Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Richard E. Bohner
Docket No. A-15-27
Decision No. 2638
May 26, 2015

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Richard E. Bohner (Petitioner) appeals a decision by an Administrative Law Judge (ALJ) sustaining his exclusion from participation in Medicare, Medicaid, and other federal health care programs for four years. *Richard E. Bohner*, DAB CR3479 (2014) (ALJ Decision). Petitioner, who was a senior executive of a medical device manufacturer, pled guilty as a responsible corporate officer to one misdemeanor count of introducing adulterated and misbranded medical devices into interstate commerce in violation of federal law and was sentenced to eight months incarceration. The ALJ sustained the Inspector General's (I.G.) determination that Petitioner had been convicted of an offense related to fraud in the delivery of a health care item or service, authorizing his exclusion under section 1128(b)(1)(A) of the Social Security Act (Act).[1] The ALJ also determined that a four-year period of exclusion, one year longer than the statutory minimum, was within a reasonable range based on the presence of aggravating and mitigating factors specified in the regulations.

For the reasons explained below, we sustain the ALJ Decision.

Legal Background

Section 1128(b)(1)(A) of the Act authorizes the Secretary of Health and Human Services to exclude, from participation in any federal health care program, "[a]ny individual or entity that has been convicted … under Federal or State law … of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct … in connection with the delivery of a health care item or service[.]" An exclusion under section 1128(b)(1)(A) is for three 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

[1] The current version of the Social Security Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact-toc.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section.

is appropriate because of aggravating circumstances." Act § 1128(c)(3)(D); 42 C.F.R. § 1001.201(b)(1). Among the factors that may serve as bases for lengthening the period of exclusion, the I.G. relied here on the following two: 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). The relevant mitigating factor the I.G. found here was that the excluded individual or entity "was convicted of 3 or fewer offenses, and the entire amount of financial loss… due to the acts that resulted in the conviction and similar acts is less than $1,500." Section 1001.201(3)(i).

In reviewing whether "'[t]he length of exclusion is unreasonable,' 42 C.F.R. § 1001.2007(a)(1)(ii), the ALJ may not substitute his or her judgment for that of the I.G. or determine what period of exclusion would be 'better.'" *Craig Richard Wilder*, DAB No. 2416, at 8 (2011), citing *Paul D. Goldenheim, M.D., et al.*, DAB No. 2268, at 21 (2009), *aff'd in part sub nom Friedman et al. v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012); s*ee also Barry D. Garfinkel M.D.*, DAB No. 1572, at 6-7, 10-11 (1996), *aff'd*, *Garfinkel v. Shalala*, No. 3-96-604 (D. Minn. June 25, 1997). "Instead, the ALJ's role is limited to considering whether the period of exclusion imposed by the I.G. was within a reasonable range, based on demonstrated criteria." *Wilder* at 8; *see also* 57 Fed. Reg. 3298, 3321 (Jan. 29, 1992) ("the I.G. has 'broad discretion' in setting the length of an exclusion in a particular case, based on the I.G.'s 'vast experience' in implementing exclusions.").

Thus, the Board has long held that "'it is not the number of aggravating factors that is determinative rather, it is the quality of the circumstances, whether aggravating or mitigating, which is controlling in analyzing these factors.'" *Wilder at 8, quoting Joseph M. Ruske, Jr., R.Ph.*, DAB No. 1851, at 11 (2002). An ALJ's role is not to review the I.G.'s decision-making process, but "to conduct a *de novo* review of the existence of aggravating and mitigating factors identified at 42 C.F.R. § 1001.102 and determine whether the length of the exclusion sought to be imposed by the I.G. *falls within a reasonable range*." *Ruske* at 11 (emphasis added). A "reasonable range" refers to "a range of exclusion periods that is more limited than the full range authorized by the statute and that is tied to the circumstances of the individual case." *Id*.

Standard of Review

The regulations set the Board's standard of review in I.G. exclusion cases. The standard of review on a disputed factual issue is whether the ALJ decision is supported by substantial evidence on the whole record; the standard of review on a disputed issue of law is whether the ALJ decision is erroneous. 42 C.F.R. § 1005.21(h); *see also Garfinkel*, DAB No. 1572, at 5 (recognizing that under the regulation "[w]e have a limited role in reviewing ALJ decisions in exclusion cases").

Factual Background[2]

a. Petitioner's role in medical device companies

During the time period relevant to this appeal, Petitioner was a vice president – first of Human Resources and Regulatory Affairs, and then of Operations – of Synthes Inc. (Synthes), the American branch of a multinational medical device manufacturing corporation that specialized in "trauma products." ALJ Decision at 1-3. Synthes had purchased Norian Corporation, which produced "bone cement" products that were used for surgical bone repair. *Id*. This case, and related cases involving three other Synthes senior executives, arose from Synthes' and Norian's promotion, in violation of federal law, of Norian bone cement products to perform surgical repairs of spinal fractures. *Id*. Synthes did this promotion without the approval of the Food and Drug Administration (FDA) required for such use and contrary to specific warnings on labels the FDA approved that the products were not to be used for those purposes. *Id*. at 7-9.

The two products were calcium phosphate bone cements called Norian Skeletal Repair System (Norian SRS) and its successor, Norian XR, consisting of Norian SRS with barium sulfate added to make the cement more visible on X-rays during surgery. *Id*.; I.G. Ex. 5, at 11, 28. The FDA classified both products as "significant risk devices," meaning that they presented the potential for serious risk to patient health and safety. ALJ Decision at 7-8. In particular, the use of bone cement products in the spine and for repairs of spinal fractures posed the risk that the cement, which is in a liquid or viscous state when injected into the spine, could leak into the venous system via the many blood vessels near the spine and cause pulmonary embolism and death. *Id*.

The manufacturer of any device must obtain the FDA's approval to market the device for a particular use. For significant risk devices, the FDA's approval process may require the manufacturer to conduct clinical trials on human subjects, which trials require review and approval by an "Institutional Review Board." This process may be long and expensive but is necessary to ensure that the clinical trial is properly monitored and human subjects are protected. *Id*.

