Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Eduardo Miranda, M.D.
Docket No. A-16-118
Decision No. 2755
December 22, 2016

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Eduardo Miranda, M.D. (Petitioner) appeals a decision by an Administrative Law Judge (ALJ) upholding on the written record his exclusion by the Inspector General (I.G.) from participation in all federal health care programs for a period of 13 years. *Eduardo Miranda, M.D.*, DAB No. CR4639 (2016). The ALJ concluded that the I.G. was required to exclude Petitioner for a minimum period of five years pursuant to section 1128(a)(1) of the Social Security Act (Act).[1] The ALJ further concluded that a 13-year exclusion is reasonable based on the two aggravating factors on which the I.G. relied.

On appeal, Petitioner does not dispute that the I.G. was required to exclude him for five years, nor does Petitioner dispute the existence of the two aggravating factors. However, Petitioner challenges the ALJ's conclusion that a 13-year exclusion is reasonable, asserting that the ALJ Decision "fails to properly evaluate the quality of the circumstances surrounding the aggravating factors cited and relied upon by the I.G." Petitioner's (P's) Br. at 4.

For the reasons set out below, we conclude that the 13-year period of exclusion is within a reasonable range based on the two aggravating factors and the absence of mitigating factors. Accordingly, we affirm the ALJ's decision to uphold the exclusion imposed by the I.G.

[1] The current version of the Act can be found at www.ssa.gov/OP_Home/ssact/ssacttoc.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

Legal Background

Section 1128(a)(1) of the Act states that the Secretary of the Department of Health and Human Services "shall exclude" from participation in federal health care programs "[a]ny individual or entity that has been convicted, under Federal or State law, of a criminal offense related to the delivery of an item or service under title XVIII [Medicare] or under any State health care program." When an exclusion is imposed under section 1128(a)(1), section 1128(c)(3)(B) requires that the "minimum period of exclusion . . . be not less than five years[.]"[2]

The mandatory five-year minimum period of an exclusion under section 1128(a)(1) may be extended based on the application of the aggravating factors in 42 C.F.R. § 1001.102(b). The two aggravating factors found by the I.G. in this case are: "[t]he acts resulting in the conviction, or similar acts, . . . caused, or were intended to cause, a financial loss to a Government program or to one or more entities of $5,000 or more" and "[t]he acts that resulted in the conviction, or similar acts, were committed over a period of one year or more." 42 C.F.R. § 1001.102(b)(1), (b)(2). If an exclusion period is extended based on the application of one or more aggravating factors, the I.G. may then apply any mitigating factors specified in section 1001.102(c)(1)-(3) to reduce the length of the exclusion period to no less than the mandatory minimum five years. *Id.* § 1001.102(c).

An excluded individual may request a hearing before an ALJ, but only on the issues of whether the I.G. had a basis for the exclusion and whether the length of an exclusion longer than the mandatory minimum period is unreasonable. *Id*. §§ 1001.2007(a), 1005.2(a). Any party dissatisfied with the ALJ's decision may appeal the decision to the Board. *Id*. § 1005.21.

Case Background[3]

Petitioner practiced as an oncologist, providing medical services to cancer patients. He ordered, prescribed, and administered oncology drugs obtained from a foreign source that were not Food and Drug Administration (FDA)-approved. Petitioner then billed Medicare, Medicaid, and Blue Cross/Blue Shield for the drugs and received a total of more than $1 million in reimbursement from those programs. ALJ Decision at 2 (citations omitted).

---

[2] Paragraph (G) of section 1128(c)(3) requires an exclusion of more than five years in circumstances not present here.

[3] The factual information in this section is drawn from the ALJ Decision and the record and is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace, modify, or supplement the ALJ's findings of fact.

Petitioner pled guilty in federal district court to one misdemeanor count of introducing misbranded drugs into interstate commerce, in violation of 21 U.S.C. §§ 331(a), 352(f) and 18 U.S.C. § 2. ALJ Decision at 2. The plea agreement stated that Petitioner ordered five cancer drugs from a pharmacy located in Canada and that the drugs "were not approved for distribution or use in the U.S. and were misbranded as (1) the labels did not bear the 'Rx Only' language as required by the Food and Drug Administration ('FDA'); (2) the labels did not bear National Drug Code ('NDC') numbers that FDA-approved versions bear; and (3) some of them had instructions/labeling in other languages, such as French, contrary to FDA-approved versions." I.G. Ex. 4, at 7. The court entered judgment against Petitioner on November 25, 2014, sentenced him to five years' probation, and ordered him to pay the health care programs $1,004,438.50 in restitution. ALJ Decision at 2.

