Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Michael D. Huggins,
(OI File Number: 3-05-40179-9),

Petitioner,

v.

The Inspector General.

Docket No. C-13-166

Decision No. CR3480

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, Michael D. Huggins, from participating in the Medicare, Medicaid, and all federal health care programs for a minimum period of five years. For the reasons discussed below, I find that the I.G. is authorized to exclude Petitioner and that the period of exclusion is not unreasonably long.

Background

Petitioner Huggins 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 knowledge and consent – indeed, his active encouragement – the company engaged in some nefarious behavior, illegally marketing its bone cement products for unapproved and dangerous uses, to the detriment of patients unfortunate enough to have been administered those products.

Petitioner Huggins, along with three of his subordinates at Synthes, Synthes itself, and Norian Corporation, a wholly-owned subsidiary of Synthes, were charged in a multi-count criminal indictment. While the corporations were charged with the bulk of the offenses, Petitioner Huggins 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) and (2)). I.G. Ex. 5 at 54. He pled guilty, and, on November 21, 2011, the federal district court convicted him. I.G. Exs. 7, 12.

In a notice letter dated September 28, 2012, the I.G. advised Petitioner that he would be excluded from program participation for a minimum period of five years. The letter explained that the I.G. took this action pursuant to section 1128(b)(1) of the Act, because Petitioner Huggins 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. 2. Similar letters were sent to Petitioner Huggins' subordinates/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 a brief (P. Br.) and 15 exhibits (P. Exs. 1-15). The I.G. submitted a reply brief (I.G. Reply) with six additional exhibits (I.G. Exs. 28-33).[3] In the absence of any objections, I admit into evidence I.G. Exs. 1-33 and P. Exs. 1-15.

Petitioners Higgins, Walsh, and Bohner submitted a "Joint Brief" addressing common legal issues (P. Joint Br.), along with 13 joint exhibits (P. Joint Exs. 1-13). Although he

[1] The related cases are: Thomas B. Higgins, C-13-164; John J. Walsh, C-13-167; and Richard E. Bohner, C-13-168.

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

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

did not join with his co-petitioners for all purposes, Petitioner Huggins adopted the factual and legal arguments made on their behalf with respect to 42 C.F.R. § 1001.201(b)(2)(iii) (adverse impact). I therefore also consider the arguments presented in P. Joint Br. at 34-42, and admit 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 51.[4]

Issues

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

Discussion

1. ***Petitioner Huggins 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]

[4] Petitioner 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 Huggins responded that he would reiterate his written arguments: 1) challenging the "common sense/nexus" test for determining whether a conviction "relates to" fraud within the meaning of section 1128(b)(1); 2) that only conduct underlying the "offense of conviction" should be considered here; 3) that the record does not justify excluding him; and 4) that the regulations governing these proceedings wrongfully exclude factors that should be considered mitigating. He criticizes the quality of the I.G.'s reply brief as failing "to engage his arguments in critical respects." He also suggests that oral argument "would add a dimension to this proceeding that cannot be conveyed adequately in writing." P. Response at 2, 3, 5. I disagree. I find that the parties have well presented their arguments, that every nuance of this case has been explored in their submissions, and that oral arguments would unnecessarily delay its resolution, without adding anything new.

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

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).[6]

Here, until February 2004, Petitioner Huggins was the president of Synthes North America, a subsidiary of Synthes. He left that position in 2004 to become president of the Global Synthes Spine Division. He was the most senior officer in the Synthes chain of command except for its chief executive officer, Hansjörg Wyss. I.G. Ex. 5 at 1, 2; I.G. Ex. 21 at 3.

In a 97-count indictment, Petitioner Huggins, three other Synthes executives, Synthes itself, and Norian Corporation were charged with multiple offenses.[7] Petitioner Huggins was charged with 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 21, 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 nine months imprisonment, and ordered him to pay a $100,000 fine, which is the statutory maximum. I.G. Exs. 7, 12; I.G. Ex. 10 at 11; I.G. Ex. 17 at 13. His prison sentence significantly exceeded federal sentencing guidelines for such an offense (0-6 months). I.G. Ex. 21 at 20.

---

[6] 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.

[7] 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)(1)). 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.

Petitioner concedes that he was convicted of a criminal offense – one count of introducing adulterated and misbranded medical devices into interstate commerce, in violation of 21 U.S.C. §§ 331(a) and 333(a)(1). P. Br. at 2-3, 5. But he argues that his conviction does not justify exclusion under section 1128(b)(1), because he was not convicted of fraud or a crime "relating to" fraud.

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 "a culpable mental state," which is not necessary for conviction as a responsible corporate officer. P. Br. at 5-6.

If I accepted Petitioner's argument, I would have to 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) of the FDCA does not require a finding of intent or knowledge, Petitioner reasons, his crime is not "related to" fraud, and he should not be excluded.

Petitioner's argument fails because it ignores the plain language of section 1128(b). Under that statute, the I.G. may exclude based on a conviction *relating to* fraud. It does not require a conviction for fraud itself, as Petitioner's argument suggests. In *Friedman et al. v. Sebelius*, 686 F. 3d 813 (D.C. Cir. 2012), the D.C. Circuit affirmed the Departmental Appeals Board's 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) ("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."), *aff'd*, *Patel v. Thompson*, 319 F.3d 1317 (11th Cir. 2003); *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).

Moreover, the regulations governing these proceedings direct me to admit "[e]vidence of crimes, wrongs, or acts other than those at issue in the instant case . . . 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). If I were limited to considering the generic elements of the offense to which Petitioner pled guilty, this regulation would serve no purpose.

Finally, ignoring the conduct underlying the conviction would defeat the purpose of the statute, which is to protect program beneficiaries and program integrity from those who have shown themselves to be untrustworthy. If I relied solely on the language of 21 U.S.C. §§ 331(a) and 333(a)(1), I would not know the extent of Petitioner's involvement in the illegal activity. Based solely on the language of the statute, all I know is that he introduced adulterated and misbranded medical devices into interstate commerce. Nothing in those provisions refers to conviction as a "responsible corporate officer." Unless I look at the indictment, the guilty plea, or other of the court documents, I would not know whether Petitioner pled guilty as a responsible corporate officer or because he admitted that he personally willed the violation. Indeed, under Petitioner's theory, the I.G. could not exclude *anyone* convicted under sections 331(a) and 333(a)(1), even the defendant who admitted that he knowingly and deliberately introduced a dangerous product into interstate commerce. Congress plainly did not intend such a result. *See Narendra M. Patel, M.D.*, DAB No. 1736.