In December 2001, the FDA approved Norian SRS for use as a "bone void filler" with a label restricting its use to filling bone voids that are *not* intrinsic to the stability of the bony structure in the extremities, spine, and pelvis, and warning that it was not to be mixed with any other substance. *Id*. In December 2002, the FDA approved Norian XR (Norian SRS with barium sulfate added) with the same restrictions and with the additional warning that it was not intended for treatment of vertebral compression

[2] This summary derives from the undisputed facts in the ALJ Decision and the record and is intended to provide context for our discussion and is not intended to present new findings of fact. We refer the reader to the ALJ Decision for a detailed narrative of the facts.

fractures [VCFs]. *Id*. This requirement followed the FDA's expressions of concern, including at a meeting with Synthes' personnel in May 2002, that some surgeons had been using bone void fillers in the spine for load-bearing indications. Synthes and Norian promised that they would not promote Norian XR for vertebroplasty or other load-bearing indications without FDA approval. *Id*. at 11-12.

b. Acts underlying criminal charges

Nonetheless, between August and December 2002, before the FDA had approved Norian XR for any purpose, Synthes and Norian trained surgeons to mix Norian SRS with barium sulfate and to use the resulting mixture in "vertebroplasty" surgeries for vertebral compression fractures. *Id*. at 8. Then, between August 2003 and January 2004, the companies trained spine surgeons to use Norian XR in vertebroplasty as part of a "test market" to gathering clinical data about the surgeries the Synthes-trained physicians performed. *Id*. at 8-9. Throughout those periods, Synthes promoted this "off-label" use of the Norian bone cements to treat vertebral compression fractures, a purpose for which they had not been approved. *Id*. at 1-4, 7-9; *see* P. App. Br. at 4-5 (conceding that Synthes trained spine surgeons in and promoted the use of the bone cements for unapproved vertebroplasty-type surgeries as part of a "test market" that "crossed the line" into "unauthorized clinical testing").

Several events indicative of problems with using the bone cements for repair of spinal fractures occurred around the period when Synthes was promoting the bone cements for those unapproved uses that the labels warned against. On February 8, 2001, two patients suffered "hypotensive events" while undergoing spine surgeries with an unapproved Norian cement with the same chemical formulation as Norian SRS. ALJ Decision at 10. A Synthes sales representative was present at each of these "off-label" surgeries. *Id.* In May 2002, researchers at the University of Washington conducting Synthes-commissioned studies on Norian SRS reported the "alarming" effect the cement had on a pig, which suffered fatal "fulminant cardiopulmonary arrest" with a "disproportionate and massive" clot of its pulmonary artery system within a minute of being injected with two cubic centimeters of the product. *Id*. The researchers reported that they had expected to kill the pig "with the full 10cc load in a slow and progressive fashion" but "not suddenly and with a relatively small dose." *Id*. They expressed a "need to worry about a coagulogenic effect of the substance itself." *Id*. They stated that this "could represent an uncontrolled activation of the coagulation cascade." *Id*.

On January 13, 2003, a patient died during a "vertebroplasty/kyphoplasty" procedure for which the surgeon had used Norian SRS mixed with barium sulphate, the combination that became Norian XR.[3] *Id*. at 12. No autopsy was performed and no medical device report was filed with the FDA. *Id.* On September 19, 2003, a second patient died during spinal surgery using Norian XR; no autopsy was performed and the medical device report that was filed did not mention that the procedure was a vertebroplasty/kyphoplasty using Norian XR. *Id*. at 13. On January 22, 2004, a third patient died while undergoing kyphoplasty surgery to treat a vertebral compression fracture. *Id*. at 14. According to the autopsy report, this patient lost blood pressure almost immediately after the surgeon introduced the bone cement, and died a minute or two later. *Id*. at 20. The autopsy report also found "foreign material" inside what the examiners presumed were capillaries and clumps of this material inside larger blood vessels of the lungs; this material was indistinguishable from the clumps found in the patient's spine. *Id*.

Synthes executives were aware of these adverse events and of concerns over the involvement of Norian bone cements but continued with their test marketing of the products. *Id*. at 9-15.

c. Criminal indictment and plea

Petitioner, like the other three senior executives, agreed to plead guilty to charges "under the 'responsible corporate officer' doctrine with the strict liability misdemeanor offense of introduction into interstate commerce of medical devices that were adulterated … and misbranded." I.G. Ex. 9, at 1; *see* I.G. Exs. 6, at 1; 7, at 1; 8, at 1. The plea agreement described the crime as arising "from Synthes's illegal test marketing and promotion of its medical devices Norian SRS and Norian XR in the United States between May 2002 and July 2004 and from the defendant's role as a corporate officer with responsibility to prevent such violations." I.G. Ex. 9, at 1.

Thereafter, in June 2009, a 97-count indictment was filed in the U.S. District Court for the Eastern District of Pennsylvania that charged Synthes, Norian, and the four senior Synthes executives, including Petitioner, with violations of federal law relating to the test marketing and promotion of the bone cements for unapproved uses in spinal surgery. Synthes and Norian were each charged with multiple counts of introducing adulterated and misbranded medical devices into interstate commerce, in violation of the federal Food, Drug, and Cosmetic Act (FDCA) at 21 U.S.C. § 331(a). Norian was also charged with a count of conspiracy under 18 U.S.C. § 371 and counts of making false statements under 18 U.S.C. § 1001.

[3] "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. ALJ Decision at 12 n. 9, citing I.G. Ex. 5, at 9.

The crime referenced in Petitioner's plea agreement was set forth in Count 97 of the indictment. I.G. Ex. 5, at 1-28, 54; I.G. Ex. 14, at 1; P. Joint Ex. 3, at 31-32. The charge in that indictment count stated that -- "Between in or about August 2003 and January 21, 2004, defendant[] . . . RICHARD E; BOHNER [and the other defendants] were senior executive[s] of Synthes, and responsible corporate officers of Synthes under 21 U.S.C. §§ 331(a), 333(a)(1) and 352(a) during the time when Synthes introduced and caused the introduction into interstate commerce of quantities of Norian XR . . ., which were adulterated and misbranded." I.G. Ex. 5, at 54. Count 97 specifically incorporated paragraphs 1-93 of Count One of the indictment, which describe Petitioner's criminal conduct in more detail. *Id*. at 1-28, 54.