By letter dated May 29, 2015, the I.G. notified Petitioner that, pursuant to section 1128(a)(1) of the Act, he was being excluded from Medicare, Medicaid, and all federal health care programs for a minimum period of 13 years based on the aggravating factors in 42 C.F.R. § 1001.102(b)(1) and (b)(2). I.G. Ex. 1. With respect to the aggravating factor in section 1001.102(b)(1), the I.G. stated that the "court ordered you to pay restitution of approximately $1,004.400." *Id*. at 2. With respect to the aggravating factor in section 1001.102(b)(2), the I.G. stated that the "acts occurred from about October 2007 to about January 2009." *Id*.

Petitioner timely requested a hearing before the ALJ. The parties submitted briefs and exhibits, all of which the ALJ accepted into evidence, and the parties agreed that an in-person hearing was not necessary. The parties also agreed that Petitioner was convicted of a crime related to the delivery of an item or service under Medicare or a state health care program and must be excluded from program participation for at least five years. The ALJ therefore determined that the sole issue before her was "whether the length of the exclusion is reasonable." ALJ Decision at 2.

The ALJ concluded that "[b]ased on the aggravating factors and the absence of any mitigating factors, a thirteen-year exclusion is reasonable." ALJ Decision at 2. Specifically, the ALJ concluded that "the IG may justifiably increase significantly Petitioner's period of exclusion" based on the aggravating factor at section 1001.102(b)(1) ("Program financial loss") because "[a]t a minimum . . . Petitioner's crimes cost [Medicare, Medicaid, and Blue Cross/Blue Shield] significant financial losses – 200 times greater than the $5,000 threshold for aggravation[.]" *Id*. at 3. The ALJ also concluded that the aggravating factor specified in section 1001.102(b)(2) ("Length of criminal conduct") was present because "the acts that resulted in Petitioner's conviction and similar acts were committed over a period that exceeded the one year necessary to

constitute an aggravating factor." *Id*. at 4. The ALJ further concluded that "no mitigating factor offsets the aggravating factors present in this case" because none of the three mitigating factors specified in section 1001.102(c) were present here. ALJ Decision at 4-5.

Standard of Review

Our standard of review of an exclusion imposed by the I.G. is established by regulation. We review a disputed issue of fact as to "whether the initial decision is supported by substantial evidence on the whole record." 42 C.F.R. § 1005.21(h). We review a disputed issue of law as to "whether the initial decision is erroneous." *Id*.

Analysis

Petitioner argues on appeal that the ALJ did not apply the correct standard of review in determining whether the 13-year period of exclusion was not unreasonable. According to Petitioner, the ALJ "refused to consider the individual circumstances of [his] case" and instead "rigidly considered only the amount of restitution [he] was ordered to pay and the length of the underlying offense and essentially rubber-stamped the 13-year exclusion." P's Br. at 5. Petitioner maintains that the correct standard of review "clearly requires an evaluation of 'the quality of the circumstances surrounding' the aggravating factors relied upon by the I.G." *Id*. Petitioner takes the position that "those circumstances show that these two factors deserve little weight." *Id*. at 6. Petitioner therefore requests that "the exclusion period imposed by the I.G. be reduced to five years, or to a reasonable period of less than 13 years." *Id*. at 16.

As discussed below, we conclude that the ALJ applied the correct standard of review and did not err in finding the 13-year period of exclusion not unreasonable based on the aggravating factors in sections 1001.102(b)(1) and (b)(2).

1. *The ALJ did not err in according significant weight to the aggravating factor in section 1001.102(b)(1).*

The ALJ's decision to accord "significant weight" to the aggravating factor in section 1001.102(b)(1) is consistent with Board and court precedent. The Board has held that that the amount of restitution ordered by a court is "a reasonable valuation of financial losses of the program."[4] *Laura Leyva*, DAB No. 2704, at 9 (2016) and Board decisions cited therein. The Board has further held that "it is entirely reasonable to consider a program loss amount substantially larger than the $5,000 threshold . . . an 'exceptional

[4] Moreover, as the ALJ pointed out, in this case, it was not necessary to rely on the restitution amount to infer the amount of the program loss since the latter amount "has been firmly established by the court[.]" ALJ Decision at 3.

aggravating factor' to be accorded significant weight." *Id*., citing *Sushil Aniruddh Sheth, M.D.*, DAB No. 2491, at 7 (2012), *aff'd, Sheth v. Burwell*, No. 14-5179, 2015 WL 3372286 (D.C. Cir. May 7, 2015), citing *Jeremy Robinson*, DAB No. 1905, at 12 (2004) and *Donald A. Burstein, Ph.D.*, DAB No. 1865, at 12 (2003).