The "modified categorical" approach. In the alternative, Petitioner argues that I may consider only "particular materials that substantiate the offense of conviction. . . ." P. Br. at 7. To support this proposition, he relies on cases arising under the Armed Career Criminal Act (ACCA), 18 U.S.C. § 924(e). But cases arising under the ACCA are not dispositive here. *See Friedman*, 686 F.3d at 819 ("Whether the Congress intended the categorical or the circumstance-specific approach is to be discerned from the text, structure, and purpose *of the particular statute at issue*." (emphasis added)).

Here, we are necessarily concerned about the factual underpinnings of Petitioner's crime in order to determine whether it is "related to" fraud (*see* above discussion). In contrast, the ACCA courts are limited to determining the generic elements of the defendant's crime.

The ACCA imposes a minimum 15-year sentence enhancement on defendants who are convicted of illegally possessing firearms and have three prior convictions for "violent felonies" or serious drug offenses. In stark contrast to section 1128 of the Social Security Act, the ACCA sentencing court considers only the statutory definition of a prior offense,

unless that statutory definition is ambiguous. In that case, the court may have to consider additional materials, such as charging documents, jury instructions, or plea agreements. *Taylor v. United States*, 495 U.S. 575 (1990) (holding that the sentencing court may consider charging documents, jury instructions, and elements of the statute); *Shephard v. United States*, 544 U.S. 13 (2005) (extending the *Taylor* reasoning to convictions based on plea agreements); *United States v. Alston*, 611 F.3d 219 (4th Cir. 2010). By limiting the ACCA sentencing courts to facts "inherent in the conviction" or admitted to by the defendant at the time of the conviction, *Taylor* and its progeny prevented the courts from "becoming forums in which the prosecution and defense attempt to reproduce the defendant's earlier trial." At the same time, these decisions addressed the "concern that a wider inquiry would violate the Sixth Amendment right to trial by jury." *Alston*, 611 F.3d at 225 (quoting *United States v. Dean*, 604 F.3d 169, 172 (4th Cir. 2010)). Such considerations do not apply here.

Nevertheless, based on this line of cases, Petitioner argues that I may consider only the facts that he specifically admitted as part of his plea agreement. He then claims that he and his company admitted essentially nothing, except that he was a corporate officer. According to Petitioner, he did not even admit to the facts set forth in his plea agreement; he admitted only that the government could have proven those facts at trial. P. Br. at 7-8. In this way, he attempts to fit within the ambit of the Fourth Circuit's decision in *Alston*.

The *Alston* court applied the *Shephard* analysis to a situation in which the defendant's earlier assault conviction was based on an *Alford* plea – a guilty plea in which the defendant maintains his innocence but admits that, at trial, the prosecution could produce evidence sufficient to establish his guilt. *See North Carolina v. Alford*, 400 U.S. 25 (1970). The assault statute to which he pled was ambiguous; it might or might not have been a "violent felony" within the meaning of the ACCA. When Mr. Alston entered his plea, the prosecution described the evidence it would have presented, and the judge was satisfied that the prosecution's evidence established assault. But Defendant Alston steadfastly maintained his innocence. Based on these facts, the *Alston* court "could not say" that the facts needed to establish a violent crime were "inherent in the fact of [Mr. Alston's] conviction." The ACCA sentencing court could therefore not determine that those facts underlay the conviction without risking a violation of the Sixth Amendment.

Obviously, Sixth Amendment considerations do not apply to these administrative proceedings, and, as discussed above, I am free, indeed obligated, to examine the facts underlying Petitioner's conviction. In any event, I do not agree that neither Petitioner Huggins nor Synthes admitted to any fraudulent conduct. First, whether Petitioner's plea agreement is an *Alford* plea is far from certain. Petitioner Huggins conceded that, "if the case had gone to trial, the United States *would have proven*" the factors described in paragraph 9 of the plea agreement. I.G. Ex. 7 at 4 (Plea Agreement ¶ 9) (emphasis added). Presumably, in accepting his plea, the district court would have clarified any

ambiguity as to the nature of the plea. However, Petitioner has not submitted a transcript of those court proceedings.

In any event, contrary to Petitioner's suggestion that Synthes also entered an *Alford* plea, the company's plea agreement includes a straight-forward admission of guilt: "With respect to Synthes's conduct, the parties stipulate to the following facts and basis for the plea and criminal fine. . . ." I.G. Ex. 23 at 5 (Plea Agreement ¶ 8).

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

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

I.G. Ex. 21 at 1.

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 54; I.G. Ex. 12 at 1.

Notwithstanding the judgment, Petitioner insists that the information underlying his conviction "is entirely set forth in paragraph 9 of the plea agreement" and "is disconnected from fraud." P. Br. at 13. Whether Petitioner Huggins can so truncate the bases for his conviction is a question I need not resolve, since 1) the facts set forth in paragraph nine, by themselves, justify the exclusion; and 2) in the alternative, other admissible and compelling evidence establishes his personal participation in introducing adulterated and misbranded devices into interstate commerce. 42 C.F.R. § 1005.17(g).

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. 7 at 5; *see* I.G. Ex. 21 at 2. 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 ¶ 10; I.G. Ex. 7 at 5 (Plea Agreement ¶ 9(c)). 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).[8]

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. 7 at 5 (Plea Agreement ¶ 9(e)).

In December 2001, the FDA approved, "via the 510(k) process," Norian SRS for use as a "bone void filler." It was 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. 7 at 5-6 (Plea Agreement ¶ 9(f)) (emphasis added).

The FDA became concerned that some surgeons were nevertheless using bone void fillers in the spine for load-bearing indications. I.G. Ex. 7 at 6 (Plea Agreement ¶ 9(g)). 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. 7 at 6-7 (Plea Agreement ¶ 9(g)). 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; I.G. Ex. 28.

