the FDA warnings that these products are "intended for treatment of bony voids or defects that are not intrinsic to the stability of the bone structure." Because using bone cements to treat vertebral compression is intrinsic to the stability of the vertebral body, the letter says, the products *should not be used* for that purpose. "Synthes urges you to seriously consider whether the use of *any* bone cement or bone void filler is appropriate in the treatment of vertebral compression fractures." The letter concludes that "Synthes is dedicated to the improvement of orthopedic care. We will continue to explore new approaches to the treatment of vertebral compression fractures." I.G. Ex. 27-76 at 1.

As Judge Davis observed, Petitioner Walsh omitted critical facts. The revised letter does not tell the physicians that the FDA previously warned against using Norian XR and Norian SRS in surgeries to treat vertebral compression fractures; it says nothing specifically about the hypotensive events or the deaths that had occurred during spinal surgeries using Synthes bone cements; it does not mention the warnings from the University of Washington researchers about the potentially lethal risks of leakage and blood clotting. *See* I.G. Ex. 21 at 12 (Judge's Memorandum ¶ 25). The letter "should have been more forthright and plain in the statement of dangers posed by the use of [Norian XR in] vertebroplasties to treat [vertebral compression fractures]." I.G. Ex. 15 at 74.

- The FDA investigated Synthes from May 11 through June 18, 2004. Judge Davis concluded that Petitioner Walsh "intentionally or knowingly made false statements to the FDA investigator." I.G. Ex. 15 at 75; I.G. Ex. 18 at 61; *see* I.G. Ex. 27-78 at 49-50, 108-10; I.G. Ex. 27-79 at 25-27, 47-49.

- During the FDA investigation, Petitioner Walsh drafted a memorandum "clarifying" that, with the exceptions spelled out in the warning label, using Norian XR "in association with Vertebroplasty and Kyphoplasty are completely appropriate and 'on-label.'" P. Ex. 20. To reach this conclusion, he proffered unique definitions of those terms (vertebroplasty and kyphoplasty), definitions at odds with the FDA's published reports. *See* I.G. Ex. 27-21. Petitioner Walsh repeated his claim to the sentencing court, and Judge Davis appropriately rejected it. I.G. Ex. 15 at 66-68. The judge also questioned the timing of the

> memorandum, suggesting that its purpose was to deceive the FDA investigator. I.G. Ex. 18 at 57-59. As noted above, had he legitimately held the position he espoused in this memorandum, he should have presented it to the FDA back in October, when he learned of the agency's contrary views.

These facts establish that, from early in his tenure at Synthes Spine, Petitioner Walsh knew about and participated in the illegal test marketing that 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. Relying on the word "other" in the phrase "fraud, theft, embezzlement, breach of fiduciary responsibility, or *other* financial misconduct," Petitioner Walsh (along with Petitioners Higgins and Boehner) argues that he should not be excluded, because his conviction is not "related to" financial misconduct, and section 1128(b)(1)(A) permits exclusion only for forms of 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. *See* I.G. Ex. 17 at 27-28 ("[T]here's abundant evidence in the record to support the government's contention that the financial motive perhaps operated to cloud judgments . . . ."); I.G. Ex. 17 at 67-68, 76; I.G. Ex. 20 at 5, 8, 14; I.G. Ex. 21 at 6; 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."), *aff'd*, *Morgan v. Sebelius*, 694 F.3d 535 (4th Cir. 2012).

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 position has been affirmed by the Fourth Circuit Court of Appeals. *Morgan v. Sebelius*, 694 F.3d 535.[14] 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

[14] 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").

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

The Fourth Circuit 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.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 three-year exclusion is not unreasonably long.

Having found a basis for the exclusion, I now consider whether a three-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 16-18 (2000) (citing 57 Fed. Reg. 3298, 3321 (1992)).