On December 13, 2011, the sentencing judge entered judgment against Petitioner, sentenced him to eight months imprisonment, and ordered him to pay the maximum fine of $100,000.[4] In determining the length of Petitioner's prison sentence, the judge departed upward from the applicable sentencing guidelines, which provided for a maximum sentence of six months incarceration, based on his finding that Petitioner knew about and participated in the illegal test marketing of the bone cements, which "amounted to unauthorized clinical trials… in violation of the FDCA," and that Petitioner "knew at the time the clinical trials were planned and were conducted that the trials violated the FDCA." I.G. Ex. 15, at 45.

d. I.G. exclusion notices and appeals

In a notice dated September 28, 2012, the I.G. informed Petitioner that he would be excluded from program participation for four years under section 1128(b)(1) of the Act because of his conviction of a misdemeanor offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service. The I.G. sent similar notices to the three other senior executives excluding them on the same grounds for periods of three to five years.

Petitioner and the other executives timely requested ALJ hearings to challenge the exclusions. The ALJ declined the I.G.'s request to consolidate the appeals but heard them under the same briefing schedule and permitted the four petitioners to file both individual briefs and one joint brief addressing common legal issues.

[4] Synthes pled guilty to one misdemeanor of violating the FDCA and Norian pled guilty to one count of conspiracy and multiple counts of introducing an adulterated and misbranded medical device into interstate commerce. I.G. Exs. 23, 24. Synthes was required to pay a $200,000 penalty and to forfeit $469,800 to the government, and Norian was required to pay $22,500,000 in penalties. I.G. Exs. 22, at 1, 39; 23, at 1; 25, at 2-4; 26, at 2. Two of the other senior executives received prison terms of nine months, and one received a term of five months, and each was fined $100,000. I.G. Exs. 11-13.

The ALJ received the parties' exhibits and overruled Petitioner's objections to some of the I.G.'s exhibits. The parties agreed that an in-person hearing was not required, and the ALJ decided the case on the written record. ALJ Decision at 3.

e. ALJ Decision

In Petitioner's case, the ALJ made the following findings of fact and conclusions of law (FFCLs):

> 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.*
>
> 2. *A four-year exclusion is not unreasonably long.*

Id. at 3, 16. Regarding the first FFCL, the ALJ based her conclusion that Petitioner's offense was "related to" fraud within the meaning of section 1128(b)(1)(A) on court documents from the criminal cases of Petitioner and the other defendants, including the indictment, Petitioner's guilty plea, the transcript of Petitioner's sentencing, and the federal judge's order ruling on proposed corrections to the defendants' pre-sentence report. *Id*. at 3-15.

The ALJ further concluded that Petitioner had been informed of the hypotensive events, the pig study, and concerns from doctors that the bone cement could leak into the vascular system. *Id*. at 10-11. She cited the federal judge's findings that Petitioner and the other three senior executives were aware of, and involved, in the process of approving the "test market" of Norian SRS cement for unapproved uses in spinal surgery, and that they played a role in the "continuing deception" of an FDA investigator who investigated Synthes during May and June 2004. *Id*. at 14-15. The ALJ also inferred from the companies' illegal marketing and promotion of its bone cements for unapproved uses that company employees had acted intentionally and deliberately, and that their conduct, thus, was "'related to' fraud, if not actual fraud." *Id*. at 9. The ALJ concluded that Petitioner's conviction was thus factually related to fraud, and that the I.G. appropriately excluded him from program participation under section 1128(b). *Id*. at 14-15.

The ALJ rejected Petitioner's argument that she could not consider documents other than his plea agreement, which Petitioner said showed that he pled guilty as a responsible corporate officer without admitting any knowledge of or involvement in the crime. The ALJ found, however, that the facts Petitioner admitted in his plea agreement established that his crime was related to fraud even without regard to his personal involvement in the companies' illegal activities. *Id*. at 7-9. The ALJ noted that Petitioner had admitted both

that the companies had illegally test marketed and promoted the bone cements for unapproved uses and that he had been responsible for preventing such illegal conduct. She concluded that the facts he conceded in the plea agreement "would, by themselves, establish the necessary connection between his crime and fraud." *Id*. at 7.

The ALJ also rejected Petitioner's arguments that his offense was not related to fraud because fraud was not a stated component of his criminal conviction and was not mentioned in his plea agreement. The ALJ noted that the Board has long rejected efforts to limit section 1128 exclusion authority to the bare elements of the criminal offense and has found extrinsic evidence of circumstances of the crime relevant to making the "related to" determination. *Id*. at 5, 7, citing *Narendra M. Patel, M.D.*, DAB No. 1736 (2000), *aff'd*, *Patel v. Thompson*, 319 F.3d 1317 (11th Cir. 2003). The ALJ also relied on Board decisions in rejecting Petitioner's argument that all of the offenses section 1128(b) specifies ("fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct") must involve financial misconduct for the exclusion authority to apply. *Id*. at 15-16, citing *Breton Lee Morgan, M.D.*, DAB No. 2264 (2009), *aff'd*, *Morgan v. Sebelius*, 694 F.3d 535 (4th Cir. 2012). She nonetheless found that Petitioner's illegal activity did relate to financial misconduct, citing the federal judge's finding that Petitioner and his cohorts were motivated by financial gain in the form of profits and avoidance of the expense of securing the required FDA approval to use the bone cements to repair spinal fractures. ALJ Decision at 15.

With respect to her second FFCL, the ALJ found that the four-year period of exclusion, an increase of one year beyond the statutory minimum, was not unreasonable in light of the presence of two aggravating factors: 1) Petitioner's eight-month period of incarceration based upon his conviction; and 2) the adverse impact of Petitioner's criminal conduct on program beneficiaries and other individuals. The ALJ concluded that the eight-month jail term, two months longer than the maximum provided in the sentencing guidelines, by itself justified the one-year increase in the period of exclusion. *Id*. at 18.