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 the treatment of*

---

[8] The process is referred to as the "510(k) process." Section 510(k) of the FDCA requires device manufacturers to notify the FDA of their intent to introduce a device into commercial distribution for the first time or to reintroduce a device that will be changed significantly or modified to the extent that its safety or effectiveness could be affected. If a manufacturer's modified device is "substantially equivalent" to the original device, the manufacturer may follow an "expedited, streamlined" version of the 510(k) process; however, the "special 510(k) process" cannot be used when the proposed change or modification affects the device's intended use. I.G. Ex. 5 at 4-5 (Indictment ¶¶ 11-15).

vertebral compression fractures. I.G. Ex. 7 at 6-7 (Plea Agreement ¶ 9(g)) (emphasis added).

As it happened, the FDA's concerns were well-founded. Some 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. 7 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. 7 at 8 (Plea Agreement ¶ 9(i)).

Throughout this time (December 2002 until January 2004), the companies were promoting the off-label use of Norian XR – in vertebroplasty surgeries to treat vertebral compression fractures – in violation of the FDCA, 21 U.S.C. § 351(f)(1). I.G. Ex. 7 at 8 (Plea Agreement ¶ 9(j)).

Although he did not mention his own involvement in the illegal activity, Petitioner Huggins acknowledged that, as a corporate officer, he was responsible for preventing such violations. I.G. Ex. 7 at 1, 5 (Plea Agreement ¶¶ 1, 9(a)).

Petitioner admits that the companies illegally test marketed and promoted their cements. I.G. Ex. 7 at 1 (Plea Agreement ¶ 1). 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 Huggins' 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 Huggins' knowledge of and participation in the underlying fraud. Just because prosecutors don't *need* to establish actual knowledge to sustain a conviction under the FDCA does not mean that the corporate officer didn't *have* actual knowledge. The biggest difference between this and the *Friedman* case is that, in *Friedman*, no compelling evidence established that the corporate officials were aware of their company's illegal activity. *See Paul D. Goldenheim et al.*, DAB No. 2268 (2009) at 13-14 n. 9; *aff'd in part sub nom. Friedman v. Sebelius*, 686 F.3d 813. In contrast, when he sentenced Petitioner Huggins, Judge Davis concluded:

> All that occurred either happened at [Petitioner Huggins'] direction, or with his full knowledge, or under his command and control. He committed much of the illegal conduct himself. The scope of this behavior and the magnitude of the wrong perpetuated on unsuspecting users of the untested, and unapproved product was extreme.

I.G. Ex. 21 at 20; *see* I.G. Ex. 17 at 73 (explaining that Defendant Huggins will be sentenced to jail "not because you're the responsible corporate official who is standing up and taking the burden for things that happened on his watch . . . . This is more . . . . You're being punished because of decisions that you personally made and participated in.").

Deference to the district court findings. Petitioner challenges reliance on the district court's sentencing documents, arguing that they are not entitled to issue-preclusive effect, do not constitute evidence, and were improperly arrived at. P. Br. at 14-16. 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 issue-preclusive effect to the sentencing documents. Rather, the I.G. argues that the district court's findings merit considerable deference. I.G. Reply at 26, (citing *Emem Dominic Ukpong*, DAB No. 2220 at 2, 3 (2008); *W. Scott Harkonen*, DAB No. 2485 at 17, 18 (2012)). 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. Indeed, the *Monarch* 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.

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." 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. *Monarch*, 192 F.3d at 304-06.

Here, Petitioner Huggins may not challenge his conviction nor attack collaterally any facts adjudicated as part of that conviction. 42 C.F.R. § 1001.2007. 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.17-42.

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, described by the *Monarch* court, do not apply in this case 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,

81; I.G. Ex. 17 at 3.[9] In contrast, here, Petitioner Huggins waived his right to a hearing. P. Br. at 51;

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 Huggins had to challenge the government's evidence and argument before the sentencing judge. I.G. Ex. 10 at 20-27; I.G. Ex. 17 at 3. *See* I.G. Ex. 15; I.G. Ex. 17 at 5 (defense agreeing that it had no additional factual corrections or amendments to make to the court's determinations order). He declined the opportunity to make a statement at his sentencing hearing (I.G. Ex. 17 at 63) and has declined to testify during these proceedings. P. Br. at 51;

5) Although Judge Davis characterized his findings as true "beyond any reasonable question," the standard of proof in sentencing enhancement is "preponderance of evidence." I.G. Ex. 21 at 16-17 (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, 932-33 (W.D. MI 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).

Whether or not the sentencing judge's findings are entitled to issue-preclusive 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.

Petitioner also complains that the sentencing court findings are entitled to no weight because they were "rooted in grave procedural deficiencies." P. Br. at 15-16. This administrative forum is hardly the place to challenge a federal district court's findings. As Judge Davis explained when he imposed the unusually stiff jail sentence, Petitioner had the right to appeal the sentence and the findings that underlay it. I.G. Ex. 17 at 81,

[9] Petitioner criticizes Judge Davis for taking the testimony of FDA Consumer Safety Officer/Investigator Joseph Despins on the day of sentencing. P. Br. at 16. Although he was given the opportunity to question Investigator Despins at the time, Petitioner declined to do so. I.G. Ex. 17 at 63.

84-85; *see* I.G. Ex. 7 at 10 (Plea Agreement ¶ 13b). Petitioner's recourse for correcting perceived procedural errors thus lies elsewhere. Unless reversed by the appellate court, Judge Davis's findings stand.

The district court's findings. Petitioner Huggins' involvement in the crime is established by overwhelming evidence. Judge Davis arrived at his factual findings "*beyond any reasonable question.*" I.G. Ex. 21 at 17 (Judge's Memorandum) (emphasis added). Among the many examples cited by Judge Davis (and supported by compelling documentary evidence) are the following:

- In early 2000, Synthes planned to conduct a clinical trial of Norian SRS without FDA approval. The plan was to identify surgeons, select test sites, provide product, train surgeons, observe surgeries, and compile and review data. After learning about the company's plans, Synthes regulatory personnel "strenuously" warned that such trials would be illegal. On August 23, 2000, Michael Sharp, an employee in the regulatory department, sent a memo to Synthes executives, expressing concern that the regulatory department had been unaware that such a trial was being considered. He warned that "[w]e cannot 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." I.G. Ex. 27-17. Richard Bohner, Synthes Vice President of Human Resources and Regulatory Affairs, forwarded a copy of the Sharp memo to Petitioner Huggins. I.G. Ex. 21 at 4-5 (Judge's Memorandum ¶ 2); I.G. Ex. 27-18.

