Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Richard E. Bohner,
(OI File Number: 3-05-40179-9),

Petitioner,

v.

The Inspector General.

Docket No. C-13-168

Decision No. CR3479

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, Richard E. Bohner, from participating in Medicare, Medicaid, and all federal health care programs for a minimum period of four 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 Bohner was a senior executive at 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 full knowledge and at least tacit consent, 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.

Along with three of his colleagues at Synthes, Synthes itself, and Norian Corporation, a wholly-owned subsidiary of Synthes, Petitioner Bohner was charged in a multi-count criminal indictment. While the corporations were charged with the bulk of the offenses, Petitioner Bohner 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 December 13, 2011, the federal district court convicted him. I.G. Exs. 9, 14; *see* P. Joint Ex. 3 at 31-32.

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 four years. The letter explained that the I.G. took this action pursuant to section 1128(b)(1) of the Act because Petitioner Bohner 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. 4. Similar letters were sent to his 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. 1 through 27-81).[2] Petitioner submitted his individual brief (P. Br.) and, with Petitioners Higgins and Walsh, a "Joint Brief" addressing common legal issues (P. Joint Br.). Petitioner also submitted 20 exhibits for his individual case (P. Exs. 1-20), and, with Petitioners Higgins and Walsh, 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 John J. Walsh, C-13-167.

[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 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. 1-20, 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 24. 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 four-year period of exclusion fall within a reasonable range.

Discussion

1. ***Petitioner Bohner 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).

Here, from 1997 until January 2002, Petitioner Bohner served as Vice President of Human Resources and Regulatory Affairs at Synthes. In January 2002, he became Vice

[4] Petitioner Bohner asked to present oral argument so that he could further address issues raised (i.e., the standard for adjudging a "relationship to fraud"; why his offense does not factually relate to fraud; the problems with the I.G.'s reliance on the district court record; and why the I.G. is wrong in asserting that Petitioner knowingly engaged in wrongdoing). I am not convinced that oral argument would serve any useful purpose. Petitioner has argued his case thoroughly, exploring every nuance. Oral argument 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.

President of Operations, reporting directly to Michael Huggins, the company president. P. Joint Ex. 3 at 20, 26; I.G. Ex. 5 at 2; I.G. Ex. 27-79 at 52; *see* P. Exs. 1, 2.

In a 97-count indictment, Petitioner Bohner, three other Synthes executives, Synthes itself, and Norian Corporation were charged with multiple offenses.[6] Petitioner Bohner 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. He pled guilty to that count, and, on December 13, 2011, the Federal District Court for the Eastern District of Pennsylvania entered judgment against him, sentenced him to eight months imprisonment, and ordered him to pay the maximum fine of $100,000. I.G. Ex. 9; I.G. Ex. 14; I.G. Ex. 10 at 26; P. Joint Ex. 3 at 31-32.

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 2.

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 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

[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.

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 element 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 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 asserts 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]

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

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

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. 14 at 1; P. Joint Ex. 3 at 31-32. 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.") (emphasis added).

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 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. 9 at 5 (Plea Agreement ¶ 9(b)); *see* P. Joint. Ex. 3 at 17-18, 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. 9 at 5 (Plea Agreement ¶ 9(c)); *see* P. Joint Ex. 3 at 18, 21. 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. 9 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. 9 at 5-6 (Plea Agreement ¶ 9(f)) (emphasis added); *see* P. Joint Ex. 3 at 21.

The FDA became concerned that some surgeons were nevertheless using bone void fillers in the spine for load-bearing indications. I.G. Ex. 9 at 6 (Plea Agreement ¶ 9(g)); P. Joint Ex. 3 at 22. 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. 9 at 6-7 (Plea Agreement ¶ 9(g)); *see* P. Joint Ex. 3 at 23. 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; 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. 9 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. 9 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. 9 at 7-8 (Plea Agreement ¶ 9(i)); P. Joint Ex. 3 at 24.

