Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: August 28, 2009
Paul D. Goldenheim, M.D., Howard R. Udell, Michael Friedman,	
Petitioners,	Civil Remedies CR1883, CR1884, CR1885
	App. Div. Docket Nos. A-09-56, A-09-57, A-09-58
- v. -	
	Decision No. 2268
Inspector General.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISIONS

Paul D. Goldenheim, M.D., Howard R. Udell, and Michael Friedman (Petitioners), appeal decisions by Administrative Law Judge (ALJ) Carolyn Cozad Hughes sustaining their exclusions from participation in the Medicare, Medicaid, and other federal health care programs for 15 years. Paul D. Goldenheim, M.D., DAB CR1883 (2009); Howard R. Udell, DAB CR1884 (2009); Michael Friedman, DAB CR1885 (2009) (ALJ Decisions). The Inspector General (I.G.) excluded each Petitioner under section 1128(b)(1) of the Social Security Act (Act) for conviction of a misdemeanor offense relating to fraud in the delivery of a health care item or service, and section 1128(b)(3) for conviction of a

misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

Petitioners were senior executives of Purdue Frederick Company (Purdue), a pharmaceutical manufacturer, and each pled guilty to a misdemeanor count of introducing a misbranded drug, OxyContin, into interstate commerce. Petitioners make various arguments relating to the exclusions under each statutory section. However, the thrust of their arguments is that they should not have been excluded because they were not convicted of fraud and had no knowledge of or participation in Purdue's fraudulent promotion of OxyContin, but were instead convicted based on their positions as responsible corporate officers of Purdue. Essentially, Petitioners argue that the exclusion statutes do not reach individuals convicted under the responsible corporate officer doctrine. The ALJ rejected these arguments, and so do we, for the reasons explained below. We therefore sustain the exclusions, but we reduce the length of Petitioners' exclusions to 12 years, on the ground that the record does not contain substantial evidence to support application of one of the aggravating factors – adverse impact on program beneficiaries and others – found by the I.G. and the ALJ.

Legal Background

Section 1128(b) of the Act, in relevant part, permits the Secretary to exclude from participation in any federal health care program the following individuals or entities:

> (1) Conviction relating to fraud. —Any individual or entity that has been convicted . . . under Federal or State law—
>
> > (A) of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—
> >
> > (i) in connection with the delivery of a health care item or service . . .
> >
> > * * * *
>
> (3) Misdemeanor conviction relating to controlled substance. —Any individual or entity that has been convicted, under Federal or State law, of a criminal

> offense consisting of a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

Exclusions under these provisions are 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 is appropriate because of aggravating circumstances." Section 1128(c)(3)(D) of the Act.

Regulations at 42 C.F.R. §§ 1001.201 and 1001.401 charge the I.G. with exercising these exclusion authorities and specify aggravating and mitigating factors that the I.G may consider in setting the period of the exclusion. For exclusions under section 1128(b)(1) the aggravating factors relevant to this case include:

> (i) The acts resulting in the conviction, or similar acts that caused, or reasonably could have been expected to cause, a financial loss of $5,000 or more to a Government program or to one or more other entities, or had a significant financial impact on program beneficiaries or other individuals. (The total amount of financial loss will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made);
>
> (ii) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;
>
> (iii) The acts that resulted in the conviction, or similar acts, had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals; . . .

42 C.F.R. § 1001.201(b)(2). For exclusions under section 1128(b)(3), the aggravating factors relevant to this case include:

> (i) The acts that resulted in the conviction or similar acts were committed over a period of one year or more;
>
> (ii) The acts that resulted in the conviction or similar acts had a significant adverse mental, physical or financial impact on program beneficiaries

> or other individuals or the Medicare, Medicaid or other Federal health care programs. . .

42 C.F.R. § 1001.401(c)(2). For both types of exclusions, a mitigating factor is that the individual's cooperation with federal or state officials resulted in others being convicted or excluded from Medicare, Medicaid or other federal health care programs, additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or, the imposition of a civil money penalty against others. 42 C.F.R. §§ 1001.201(b)(3)(iii), 1001.401(c)(3)(i). A mitigating factor applicable to an exclusion under section 1128(b)(1) is that "the record in the criminal proceedings . . . demonstrates that the court determined the individual had a mental, emotional or physical condition" that reduced his culpability. 42 C.F.R. § 1001.201(b)(3)(ii).

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 initial decision is supported by substantial evidence on the whole record; the standard of review on a disputed issue of law is whether the initial decision is erroneous. 42 C.F.R. § 1005.21(h); see also Barry D. Garfinkel, M.D., DAB No. 1572, at 5 (1996) (recognizing that under the regulation "[w]e have a limited role in reviewing ALJ decisions in exclusion cases"), aff'd, Garfinkel v. Shalala, No. 3-96-604 (D. Minn. June 25, 1997).

Case Background[1]

During the time period relevant to this appeal, December 1995 through June 2001, Petitioners were vice presidents or executive vice presidents of Purdue, and Petitioner Friedman became Chief Operating Officer.[2] Purdue developed and marketed OxyContin, an

[1] This summary derives from the ALJ Decision and the record. This summary is intended to provide context for our discussion and is not intended to present new findings of fact.

[2] Petitioner Goldenheim was Purdue's Group Vice President of Scientific and Medical Affairs and then Executive Vice President of Worldwide Research and Development; Petitioner

(Continued . . .)

opioid analgesic and Schedule II controlled substance. ALJ Decisions at 1. The diversion and abuse of OxyContin was described in 2001 by the U.S. Department of Justice as a "major problem," particularly in the eastern United States, where it was viewed as "a suitable substitute for heroin." P. Ex. 94, at 1.

In May 2007 Petitioners and Purdue were charged in the United States District Court for the Western District of Virginia with introducing a misbranded drug, OxyContin, into interstate commerce, in violation of the federal Food, Drug, and Cosmetic Act (FDCA) at 21 U.S.C. §§ 331(a), 352(a), and 333(a). ALJ Decisions at 1, citing I.G. Ex. 5 (Information). The FDCA, as relevant here, prohibits the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic "that is adulterated or misbranded." 21 U.S.C. § 331(a). Purdue as a corporation pled guilty to felony misbranding of OxyContin with intent to defraud or mislead, and each Petitioner pled guilty, as a responsible corporate officer, to the misdemeanor charge of misbranding, under 21 U.S.C.A. §§ 331(a), 333(a)(2). See ALJ Decisions at 6; United States v. Purdue Frederick Co., 495 F.Supp. 2d 569, at 570 (W.D. Va. 2007). The defendants were all convicted pursuant to their pleas. United States v. Purdue Frederick Co.; I.G. Exs. 6-8 (judgments in criminal case).

The "Agreed Statement of Facts" Petitioners signed in the criminal case describes a campaign of misinformation about the dangers of OxyContin that Purdue perpetrated to boost its sales of the drug. I.G. Ex. 9, ¶¶ 19-43. These efforts lasted over five and a half years during which the sales of OxyContin increased more than tenfold. ALJ Decisions at 10, 12. "Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001," Petitioners agreed, "certain" Purdue "supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications . . . ."