  This was one of many stark warnings to Petitioner Huggins and his colleagues, which undermine his repeated claims that he simply did not understand that the clinical trials would be illegal.

- 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**.[10] A Synthes sales representative was present at the off-label surgeries. I.G. Ex. 21 at 5 (Judge's Memorandum ¶ 3); I.G. Ex. 27-25 at 1; I.G. Ex. 27-26; *see* I.G. Ex. 27-37 at 20. Petitioner Huggins knew about these events, because he sent a March 16 e-mail to the appropriate staff, stating, "Steve, You need to real [sic] in your salesforce ASAP." I.G. Ex. 27-26. He subsequently sent his own memo to the sales representatives, dated March 29, 2001, which referred to the incidents and reminded them that Synthes is not supposed to

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

promote the off-label use of its products. I.G. Ex. 21 at 5 (Judge's Memorandum ¶ 3); I.G. Ex. 27-37 at 20.[11]

- Petitioner Huggins attended a November 15, 2001 meeting of the Synthes Management Review Board, at which the participants decided not to pursue a clinical study aimed at obtaining FDA approval for using Norian SRS mixed with barium sulfate in vertebroplasty surgeries to treat vertebral compression fractures. The company officials instead decided "to get a few sites to perform 60-80 procedures and help them publish their clinical results." They rejected the safer – and lawful – approach because of the cost (about three years and a million dollars plus loss of Synthes's competitive advantage in the bone cement market). I.G. Ex. 21 at 5-6 (Judge's Memorandum ¶ 4); I.G. Ex. 27-5 at 2-3.

  In a subsequent discussion, reported as an addendum to the meeting, Petitioner Huggins met with CEO Wyss and Thomas Higgins, the president of Synthes Spine (a division of Synthes). They discussed one of the meeting's presentations, made by a University of Washington researcher, regarding "the serious nature of complications associated with [the vertebroplasty] procedure." The executives nevertheless ratified the Board's decision to proceed with a limited test involving at least 50 patients, whose cases they would follow before releasing the product to the broad medical market. I.G. Ex. 21 at 6 (Judge's Memorandum ¶ 4); I.G. Ex. 27-5 at 3.

  Thus, Petitioner Huggins knew that the FDA had to approve the test, but he decided not to seek FDA approval because of the time and costs. I.G. Ex. 21 at 6 (Judge's Memorandum ¶ 4); I.G. Ex. 27-5 at 2-3; *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. 29 at 2-3.

  Such high-level interest belies Petitioner's suggestion that the Norian project was simply too insignificant to merit his involvement. *See* P. Br. at 18-21.

- On December 20, 2001, the FDA approved Norian SRS for use as a bone void filler in the spine, but only for "bony voids or defects that are not intrinsic to the stability of the bony structure." The label warned: "Do not mix . . . with any other

[11] Synthes reported the hypotensive events to the FDA, as required, apparently at Dr. Sharp's insistence. *See* I.G. Ex. 27-37 at 20 (in which Dr. Sharp asserts: "My judgment is that these are clearly MDR [medical device report] reportable."). Dr. Sharp left Synthes, and, as discussed below, subsequent incidents, although fatal, were not reported. I.G. Ex. 17 at 23.

substance." I.G. Ex. 21 at 6 (Judge's Memorandum ¶ 5); I.G. Ex. 27-11; *see* I.G. Ex. 7 at 5-6 (Plea Agreement ¶ 9(f)).

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

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

I.G. Ex. 28 at 1, 2 (emphasis added); I.G. Ex. 21 at 7 (Judge's Memorandum ¶ 7); *see* I.G. Ex. 27-31 at 5-17 for a chilling account of potential risks posed by using Norian SRS in vertebroplasty surgeries.

- By at least May 2002, Petitioner Huggins had learned that the chemical composition of Norian SRS posed lethal risks when used in the spine in vertebroplasties. He knew that it appeared to have:

> a rapid and extremely coagulogenic effect on the blood of animals. He knew, or should have known, that the planned development of a cement to treat vertebral compression fractures was potentially suspect, and caution and strict adherence to regulatory procedure [were] required. Importantly, Huggins knew, or should have known, of the need for further testing before the product could be safely used on humans.

I.G. Ex. 21 at 7 (Judge's Memorandum ¶ 7); I.G. Ex. 5; I.G. Ex. 31 at 1-2. Indeed, in an e-mail dated May 30, 2002, Petitioner Huggins expressed second thoughts about the "spine plan." I.G. Ex. 21 at 7 (Judge's Memorandum ¶ 8); I.G. Ex. 27-8.

- On May 8, 2002, representatives from the FDA conferred 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." I.G. Ex. 27-13 at 2; I.G. Ex. 29 at 3-4; *see* I.G. Ex. 7 at 6-7 (Plea Agreement ¶ 9(g)); I.G. Ex. 27-35 at 4, 5; I.G. Ex. 21 at 8-9 (Judge's Memorandum ¶ 11).

- In June 2002 e-mails to Synthes executives, Dr. Kenneth Lambert, a physician consultant, characterized as "necessary and proper" the company's earlier decision to declare a moratorium on the use of Norian SRS in the spine "because of **several cases . . . that caused serious concerns about the safety of its use**." Dr. Lambert expressed concern that controlled studies had begun and asked, rhetorically, what had changed, answering that nothing had changed except a journal article describing a death involving the use of SRS. He warned that giving SRS to a surgeon for his use without any protocol "amounts to human experimentation whose only defense seems to be that it will be a small study." He opined that the company should be "uncomfortable" with any surgeon who is "comfortable" using SRS. He specifically warned that the "company could suffer serious consequences if [the studies] are not done properly. Having the FDA take approval away may not be the worst consequence." Petitioner Huggins received a copy of this e-mail "almost immediately." I.G. Ex. 21 at 8 (Judge's Memorandum ¶ 9); I.G. Ex. 27-32 at 4, 6.

  Lest there be any doubt that Petitioner Huggins got the message, Dr. Lambert sent him a separate memo on June 11, 2002, expressing his concern "that the toothpaste almost got out of the tube while many important people were not in the loop." He emphasized that Norian SRS was unique because "it is manufactured by the surgeon in the patient[']s body." He reiterated his concern that the company could suffer serious consequences if it did not act properly and attached his responses to facility staff "so that [Petitioner Huggins would be] as informed as possible" when making his "important decisions." I.G. Ex. 21 at 8 (Judge's Memorandum ¶ 10); I.G. Ex. 27-32 at 5.