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. 9 at 8-9 (Plea Agreement ¶ 9(j)); P. Joint Ex. 3 at 24-25.

Petitioner Bohner acknowledged that he was responsible for preventing such violations. I.G. Ex. 9 at 1, 5 (Plea Agreement ¶¶ 1, 9(a)); P. Joint Ex. 3 at 19-20.

Petitioner admits that the companies illegally test marketed and promoted their cements. I.G. Ex. 9 at 1 (Plea Agreement ¶ 1); *see* P. Joint Ex. 3 at 17-19 (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 Bohner'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 Bohner'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.

- Petitioner Bohner was brought into the process early on. Michael Sharp, PhD, an employee in the regulatory department, copied him on an August 23, 2000 memorandum to employees of the Spine Division. The memorandum reminded its recipients that Synthes did not "have a spine indication for Norian SRS at this time." Dr. Sharp wrote that he had learned that Synthes planned a "test market" of Norian SRS for October and November 2000, with a subsequent launch date of March 2001; he complained that "[r]egulatory is unaware that this is even being considered." He emphasized that the company could *not* promote the use of Norian SRS for unapproved indications, and "this is especially true for use in the spine, where FDA has previously made it clear to Norian that any intra-spinal use would require additional approval." He concluded by warning that "any suggestion on our part" that Norian SRS could be used in vertebroplasty "would be considered promotion of an unapproved use of [Norian] SRS." I.G. Ex. 27-17.

  Petitioner Bohner responded to the memorandum, advising Michael Huggins, president of Synthes North America, that they needed to be "careful" if they

planned a "test market" for Norian SRS and the spine: "We have no indication for this, as you know!" I.G. Ex. 27-17.

- On February 8, 2001, two patients, undergoing spine surgeries using an unapproved Norian cement with the same chemical formulation as Norian SRS, suffered hypotensive events. A Synthes sales representative was present at the off-label surgeries. I.G. Ex. 27-25 at 1; I.G. Ex. 27-26; *see* I.G. Ex. 27-37 at 20. Dr. Sharp informed Petitioner Bohner of these events in a March 16 e-mail, which Petitioner Bohner forwarded to President Huggins. President Huggins responded in an e-mail to appropriate staff (copy to Petitioner Bohner), stating, "Steve, You need to real [sic] in your salesforce ASAP." I.G. Ex. 27-26.

- In a memorandum dated March 19, 2001, Dr. Sharp explained to Petitioner Bohner that he "made it clear [to Tom Higgins, president of Synthes Spine, 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." Dr. Sharp also "made it clear that the spine company should not be providing SRS to any account . . . that there is absolutely no reasons that a spine consultant should ever be discussing SRS with a surgeon or providing the product." I.G. Ex. 27-18.

- 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). Petitioner Bohner learned about these studies and the concerns of the researchers at least as early as July

2003, when he attended a Norian XR Safety Meeting (discussed below), at which the pig studies and the February 2001 hypotensive events were discussed. I.G. Ex. 27-38 at 6-8, 12; I.G. Ex. 27-40; *see* I.G. Ex. 27-37.

- 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 Bohner received a copy of the meeting's 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. 9 at 6-7 (Plea Agreement ¶ 9(g)).

- According to Synthes Project Manager Josi Hamilton, on May 16, 2002, Petitioner Bohner endorsed the "vertebroplasty test market using cavity creation system and [Norian] SRS." I.G. Ex. 27-9; *but see* I.G. Ex. 78 at 121 (denying that he needed to "endorse" the markets).

- President Huggins copied Petitioner Bohner on an e-mail sent to employees in the spine division on May 30, 2002. The e-mail suggested that shipments of the product were being sent out "without proper protocols, surgeon sponsors, etc." It expressed concern that "Spine" had been "bypassing the needed blocking and tackling without thinking this all the way through." President Huggins also reported that he spoke to Dr. Lambert, "who is very concerned about the Spine plan." President Huggins called a meeting to discuss the situation. I.G. Ex. 27-8.