(Continued . . .)
Udell was Group Vice President and then Executive Vice President and General Counsel; and Petitioner Friedman was Group Vice President and then Executive Vice President and Chief Operating Officer. I.G. Ex. 9, at 1-2.

I.G. Ex. 9, ¶ 20. In so doing Purdue misled its own sales managers and representatives as well as health care providers, employing graphs, charts and other materials that wrongly depicted OxyContin as safer and more effective than other opioid pain killers. Id. ¶¶ 19-43. Purdue repeatedly minimized and concealed the risks and dangers of OxyContin, despite its own contrary research and clinical studies and the accounts of patients experiencing addiction to OxyContin and withdrawal when they attempted to discontinue its use. Id. Purdue embarked on these efforts to promote OxyContin after its market research showed that physicians were concerned about OxyContin's potential for abuse, addiction and side effects. Id. ¶ 19. Petitioners, while not agreeing that they had personal knowledge of these facts, agreed that they were true, and admitted that they were "responsible corporate officers" of Purdue who "had responsibility and authority either to prevent in the first instance or to promptly correct certain conduct resulting in the misbranding of a drug introduced or delivered for introduction into interstate commerce." Id. ¶¶ 11, 45, 46. In their plea agreements, Petitioners specifically agreed "that the Court can accept the Agreed Statement of Facts as the factual basis for [their] guilty plea[s]." I.G. Exs. 2-4, at 2. In the Agreed Statement of Facts, as well, Petitioners agreed that "the Court may accept these facts, as agreed to by defendant [Purdue], as part of the factual basis supporting the guilty pleas by the individual defendants." I.G. Ex. 9, ¶ 46.

Pursuant to their plea agreements, Petitioners were each convicted and sentenced to three years probation and agreed to pay fines of $5,000 and to provide 400 hours each of community service related to prescription drug abuse treatment or prevention. ALJ Decisions at 1-2; I.G. Exs. 2-8. Petitioners were also ordered to pay "disgorgement" to the Virginia Medicaid Fraud Control Unit's Program Income Fund in the amounts of $7.5 million (Goldenheim), $8 million (Udell), and $19 million (Friedman). ALJ Decisions at 1-2. Purdue itself paid some $575 million under its plea agreement, including $160 million characterized in the plea agreement as restitution to federal government health care agencies and state governments in settlement of their civil claims against Purdue.[3] Id. at 10; I.G. Ex. 1, at 4-5.

[3] The ALJ reported payments by Purdue totaling approximately $575 million, including, in addition to the $160 million in restitution to federal and state governments, $276.1

(Continued . . .)

In notices dated March 31, 2008, the I.G. informed Petitioners that they would each be excluded from program participation for a period of 20 years under sections 1128(b)(1) and (b)(3) of the Act because of their convictions 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, and relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance.[4] I.G. Exs. 12-14. After Petitioners timely requested hearings before an ALJ, the I.G. reduced each of the exclusions to 15 years, based on receipt of information showing Petitioners' cooperation with federal and state law enforcement officials. ALJ Decisions at 1-2, and n.1; I.G. Ex. 18. The parties agreed that the ALJ could decide their appeals based on their written submissions and submitted consolidated briefs and exhibits. The ALJ issued three essentially identical decisions (any factual differences were not material) sustaining each Petitioner's exclusion for 15 years under sections 1128(b)(1) and (3). In each decision she made the following findings of fact and conclusions of law (FFCLs):

> *A. Petitioner may be excluded because he was convicted of a misdemeanor offense relating to fraud in connection with the delivery of a health care item or service within the meaning of section 1128(b)(1) of the Act.*

(Continued . . .)
million in forfeiture to the United States, $3.47 million to Medicaid programs for improperly calculated rebates, $5.3 million to the Virginia Medicaid Fraud Control Unit's Program Income Fund, and $130 million set aside to settle private civil claims. ALJ Decisions at 10. The sentencing court used a somewhat higher figure for Purdue's total payments, citing "monetary sanctions totaling $600 million, reported to be one of the largest in the history of the pharmaceutical industry." 495 F.Supp. 2d at 572. Neither party objected to the ALJ's findings, which we use here when referring to Purdue's total payments.

[4] In a separate matter, Purdue agreed to be excluded for 25 years. I.G. Ex. 16, at 8-9 (settlement agreement).

B. Petitioner may be excluded because he was convicted of a misdemeanor offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance within the meaning of section 1128(b)(3) of the Act.

C. The 15-year exclusion falls within a reasonable range.

1. Three aggravating factors justify substantially lengthening the period of exclusion beyond the three year baseline.

2. Just one mitigating factor justifies decreasing the length of Petitioner's exclusion.

ALJ Decisions at 6-14. The ALJ concluded that Petitioners were convicted of a misbranding offense "relating to fraud" because there was a "nexus or common sense connection" between the conduct giving rise to Petitioners' offenses of conviction, as that conduct was described in the Agreed Statement of Facts, and Purdue's fraudulent misbranding. Id. at 6-7. The ALJ cited Board cases holding that such a nexus or common sense connection was all that was required to establish that a criminal offense was "related to" the delivery of an item or service under a federal or state health care program, requiring exclusion under section 1128(a)(1) of the Act. Id. at 7, citing Timothy Wayne Hensley, DAB No. 2044 (2006), Neil R. Hirsch, M.D., DAB No. 1550 (1995), and Chander Kachoria, R.Ph., DAB No. 1380 (1993). The ALJ noted that Purdue's misbranding comprised "multiple instances" over a period of years in which "Purdue supervisors and employees 'with the intent to defraud or mislead' . . . marketed and promoted" OxyContin "as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications." ALJ Decisions at 6, citing I.G. Ex. 9, and 495 F.Supp. 2d at 569, 571. Petitioners' claimed lack of knowledge of Purdue's fraud did not render them "blameless," she held, because they had admitted being "'responsible corporate officer[s]'" charged with "the 'responsibility and authority' to prevent in the first instance or to correct promptly the conduct that resulted in the drug's misbranding." Id. at 7-8, citing I.G. Ex. 9 (Agreed Statement of Facts); 14-15. The ALJ further concluded that their offenses directly related to unlawful distribution of a controlled substance because they were based on illegal

misbranding in connection with Purdue's delivery of OxyContin into interstate commerce. She concluded that the 15-year exclusions the I.G. imposed were reasonable, based on the existence of three aggravating factors relating to the financial losses to government programs, the duration of the offenses, and the impact of those offenses on individuals, and only one mitigating factor, Petitioners' cooperation with government authorities, which the I.G. had considered in reducing the exclusions from 20 to 15 years.

Petitioners' appeals of the ALJ Decisions were consolidated for briefing and decision at their request. The record in this appeal comprises the parties' briefs, the reply briefs they submitted with the Board's permission under 42 C.F.R. § 1005.21(c) and the transcript of an oral argument convened at Petitioners' request following completion of briefing. Petitioners submitted proposed corrections to the transcript of the oral argument identifying what they allege are prejudicial errors in transcription. However, many of their "corrections" do not identify actual transcription errors but, rather, propose the insertion of such edits as quotation marks and paragraph breaks. None of the alleged "errors" are prejudicial since they do not impact our decision. Accordingly, we do not order any corrections to the transcript.[5]

[5] We do, however, note Petitioners' correction that attorney Mary Jo White was Petitioner Udell's counsel in the criminal proceeding, and not in the ALJ proceeding as indicated in the transcript. Tr. at 3.