- Petitioner Huggins participated in a Management Review Board Meeting on September 17, 2002, at which the subject of vertebroplasty was "prominent on the agenda." 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 Huggins, decided to proceed with and fully launch the illegal Norian XR test markets by December 2002. I.G. Ex. 27-35 at 4, 5; I.G. Ex. 21 at 8-9 (Judge's Memorandum ¶ 11); *see* I.G. Ex. 27-36. Again, this

high-level involvement undermines Petitioner's suggestion that this project was too insignificant to merit his attention.

- The September 17 conference included a presentation regarding the May 2002 conference, during which the FDA insisted that Norian XR bear the warning that it was not to be used in vertebroplasties (discussed above). I.G. Ex. 21 at 9 (Judge's Memorandum ¶ 11); I.G. Ex. 27-36 at 15.

- On January 13, 2003, **a patient of Dr. Barton Sachs died** during a vertebroplasty/kyphoplasty[12] 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. 21 at 9 (Judge's Memorandum ¶ 12); I.G. Ex 27-37 at 8; I.G. Exs. 27-49 through 27-51.[13] Petitioner Huggins learned about this death shortly thereafter. I.G. Ex. 21 at 9 (Judge's Memorandum ¶ 13), *see* I.G. Ex. 27-38 at 8; I.G. Ex. 27-39; I.G. Ex. 27-52.

  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 Huggins 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. 21 at 9 (Judge's Memorandum ¶ 14); I.G. Ex. 27-37. The plan includes a "Release to Market Strategy" that describes the "back table mixing" of Norian SRS with barium sulfate (which became Norian XR, but was not then approved). It says that "this part of the test market began in September 2002 and that two sites were selected to participate" in Phase I (which included Dr. Sachs). I.G. Ex. 27-37 at 77; *see* I.G. Ex. 6 at 7; I.G. Ex. 7 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

---

[12] "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).

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

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 Huggins – 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. 21 at 9-10 (Judge's Memorandum ¶ 15); I.G. Ex. 27-38 at 22; I.G. Ex. 27-39. They decided to proceed with the market plan, obtaining a larger case base, at multiple sites, which, they said, would allow them better to estimate the rate of complications. "This will help us *determine our associated level of risk and decide what level is too high*." I.G. Ex. 21 at 9-10 (Judge's Memorandum ¶ 15) (Judge's emphasis); I.G. Ex. 27-39 at 2; I.G. Ex. 27-40. As Judge Davis observed:

  > These determinations, of course, can be made properly only in accordance with FDA regulatory protocol. A test market cannot be used to determine the safety and efficacy of a significant risk medical device.

  I.G. Ex. 21at 10 (Judge's Memorandum ¶ 15).

  Petitioner Huggins knew "beyond all reasonable question" that unauthorized [Norian] XR studies were planned. He also knew about the risks of blood clotting and cement leakage from its use in vertebroplasties. I.G. Ex. 21 at 10 [Judge's Memorandum ¶ 15).

- Josi Hamilton, the Norian XR Project Manager, sent Petitioner Huggins a copy of the minutes from the July 18 meeting.

  > [D]emonstrating his complete support of the unauthorized clinical trials of '200 or so' [Norian] XR cases going forward, [Petitioner Huggins] responded: "We should discuss these minutes. . . . I need clarification of a couple of points. We agreed to better document and follow-up on the outcomes of the additional 200 or so cases. We need to understand what the protocol will be to document the cases. Also, we really need to have a conversation with Dr. . . . Chapman who is conducting the studies at Univ. of WA. . . ."

  I.G. Ex. 21 at 10 (Judge's Memorandum ¶ 16) (quoting I.G. Ex. 27-41).

- At an August 14, 2003 Strategic Planning Meeting, Petitioner Huggins 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. Petitioner

Huggins pointed out during the meeting that Synthes had a "poor record" in obtaining pre-market approvals from the FDA. I.G. Ex. 21 at 11 (Judge's Memorandum ¶ 17); I.G. Ex. 27-55.

- 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.* I.G. Ex. 21 at 11 (Judge's Memorandum ¶ 18); *see* I.G. Ex. 17 at 36 ("[I]t doesn't even use the term vertebral compression fracture. It doesn't use the term vertebroplasty. It does not give any term that someone looking on this sort of information would look for. . . .").

- Petitioner Huggins 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. 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. Ex. 21 at 11 (Judge's Memorandum ¶ 19); I.G. Exs. 27-62, 27-65, 27-66.

- In another e-mail, dated October 1, 2003, Product Manager Hamilton advised Petitioner Huggins 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. 21 at 11 (Judge's Memorandum ¶ 20); I.G. Ex. 27-68.

- Project Manager Hamilton sent another e-mail to Petitioner Huggins and others on October 15, 2003. The e-mail described her interviews with the 19 surgeons

selected to use Norian XR in vertebroplasties for vertebral compression fractures. They discussed the death of Dr. Nottingham's patient and complications associated with using Norian XR on an elderly patient population. I.G. Ex. 21 at 12 (Judge's Memorandum ¶ 21); I.G. Ex. 27-65.

> Thus, [Petitioner] Huggins was fully advised of the substantial questions raised by Drs. Nottingham and Lane as to the safety of the bone cement. Further, Dr. Lane directly asked whether the test market was an appropriate method for the collection of the information Synthes was gathering. He encouraged Synthes to disclose its approach to the Institutional Review Boards of the affected hospitals and the FDA. In short, Dr. Lane urged Synthes to reveal its high-risk approach.

I.G. Ex. 21 at 12 (Judge's Memorandum ¶ 21).

- Petitioner Huggins and others met on October 31, 2003, to consider the serious questions surrounding the use of Norian XR in unauthorized clinical trials (e.g., the death of Dr. Nottinham's patient, the University of Washington pig studies). They also considered their "competitors' status."[14] 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. 21 at 12 (Judge's Memorandum ¶ 22); I.G. Ex. 27-67.