Petitioner argues that this aggravating factor "deserves little weight" despite the fact that the court ordered him "to pay a relatively large amount in restitution" to the insurers who had reimbursed him "for cancer medications and related services he provided to his patients." P's Br. at 6. Petitioner explains this argument as follows:

> The only reason [Petitioner] was not entitled to those payments is that he unknowingly received the drugs from an unapproved supplier in Canada that had provided drugs that were not properly packaged for distribution in the United States. . . . There is no evidence or allegation that [Petitioner] should not have prescribed, administered, or sought reimbursement for any of the drugs in question, assuming they had come from an approved supplier and had the proper labeling. Thus, if [Petitioner] had . . . ordered the drugs from an approved supplier, he would have been entitled to reimbursement of the entire $1,004,438.50 for the drugs and services he provided. In other words, Medicare, Medicaid, and Blue Cross/Blue Shield would have paid or "lost" the same amounts even if there had been no violation.

Id.; *see also* P's Reply Br. at 3-4.[5]

Where an exclusion period has been extended to more than the mandatory minimum five years based on one or more aggravating factors, only the mitigating factors specified in the regulations may be considered and applied to reduce the length of the exclusion to no less than five years. 42 C.F.R. § 1001.102(c). Even assuming Petitioner's patients suffered no harm from the misbranded drugs, that does not fall within the scope of any of

[5] The procedural regulations that apply here state: "The Board will not consider issues not raised in the notice of appeal or in the opposing party's response, nor issues which could have been presented to the ALJ but were not. 42 C.F.R. § 1005.21(e). Petitioner argued in his brief before the ALJ that "the restitution amount included payment for legitimate and proper services and treatments to patients that were beyond the scope of the strict liability misdemeanor conviction." P.'s Informal Br., 3rd- 4th pages. Since this arguably suggests the argument in Petitioner's appeal brief, we address the latter argument here.

the mitigating factors.[6] Indeed, the regulations establish as a separate aggravating factor that "[t]he acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on one or more program beneficiaries or other individuals[.]" 42 C.F.R. § 1001.102(b)(3). The absence of that aggravating factor, if any, does not detract from the significance of the aggravating factor in section 1001.102(b)(1).

In addition, Petitioner points to nothing in the record to support his underlying assumption that the misbranded drugs he ordered, prescribed and administered to cancer patients were the same as the FDA-approved drugs marketed under the same names. Indeed, Petitioner ignores the fact that the purpose of requiring that drugs have FDA approval is to ensure that they are safe and effective. *See, e.g.*, I.G. Ex. 3 (Criminal Information in Petitioner's case) at 2 (stating that FDA was "charged with the responsibility of protecting the health and safety of the American public by[] enforcing the Food, Drug and Cosmetic Act" and that FDA "enforced statutes which required that drugs bore labels and labeling that enabled health care providers and consumer[s] to use them in a safe manner[.]")

Accordingly, we conclude that the very large amount of restitution ordered by the court is a sufficient basis for extending Petitioner's period of exclusion beyond the mandatory minimum of five years.

---

[6] Section 1001.102(c) states:

> . . . . Only the following factors may be considered mitigating—
> (1) The individual or entity was convicted of 3 or fewer misdemeanor offenses, and the entire amount of financial loss (both actual loss and intended loss) to Medicare or any other Federal, State or local governmental health care program due to the acts that resulted in the conviction, and similar acts, is less than $1,500;
> (2) The record in the criminal proceedings, including sentencing documents, demonstrates that the court 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; or
> (3) The individual's or entity's cooperation with Federal or State officials resulted in—
> (i) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,
> (ii) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or
> (iii) The imposition against anyone of a civil money penalty or assessment under part 1003 of this chapter.

2. *The ALJ did not err in according some weight to the aggravating factor in section 1001.102(b)(2).*

In upholding the I.G.'s imposition of a 13-year exclusion, the ALJ also gave weight to the aggravating factor in section 1001.102(b)(2). Petitioner acknowledges that the acts that resulted in his conviction were committed over approximately 15 months. P's Br. at 8. Since that period exceeds the 12-month threshold for this aggravating factor, it was a proper basis for extending Petitioner's exclusion beyond the minimum five-year period.