Analysis

I. The ALJ's determination that Petitioners were each convicted of a misdemeanor offense relating to fraud in connection with the delivery of a health care item or service, authorizing their exclusions under section 1128(b)(1) of the Act, was legally correct and supported by substantial evidence.[6]

That Petitioners were not convicted of fraud does not preclude their exclusion.

Petitioners argue that the misbranding offense for which they were convicted was not related to Purdue's fraud because unlike Purdue, the corporation, they as individuals were not convicted of fraudulent conduct. That Petitioners were not specifically convicted of fraud in connection with the misbranding, however, does not mean that the offense did not relate to fraud within the meaning of section 1128(b)(1), authorizing the I.G. to exclude them.

As the ALJ correctly pointed out, the I.G.'s exclusion authority in section 1128(b)(1) is "much broader" than Petitioners argue. ALJ Decisions at 7. By its terms section 1128(b)(1) 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. This analysis is consistent with the Board's and a court's reading of comparable language in section 1128(a)(2), requiring the exclusion of anyone convicted of an offense "relating to neglect or abuse of patients" in connection with the delivery of a health care item or service. In Carolyn Westin, DAB No. 1381 (1993), aff'd sub nom Westin v. Shalala,

[6] Petitioners' arguments on this and the ALJ's other determinations relate to their contention that the I.G. should not have excluded them, and that the duration of the exclusions is unreasonable, because they were not convicted of fraud, but were instead convicted based on their status as responsible corporate officers. In making these arguments they cite numerous ALJ and some Board decisions they claim are distinguishable or support their appeal. We have fully considered all arguments Petitioners raised on appeal, regardless of whether we have provided a detailed written analysis of all of those arguments in this decision or addressed each of the decisions they cite.

845 F.Supp. 1446 (D. Kan. 1994), the Board held that "the I.G. did not have to prove that Petitioner [who was convicted of disregard of a state health regulation for failing to file an incident report] committed patient abuse or neglect" to exclude her under section 1128(a)(2). DAB No. 1381, at 11. 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." The district court in sustaining the Board's decision held that-

> there is no requirement that the Secretary demonstrate that actual neglect or abuse of patients occurred, nor is there a requirement that the individual or entity be convicted of an actual offense of patient neglect or abuse. The phrase "relating to" clearly encompasses a broader range of conduct than actual neglect or abuse.

845 F.Supp. at 1451.

In addition, as discussed earlier, the Board, addressing section 1128(a)(1) of the Act requiring exclusion for a criminal offense "related to" the delivery of an item or service under a federal or state health care program, has held that "related to" means a nexus or common sense connection. See Scott D. Augustine, DAB No. 2043 (2006), cited in P. Reply Br. at 3, n.1; ALJ Decisions at 7, citing Timothy Wayne Hensley and Neil R. Hirsch, M.D. The facts here support the ALJ's finding of a nexus or common sense connection between Petitioners' misdemeanor misbranding offense and Purdue's fraudulent misbranding. The actual misbranding that resulted in Petitioners' convictions was the fraudulent misbranding of OxyContin. As the ALJ aptly noted, "but for the fraud" of Purdue, "there would have been no crime and no conviction" of Petitioners.[7] ALJ Decisions at 7.

[7] Petitioners' argument that the ALJ was mistaken "as a matter of law" because the fraudulent nature of Purdue's misbranding was not a necessary component of their convictions as responsible corporate officers of Purdue, is speculative and irrelevant. There is no dispute that Purdue's misbranding was fraudulent, and the issue is whether Petitioners' offenses related to that fraud. Whether the I.G. could have excluded Petitioners had Purdue not been convicted of fraudulent misbranding is not an issue before us.

Petitioners argue that the "nexus or common sense connection" analysis the ALJ employed is inapplicable because the Board developed this approach to determine whether an offense "related to the delivery" of an item or service under section 1128(a)(1) of the Act. P. Reply Br. at 3, n.1, citing Scott D. Augustine. They argue that "the breadth of offenses deemed to be 'related to' the delivery of an item or service . . . do[es] not inform the meaning of 'related to' when the phrase is used [in sections 1128(b)(1) and (3)] in the context of a specifically enumerated offense such as fraud." P. Reply at 3, n.1. In Carolyn Westin, the Board and the court, however, did employ a comparable approach in concluding that a conviction was "related to" specific offenses enumerated in the exclusion statute. Viewing "relating to" in section 1128(b)(1) as having the same meaning as "related to" in section 1128(a)(1) is moreover consistent with the principle of according the same meaning to the same word or phrase in different parts of a statute. 3A Norman J. Singer and J.D. Shambie Singer, Sutherland Statutory Construction § 74:4 (6th ed. database updated June 2009); 2A Sutherland Statutory Construction § 46:6 (7th ed. database updated June 2009). The ALJ committed no error by applying the intuitive, ordinary reading of "related to" that the Board has discussed in regard to section 1128(a)(1). By any reasonable understanding, the misbranding of OxyContin, and the agreed conduct underlying Petitioners' convictions, related to fraud in connection with the delivery of a health care item or service and, thus, authorized their exclusions under section 1128(b)(1) of the Act.[8]

Petitioners also attempt to distinguish their case from one that the ALJ cited as holding that personal knowledge of the conduct underlying an exclusion is irrelevant in light of the fact of a criminal conviction. ALJ Decisions at 8, citing Lyle Kai, R.Ph., DAB No. 1979 (2005), aff'd, Kai v. Leavitt, Civ. No. 05-00514 BMK (D. Haw. July 17, 2006). They argue that the lack of knowledge that the Board there deemed irrelevant was simply Kai's knowledge of the relationship between the offense and the Medicaid program, and that, unlike here, Kai was personally

[8] Since there is no requirement that Petitioners have been convicted of fraud to be excluded under section 1128(b)(1), Petitioners' argument that the I.G. and the ALJ have wrongly imputed to them the fraudulent intent and conduct of other Purdue employees provides no basis to reverse the exclusions.

involved in relevant unlawful conduct, the mislabeling of pharmaceuticals. P. Br. at 16, n.1. Kai in fact supports Petitioners' exclusions. Kai indeed claimed a lack of knowledge of the mislabeling scheme. He also denied participating in any billing activities for items or services provided in the pharmacy department. DAB No. 1979, at 6. The court considered Kai's clamed lack of knowledge or participation irrelevant, holding that the exclusion statute "requires that a conviction need only be related to delivery of an item or service, and the convicted individual need not have actually participated in the delivery" and "it is the fact of [his] conviction relating to the scheme that is material, and not [his] particular role in that scheme." Kai v. Leavitt at 11-12. That reasoning applies here – Petitioners' conviction for an offense relating to Purdue's fraud authorizes their exclusion, regardless of their claimed lack of knowledge of or role in that fraud.