- On January 22, 2004, **a third patient died** while undergoing kyphoplasty surgery to treat a vertebral compression fracture. Dr. Hieu Ball performed the surgery. [15] An autopsy report was performed, and a medical device report filed. I.G. Ex. 21 at 12 (Judge's Memorandum ¶ 23); I.G. Exs. 27-74; 27-75. A surgeon training

[14] 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* P. Br. at 38 ("[T]he FDA . . . cleared at least three bone cements for the treatment of vertebral compression fractures beginning in April 2004.").

[15] I note that Dr. Ball was among the physicians who criticized Dr. Nottingham and his purportedly "aggressive surgical tactics." Dr. Ball also opined that "it is necessary to focus on proper patient selection." I.G. Ex. 27-62 at 2; P. Joint Ex. 9 at 1. But four months after the death of Dr. Nottingham's patient, Dr. Ball's own patient died while undergoing the procedure. I.G. Ex. 27-74. She was 83-years-old and a smoker, suffering from hypertension, atypical angina, diabetes, and asthma. I.G. Ex. 27-74 at 3; I.G. Ex. 27-75. So I don't know what Dr. Ball meant by "proper patient selection."

forum, scheduled for January 24, was cancelled immediately. Other training sessions, scheduled through February, were eventually cancelled as well. I.G. Ex. 21 at 12 (Judge's Memorandum ¶ 24).

- Thereafter, Petitioner Huggins signed a February 10, 2004 "Dear Surgeon" letter, which Synthes sent to the physicians it had selected to participate in the unauthorized clinical trials. As Judge Davis observed, the letter omitted some critical facts. It begins with general language about vertebral compression fractures, 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 repeated the FDA warnings that "[t]hese 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 went on, 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 concluded 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; I.G. Ex. 21 at 12-13 (Judge's Memorandum ¶ 25).

  Judge Davis pointed out the letter's omissions: it did 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 two hypotensive events or the three deaths that had occurred while 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. "Presented in the guise of a recent epiphany, the letter clearly stated what was long clear to [Petitioner] Huggins and the Synthes leadership but which [they] had concealed from the physicians in the test markets. . . ." I.G. Ex. 21 at 12 (Judge's Memorandum ¶ 25).

- The FDA investigated Synthes from May 11 through June 18, 2004. As part of this investigation, FDA Consumer Safety Officer/Investigator Joseph Despins interviewed Petitioner Huggins on June 7, 2004. I.G. Ex. 27-79 at 34-41. Judge Davis observed that, during the interview, Petitioner Huggins was "unable to recall many facts" and made "numerous material misrepresentations of fact" about the test markets and his knowledge of the unauthorized clinical trials. I.G. Ex. 21 at 13-14 (Judge's Memorandum ¶ 26). Petitioner challenges the judge's observation regarding Petitioner Huggins' assertions of ignorance (P. Br. at 16), but the judge's finding is well-supported by the FDA Inspection report. I.G. Ex. 27-79 at 35-40. Among Petitioner's evasive or misleading responses:

1. When asked if "the vertebroplasty test markets for Cavity Creation System and Norian SRS" could have "evolved into the subsequent test markets in 2003," Petitioner Huggins replied that "this would be speculation" and then repeated that "it would be speculation."

2. He said that he "did not know" who called the July 18, 2003 Safety Meeting (at which the participants considered their options and decided to proceed with the market plan) and that he "did not have the knowledge of the meeting exactly" and "did not know" who wrote the minutes of the meeting. He said that he believed that the outcome of that meeting was "to continue the University of Washington studies and to make sure the training was appropriate. . . ."

3. Regarding the test market plan, he said that "he was not certain if that was what happened or not." When Investigator Despins followed up, showing him documents, he admitted that the outcome of that meeting was to proceed with the Phase II Norian XR test market. When Investigator Despins asked him to identify the approving official, he stated that "as a group we agreed with the recommendation to go forward." Investigator Despins then "asked Mr. Huggins if, by being the most senior person at the meeting, if he was the approving official and he said he was."

4. Investigator Despins asked about the September 23 meeting (following the September 19 death of Dr. Nottingham's patient); Petitioner Huggins claimed that he "did not recall who organized the meeting," but conceded that he could have. He said that the discussion was on the MDR (medical device report), but that "he was struggling to remember the details." I.G. Ex. 21 at 13-14 (Judge's Memorandum ¶ 26) (quoting I.G. Ex. 27-79 at 35-40); *see* I.G. Ex. 21 at 19 ("This pattern of deception is unparalleled.").

- In describing the crime, Judge Davis quoted the testimony of Investigator Despins, who testified that a lawful test market allows the device manufacturer to gather information from end-users about the device's ease of use for *indications that have been cleared by the FDA*. A test market may not lawfully test the safety and efficacy of a device. Investigator Despins was "shocked" that Synthes considered "such an activity. . . in light of the fact that they knew that it could cause problems in the subject – in an animal." I.G. Ex. 21 at 14 (Judge's Memorandum ¶ 27) (quoting I.G. Ex. 17 at 58).[16]

[16] Petitioner blames the FDA for purportedly suggesting that Synthes obtain approval "through a 510(k) route." P. Br. at 24. I assume he means the "special 510(k) process." *See* footnote 8. As Judge Davis emphasized, such an expedited process may be used *only* if the new device is "substantially equivalent" to the manufacturer's original device. It

- The FDA issued a warning letter to Synthes on November 5, 2004. I.G. Ex. 21 at 15 (Judge's Memorandum ¶ 29); I.G. Ex. 33; *see* I.G. Ex. 27-79. The letter advised Synthes that, during its investigation, it learned that Synthes was "marketing the Norian XR for new intended uses without approval or clearance from FDA, in violation of the Act." The letter also advised the company that the FDA found violations of the Medical Device Reporting regulation (21 C.F.R. Part 803) and the Current Good Manufacturing Practice of the Quality System regulation (21 C.F.R. Part 820). I.G. Ex. 21 at 15 (Judge's Memorandum ¶ 29); I.G. Ex. 33 at 1.

- Petitioner Huggins participated in drafting Synthes's "fraudulent and deceptive" response to the FDA's investigation. They (falsely) denied that clinical trials had occurred; they claimed that the test market was conducted for cleared indications only, not to test the safety and efficacy of the bone cements. They denied training surgeons to use the cements. I.G. Ex. 21 at 14 (Judge's Memorandum ¶ 28); I.G. Ex. 16 at 70-71.