As a threshold matter, Petitioner complains that the I.G. notice letter did not mention which, if any, aggravating factors the I.G. considered in setting the length of the exclusion, which is required by regulation. 42 C.F.R. § 1001.2002(c)(2). P. Br. at 17-18. I agree that the I.G. should have included in the notice letter all of the factors he considered in setting the period of exclusion. However, whatever error this may have been is harmless. The Act provides that my review here is *de novo*. I make my decision based on the evidence adduced during these proceedings. Act § 205(b)(1); *see Vincent Baratta, M.D.*, DAB No. 1172 at 8 (1990). The I.G. provided ample notice of the factors it considered aggravating and mitigating, and Petitioner has had every opportunity to respond. *See Brian Bacardi, D.P.M.*, DAB No. 1724 at 8 n.8 (2000) (finding that Petitioner failed to show that he was harmed by the I.G.'s purported failure send him a notice of intent to exclude, as required by 42 C.F.R. § 1001.2003).

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 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 Walsh was convicted of one misdemeanor offense, and the I.G. does not allege that his crime caused program financial losses. That the I.G. imposed such a minimal period of exclusion reflects that factor.

Petitioner claims that he cooperated with law enforcement and is therefore entitled to additional consideration under section 1001.201(b)(3)(iii). In support of this claim, he provides no actual evidence, but asserts that he cooperated with the government early in its investigation, leading to both corporate and individual convictions (presumably including his own). P. Br. at 20.

"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. 2046 at 9 (citing *Stacey R. Gale*, DAB No. 1941 at 11) (emphasis in the 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 investigation of a new target or targets. Expanding an existing investigation does not qualify. *Smith*, DAB No. 2046 at 9-10.

Aside from evidence that Petitioner Walsh attempted to impede the initial FDA investigation, the record says very little about his level of cooperation with law enforcement. He therefore has not met his burden of establishing a level of cooperation needed to constitute a mitigating factor. *See Christopher Switlyk*, DAB No. 2600 (2014) (finding that cooperation with authorities is insufficient to establish a mitigating factor absent a showing that cooperation resulted in one of the outcomes identified in the regulation).

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).

Aggravating Factors. I next consider whether aggravating factors offset whatever reduction might have been justified by the one mitigating factor.

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).

Incarceration. The court sentenced Petitioner Walsh to five months in jail. I.G. Ex. 13 at 2; I.G. Ex. 18 at 71.

Petitioner points out that his jail sentence was the shortest of the sentences imposed and the only one that fell within sentencing guidelines. P. Br. at 17-18. Although true, that fact does not eliminate his incarceration as an aggravating factor. Any period of incarceration, no matter how short, justifies increasing the period of exclusion, and, in fact, five months incarceration is significant. *Jason Hollady, M.D.*, DAB No. 1855 at 12 (2002); *Stacy Ann Battle, D.D.S.*, DAB No. 1843 (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), *aff'd*, DAB No. 2061 (2007) (finding that six months home confinement justifies increase in length of exclusion).

Further, in sending Petitioner and his colleagues to jail, Judge Davis understood that individuals convicted as "responsible corporate officers" rarely, if ever, receive jail time. He acknowledged that much of the mischief at Synthes occurred before Petitioner Walsh arrived. On the other hand, Judge Davis cited Petitioner Walsh's unique status as the Director of Regulatory Affairs:

> You're in regulation. And we expect and require that you speak the truth as you understand it and know it. . . . I think that we have a right to expect and require regulation to tell these people who are so inclined that the law means something, that the law has to be respected and honored. And so, that's part of the reason that . . . I'm sending you to jail.

I.G. Ex. 18 at 70.

I consider Petitioner's incarceration, by itself, more than sufficient to offset the sole mitigating factor presented here, without regard for the significant impact his crimes had on individuals who were subjected to the off-label procedures.

Adverse impact. Unquestionably, 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.

In a statement read at sentencing, Petitioner Walsh acknowledged that he had "failed to fully protect the patients I was working for" and told the judge that he accepted "absolute and sole responsibility" for his failures.[15]

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, 38, 74.

Judge Davis did not hold Petitioner Walsh accountable for the harm suffered prior to his involvement in the scheme, and neither do I. However, as the above discussion shows, early in his tenure, he learned of the dangers posed by the off-label use of the cements (drastic drops in blood pressure, potential cement leakage, the University of Washington findings, and the two patient deaths during the off-label surgeries), and is accountable for the ongoing human experimentation that continued after his arrival.