Petitioners also argue that there is no nexus or common sense connection between their offense and fraud because their exclusions would not serve the remedial purpose of the statute, protecting the program from untrustworthy individuals. P. Reply Br. at 3, citing Travers v. Sullivan, 801 F.Supp. 394, 405 (E.D. Wash. 1992), aff'd sub nom Travers v. Shalala, 20 F.3d 993 (9th Cir. 1994). We explain below why Petitioners' convictions indicate that they were culpable for Purdue's misbranding and their exclusions serve the statute's goals.

Petitioners' convictions indicate culpability for the fraudulent misbranding.

Petitioners argue that their convictions were not related to fraud because they had no knowledge of Purdue's fraud and were convicted of a strict liability offense solely by virtue of having been responsible corporate officers of Purdue when other, unidentified employees of Purdue fraudulently promoted OxyContin. I.G. Exs. 2-4, at 1 (plea agreements). Petitioners argue that the record of their convictions "contains no evidence that they participated in, condoned, knew of, or failed to take suitable measures to prevent" misconduct by the company.[9] P. Br.

[9] Petitioners cite statements of the district court judge in their criminal case and the U.S. Attorney who prosecuted them confirming that they were not charged with personal knowledge of the misbranding or any personal intent to defraud and that the government had not established that Petitioners had an intent to

(Continued . . .)

at 30. They further argue that there is no record evidence that they "acted, or failed to act, knowingly, intentionally, recklessly, negligently, or in any manner that is in the slightest degree personally blameworthy" and that their exclusions are thus contrary to the remedial purpose of the exclusion statute, protecting government health care programs from untrustworthy individuals. P. Br. at 8-9, 14. Petitioners accuse the I.G. of mounting an impermissible collateral attack on their convictions. Petitioners' arguments, however, misrepresent the full legal significance of their convictions.

In concluding that Petitioners were "not blameless" for Purdue's fraud, the ALJ relied on two Supreme Court decisions addressing convictions under the FDCA, United States v. Dotterweich, 320 U.S. 277 (1943) and United States v. Park, 421 U.S. 658 (1975). She cited them as holding that "an individual convicted of violating the FDCA cannot claim to be blameless because the statute 'imports' to him a 'measure of blameworthiness.'" ALJ Decisions at 7, citing Park, 421 U.S. at 673. Applying this precedent, the ALJ thus found that "inherent in Petitioner[s'] conviction[s] is the finding that [they were] in a position to prevent or correct the company's fraud, but failed to do so." Id. at 7.

Petitioners advance a much different view of Dotterweich and Park. Petitioners characterize them as holding corporate officers responsible for the misconduct of others "irrespective of their action, inaction, knowledge or ignorance" and "without regard to any act or omission by those individuals," and argue that "the minimal proof required for a conviction . . . is simply the occurrence of employee misconduct and the job title of the defendant [that] give rise to liability." P. Br. at 4, 12-13. They claim that they were thus convicted based "solely" on "the spot they occupy on an organizational chart" and "effectively ha[d] no defense" to the charge of misbranding. Tr. at 9, 10.

Petitioners' argument misrepresents the Court's decisions and the significance of their own guilty pleas. While holding that the FDCA "does not . . . make criminal liability turn on 'awareness of some wrongdoing' or 'conscious fraud,'" Park, 421

(Continued . . .)
mislead. P. Br. at 31, citing 495 F.Supp. 2d at 571, 576 and P. Ex. 2, at 11. The I.G. does not dispute those statements.

U.S. at 672-73, the Court did not impose strict liability under the FDCA solely on the basis of a defendant's title or position in the corporation, as Petitioners argue. Instead, under those decisions, liability attaches to the defendant's failure to exercise the responsibility and authority attendant to his or her corporate position, and it is a defense that the defendant corporate officer was powerless to stop the illegal conduct.

The following excerpts from the two cases reveal the extent to which Petitioners' selective parsing (which we have only summarized here) obfuscates the cases in a manner that minimizes the full impact of Petitioners' failure to have taken any action to stop or prevent Purdue's fraudulent conduct. In Dotterweich, the Court held:

> Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon **those who have at least the opportunity of informing themselves** of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

320 U.S. at 284-85 (emphasis added). In Park, the Court explained its earlier holding, stating:

> The rationale of the interpretation given the [Food, Drug, and Cosmetic] Act in Dotterweich, as holding criminally accountable the persons whose **failure to exercise the authority and supervisory responsibility reposed in them** by the business organization resulted in the violation complained of, has been confirmed in our subsequent cases. . . . the Act **punishes 'neglect where the law requires care, or inaction where it imposes a duty**.' . . . 'The accused, if he does not will the violation, usually **is in a position to prevent it** with no more care than society might reasonably expect and no more exertion than it might reasonably exact from one who assumed his responsibilities.'

421 U.S. at 671, citing Morissette v. United States, 342 U.S. 246, 255, 256 (1952) (emphasis added). The Park Court further stated:

> The duty imposed by Congress on responsible corporate agents is, we emphasize, one that requires the highest standard of foresight and vigilance, **but the Act, in its criminal aspect, does not require that which is objectively impossible**. **The theory upon which responsible corporate agents are held criminally accountable for 'causing' violations of the Act permits a claim that a defendant was 'powerless' to prevent or correct the violation to 'be raised defensively at a trial on the merits.'** United States v. Wiesenfeld Warehouse Co., 376 U.S. 86, 91, 84 S.Ct. 559, 563, 11 L.Ed.2d 536 (1964). If such a claim is made, the defendant has the burden of coming forward with evidence, but this does not alter the Government's ultimate burden of proving beyond a reasonable doubt the defendant's guilt, including his power, in light of the duty imposed by the Act, to prevent or correct the prohibited condition.
>
> * * * *
>
> The concept of a 'responsible relationship' to, or a 'responsible share' in, a violation of the Act indeed imports some measure of blameworthiness; but it is equally clear that the Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of the facts that **the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so.** The failure thus to fulfill the duty imposed by the interaction of the corporate agent's authority and the statute furnishes a sufficient causal link. The considerations which prompted the imposition of this duty, and the scope of the duty, **provide the measure of culpability**.

Id. at 673-74 (emphasis added).

Petitioners' convictions under the FDCA mean that, as Purdue's senior executives, they had, but failed to exercise, the duty and responsibility, and the power and authority, to learn about and curtail the fraudulent activities of Purdue employees. They had, as they recognized, "responsibility and authority either to

prevent in the first instance, or to promptly correct" the misbranding, but failed to do so. See I.G. Ex. 9, ¶¶ 11, 45 (Agreed Statement of Facts, incorporating language from Park). Petitioners thus bear a measure of culpability and blameworthiness for the conduct that Purdue employees engaged in over a long period of time during Petitioners' stewardship of the company.