The court concluded: "The sad truth is that [Petitioner] Huggins . . . and his corporate conspirators, surreptitiously committed to a course of experimentation on humans in order to capture a large share of a growing, and extremely lucrative, market." I.G. Ex. 21 at 17 (Judge's Memorandum).

Financial Misconduct. Relying on the word "other" in the phrase "fraud, theft, embezzlement, breach of fiduciary responsibility, or *other* financial misconduct," Petitioner argues that section 1128(b)(1)(A) permits exclusion only for forms of financial misconduct. He argues that he should not be excluded, because his conviction is not "related to" financial misconduct. P. Br. at 4-5.

There are two problems with this argument. First, as Judge Davis, found, Petitioner and his cohorts were, in fact, motivated by financial gain. They wanted to avoid the expense associated with seeking FDA approval, and they hoped that their actions would engender enormous profits. I.G. Ex. 21 at 6 (Judge's Memorandum ¶ 4); *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. 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

---

could not be used when the proposed change affects the intended use. *See* I.G. Ex. 5 at 5 (Indictment ¶ 14). Judge Davis cited multiple instances in which regulatory staff and consultants explained this distinction to Petitioner Huggins.

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

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

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

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

---

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

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

Incarceration. The court sentenced Petitioner Huggins to nine months in jail, a sentence that is significantly longer than called for by federal sentencing guidelines (a minimum of no jail time and a maximum of six months). I.G. Ex. 12 at 2; I.G. Ex. 17 at 4.

Judge Davis did not take the sentencing guidelines lightly. He also recognized that, under the terms of his plea agreement, Petitioner waived his right to appeal the sentence, so long as it was no longer than six months. "But the fact of the matter is that [nine months] is the minimal sentence that I think is appropriate to protect the societal interest in this matter." I.G. Ex. 16 at 78; *see* I.G. Ex. 7 at 10 (Plea Agreement ¶ 13b(2) and(3)). Judge Davis explained that he departed from the guidelines, because the crime was much worse than any other case brought against a responsible corporate officer. Alluding to the facts underlying the Supreme Court's decision in *United States v. Park*, 421 U.S. 658 (1975), he noted that

> Huggins' actual conduct in choosing to pursue the unauthorized clinical trials far overshadows his personal attributes. This case does not involve standard Park-doctrine behavior, in which the unaware corporate official is held strictly liable for the conduct of his subordinates. This matter presents the question of the sentencing consequences of the direct, knowing, intelligent, and intentional choices made by Huggins himself.

I.G. Ex. 21 at 18 (Judge's Memorandum). Judge Davis explained that he was going to increase Petitioner Huggins' period of incarceration beyond sentencing guidelines "because I actually do not believe that the range adequately encompasses the societal harm and damage that you've done." I.G. Ex. 17 at 77. "I do it because it is necessary; because what has occurred in this case, in terms of wrongfulness, it's eleven on a scale of ten." I.G. Ex. 17 at 78.

---

[18] Although, arguably, "the acts that resulted in the conviction, or similar acts, were committed over a period of one year or more," the I.G. here did not cite this aggravating factor as a basis for increasing the period of exclusion. I.G. Ex. 7 at 8 (Plea Agreement ¶ 9(j)) (admitting that, from *December 2002 until January 2004*, companies were promoting off-label use of Norian XR in violation of the FDCA); *see* 42 C.F.R. § 1001.201(b)(2)(ii).

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

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

Adverse impact. Petitioner argues that he is not subject to an increased period of exclusion based on the adverse impact suffered by patients, because he was convicted as a responsible corporate officer, a strict liability offense "characterized by a *failure* to act." Thus, he reasons, he was convicted of an "omission," not an "act," so "a textual basis is lacking on which to apply the aggravating factor." P. Br. at 43. Even if I agreed that the regulation excuses a more "passive" criminal from the ultimate impact of his crime on individuals (which I do not), Petitioner's argument fails because the regulation directs me to consider "similar acts." The drafters of the regulation recognized "numerous cases" where, notwithstanding evidence of additional wrong-doing, the individual pleads guilty to just one charge as a condition for entering into a plea agreement. They considered it the I.G.'s responsibility to review "*all factors surrounding a case* to determine the reasonable length of an exclusion." They likened their approach to "sentencing in the criminal context, where a judge may consider many different acts of the defendant in setting the appropriate sentence, not just the ones that form the basis for the exclusion." 57 Fed. Reg. 3298, 3315 (Jan. 29, 1992) (emphasis added).

---

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

Unquestionably, Petitioner Huggins and his colleagues at Synthes "surreptitiously committed to a course of experimentation on humans . . . ." I.G. Ex. 21 at 17 (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. 17 at 58 (Inspector Despins expressing his "shock" that "such an activity would be considered in humans in light of the [pig studies]"); I.G. Ex. 27-32 at 5, 6.

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." I.G. Ex. 15 at 19. They were subjected to the risks of Norian SRS and Norian XR without their full informed consent and without the FDA's authorization. Some were injured and some died. By conducting the unauthorized trials of these cements, the judge found, Synthes employees "disregarded the safety of all members of society." I.G. Ex. 15 at 19, 31; I.G. Ex. 27-37 at 20.

> Huggins and his confederates closed their eyes to the deaths of two unsuspecting patients, who, as it turned out, were little more than subjects in a Synthes experiment. It took a third death before Huggins and his subordinates chose to comply with the unwavering directives of the FDA. . . .

I.G. Ex. 21 at 18 (Judge's Memorandum). Judge Davis's conclusions are supported by compelling evidence.

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

- On February 8, 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. 21 at 5 (Judge's Memorandum ¶ 3); 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. 21 at 9 (Judge's Memorandum ¶ 12); 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. P. Br. at 44. But Petitioner Huggins 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, the Synthes executives bear significant responsibility and should not now benefit from their failure to investigate adequately and their failure to disclose the findings so that others could investigate. As Judge Davis recognized, failing to report and investigate such a death is a dangerous practice and puts all future patients at risk.