- Petitioner Bohner knew about the physician training for the test marketing. The employee who assembled training materials copied him on the June 4, 2002 memo to President Huggins describing the training materials. I.G. Ex. 27-33.

- Petitioner Bohner 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." The participants, including Petitioner Bohner, decided to proceed with and fully launch the illegal Norian test markets by December 2002. I.G. Ex. 27-35 at 4-7; *see* I.G. Ex. 15 at 81. The conference included a presentation about the FDA's insistence that Norian XR bear the warning that it was not to be used in vertebroplasties. I.G. Ex. 27-36 at 15; *see*

above (discussion of May 8, 2002 FDA meeting with Synthes personnel); I.G. Ex. 27-13 at 2.

- On January 13, 2003, a patient of Dr. Barton Sachs died during a vertebroplasty/kyphoplasty[9] 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 27-37 at 8; I.G. Exs. 27-49 through 27-51.[10]

  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?

- On February 10, 2003, Petitioner Bohner 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. 27-32. 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. 9 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 Bohner – 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. 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 to determine our associate level of risk and decide what level is too high.*" I.G. Ex. 27-39 at 2; I.G.

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[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).

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

Ex. 27-40. Not only did Petitioner Bohner 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 in a related case: "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 Bohner 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. 27-55 at 1.

- 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 Bohner. I.G. Ex. 27-58.

- On September 19, 2003, a second patient died during spinal surgery using Norian XR. Dr. Paul Nottingham performed the surgery. 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*.

- Petitioner Bohner 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. 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. Exs. 27-62, 27-65, 27-66.

- In another e-mail, dated October 1, 2003, Product Manager Hamilton advised Petitioner Bohner and others of 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, 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. 27-68.

- 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. Exs. 27-74; 27-75. [11]

- The FDA investigated Synthes from May 11 through June 18, 2004. On June 16, 2004, the FDA investigator interviewed Petitioner Bohner, and, as Judge Davis concluded, like his colleagues, Petitioner Bohner "play[ed] his role in that continuing deception" of the FDA investigator. I.G. Ex. 19 at 31; I.G. Ex. 27-78 at 119-23; I.G. Ex. 27-79 at 52-55.

  > [Bohner's interview] was [the] interview that everybody gave. . . . Nobody knew nothing about anything. I have never seen so many highly paid, highly intelligent people who went to so many meetings that they can't remember who was there, they can't remember what was talked about, they can't remember who took the minutes, they can't remember who ran the meeting. It was actually – it was remarkable.

  I.G. Ex. 19 at 31.

  At sentencing, the assistant United States attorney cited some well-supported examples of Petitioner's dissembling, comparing his interview responses to the notes/diary entries he made during the July 18, 2003 safety meeting (at which the participants – himself included – opted to proceed with the illegal test market). I.G. Ex. 19 at 27-30. His notes show that he listened to the presentations and well understood the implications of the company's test market. He listed the attendees, quotes one of the consultants who charged: "there's a massive cover-up and many clinical problems" and accused Synthes employees of not doing the required medical device reports. A second attendee asked why there had been three cases of elevated hypotension. The product manager said that "cement leakage is the

[11] 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. 27-73. 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."

> main concern." The second attendee suggested making the launch decision after a test market of 200-300 patients and getting involved with a hospital study. Petitioner Bohner's notes also refer to a potentially damaging article from the University of Washington researchers concerning Norian and the dangers it poses. I.G. Ex. 27-80 at 10; *see* I.G. Ex. 19 at 29.
>
> Notwithstanding his fairly detailed notes, Petitioner Bohner later claimed that he did not recall the discussion. He told the FDA investigator that he did not know who ran the meeting; nothing was asked of him; he took no active part. He said that he didn't specifically know why the meeting was called beyond reviewing the topics listed in the minutes. He denied that there had ever been a test market, "just data collected from what surgeons were doing on their own," a statement that was completely untrue. When asked if he had any knowledge or role in the outcome, he said that the "decision was a business decision for the company involved." He denied that "regulatory affairs" would have been involved in the decision: "As I said earlier, regulatory affairs does not get involved in test market decisions since it is already an approved product." He denied any recollection of discussions about a clinical study. I.G. Ex.27-78 at 122- 123; I.G. 27-79 at 53-54; *see* I.G. Ex. 19 at 29-30.