If indeed the fraud occurred despite Petitioners having exercised "the utmost care" and having taken "extraordinary measures" to ensure that the company behaved lawfully, and despite their having not "avoid[ed] any duty to prevent" the fraud, (Tr. at 12; P. Br. at 5), then at trial they could have mounted the affirmative defense that they were powerless to stop the misbranding. As the Court observed, the misbranding statute "does not require that which is objectively impossible." Instead, Petitioners pled guilty to criminal charges and collectively forfeited $34.5 million in personal funds. They did so while represented by counsel, and signed an Agreed Statement of Facts that incorporated some of the language from Park. To argue now that there is "no evidence" that they should have been aware of the fraud, "no evidence" that they behaved negligently, and "no evidence" that they are "in the slightest degree personally blameworthy" is disingenuous. P. Br. at 5, 14. Having declined their opportunity at trial to establish that they were powerless with respect to the fraud, they cannot now be heard to complain of a lack of evidence that they were *not* powerless. Given the meaning of a charge under the FDCA and the available defense, it cannot be "assume[d] on this record that the utmost care was exercised" by Petitioners, as they claim. Tr. at 39. By mischaracterizing the import of their misbranding conviction under the FDCA, it is Petitioners, and not the I.G., who effectively mount a collateral attack on their convictions.

There was thus no error in the ALJ's conclusions that "inherent in [each] Petitioner's conviction is the finding that he was in a position to prevent or correct the company's fraud, but failed to do so" and that their convictions as a matter of law meant, "at a minimum, a culpable omission." ALJ Decisions at 7.

Petitioners' exclusions serve the remedial purposes of the exclusion statute.

Petitioners' argument that their exclusions do not serve the remedial purpose of the statute – and therefore did not relate

to fraud (P. Reply Br. at 3) - rests on their position that they are entirely unculpable for Purdue's misbranding. Since we conclude that their convictions evidence their culpability as a matter of law, we reject that argument. Petitioners' trustworthiness, moreover, is not left unblemished by the absence of evidence that they had any fraudulent intent, as the concept of untrustworthiness is not limited to the propensity to engage in fraudulent, deceitful conduct, as Petitioners' argument suggests. The definition of "trustworthy" includes "worthy of confidence" and "reliable." Webster's 3rd New Int'l Dictionary at 2457 (1976). The I.G. could reasonably conclude that Petitioners are not reliable or worthy of confidence with respect to federal health care programs, given that their convictions confirm their culpable failure with respect to the unlawful and fraudulent promotion of OxyContin that Purdue carried out for over five years while under Petitioners' management and that ended with Purdue agreeing to forfeit some $575 million, of which $160 million was for restitution to the federal and state governments.[10]

Petitioners cite two ALJ decisions upholding exclusions for misbranding convictions under section 1128(b)(1) where the record of the criminal cases established an intent to defraud or mislead. P. Br. at 10-11, citing Stephen J. Weiss, DAB No. CR581 (1999) and Michael M. Bouer, DAB CR345 (1994). Those cases do not address the circumstances here or the responsibilities borne by corporate officers whose companies engage in misbranding under their watch. This is not surprising given Petitioners' assertion that this is a case of first impression. Nothing in those ALJ decisions or in any Board decisions Petitioners cite holds that misdemeanor misbranding convictions of responsible corporate officers do not "relate to" the underlying fraudulent misbranding carried out by their companies.

Petitioners also argue that the I.G. abused his discretion by "render[ing] meaningless Congress' distinction between felonies and misdemeanors, not only in the FDCA, but in the exclusion

[10] Petitioners' argument that the conduct underlying Purdue's guilty plea consisted primarily of "isolated statements" by some sales department personnel (P. Br. at 6) grossly understates the breadth and duration of the fraudulent conduct detailed in the Agreed Statement of Facts.

statute itself." Tr. at 16. We find no basis to make the connection Petitioners ask us to make. That Congress distinguished between misdemeanors and felonies for purposes of determining whether exclusion should be mandatory or discretionary is irrelevant to whether an individual's misdemeanor offense is "related to fraud" for purposes of a permissive exclusion. Furthermore, this argument is premised on Petitioners' argument, which we have already rejected, that there were no fraudulent acts underlying their misdemeanor convictions.

We thus sustain the ALJ's determination that Petitioners were each convicted of an offense relating to fraud under section 1128(b)(1) of the Act.

II. The ALJ's determination that Petitioners were each convicted of a misdemeanor offense relating to the unlawful distribution of a controlled substance authorizing their exclusion under section 1128(b)(3) of the Act was legally correct and supported by substantial evidence.

Section 1128(b)(3) of the Act authorizes the I.G. to exclude any individual or entity that has been convicted of a criminal offense consisting of a misdemeanor "relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance." The ALJ held that the misbranding of OxyContin was "directly related" to the drug's unlawful distribution because the FDCA provision under which they and Purdue were convicted prohibited the introduction into interstate commerce of a misbranded drug, in this case OxyContin. ALJ Decisions at 8, citing 21 U.S.C. § 331(a).

On appeal, Petitioners argue, as they did below, that there was no illegality in Purdue's delivery of OxyContin into interstate commerce because Purdue provided OxyContin to physicians legally, as it was licensed to do by the Drug Enforcement Administration. They argue that the meaning of the language of section 1128(b)(3) encompassing misdemeanors relating to "the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance" is framed by the Controlled Substances Act (CSA), 21 U.S.C. §§ 841 et seq. The CSA makes it illegal to "knowingly or intentionally . . . manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" a controlled substance except as authorized thereunder. 21 U.S.C. § 841(a). Petitioners argue that exclusions under section 1128(b)(3) should be limited to

convictions under the CSA or a similar statute for crimes such as the "transfer of illegal street drugs or the diversion of prescription drugs for non-medical uses," and not the lawful delivery of an approved product into interstate commerce. P. Br. at 21.

Petitioners' argument that Purdue was authorized to provide a controlled substance misses the point. Petitioners and Purdue were not convicted for distributing controlled substances that they were not licensed to distribute, but for distributing misbranded drugs. Petitioners' argument also fails because section 1128(b)(3) does not refer to, adopt or incorporate the CSA for the purpose of determining whether the distribution of a controlled substance is unlawful. The language of section 1128(b)(3) and the CSA, moreover, are not coextensive, and the exclusion statute does not require that the illegal distribution be knowing or intentional, as does the CSA. Petitioner points to nothing in the statute or legislative history that would limit an exclusion under section 1128(b)(3) to convictions under the CSA or similar statutes. (The legislative history simply describes section (b)(3) as authorizing exclusions for "convictions relating to controlled substances," S. Rep. No. 100-109, at 6 (1987).) Purdue's distribution of OxyContin was unlawful because Purdue illegally misrepresented the dangers of OxyContin specifically to increase the amount of the drug that it distributed for sale. That the FDCA may refer to interstate commerce in part to establish federal jurisdiction does not, contrary to what Petitioners argue, alter this integral aspect of Purdue's crime. Our determination that Petitioners' convictions related to Purdue's acts under section 1128(b)(1) applies equally to section 1128(b)(3). We thus affirm the ALJ's conclusion that Petitioners were convicted of a misdemeanor offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance, authorizing their exclusions under section 1128(b)(3) of the Act.