The ALJ also found that Petitioner and his colleagues had placed lives of unknowing individuals at risk and that, even without a showing of additional harm, "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." *Id*. at 19. She rejected Petitioner's argument that the three people who died during spinal surgery immediately after being injected with bone cement likely died from their underlying health problems. *Id*. at 19-21. She noted, among other things, that the autopsy performed on one of the deceased patients showed findings similar to those in the pig studies. *Id*. at 20. She also noted, "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[]" and cited the sentencing judge's recognition that the patients "did not know about these

negative events!" *Id*. at 21, citing I.G. Ex. 16 at 7-9; see I.G. Ex. 20, at 23. She concluded that "[i]n 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." *Id*. at 21.

The ALJ found one mitigating factor applicable, that Petitioner was convicted of only one offense and the I.G. did not allege that his crime caused any financial loss to the Medicare program. *Id*. at 21-22; 42 C.F.R. § 1001.201(b)(3)(i). The ALJ concluded, however, that the "relatively short period of exclusion reflects that factor." ALJ Decision at 22. The ALJ stated that she could not consider other factors that Petitioner raised with respect to assessing his trustworthiness because the regulations limited her review to the mitigating factors set forth in the regulations. *Id*., citing 42 C.F.R. § 1005.4(c)(1).

Analysis

On appeal before us, Petitioner argues that the ALJ Decision should be reversed on two grounds. First, Petitioner primarily contends that his exclusion was unauthorized because he was not convicted of a misdemeanor criminal offense "relating to fraud" as required under section 1128(b)(1)(A) of the Act. *See also* 42 C.F.R. § 1001.201(b)(1). Second, Petitioner argues that the ALJ improperly applied an aggravating factor in determining the length of his exclusion.

For the reasons set forth below, we find these arguments without merit.

I. *The ALJ did not err in concluding that Petitioner's exclusion was authorized under section 1128(b)(1)(A) because his misdemeanor conviction was "related to fraud."*

Petitioner's argument that his misdemeanor offense of introducing adulterated and misbranded medical devices into interstate commerce was not "related to fraud" as required for his exclusion is based on one theme -- that he did not agree to plead guilty to, and was not convicted of, any offense "involving fraud" as an element. In support of his argument, Petitioner cites "the absence of any finding by the Court, argument by the government, or agreement by the parties that [his] offense *involved fraud*." P. App. Br. at 2 (emphasis added). He asserts that, in pleading guilty, he did not agree "that he or anyone else committed fraud or acted intentionally." *Id*. at 7. Petitioner further asserts that his "plea agreement contains no such concession, and he did not admit to any facts at his plea hearing establishing fraud." *Id*. at 16. In this vein, Petitioner argues that he pled guilty as a "responsible corporate officer" to a "strict liability misdemeanor offense" that

"contains no state of mind requirement at all." *Id*. at 8-9; *see* I.G. Ex. 9, at 1 (May 2009 plea agreement stating that Petitioner agreed to plead guilty under the "'responsible corporate officer' doctrine with the strict liability misdemeanor offense of introduction into interstate commerce of medical devices that were adulterated … and misbranded").

We disagree. As we discuss below, there is no error in the ALJ's conclusion that the acts underlying Petitioner's conviction were "related to fraud."

A. *Petitioner's conviction as a "responsible corporate officer" is sufficient to show that his offense related to the companies' fraudulent conduct.*

The Board has held that section 1128(b)(1) of the Act "does not restrict exclusions to only offenses constituting or consisting of fraud, but requires merely that the offense at issue be one 'relating to' fraud." *Goldenheim* at 10 (2009).[5] In *Goldenheim*, the Board cited *Carolyn Westin*, DAB No. 1381, at 11 (1993) *aff'd sub nom Westin v. Shalala*, 845 F. Supp. 1446 (D. Kan. 1994), an exclusion for an offense "relating to" neglect or abuse of patients under section 1128(a)(2), where the Board held that the I.G. "met his burden of proof by establishing" that "the offense of which Petitioner was convicted was related to patient neglect." *Goldenheim* at 10-11, citing *Westin v. Shalala* at 1451 ("no requirement that the Secretary demonstrate that actual neglect or abuse of patients occurred" or that the excluded individual "be convicted of an actual offense of patient neglect or abuse"; "[t]he phrase 'relating to' clearly encompasses a broader range of conduct than actual neglect or abuse"). In *Goldenheim*, as it had in *Westin*, the Board applied to other provisions using the same phrase its holding in section 1128(a)(1) exclusion cases (providing for mandatory exclusion for criminal offenses "related to" delivery of an item or service under a federal or state health care program) that "related to" meant a "nexus or common sense connection." *Goldenheim* at 12. The Board noted that "[v]iewing 'relating to' in section 1128(b)(1) as having the same meaning as 'related to' in section 1128(a)(1) is . . . consistent with the principle of according the same meaning to the same word or phrase in different parts of a statute." *Id*. (citations omitted). Thus, the ALJ here correctly rejected Petitioner's argument that the I.G. here was required to demonstrate that Petitioner was convicted of fraud or of an offense involving fraud to exclude Petitioner under section 1128(b)(1). ALJ Decision at 4.

[5] In considering a similar question about determining whether a felony offense was committed "in connection with the delivery of" a health care item or service as required for an exclusion under section 1128(a)(3) of the Act, a court recently stated that:

> [T]he phrases "in connection with," "in relation to," or "related to" are generally interpreted expansively. *See Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 739 (1985) ("relate to" has a "broad common-sense meaning" and a statutory provision containing the phrase therefore has "broad scope"); *see also Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992); *United States v. Loney*, 219 F.3d 281, 283–84 (3d Cir. 2000).

Harkonen v. Sebelius, 2013 WL 5734918, at *7 (N.D. Cal. Oct. 22, 2013).

The Board in *Goldenheim* expressly rejected the argument, made by Petitioner here, that a corporate officer's conviction of a strict liability offense of misbranding and adulteration based on the company's conduct is not a ground for exclusion under section 1128(b)(1) because the conviction itself does not contain a fraudulent intent element. In *Goldenheim*, the Board upheld exclusions under section 1128(b)(1) of senior executives of a pharmaceutical company who were convicted, as responsible corporate officers, of misdemeanors under the FDCA for introducing a misbranded drug, OxyContin, into interstate commerce. The Board held that, under two Supreme Court decisions that developed the responsible corporate officer doctrine for convictions under the FDCA, the petitioners indeed bore a measure of culpability and blameworthiness for the company's conduct under their stewardship for which the company was convicted of felony misbranding. *Goldenheim* at 13-17, citing *United States v. Dotterweich*, 320 U.S. 277 (1943) and *United States v. Park*, 421 U.S. 658 (1975). On appeal, the U.S. Court of Appeals for the District of Columbia held that the executives' convictions for misbranding under the FDCA were related to fraud, authorizing their exclusions under section 1128(b)(1) of the Act. *Friedman*, 686 F.3d at 818-24. The D.C. Circuit held that the I.G. could look beyond the generic criminal offense with which a petitioner is charged and consider the facts underlying his particular conviction in determining whether the conviction is "related to fraud." *Id*. at 822-23.