These facts establish that, as Judge Davis concluded, Petitioner Bohner was "aware of and involved in the process of approving the [Norian] SRS test market in the spine." I.G. Ex. 27-15 at 81. 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 Bohner (along with Petitioners Higgins and Walsh) 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.[12] 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 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.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 four-year exclusion is not unreasonably long.

Having found a basis for the exclusion, I now consider whether a four-year period of 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)).

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

[12] 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").

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).[13]

Incarceration. Based on Petitioner's "offense level" and criminal history, federal sentencing guidelines called for a minimum sentence of no jail time and a maximum of six months. P. Joint Ex. 3 at 15, 16; *see* P. Joint Ex. 3 at 15, 16 (in which Judge Lawrence F. Stengel accepted Petitioner's guilty plea and characterized as "very unlikely" the prospect of the court imposing a sentence longer than six months). Under the terms of his plea agreement, Petitioner waived his right to appeal the sentence, so long as his period of incarceration was no longer than six months. I.G. Ex. 6 at 11 (Plea Agreement ¶ 13b(2) and(3)). Judge Davis nevertheless sentenced Petitioner Bohner to eight months in jail. I.G. Ex. 14 at 2; I.G. Ex. 19 at 16-17.

Judge Davis departed from the guidelines because Petitioner's crime was so 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), Judge Davis found:

> What sets this apart [from the other *Park*-doctrine cases] is that there is direct action by . . . the three [Messrs. Higgins, Huggins and Bohner] . . . in terms of development of the scheme, the implementation of the scheme, the deception of the FDA, the . . . alarming results of the animal studies coming directly to these gentlemen, the strident warnings from the doctors who were saying, ["]I used your product and I have serious questions.["] One of them says you need to go to the FDA right now. You need to go to the institutional review boards.
>
> You have the Synthes consultant, medical consultant, telling these people[,] each and every one of them, this is human experimentation, and the only defense you'll have is that it was on a small scale, and loss of approval by the FDA might be the least of the consequences you suffer. So this is not a *Park* doctrine case in the traditional sense. The decision makers are here, right. And that's why the sentence stands apart from other cases, because these are the people who decided and repeatedly decided and repeatedly decided.

I.G. Ex. 19 at 25-26.

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[13] 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. 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).

Judge Davis also found that, because he was in charge of regulatory compliance, Petitioner Bohner had a special obligation to "speak loud and long and clear about what people need to do." I.G. Ex. 19 at 22. The judge agreed that the "law expects that when people are put in an unpleasant position, [they] follow the law." I.G. Ex. 19 at 20. Although Petitioner "did express some concern," in the judge's view, "he could have done a whole lot more." I.G. Ex. 19 at 26-27. Significantly, he tended to express his concerns to those "a couple of steps down" from him on the corporate ladder. "He doesn't say it in the safety meetings; he doesn't say it in the management meetings. He doesn't say it when the decisions are being made." I.G. Ex. 19 at 43-44.

Any period of incarceration, no matter how short, justifies increasing the period of exclusion. Eight 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 (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.[14]

Petitioner points out that, during his period of incarceration, he was effectively excluded from program participation; he suggests that, because of this, the fact of his incarceration should not be given significant weight. P. Br. at 23. But, in this regard, his position is no different than that of any excluded individual sentenced to jail time. Affording credit

[14] 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 Bohner's 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).

because an individual cannot participate in a federal healthcare program while jailed would defeat the purpose of the regulation, which anticipates that the I.G. will *increase* the period of exclusion for someone who has been incarcerated because of his crime.