III. Based on the existence of two aggravating factors and one mitigating factor, 12 years is a reasonable period of exclusion.

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 judgment for that of the I.G. or determine what period of exclusion would be "better." See, e.g., Barry D. Garfinkel, M.D. at 6-7, 10-11 (ALJ's role "was not to determine what period of exclusion would be 'better' but whether the period imposed by the I.G. was within a reasonable range). 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. Id.; 57 Fed. Reg. 3298, 3321 (Jan. 29, 1992). The preamble to Part 1001 indicates that 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. 57 Fed. Reg. at 3321. The preamble further advises that the specified aggravating and mitigating factors are not intended to have specific values; the weight accorded to each "cannot be established according to a rigid formula, but must be determined in the context of the particular case at issue." 57 Fed. Reg. at 3314-15.

The ALJ determined that three aggravating factors justified substantially increasing the period of Petitioners' exclusions: the financial loss to health care programs, the duration of the crimes, and the adverse impact on program beneficiaries and others. She determined that the I.G. had reasonably reduced the exclusions from 20 to 15 years based on one mitigating factor, Petitioners' cooperation with law enforcement authorities. She concluded that 15-year exclusions were within a reasonable range. ALJ Decisions at 9-14. As explained below, we reverse the ALJ's determination with regard to one of the three aggravating factors, and conclude that 12 years is a reasonable period of exclusion.

The financial loss to government programs was an aggravating factor.

The ALJ found that the fraudulent misbranding underlying Petitioners' convictions caused "staggering financial losses" to government programs, as evidenced by the "enormous" amounts Purdue and Petitioners agreed and were required to pay in their criminal case. ALJ Decisions at 10. She concluded that restitution is a reasonable measure of program losses, and that

restitution in amounts so substantially greater than the $5,000 statutory standard was "an 'exceptional[ly] aggravating factor' that is entitled to significant weight." Id. at 11, citing Jeremy Robinson, DAB No. 1905 (2004), and Donald A. Burstein, Ph.D., DAB No. 1865 (2003). She further found that the fraudulent marketing scheme "reasonably could" have been expected to cause losses of more than $5,000, given the "massive" sales of OxyContin that took place during the period of the scheme. Id. at 11-12.

Petitioners on appeal make an argument the ALJ rejected, that the restitution Purdue paid "bears no relationship to any financial losses suffered by government programs or any other entity, and . . . that the Sentencing Court therefore 'declined to make any finding that the misbranding caused any financial harm.'" ALJ Decisions at 10-11, citing P. ALJ Br. at 38; see P. Br. at 32, 34 (amounts paid do not establish that the misbranding "had a significant financial impact or caused any financial loss"). They also argue that there is no showing that the misbranding resulted in doctors writing additional prescriptions for OxyContin.

The regulation, however, does not require the I.G. to establish actual losses to federal programs, as it permits an aggravating factor to be established if the acts underlying the conviction "reasonably could have been expected to cause" losses over $5,000. The ALJ concluded, and we agree, that this standard was met because "the fraudulent marketing scheme 'reasonably could' be expected to increase dramatically OxyContin sales, and . . . a good portion of that increase would represent sales for a drug that should not have been prescribed" and that "the drug recipient, a government program or other third party payor – wrongly paid for that inappropriate drug." ALJ Decisions at 12. Additionally, the record does support a finding of actual loss. As the ALJ observed, the judge who presided over the criminal case stated that the restitution amounts would "likely cover costs that the government had incurred in this healthcare program." P. Ex. 5, at 61; ALJ Decisions at 11. It is not disputed that restitution, as Purdue's $160 million payment was described, generally means reparation or compensation for injuries. The ALJ's finding of considerable financial losses to government programs was thus supported by substantial evidence.

Petitioners' argument that the payments were negotiated simply to dispose of the criminal and civil cases against Purdue rather than compensate injured parties (payments were "all Purdue

could afford to pay" for "the different government entities . . . to be satisfied" while granting Purdue "global peace," Tr. at 42; "Purdue wanted peace with the government," P. Ex. 5, at 52) provides no basis to ignore the sentencing judge's description of the payments or the plain facts. The federal and state governments sought to recover from Purdue and Petitioners costs those governments had incurred in responding to the abuse of OxyContin. To resolve those claims Purdue paid the federal and state governments approximately $575 million, including $160 million specifically described in Purdue's plea agreement as restitution to the federal and state governments. I.G. Ex. 1, at 4-5. Thus, the federal and state governments were injured parties, and, but for the misbranding, which is the only criminal misconduct described in the record, there would have been no payments to them from Purdue and Petitioners. See, e.g., I.G. Ex. 9 (Agreed Statement of Facts); 495 F.Supp. 2d 569. Purdue's attorney in the criminal case, while voicing denial of a connection between Purdue's criminal conduct and damages to government programs, nonetheless conceded that some payments would be to compensate those programs for harm attributable to the misbranding. P. Ex. 5, at 43-44. There is, thus, substantial evidence that the acts resulting in Petitioners' convictions caused financial losses to government programs that were vastly in excess of the $5,000 threshold for financial loss to be considered an aggravating factor.

Petitioners also argue that the record does not establish the actual amount of losses to government programs, and assert that Purdue's review of electronic call notes that its sales representatives entered into personal data assistants to track their contacts with physicians shows that unsupported claims of OxyContin's advantages over other drugs were arguably discussed in only 0.2% of sales calls. Tr. at 13-14; P. Ex. 4, at 2. The application of this aggravating factor, however, does not require calculating damages to be awarded to injured parties, but, rather, merely determining the extent to which any losses flowing from the acts (or similar acts) that resulted in conviction exceeded $5,000. See Jason Hollady, M.D., DAB No. 1855 (2002) (restitution, although not finally established, was evidence that the amount of harm was substantial and exceeded the threshold for it to be an aggravating factor). Even accepting Petitioners' argument about the survey of its sales representatives, the financial losses would range from $320,000 to over $1.15 million, depending on whether the .2% figure is applied to the $160 million Purdue paid as restitution to federal and state government programs, or to the $575 million

that Purdue paid in total. Calculated either way, the losses under Petitioners' own theory are still far above the $5,000 threshold.

Even if we were to disregard the restitution made by the corporation and rely only on the dollar amounts disgorged by Petitioners, the losses to government programs were substantially more than $5,000. Petitioners argue that the $34.5 million they personally disgorged to the Program Income Fund of the Virginia Medicaid Fraud Control Unit does not represent losses to government programs or other entities. They note that the "restitution ordered" section of the judgment against each Petitioner is blank, and argue that federal courts have described disgorgement as an equitable remedy not intended as compensation for injuries. I.G. Exs. 6-8, at 4; P. Br. at 33-34 (citations omitted). The I.G. does not dispute Petitioners' description of the court cases they cite, but correctly cites other federal court cases holding (as do the cases Petitioners cite) that disgorgement represents illegal profits, ill-gotten gains, or unjust enrichment, the characterization that the ALJ employed. I.G. Br. at 33-34 (citations omitted); ALJ Decisions at 10. It is not unreasonable to find a link between the disgorgement amounts, which Petitioners did not dispute represent bonuses they received from Purdue relating to OxyContin sales, and Purdue's misbranding and sale of OxyContin. Indeed, Petitioners agreed that their payment would result in funds being returned to the Medicaid program. P. App. A, Tab 8, at 14, n.6 (letter from Petitioners' counsel to I.G.). We conclude that either or both the restitution paid by Purdue and the money disgorged by Petitioners establishes the existence of the aggravating factor.