Petitioner nevertheless argues that the circumstances surrounding this factor show that it is entitled to "little weight." P's Br. at 8. Petitioner maintains that "[l]ike all of the aggravating and mitigating factors, it must be evaluated in light of the overarching purpose of protecting federally-funded health care programs from 'untrustworthy individuals.'" *Id*., citing *Vinod Chandrashekhar Patwardhan, M.D.*, DAB No. 2454 (2012) and *Jeremy Robinson*. Petitioner explains as follows:

> Here, the length of [Petitioner's] offense has no bearing on his trustworthiness or "integrity" because it was completely unknowing and unintentional. There is no evidence that [Petitioner] committed any intentional wrongdoing or participated in a fraudulent scheme. . . .
>
> Furthermore, it is uncontroverted that [] as soon as [Petitioner] learned that QSP [the supplier from which he ordered the drugs] was an unapproved supplier that was selling drugs that were not approved for distribution in the United States, [Petitioner] immediately stopped using them . . . .

Id. at 9; *see also* P's Reply Br. at 5.

Petitioner's argument has no merit. Petitioner's alleged lack of intent to order and administer misbranded drugs on its face is not one of the mitigating factors specified in the regulation; accordingly, it cannot be considered in determining whether Petitioner's exclusion for more than the mandatory minimum five years is unreasonable.

Moreover, although Petitioner is correct that the purpose of an exclusion is "to protect federally-funded health programs from untrustworthy individuals" (*see, e.g.*, *Patwardhan* at 6, quoting *Burstein* at 12), "general 'trustworthiness'" is not "an independent basis, i.e., independent from the specified aggravating and mitigating factors, for determining whether the period of an exclusion is unreasonable." *Mohamed Basel Aswad, M.D.*, DAB No. 2741, at 11 (2016), citing *Sheth*, DAB No. 2491. In *Sheth*, the Board stated in part that "[t]he aggravating and mitigating factors . . . were designed to evaluate" the

"threat that Petitioner poses to the Medicare program and its beneficiaries." *Sheth* at 16, citing *Robinson* and *Joann Fletcher Cash*, DAB No. 1725 (2000). Accordingly, as the Board stated in *Robinson*, the "aggravating and mitigating factors reflect the degree or level of the provider's untrustworthiness." *Robinson* at 11 (citing *Cash* at 18).

Petitioner does not dispute that the aggravating factor in section 1001.102(b)(2) is present here. Thus, even if the circumstances surrounding this aggravating factor do not show that Petitioner is extremely untrustworthy, it is still entitled to some weight in determining the length of the exclusion period. The ALJ relied primarily on the aggravating factor discussed in the preceding section and thus did not give undue weight to the aggravating factor in section 1001.102(b)(2).[7]

3. *The ALJ's conclusion that a 13-year exclusion is not unreasonable is supported by substantial evidence and free of legal error.*

As noted above, under 42 C.F.R. § 1001.2007(a)(1), where, as here, a petitioner challenges the length of an exclusion, the issue before the ALJ is whether the length of the exclusion "is unreasonable." The preamble to the final regulations explains that the regulations vest "broad discretion" in the I.G. to determine the length of exclusion. 57 Fed. Reg. 3298, 3321 (1992). The preamble further states: "So long as the amount of the time chosen by the [I.G.] is within a reasonable range, based on demonstrated criteria, the ALJ has no authority to change it[.]" *Id*. As discussed below, we find no error in the ALJ's conclusion that the 13-year exclusion imposed on Petitioner was within a reasonable range and not unreasonable.

[7] Even if Petitioner did not intend to order misbranded drugs, it does not necessarily follow that Petitioner can be trusted to treat cancer patients with safe and effective drugs. We agree with the ALJ that "even accepting that [Petitioner] was not aware of the drugs' origins does not mean that he is not a threat to federal health care programs. His actions were either deliberate or negligent, and a negligent physician can do much harm." ALJ Decision at 5.

Since we need not reach the issue of Petitioner's intent, we do not address the I.G.'s objection to the reference in Petitioner's reply brief to certain evidence not in the record to support his assertion that he unknowingly ordered misbranded drugs. *See* I.G. Sur-Reply at 2, citing P's Reply Br. at 8, n.2 and n.3.