Adverse impact. Unquestionably, Petitioner Bohner and his colleagues at Synthes placed the "lives of the unknowing" at risk. I.G. Ex. 19 at 46. Indeed, Judge Davis expressed genuine shock at the company's response to the pig studies: "[H]ow do you do this on humans when you haven't even completed studies on animals and the animals that you have injected the . . . substance in – who has had a massive clot and died far . . . more quickly than was expected with twenty percent of the material that was expected?" I.G. Ex. 19 at 36. He found it "unheard of" to test a class 3 substance on humans before testing it on animals. I.G. Ex. 19 at 38. 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, Synthese employees "disregarded the safety of all members of society." I.G. Ex. 15 at 19, 31; I.G. Ex. 27-37 at 20.

Any one of the following examples of adverse effects, by itself, justifies increasing the period of exclusion:

- 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. 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. 27-37 at 8; I.G. Exs. 27-49 through 27-51.

  Petitioner complains that the I.G. has not proven that the Norian cement directly caused this (and the other) deaths. But Petitioner Bohner 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.

- 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). 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. Exs. 27-62, 27-65, 27-66. At least one other physician opined that "Norian XR is potentially dewatering and causing episodes of hypotension." 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. Exs. 27-74, 27-75. Unlike the other fatalities, this time 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 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 Bohner concedes that three the 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* I.G. Ex. 16 at 7-9 (Judge's Memorandum ¶¶ 19, 25 ("[U]nfortunately,[the patient] 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 nevertheless 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 trained them to use those weapons.

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 four-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 Bohner 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 1001.201(c)(3). In support of this claim, he points out that the plea agreements of the four defendants (himself and Messrs. Higgins, Huggins, and Walsh) were conditioned on all agreeing to plead guilty. He argues that his willingness to plead guilty thus helped secure the convictions of all. P. Br. at 23-24.

"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 (2006) at 10. 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. 1941at 11 (2004)) (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.

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 and his colleagues jointly agreed to plead guilty.

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).

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 for a significant period of exclusion. Based on all of the circumstances described above, I find that a four-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

Richard E. Bohner,
(OI File Number: 3-05-40179-9),

Petitioner,

v.

The Inspector General.

Docket No. C-13-168

Date: November 25, 2014

ADDENDUM TO DECISION CR3479: RULING ON OBJECTIONS TO EXHIBITS

The Inspector General for the Department of Health and Human Services (I.G.) has excluded Petitioner, Richard E. Bohner, from participating in all federal health care programs for a minimum period of four years, pursuant to section 1128(b)(1) of the Social Security Act. Petitioner Bohner 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 to all of its allegations. He claims that he did not even see the indictment before he pled guilty. Petitioner Richard E. Bohner's Responses and Objections to I.G.'s Informal Exhibit List (P. Objections) at 2.

Petitioner executed his plea agreement on May 26, 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, 9; I.G. Ex. 10 at 9. He pled guilty, and more than two years later, on December 13, 2011, the district court entered judgment against him. I.G. Ex. 10 at 26; I.G. Ex. 14. It seems odd that Petitioner Bohner 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. 14. 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 Bohner is plainly wrong. I.G. Ex. 5 at 1-28, 54. Further, Petitioner Bohner 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. 9 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. Sebelius*, 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 circumstances of the offense." *Ukpong*, DAB No. 2220 at 2; *Gena C. Randolph*, DAB

[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.

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 Bohner 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 Bohner 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 21-22 (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]

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

[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.

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 Bohner 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. In contrast, here, Petitioner Bohner waived his right to a hearing. P. Br. at 24.

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 Bohner had to challenge the government's evidence and argument before the sentencing judge. I.G. Ex. 10 at 20-28.; *see, e.g.*, I.G. Ex. 19 at 43 (offering Defendant Bohner the opportunity to present

"any other information or testimony") He did not testify at the sentencing hearing and 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 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 analysis of the evidence as having "no independent evidentiary value," Petitioner Bohner 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).