Petitioners object to the ALJ's "alternative reliance" on the civil settlement agreement between the United States and Purdue as establishing the amount that Purdue paid to the government. The ALJ rejected Petitioners' argument that Rule 408 of the Federal Rules of Evidence, prohibiting the introduction of settlement agreements as admissions of liability, did not apply because Petitioners were not parties to that agreement (Purdue was), and because the regulations governing these proceedings apply Rule 408 only to offers of compromise or settlement made "in this action[.]" ALJ Decisions at 4, citing 42 C.F.R. § 1005.17(f). On appeal, Petitioners demonstrate no error in the ALJ's holding, but cite the "well-established legal principle" that settlement agreements cannot be used to establish liability, "particularly . . . where, as here, the

settlement agreement specifically includes a provision that it is made *without* any admission of fault or liability." P. Br. at 34-35, citing I.G. Ex. 16, at 3. The absence from the settlement agreement of an admission of liability is meaningless in the context of these proceedings, given Petitioners' and Purdue's guilty pleas to the misbranding offenses and the account of the fraudulent misbranding in the Agreed Statement of Facts.[11] Moreover, the ALJ cited the settlement agreement only in reference to the amounts that each Petitioner disgorged, information that, like much of the information in that agreement, appears elsewhere in the record, such as in the Agreed Statement of Facts and the published opinion of the district court. ALJ Decisions at 11. That this information resulted from negotiations does not bar its use here or detract from its evidentiary value. P. Br. at 37; Tr. at 21.

The ALJ's finding that Petitioners' crimes had an adverse impact on program beneficiaries and others is not supported by substantial evidence.

It is an aggravating factor if the acts that resulted in the conviction or similar acts "had a significant adverse" physical or mental impact on program beneficiaries or other individuals. 42 C.F.R. §§ 1001.201(b)(2)(iii), 1001.401(c)(2)(ii). The ALJ found a significant adverse physical or mental impact on program beneficiaries or others because she deemed it "disingenuous to suggest that allowing those risks [of OxyContin addiction] to be misrepresented for more than five years had no adverse impact on program beneficiaries or others," and because "the question of harm has already been adjudicated in the criminal proceedings." ALJ Decisions at 13-14. We conclude that substantial evidence does not support the ALJ's application of this aggravating factor. While Petitioners have not disputed that substantial harm befell individuals who abused or were addicted to

[11] Petitioners also state that under the settlement agreement, it was not Purdue (i.e., Purdue Frederick) that agreed to make the corporate payments, but Purdue Pharma, which Petitioners state was not convicted of any crime. P. Br. at 38. The decision of the sentencing court, however, states that Purdue Frederick made those payments. 495 F.Supp.2d at 569, 572. It is clear in any event that those payments were made in connection with Purdue's marketing of OxyContin and its criminal conviction therefor, regardless of which of its organizational personas supplied the funds.

OxyContin, the record here does not establish the causal connection between that harm and the misbranding that occurred here that is required to find the existence of this aggravating factor.

Although the ALJ correctly observed that "[n]othing in the language of the regulation requires a 'direct and proximate' relationship between the acts underlying the conviction and the adverse impact on beneficiaries," id. at 13, the regulation does require a relationship, which the sentencing court's finding did not establish. As the ALJ noted, the judge stated at sentencing that "the potential damage by the misbranding disclosed in this case was substantial." I.G. Ex. 10, at 117 (emphasis added). A finding of only "potential" damage does not satisfy the plain language of the regulation requiring that the acts resulting in conviction or similar acts must have "had a significant adverse" physical or mental impact on program beneficiaries or other individuals. 42 C.F.R. §§ 1001.201(b)(2)(iii), 1001.401(c)(2)(ii) (emphasis added). Moreover, the judge in the criminal case observed that courts in "numerous civil suits" filed by individuals harmed by OxyContin had "consistently found that despite extensive discovery, plaintiffs were unable to show that Purdue's misbranding proximately caused their injuries." 495 F.Supp. 2d at 575 (citations omitted). Although we observed that the regulation does not require proximate causation, the judge's statement nonetheless informs our conclusion that the question of harm to individuals was not adjudicated in the criminal proceeding.

Furthermore, the materials from the criminal proceeding that establish both the relationship between Petitioners' offenses and fraud and the existence of the aggravating factor of financial loss to government programs (such as the Agreed Statement of Facts, the plea agreements, and the published opinion of the presiding judge) do not alone establish a link between the misbranding and the extensive harm that other documents of record show has been caused by OxyContin. While Purdue's plea agreement set funds aside for settlement of "private civil liabilities" related to OxyContin, the agreement makes no findings of such harm and moreover precludes restitution other than as set forth in the agreement. The court accepted the plea agreement over the objection of "a number of alleged victims" who contended that the amounts allocated to private parties were insufficient. 495 F.Supp. 2d at 573.

For these reasons, we conclude that the record does not establish that the acts underlying Petitioners' convictions actually "had a significant adverse" impact on individuals.

The duration of the misbranding was an aggravating factor.

The ALJ determined that the fraud underlying Petitioners' convictions occurred from on or about December 12, 1995 until on or about June 30, 2001, more than the one year necessary to establish the existence of an aggravating factor under 42 C.F.R. §§ 1001.201(b)(2)(ii) and 1001.401(c)(2)(i). As noted earlier, both sections provide that an aggravating factor is established when the acts that resulted in the conviction or similar acts were committed over a period of one year or more. ALJ Decisions at 12, citing I.G. Ex. 9, ¶ 20 (Agreed Statement of Facts). Petitioners argue that the record of their convictions "does not establish that Petitioners engaged in any '*acts* that resulted in the conviction or [any] similar *acts*' . . . because it contains no evidence that they participated in condoned, knew of, or failed to take suitable measures to prevent misconduct." P. Br. at 30 (emphasis, brackets in original). We rejected that argument above in sustaining the ALJ's conclusion that the I.G. had a basis to exclude Petitioners, whose convictions meant "at a minimum, a culpable omission." ALJ Decisions at 7. Petitioners provide no evidence that their culpability, which we have concluded was established by their guilty pleas, did not extend throughout the period of the misbranding.

The ALJ correctly determined that only one mitigating factor applied.