Petitioner argues that the 13-year exclusion imposed on him is not within a reasonable range, asserting that "[o]ther cases involving the same exclusion period are far more egregious." P's Br. at 10. According to Petitioner, "in virtually every instance, the offense was a felony; there were more aggravating factors; and the circumstances surrounding those factors show[] far more reason to consider the petitioner untrustworthy and a continuing threat to federally-funded health care programs." *Id*. at 10-11.[8]

The Board has consistently held that comparisons with other cases where petitioners were excluded are of limited value and not dispositive. In a recent decision summarizing its treatment of this issue, the Board stated:

> The Board has made it clear that the assessment of aggravating factors (and mitigating factors, if any), is first and foremost case-specific. Every case involves a complex interaction of diverse circumstances and regulatory factors with varying weights. For this very reason case comparisons, while sometimes informative for the ALJ's or the Board's decision-making in a given case, are of limited value and ultimately are not dispositive on the question of reasonableness of an exclusion period in a given case. *See, e.g.*, *Sheth, M.D.*, DAB No. 2491, at 6.

Eugene Goldman, M.D., a/k/a Yevgeniy Goldman, M.D., DAB No. 2635, at 11 (2015)

Thus, the ALJ was correct to focus on the specific facts of this case: that the acts resulting in Petitioner's conviction caused significant financial losses to healthcare programs, i.e., more than 200 times the $5,000 required for an aggravating factor under section 1001.102(b)(1); that the acts that resulted in the conviction occurred over a period that exceeded the one year required for an aggravating factor under section 1001.102(b)(2); and that there were no mitigating factors as defined in section 1001.102(c)(1)-(3). The ALJ concluded that, in light of these facts, the 13-year exclusion imposed by the I.G. was not unreasonable. ALJ Decision at 5-6.

Moreover, the cases Petitioner cites are not a sufficient basis on which to conclude otherwise. Petitioner identifies seven cases in which there were three or more aggravating factors and no mitigating factors, and a 13-year exclusion was imposed by the I.G. and upheld by the ALJ (and by the Board where the petitioner appealed). P's Br. at 11-13. Petitioner also identifies three cases in which an exclusion of 13 years or more imposed by the I.G. was reduced by the ALJ to 12 years or less. *Id*. at 13-14. Petitioner asserts that these cases are "[i]n stark contrast" to his since his "offense was a

[8] Petitioner asserted before the ALJ that most of the cases the I.G. cited in its informal brief to support the 13-year exclusion "involved much more serious offenses and incarceration, [yet] many still had lesser terms of exclusion[.]" P's. Informal Br., 8th – 9th pages (citing cases). According to Petitioner, this showed that the I.G. "did not take into account the circumstances of Petitioner's individual case." *Id*. Petitioner relies on different cases in his appeal brief, however.

misdemeanor, strict-liability offense, and only *two* aggravating factors were even claimed" and "the weight that those factors should receive under the circumstances is minimal." *Id*. at 15 (italics in original); *see also* P's Reply Br. at 7. However, as we discussed above, Petitioner's alleged lack of intent to commit the offense is not a mitigating factor under the applicable regulations. Furthermore, we concluded above that the ALJ properly accorded significant weight to one of the aggravating factors. Thus, Petitioner's case is not as distinguishable from the other cases as he maintains.

Petitioner also identifies two cases in which petitioners who were convicted of the same offense as he was (causing misbranded drugs to be introduced into interstate commerce) were excluded for five years. P's Br. at 15, citing *Leo Parrino*, DAB No. CR3287 (2014) and *Linda Schmidt*, DAB No. CR3746 (2015). Petitioner takes the position that he should have been excluded for only five years because all three cases are "equivalent." P's Reply Br. at 8. However, the amount of restitution Petitioner was required to pay is many orders of magnitude greater than the restitution amount in both *Parrino* and *Schmidt* ($14,098 and $20,000, respectively). Petitioner argues that that difference is "essentially cancel[led] . . . out" because the acts that resulted in the conviction took place over a longer period of time in *Parrino* and *Schmidt* (which Petitioner identified as 54 months and 27 months, respectively) than in Petitioner's case (15 months). *Id*. However, as discussed above, the ALJ relied primarily on the restitution amount in concluding that Petitioner's exclusion for 13 years was not unreasonable and gave only some weight to the length of time over which the acts resulting in the conviction occurred. We see no reason to conclude that the fact that Petitioner committed acts of so vastly greater impact is somehow outweighed because he did so over a somewhat shorter time frame than in the other two cited cases. We conclude that, even if the relatively small differences in the lengths of time involved were considered to be significant, that would not establish that Petitioner was improperly treated differently from petitioners in similar cases.

Accordingly, we conclude that Petitioner has not shown that the ALJ erred in concluding that a 13-year period of exclusion in his case was not unreasonable and was within a reasonable range.

Conclusion

For the foregoing reasons, we affirm the ALJ Decision.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Christopher S. Randolph
Presiding Board Member