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

- On September 19, 2003, Dr. Nottingham's patient died while undergoing the unapproved surgery. Again, no autopsy was performed, and, although a medical device report was filed, it did not accurately describe the procedure (vertebroplasty using Norian XR). I.G. Ex. 21 at 11 (Judge's Memorandum ¶ 18). During the surgery, the patient experienced what the surgeon described as a "drastic drop in blood pressure." He also noted a "cement leak." I.G. Ex. 21 at 11 (Judge's Memorandum ¶ 19); I.G. Exs. 27-62, 27-65, 27-66. At least one other physician opined that "Norian XR is potentially de-watering and causing episodes of hypotension." I.G. Ex. 21 at 11-12 (Judge's Memorandum ¶ 20); I.G. Ex. 27-68. Even if Dr. Nottingham's patient had survived, a hypotensive event is an "adverse impact." A cement leak is an adverse impact.

- On January 22, 2004, Dr. Ball's patient died while undergoing surgery to treat a vertebral compression fracture using Norian XR. I.G. Ex. 21 at 12 (Judge's Memorandum ¶ 23); I.G. Exs. 27-74, 27-75.

  Only Dr. Ball's patient underwent an autopsy. As with the experimental pig, this patient died within a minute or two of the surgeon's introducing the cement. According to the autopsy report, "[i]mmediately following the installation of [the Norian XR] cement bilaterally . . . her blood pressure decreased and [she] was unresponsive to CPR." I.G. Ex. 27-75 at 3; 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; I.G. Ex. 27-75 at 4. Except for the amount, this material was "indistinguishable" from the clumps they found in her spine. I.G. Ex. 27-75 at 5; P. Joint Ex. 11 at 5. Petitioner does not explain the presence of the same "foreign material" in both the

> lungs and the spine. There may be other explanations; however these findings are consistent with the risks described by the many researchers who warned that Norian XR could enter the venous system and travel to the lungs. I consider this compelling evidence that the unapproved use of the Norian cement "had a significant adverse physical . . . impact" on Dr. Ball's patient.

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

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, e.g.*, I.G. Ex. 21 at 11, 12 (Judge's Memorandum ¶¶ 19, 25).

According to Petitioner, at least one of these patients (Dr. Sachs') needed and obtained "cardiologist clearance to undergo procedure with general anesthesia." The patient herself signed a "special form" acknowledging the heightened risk. P. Joint Br. at 37. Petitioner does not provide copies of the patient consent nor the cardiologist's clearance, but relies on Product Manager Hamilton's notes of her telephone conversation with Dr. Sachs. P. Joint Ex. 6. This hearsay-on-hearsay comes from individuals with a vested interest in avoiding responsibility for the negative outcome, and I do not consider it very reliable. Nevertheless, accepting Ms. Hamilton's version of Dr. Sachs' version, I see no claim that the cardiologist cleared the patient for anything more drastic than an approved surgical procedure involving general anesthesia. I see no evidence that either the cardiologist or the patient realized that she would undergo an unapproved and highly experimental procedure, known to cause hypotensive events, a procedure that presented the "unique risk" of the cement's entry into the venous system and transport to the lungs. I.G. Ex. 27-31 at 11.

Petitioner disavows any responsibility for the surgeries, pointing out that physicians often use medical devices in unapproved ways and suggesting that the physicians themselves are accountable for any adverse outcome. 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 they recruited and trained the willing gunmen.

By subverting the FDA process, Petitioner Huggins and his colleagues made already-risky procedures even more dangerous. I.G. Ex. 17 at 21.

> And the communications that came back from the University of Washington researchers were . . . enough to stop a freight train . . . . All they did was make you pause, make you hesitate, because you wrote your famous "I have second thoughts" memo. But nevertheless the second thoughts dissipated and we proceeded.

I.G. Ex. 17 at 71.

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

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

Here, Petitioner Huggins 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(b)(3)(iii). In support of this claim, he points to the timing of his guilty plea relative to the timing of his company's guilty plea and suggests a relationship between his taking "responsibility for whatever it is that [Synthes] may have done that violated the FDCA" and the company's guilty plea. Even among unsuccessful arguments of "cooperation with law enforcement," this one is exceptionally weak.

"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')."[20] *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. 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.

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

Petitioner also complains that the regulations are too narrow, because they omit factors, such as character, trustworthiness, and reputation, that, in his view, should be considered mitigating. P. Br. at 47-48. But the statute provides that any deviation from the prescribed three-year exclusion must be made "in accordance with published regulations." I am bound by the statute and regulations, and may not consider any factor not set forth in the regulations. *See* 42 C.F.R. § 1005.4(c)(1).

In Petitioner's view, these purportedly overlooked factors establish that he poses no threat to health care programs or program beneficiaries. I note that his character and reputation did not prevent him from, "over a long period of time," intentionally making "fifteen, sixteen decisional steps . . . [that] he shouldn't have made." I.G. Ex. 17 at 80.

Moreover, the Board has repeatedly observed that the exclusion remedy serves two purposes: to protect program beneficiaries and program integrity from those who have shown themselves to be untrustworthy; and to deter others from engaging in similar misconduct. *Breton Lee Morgan, M.D.*, DAB No. 2264 at 9 (citing *Jeremy Robinson* DAB No. 1905 at 3 (2004)); S. Rep. No. 109, 100th Cong., 1st Sess. (1987) ("clear and strong deterrent"); *Joann Fletcher Cash*, DAB No. 1725 at 15, 18 (discussing trustworthiness and deterrence). In imposing an expanded jail sentence, Judge Davis emphasized that he considered the penalty necessary to deter similar wrong-doing. Introducing adulterated and misbranded products into interstate commerce significantly

[20] The relevant language in section 1001.102(c)(3) (mandatory exclusions) is identical to that in section 1001.201(b)(3)(iii).

endangers the public. *United States v Park*, 421 U.S. 658. Yet the temptations to engage in such conduct are substantial, promising potentially enormous profits with relatively little risk to the individuals involved. Judge Davis recognized that imposing significant jail time is one of the few effective deterrents.

> [T]o the extent that other . . . manufacturers learn from what we do her today, then they need to hear the lesson loud and clear. There needs to be no mistake about what I say. It cannot be in any way ambiguous, because the conduct, the institutional conduct needs to be changed.

I.G. Ex. 17 at 76. So too is exclusion, as Petitioner himself acknowledged:

> And so, with respect to the idea that a sentence of incarceration is necessary to deter, generally, members of the public or any officials or employees in the medical device industry, we respectfully submit that exclusion sanction itself is sufficient to get the message across.

I.G. Ex. 17 at 11-13, 15.

Conclusion

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

/s/
Carolyn Cozad Hughes
Administrative Law Judge