Petitioner argues that "*Friedman* was wrongly decided" because the court employed a "circumstance-specific approach" rather than a "categorical approach" in concluding that the petitioners' offenses as responsible corporate officers related to fraud. P. App. Br. at 10-12. However, the court's holding that the I.G. could look beyond the generic criminal offense and consider the facts underlying the particular conviction in determining whether the conviction is "related to fraud" is entirely consistent with the Board's analysis in *Goldenheim* and other cases and essentially upholds the Board's analysis. *See W. Scott Harkonen, M.D.*, DAB No. 2485, at 19 (2012), *aff'd, Harkonen v. Sebelius*, No. C 13-0071 PJH, 2013 WL 5734918 (N.D. Cal. Oct. 22, 2013). We see no reason to revisit our long-standing analysis or question the court's upholding of that analysis.

Petitioner also argues that *Goldenheim* is distinguishable because the corporate officer petitioners in that case conceded that company personnel had acted to defraud and mislead (and the company was convicted of a misbranding with intent to defraud or mislead), whereas Petitioner's "plea agreement contains no such concession, and he did not admit to any facts at his plea hearing establishing fraud." P. App. Br. at 16, citing *Friedman*, 755 F. Supp. 2d at 98, 102 (D.D.C. 2011). As we discuss in the next section, however, the record of Petitioner's criminal conviction, including the indictment and the factual findings that the sentencing judge made based on his review of that record, amply supports the ALJ's determination that the companies fraudulently promoted their bone cements for unauthorized uses in repairing spinal fractures, in violation of the FDCA.

Moreover, as the ALJ found, the record here shows that Petitioner was aware of the companies' conduct while it occurred but did not take any action to stop it. *See* ALJ Decision at 9-15 (discussing Petitioner's role, along with other corporate officers, in planning and executing the fraud, and record citations therein).

B. *The record supports the ALJ's determination that the companies' and Petitioner's conduct "related to fraud."*

Petitioner argues that his offense was not related to fraud because "[t]he word 'fraud' does not appear in [Petitioner's] Plea Agreement," which "also does not state that [he] engaged in intentional wrongdoing [or] that Synthes, its affiliated company, Norian, or the employees of these companies engaged in fraud or any other intentional wrongdoing." P. App. Br. at 1-2. The ALJ rejected the argument that Petitioner's conduct could not be found "related to fraud" within the meaning of section 1128(b)(1) simply because the court documents did not state an actual fraud charge or an element of intent. ALJ Decision at 4-9. As discussed above, the ALJ was correct in rejecting that argument. Nonetheless, the ALJ also found that the record of Petitioner's criminal case showed a "well-documented level of malfeasance engaged in by the Synthes executives." *Id*. at 6. Substantial evidence in the record supports the ALJ's finding.

As the ALJ noted, the count to which Petitioner pled guilty (Count 97) incorporates "[t]he allegations in paragraphs one through 93 of Count One" of the indictment which, as the ALJ stated, "describe the crime in some detail." I.G. Ex. 5, at 54; ALJ Decision at 7. The incorporated paragraphs describe how the companies promoted and provided the bone cements to doctors for use in surgery to repair spinal compression fractures (the illegal "test market"), despite knowing that the FDA had not approved the bone cements for that use and despite promising the FDA that they would not do so absent FDA approval. I.G. Ex. 5, at 8-28. The incorporated paragraphs also charge that Petitioner and the other defendants, among other actions, "approved, organized and sponsored an illegal vertebroplasty 'test market'" through which they "conducted an unauthorized clinical trial of Norian XR for the treatment of VCFs," and "concealed from spine surgeons and from Synthes's own Spine sales force the pilot study test results indicating that a small amount of Norian SRS and/or Norian XR could accelerate blood clot formation if it escaped from bone into the venous circulation." *Id*. at 25, 26. The incorporated paragraphs further state that during the FDA investigation in May and June 2004, Petitioner and the other defendants "knowingly made a series of false statements" to the FDA investigator, in which they "concealed their knowledge" that the bone cements "had each been marketed, promoted and tested on human subjects without FDA oversight for the treatment of VCFs, an intended use that had been neither cleared nor approved by the FDA." *Id*. at 27.

Petitioner's plea agreement also incorporates paragraphs charging Norian with having "conspired to … defraud the United States and its agencies by impeding, impairing, and defeating" the FDA's functions; to "commit an offense against the United States with the intent to defraud or mislead" by introducing the unapproved bone cements into interstate commerce for unapproved purposes, and to "commit an offense against the United States by knowingly and willfully making materially false, fictitious, and fraudulent statements and representations and falsifying and concealing material facts" from the FDA. *Id*. at 24-25. Norian, which was owned by Synthes, of which Petitioner was a responsible corporate officer, pled guilty to that count of conspiracy. I.G. Ex. 24, at 1-3.

Petitioner argues that the ALJ should not have considered those indictment paragraphs that his plea agreement incorporated by reference, because they do not accurately depict the specific and limited facts to which he agreed to plead guilty. Petitioner characterizes the ALJ's finding as "hyper-technical and plain error" but with no further explanation for those descriptions. P. App. Br. at 17. In any case, Petitioner's main contention is that he "specifically admitted only to the facts in paragraph 9 of the plea agreement." *Id*. at 16. He says those facts establish only that he "failed to prevent the adulteration or misbranding of devices" because: 1) FDA approval required for the bone cements was "not obtained," 2) the products "bore inadequate directions for use;" and 3) "Synthes failed to provide the FDA" with required "premarket notification." *Id*. Petitioner asserts that these facts do not show fraud but "only establish that the company engaged in the adulteration or misbranding of medical devices." *Id*. Petitioner cites to his counsel's representation to the court during the plea hearing that "a responsible corporate officer plea" does not require "his knowledge or intent of each of those facts." *Id*.; P. Joint Ex. 3, at 27. Petitioner also implies he was unaware that the indictment count to which he pled guilty incorporated paragraphs of the indictment that described more fully the extent of his and the other defendants' conduct, as he signed the plea agreement before the indictment was filed. P. App. Br. at 7 (Petitioner "agreed in a written Plea Agreement on May 26, 2009, to plead guilty to a single misdemeanor count of an indictment (to be filed in the future)"); *see also* I.G. Ex. 5 (indictment filed June 16, 2009).