In addition to the one mitigating factor the I.G. applied, Petitioners assert the existence of two mitigating factors applicable to exclusions under section 1128(b)(1). P. Br. at 55. The first of those two mitigating factors requires that "the entire amount of financial loss . . . to a Government program or to other individuals or entities due to the acts that resulted in the conviction and similar acts [be] less than $1,500." 42 C.F.R. § 1001.201(b)(3)(i). Since we have concluded that Petitioners' acts resulted in substantial financial losses to government programs, this mitigating factor clearly does not apply here. The other factor applies if the court in the criminal proceeding determined "that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability." Section 1001.201(b)(3)(ii). The ALJ rejected

Petitioners' argument that their lack of knowledge of Purdue's misbranding meant that they were not culpable and was thus such a "condition." ALJ Decisions at 14. Since we agree that Petitioners' convictions meant that they bore a measure of culpability, we find no error in the ALJ's conclusion. In any event, we find no legal basis for investing the phrase "mental, physical or emotional condition" with any meaning other than its common sense meaning relating to a disease process or an individual's state of health. Lack of culpability, even if it existed (which it does not here) is not a disease process or health problem.

Twelve years is a reasonable period of exclusion.

As noted, the I.G. is accorded "broad discretion" in setting the length of an exclusion, based on his vast experience in implementing exclusions. The aggravating and mitigating factors that the I.G. considers in making that determination are not intended to have specific values, and one factor of significance may merit more weight than several opposing factors. 57 Fed. Reg. at 3314-15.

As discussed above, the aggravating factors present here are significant. In terms of both their duration and the costs they imposed, the offenses at issue had effects that exceed the thresholds established in the regulations many times over, with costs reaching well over one hundred million dollars. As the ALJ observed, "the fraud continued for many years. Its costs were astronomical." ALJ Decisions at 14-15.

Petitioners dispute the seriousness (and existence) of the aggravating factors primarily for the same reason they maintain they should not have been excluded in the first place, that their exclusions do not serve the statute's purpose of protecting federal programs from untrustworthy individuals. We rejected that argument in determining that the I.G. was authorized to exclude Petitioners, and it provides no basis to reduce the length of the exclusions. The I.G. could very reasonably conclude that lengthy exclusions are appropriate to protect federal programs from individuals whose culpable failure to carry out substantial responsibilities overseeing the production and sale of enormous quantities of an addictive controlled substance permitted the fraudulent promotion of such substance to flourish unchecked for over five years, notwithstanding their later cooperation with authorities.

Petitioners also argue that the length of their exclusions unreasonably exceeds those imposed in "far more egregious cases." P. Br. at 56. They cite ALJ decisions, and a Board case, involving incarceration and/or evidence of criminal intent by the excluded individuals. Comparisons with other cases are not controlling and of limited utility given that aggravating and mitigating factors "must be evaluated based on the circumstances of a particular case" (57 Fed. Reg. at 3314), which can vary widely. Nonetheless, there is ample precedent for lengthy exclusions. See, e.g., Marcia C. Smith, a/k/a Marcia Ellison Smith, DAB No. 2046 (2006) (12 years); Russell Mark Posner, DAB No. 2033 (2006) (14 years) Stacey R. Gale, DAB No. 1941 (2004) (15 years); Jeremy Robinson at 8-9 (upholding 15-year exclusion and citing cases that sustained 15-year exclusions); Stacy Ann Battle, D.D.S., DAB No. 1843, at 8 (2002) (upholding 10-year exclusion and noting that the Board has "many times" upheld exclusions for 10 years in appropriate cases). These cases generally involve financial losses far less than the amounts discussed here.

Moreover, Petitioners' culpable failures to act facilitated the commission of fraud by unidentified persons under their authority and had wide-ranging consequences; that the crime of which they were convicted did not require a showing of bad intent on Petitioners' part thus does not have the weight they assert. Notwithstanding Petitioners' assertion that a 15-year exclusion is "career-ending" (Tr. at 6), the Board has observed that a 15-year exclusion is not permanent, Jeremy Robinson, and further that "dramatic impact" on future employment opportunities does not itself "undercut a determination about the period of time needed to protect" federal programs and their beneficiaries from potential harm. Narendra M. Patel, M.D., DAB No. 1736, at 25 (2000), aff'd, 319 F.3d 1317 (11th Cir. 2003), citing Joann Fletcher Cash, DAB No. 1725, at 19 (2000).

Thus, we conclude that the two aggravating factors alone support a lengthy period of exclusion, and could arguably support 15-year exclusions, even when the one mitigating factor is considered. However, we have determined that the I.G. and the ALJ failed to establish the existence of the aggravating factor relating to adverse mental or physical impact on individuals. The ALJ gave this aggravating factor serious consideration in concluding that 15-year exclusions were reasonable; accordingly, our determination that it does not apply supports reducing the length of the exclusions. We conclude that, in the absence of

that factor, and in light of the aggravating factors we have upheld, exclusions of 12 years are reasonable.

Petitioners also argue that the mitigating factor of their cooperation with federal and state officials warrants a greater reduction of their exclusions than the five-year reduction the I.G. granted. The ALJ stated that the I.G. "determined that Petitioner[s] cooperated with law enforcement officials." ALJ Decisions at 14. Petitioners argue that this statement overlooks their cooperation with other types of governmental officials and that the ALJ also failed to recognize "the depth and breadth of Petitioners' cooperation and collaboration" with federal and state officials. P. Br. at 48. Petitioners' assertion that *the ALJ* overlooked cooperation with other than "law enforcement" officials thus does not indicate that the I.G. failed to consider all relevant evidence Petitioners provided.

In determining that this mitigating factor warranted reducing the exclusions by five years, the I.G. utilized the discretion in setting the length of exclusions that the regulations accord him and the vast experience in doing so that was acknowledged in the preamble to the regulation. The I.G. made the determination to reduce Petitioners' exclusions following their submission of the materials they cite as evidence of their cooperation. As the ALJ noted, the I.G. reduced their exclusions by 25%; this substantial percentage reduction is even larger when compared to the 12-year exclusion that we determine is reasonable here.[12] The ALJ thus did not err in concluding that the I.G. reasonably applied this mitigating factor in determining the duration of Petitioners' exclusions, in light of the significant aggravating factors that the I.G. established.

[12] It is not clear in any event that some of the efforts Petitioners cite, such as suspending sale of 160-mg OxyContin tablets deemed more susceptible to abuse by teenagers (P. Ex. 26, at 26), constitute cooperation as defined in the regulation. Additionally, Petitioners do not assert that their cooperation led to the conviction or exclusion of anyone who actively participated in Purdue's fraudulent misbranding and promotion of OxyContin; those individuals, according to Petitioners, are unidentified. Tr. at 7-8. Petitioner's inability to identify anyone who carried out the fraud bolsters our conclusion that Petitioners were culpable in their failure to exercise adequately the responsibilities vested in them by their corporate positions.

Accordingly, we revise the ALJ's FFCLs "C" and "C.1" to read as follows:

> *C. A 12-year exclusion falls within a reasonable range.*
>
> > *1. Two aggravating factors justify substantially lengthening the period of exclusion beyond the three year baseline.*

Conclusion

For the reasons explained above, we sustain Petitioners' exclusions under sections 1128(b)(1) and (3) of the Act, but reduce the length of their exclusions from 15 to 12 years.

_____/s/ _____
Leslie A. Sussan

_____/s/ _____
Constance B. Tobias

_____/s/ _____
Sheila Ann Hegy
Presiding Board Member