On January 22, 2004, Dr. Ball's patient died while undergoing surgery to treat a vertebral compression fracture using Norian XR. I.G. Exs. 27-74, 27-75. Unlike the other fatalities, an autopsy was performed. 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

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[15] On the other hand, Petitioner's acceptance of "absolute and sole responsibility" seems to have had its limits. His list of purported "failures" ("failure to broaden my focus"; failure to "do my homework"; failure "to ask the right questions"; failure "to recognize the gravity of what was happening") did not come close to acknowledging his well-documented knowledge of and participation in the fraud. I.G. Ex. 18 at 47.

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. Although there may be other explanations, 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 Walsh concedes that this patient "experienced hypotensive events and died" while undergoing surgery using the Norian cement. He points out that (like the other two patients who died) she was elderly and suffered serious underlying health problems and multiple co-morbidities, including significant coronary problems. In Petitioner's view, the patient was not harmed by the procedure because she likely died from her underlying condition. P. Joint Br. at 36-37. But Petitioner does not explain why this extraordinarily vulnerable patient – with serious underlying cardiac conditions – would undergo an elective procedure that was experimental and associated with negative cardiac events. As Judge Davis recognized, the patient did so *because she did not know about those negative events*!

Petitioner disavows any responsibility for the surgery, 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 told them how to use those weapons.

Indeed, as Judge Davis found, 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 three-year exclusion is reasonable, but why the period of exclusion is so low.

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 and the truly frightening findings of 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 jail time, and it cries for a significant period of exclusion. Based on all of the circumstances described above, I find that a three-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

John J. Walsh
(OI File Number: 3-05-40179-9),

Petitioner,

v.

The Inspector General.

Docket No. C-13-167

Date: November 24, 2014

ADDENDUM TO DECISION CR3478: RULING ON OBJECTIONS TO EXHIBITS

The Inspector General for the Department of Health and Human Services (I.G.) has excluded Petitioner, John J. Walsh, from participating in all federal health care programs for a minimum period of three years, pursuant to section 1128(b)(1) of the Social Security Act. Petitioner Walsh 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 are 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 concedes that I.G. Ex. 5, his criminal indictment, is admissible, but he argues that it should be considered for the limited purpose of determining the elements of the offense to which he pled guilty. He points out that he is named only in Count 97 of the 97-count indictment, not in all of its allegations. He claims that he did not even see the indictment before he pled guilty. Petitioner John J. Walsh 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, 8; I.G. Ex. 10 at 9. More than two years later, Petitioner pled guilty and the district court entered judgment on November 22, 2011. I.G. Ex. 10 at 25; I.G. Ex. 13. It seems odd that Petitioner Walsh would not have reviewed the indictment before he pled guilty to one of its counts.

As Petitioner acknowledges, the guilty plea and judgment refer to Count 97 of the indictment, which, by itself, makes the indictment relevant. I.G. Ex. 13. 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 Walsh is plainly wrong. I.G. Ex. 5 at 1-28, 54. Further, Petitioner Walsh 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. 8 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. 2485at 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. Sebelius*, No. C13-0071 PJH, 2013 WL 5734918 (N.D. Cal. 2013).

[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.

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 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 Walsh 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 Walsh 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 *Ukpong*, DAB No. 2220; *Harkonen*, 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 Walsh 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. at 4-15.

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; *see* I.G. Ex. 18 at 16. In contrast, here, Petitioner Walsh waived his right to a hearing. P. Br. at 20.

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 Walsh had to challenge the government's evidence and argument before the sentencing judge. I.G. Ex. 10 at 20-28. 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. 18 at 42-51. He has declined to testify during these proceedings.

5) 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; 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, played no part in their creation, and, he argues, they are not relevant to his own conviction. P. Objections at 5-7. 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 analysis of the evidence as having "no independent evidentiary value," Petitioner Walsh objects to my admitting the underlying evidence upon which Judge Davis based his opinion. P. Objections at 7. 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).