None of Petitioner's arguments persuade us that the ALJ erred in considering the indictment paragraphs incorporated in the plea agreement, for several reasons. First, at Petitioner's plea hearing in August 2009, after the indictment had been filed, the trial judge accepted Petitioner's "plea of guilty to Count 97 of the indictment" and found him "guilty of Count 97" of the indictment. P. Joint Ex. 3, at 32. Petitioner raised no objection to that finding. As noted above, Count 97 incorporates the paragraphs set forth in Count One that describe deceptive and fraudulent conduct by the companies and Petitioner in illegally promoting the bone cements and deceiving the FDA investigator. Even if the ALJ's finding were "hyper-technical" as Petitioner claims, it is legally correct. The Board has held that an ALJ may properly rely on the language in the indictment in deciding whether a petitioner's conduct underlying a criminal conviction came within the scope of the exclusion statute or regulations, or as here, whether

Petitioner's conduct was "related to fraud." S*ee Raymond Lamont Shoemaker***,** DAB No. 2560, at 5 (2014) (I.G. could properly rely on the indictment and the judgment to establish that Petitioner's acts lasted longer than one year); *Johnnelle Johnson Bing*, DAB No. 2251, at 3 (2009) (ALJ could rely on record information contained in indictment in describing nature and duration of the offense). Petitioner's attempts to downplay the underlying factual basis of Count 97 as set forth in paragraphs 1-93 of Count One of the indictment amount to a prohibited collateral attack on his conviction. 42 C.F.R. § 1001.2007(d).

Second, Petitioner's description of paragraph 9 of his plea agreement (P. App. Br. at 16) omits facts such as the illegal promotion and "test market" of the bone cements for unapproved use in spinal surgeries, in violation of FDA warnings and the companies' promise to the FDA that they would not promote Norian XR for vertebroplasty or other load-bearing indications absent approval. I.G. Ex. 9, at 4-9. Thus, contrary to Petitioner's assertions, the plea agreement as a whole fully supports the ALJ's conclusion that his offense was indeed "related to fraud." *See* ALJ Decision at 7 ("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").

Finally, other materials in the record of the criminal case, most notably the findings of the sentencing judge, demonstrate the spuriousness of Petitioner's argument that his plea as a responsible corporate officer to misbranding and adulteration indicates that he was neither aware of nor involved in the companies' illegal conduct. That such an officer may be found guilty without proof of intent or based on strict liability does not mean that Petitioner here lacked all intent. On the contrary, in determining the length of Petitioner's sentence, the judge found based on the entire record before him that Petitioner knowingly participated in the illegal marketing and promotion of the Norian SRS and Norian XR bone cements and the deception of the FDA investigator. I.G. Exs. 15 (Pre-Sentence Report Order), 19 (sentencing hearing transcript).

Although Petitioner argues that the ALJ erred in relying on these findings from the sentencing hearing, Petitioner actually cites the judge's findings that Petitioner, compared to the other defendants, "tried to steer people to the correct course" and "didn't lose sight of what he was supposed to do." P. App. Br. at 6, 15, citing I.G. Ex. 19, at 5. Petitioner's selected quotations fail to accurately depict the context of the judge's comments. For example, the judge specifically found that, among other things, Petitioner "knew for a long, long time that this was an improper and illegal course" of action and "did play his role in [the] continuing deception [of the FDA investigator] when the [investigator] was asking his questions." I.G. Ex. 19, at 10, 31. He further found that "[t]he knowledge is there. The choices are there. The agreement to proceed in a particular way is there. The circumvention of the FDA is there." *Id.* at 45. He added that Petitioner "knew what the law was. He knew what the conduct was. He knew what the line was." *Id.* at 15-16. In

his pre-sentence report order, the judge found that Petitioner "knew and was aware that the Spine Division was conducting 'test markets' that amounted to unauthorized clinical trials of SRS and XR in violation of the FDCA," that Petitioner "participated in conducting those trials," and that Petitioner "knew at the time the clinical trials were planned and were conducted that the trials violated the FDCA."[6] I.G. Ex. 15, at 45. The judge also found that Petitioner was "aware of, and involved in, the process of approving the [Norian] SRS test market in the spine." *Id*. at 81.

As mentioned above, Petitioner is precluded from collaterally attacking the trial court's findings here. The trial judge's findings that Petitioner knowingly participated in the companies' illegal acts strongly support the ALJ's conclusion that Petitioner's conviction was factually "related to fraud." In any event, as the ALJ recognized, given the other evidence of record, including Petitioner's own admissions, she did not need to rely on the trial judge's findings in order to conclude that Petitioner's offense was related to fraud. *See* ALJ Decision at 9 ("Thus, without regard to Petitioner[]'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 makes a further argument that, even if his conviction is "related to fraud," he should not be excluded under section 1128(b)(1) because his conviction is <u>not</u> "related to" financial misconduct. P. App. Br. at 12-14. Relying on the word "other" in the phrase "fraud, theft, embezzlement, breach of fiduciary responsibility, or *other* financial misconduct," Petitioner contends that the use of the word "other" at the end of the clause "strongly indicates that the preceding terms in the statute are modified by that clause." *Id*. at 12. In other words, he seeks to have us read the statutory language as requiring that the conviction not only relate to fraud but also involve financial misconduct.

The ALJ correctly rejected this argument as without merit. ALJ Decision at 16. The Board reached the same conclusion in the context of interpreting the same language used in section 1128(a)(3) of the Act. *Breton Lee Morgan, M.D.*, DAB No. 2264, at 6-10. The Fourth Circuit explicitly agreed, calling "simply not correct" Morgan's argument that the presence of the word "other" would be superfluous but for this narrowing effect. 694 F.3d at 538. We find the same reasoning applicable here to find that the conduct "related to fraud" need not also involve financial misconduct. DAB No. 2264, at 6-10.

[6] On appeal before us, Petitioner concedes knowledge of the "test market" but avers that this knowledge did "not establish that his conviction was factually related to fraud" and that "there was nothing inherently suspicious about the existence of such a test market because by the time it occurred SRS was already indicated for use in the spine." P. App. Br. at 23. In addition to being contradicted by the judge's specific finding, Petitioner's claim completely ignores the fact that the FDA **never approved** the bone cements ***for use in vertebroplasty surgery***, the specific use for which the companies were promoting it and for which they trained physicians in the test market.

Petitioner counters that the *Morgan* decision was "erroneous," but offers no persuasive reason why we should interpret differently the same words when they appear in section 1128(b)(1). P. App. Br. at 12, 14.[7]

We conclude that the ALJ's determination that the I.G. was authorized under section 1128(b)(1) to exclude Petitioner from participating in federal health care programs is supported by substantial evidence and free of legal error.

II. *The ALJ did not err in concluding that the four-year period of Petitioner's exclusion is not unreasonably long.*

The ALJ determined that two aggravating factors were present under section 1001.201(b)(1)(iii) and (iv). ALJ Decision at 17-21. More specifically, the ALJ concluded that: 1) Petitioner's acts underlying his conviction caused 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. Section 1001.201(b)(2) (iii) and (iv). The ALJ also concluded that a single mitigating factor existed because Petitioner was "convicted of 3 or fewer offenses[.]" Section 1001.102(b)(3). The ALJ further concluded that "Petitioner's [eight-month period of] incarceration, by itself, [is] sufficient to justify the relatively modest increase in his period of exclusion, particularly in light of the [sentencing] judge's significant and well-supported upward departure from the sentencing guidelines." ALJ Decision at 18.

In light of all the factual circumstances in this case, the ALJ ultimately concluded that "Petitioner's crime demonstrates that he presents a significant risk to the integrity of health care programs and the safety of program beneficiaries." *Id*. at 23. Petitioner challenges the ALJ's conclusion, arguing that the four-year period of exclusion was "unreasonable" because the ALJ "improperly applied an aggravating factor in determining the length of [his] exclusion." P. Reply Br. at 9 n.5; P. App. Br. at 3. Petitioner argues the ALJ erroneously concluded that an aggravating factor existed because the conduct underlying his conviction had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals. P. App. Br. at 27-28. However, it is not necessary for us to address Petitioner's argument in light of the fact that the presence of only one aggravating factor is sufficient under the regulations to

[7] Given our conclusion here, we need not address the ALJ's factual finding that Petitioner was indeed "motivated by financial gain." ALJ Decision at 15.

increase the length of the minimum exclusion period.[8] For the reasons discussed below, we find the ALJ did not err in concluding the four-year period of exclusion is not unreasonably long,

A. *Incarceration as Aggravating Factor*

In his initial brief to us, Petitioner did not challenge the ALJ's conclusion that an aggravating factor was present under section 1001.102(b)(2)(iv) based upon his incarceration. In any event, Petitioner cannot now credibly challenge the fact that he was convicted or that he was incarcerated for eight months based on that conviction.[9] *See e.g.*, I.G. Ex. 9 (plea agreement); I.G. Ex. 19, at 47-48 (Petitioner sentenced to eight months in jail); P. Joint Ex. 3, at 32 (Petitioner's guilty plea accepted by the court). Thus, the ALJ did not erroneously conclude that an aggravating factor existed based upon Petitioner's incarceration.

In his reply brief, however, Petitioner argues that his eight-month incarceration "does not justify lengthening the period of exclusion by a full year over the three[-]year default period provided." P. Reply Br. at 9. Petitioner fails to explain why this is so. The question now before us, therefore, is whether application of that aggravating factor justifies this increase in the length of Petitioner's exclusion from the required three-year baseline. The ALJ observed that based on Petitioner's "offense level" and criminal history, the applicable federal sentencing guidelines called for a minimum sentence of no jail time and a maximum prison sentence of six months. ALJ Decision at 17, citing P. Joint Ex. 3, at 15, 16. As previously discussed, Petitioner's sentence exceeded the maximum sentence in the guidelines by two months, a 25% increase over the maximum prison sentence. I.G. Ex. 4 at 2; I.G. Ex. 19, at 16-17, 47-48. The ALJ concluded that the judge did so "because Petitioner's crime was so much worse than any other case brought against a responsible corporate officer." ALJ Decision at 17, citing I.G. Ex. 19, at 25-26.

[8] We note, however, that in his briefs Petitioner erroneously characterized the ALJ's conclusion that there was significant adverse impact on program beneficiaries as having been based on potential adverse impact even though the language of the regulation requires actual adverse impact. P. App. Br. at 26-27; P. Reply Br. at 8-9. The ALJ actually found that "promoting unauthorized experimentation on human subjects, particularly without their informed consent, by itself, establishes a significant adverse impact on the individuals . . . subjected to it." ALJ Decision at 19. Citing the sentencing judge's finding that "'patients were directly and proximately harmed by the conduct of the Defendants and others at Synthes,'" the ALJ continued, "Unfortunately, in this case, the adverse impact on individuals went beyond subjecting them to unauthorized experimentation." *Id*.

[9] Petitioner argues "that he has always maintained that the length of his exclusion was unreasonable and neither the first or second aggravating factor applies." P. Reply Br. at 9 n.5 (citing P. Inf. Br. at 22-23). Petitioner does not explain the basis for this statement. His apparent denial of the fact that his incarceration constitutes an aggravating factor under section 1001.201(b)(2)(iv) defies logic.

As the ALJ recognized, the Board has held that "[a]ny period of incarceration, no matter how short, justifies increasing the period of exclusion," and we agree with the ALJ that "[e]ight months is, in fact, a relatively substantial period of incarceration." ALJ Decision at 18, citing *Jason Hollady, M.D.*, DAB No. 1855, at 12 (2002); *Stacy Ann Battle, D.D.S.*, DAB No. 1843 (2002) (four months in a halfway house, followed by four months home confinement justifies lengthening the period of exclusion); and *Brenda Mills, M.D.*, DAB CR1461, at 4 (2006) (six months' home confinement justifies increase in length of exclusion), *aff'd*, DAB No. 2061 (2007). Before us, Petitioner did not address any of the above-cited cases. Based upon all of the factual circumstances, we further agree with the ALJ that "Petitioner's [eight-month period of] incarceration, by itself, [is] sufficient to justify the relatively modest increase in his period of exclusion, particularly in light of the [sentencing] judge's significant and well-supported upward departure from the sentencing guidelines." ALJ Decision at 18.

B. *Mitigating Factor*

The ALJ correctly observed that the Board has characterized a mitigating factor as being "in the nature of an affirmative defense," and that a petitioner has the burden of proving any mitigating factor by a preponderance of the evidence. ALJ Decision at 22, quoting *Garfinkel*, DAB No. 1572, at 12. Here, the ALJ applied the fact that Petitioner was convicted of fewer than three criminal offenses, which is a mitigating factor under section 1001.201(b)(3)(i). The I.G. did not challenge the ALJ's application of that factor. Nor did Petitioner challenge the ALJ's conclusion that Petitioner's "relatively short period of exclusion reflects that factor." *Id*.

Petitioner has not explained why the presence of this mitigating factor justifies reducing his period of exclusion below four years.[10] Thus, we fail to see how the fact that Petitioner was convicted of fewer than three offenses demonstrates that a four-year period of exclusion is not within a reasonable range. Given the nature and breadth of Petitioner's knowing and deceptive conduct associated with his conviction, it was reasonable for the ALJ to infer that the I.G. would have imposed a longer period of exclusion but for the existence of the mitigating factor here. Thus, we conclude that the presence of this mitigating factor does not justify reducing the length of Petitioner's exclusion any further.

[10] Petitioner does not challenge on appeal the ALJ's rejection of his argument that an additional mitigating factor was present under section 1001.201(c)(3)(iii) because his cooperation with law enforcement resulted in three other corporate executives pleading guilty. ALJ Decision at 22. He also does not challenge the ALJ's rejection of his argument that the regulation is too narrow and omits factors that the ALJ should consider regarding the length of his exclusion. *Id*.

C. *Petitioner's Trustworthiness*

As federal courts and the Board have noted, section 1128's remedial purpose is to protect the federal health care programs from untrustworthy individuals. *Friedman*, 686 F.3d at 820 (D.C. Cir. 2012); *Patel* at 25, In this vein, the ALJ explained her conclusion for sustaining the four–year period of exclusion as follows:

> 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 four-year exclusion is not unreasonably long.

ALJ Decision at 23. We agree.

As a responsible corporate official, Petitioner had an affirmative obligation to ensure that the Norian XR bone cement was sold for use in a manner approved by the FDA and not promoted for these "off-label" treatment purposes and to notify health care practitioners and patients of the serious risks associated with such a treatment purpose. By his own acknowledgement to us, Petitioner failed in his obligation to do so, since he knew that others in the company were using the product for off-label treatments. Petitioner admits "that his efforts fell short" and that he "should have done more to prevent the company from promoting off-label products and conducting a test market that was eventually determined to be an unauthorized clinical trial." P. App. Br. at 6. Petitioner further states that "the fact that [he] may have been aware of this information may show that [he] failed to discharge his responsibility as a senior executive to prevent the illegal conduct from going on." *Id*. at 25. Petitioner also added:

> [N]either product [i.e., Norian SRS and Norian XR] was approved for vertebroplasty and the Norian XR label contained a label warning it was not intended for the treatment of vertebral compression fractures. Despite this, Synthes "trained spine surgeons to mix Norian SRS with barium sulfate" for treatment in vertebroplasty-type surgeries. I.G. Ex. 9 at 7. It promoted Norian XR for treatment in vertebroplasty-type surgeries and trained spine surgeons on this use as part of a test market for the device. *Id*. at 7-8. This test market crossed the line into a[n] "unauthorized clinical testing of

> Norian XR" because such data collection and risk assessment "required prior approval of the FDA, through an IDE." *Id.* at 8. During surgeries in which surgeons used Norian SRS and Norian XR, three elderly patients died.[11]

P. App. Br. at 5, citing I.G. Ex. 9, at 7-8.

The sentencing judge further highlighted the nature and breadth of Petitioner's conduct and that of the other three convicted corporate officials. The judge stated, "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. He described their conduct as "a very clear and stark and disturbing picture . . . what happened in this case is so fundamentally wrong. It's not a single small decision, right. It's major incorrect decision after major incorrect decision after major incorrect decision, choosing to turn their head." I.G. Ex. 19, at 8. He added, "[W]hen people are forced to look at it, it actually can't be justified. I mean, it is just on the wrongful conduct scale. It's an eleven on a scale of one to ten. This is way over the top, so." *Id*. at 46. These findings amply support a conclusion that Petitioner's four-year exclusion is not unreasonably long and falls within a reasonable range.

Petitioner has not pointed to any evidence in the record that persuades us the ALJ erred in concluding that a four-year period of exclusion falls within a reasonable range given the nature of the conduct underlying his conviction. We agree with the ALJ that, based upon all of the circumstances in this case, Petitioner's behavior showed indifference toward patients through his knowing and deceptive conduct, including misleading statements to the FDA and health care practitioners, and demonstrates that the federal health care programs should be protected from his participation therein.

[11] Petitioner argues that each of three patients "suffered from serious underlying health problems and multiple comorbidities, including significant coronary problems. No causal link between Norian products and their deaths was established." P. App. Br. at 5. However, as discussed earlier, an autopsy performed on one of the patients showed findings similar to those in the pig studies. In addition, the illegal conduct resulted in patients with serious underlying cardiac conditions agreeing to undergo an experimental procedure without being informed of the possible negative cardiac events.

Conclusion

For all of the foregoing reasons, we affirm the ALJ Decision.

/s/
Sheila Ann Hegy

/s/
Leslie A. Sussan

/s/
Stephen M. Godek
Presiding Board Member