Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Vinod Chandrashekhar Patwardhan, M.D.
Docket No. A-12-41
Decision No. 2454
April 10, 2012

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Vinod Chandrashekhar Patwardhan, M.D. (Petitioner) appeals the December 8, 2011 decision of Administrative Law Judge (ALJ) Carolyn Cozad Hughes excluding Petitioner from all federal health care programs for a period of 12 years. *Vinod Chandrashekhar Patwardhan, M.D.*, DAB CR2471 (2011).[1] The Inspector General for the Department of Health and Human Services (I.G.) excluded Petitioner for 23 years based on Petitioner's convictions related to the smuggling and illegal distribution of misbranded medications from other countries, including India and Honduras. The ALJ upheld the basis for the exclusion as well as the I.G.'s conclusion that three aggravating factors and no mitigating factors were present. *Id.* at 4-5. However, the ALJ concluded that a 23-year exclusion of Petitioner was "unreasonably harsh," and that a 12-year exclusion was "within a reasonable range." *Id.* at 7. Petitioner now appeals the length of the exclusion, arguing that a 12-year exclusion period remains unreasonable. Petitioner argues that five years, the statutory minimum exclusion period for mandatory exclusions, is appropriate in this case. For the reasons explained below, we affirm the 12-year exclusion of Petitioner from participation in all federal health care programs.

Statutory and Regulatory Background

The Social Security Act (Act) requires the Secretary of the Department of Health and Human Services (Secretary) to exclude an individual or entity from participation in all federal health care programs if that individual or entity has been convicted of certain criminal offenses. Act § 1128(a).[2] The Act, in relevant part, directs the Secretary to exclude:

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[1] In the criminal proceedings related to this case Petitioner's name was spelled "Vinod Chandrashekm Patwardhan." *See United States v. Patwardhan*, No. ED CR 08-00172 VAP (C.D. Cal. July 18, 2009), *aff'd*, 422 Fed. App'x 614 (9th Cir. 2011).

[2] The current version of the Act is available at http://www.socialsecurity.gov/OP_Home/ssact/ssact.htm. On this website, each section of the Act contains a reference to the corresponding chapter and section in the United States Code.

> (1) Any individual or entity that has been convicted of a criminal offense related to the delivery of an item or service under [the Medicare program] or under any State health care program.
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> * * *
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> (3) Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program (other than those specifically described in paragraph (1)) operated by or financed in whole or in part by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

Act § 1128(a)(1), (3). The Secretary has delegated her exclusion authority to the I.G. by regulation. *See* 42 C.F.R. § 1001.101(b).

Any mandatory exclusion that the I.G. imposes must be for a minimum of five years. Act § 1128(c)(3)(B); 42 C.F.R. § 1001.102(a). The I.G. may lengthen an exclusion period if any of the nine aggravating factors listed in section 1001.102(b) are present. The relevant aggravating factors in this case include:

> (1) The acts resulting in the conviction, or similar acts, that caused, or were intended to cause, a financial loss to a Government program or to one or more entities of $5,000 or more. (The entire amount of financial loss to such programs or entities, including any amounts resulting from similar acts not adjudicated, will be considered regardless of whether full or partial restitution has been made);
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> (2) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;
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> * * *
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> (5) The sentence imposed by the court included incarceration[.]

Section 1001.102(b)(1), (2), (5). If the I.G. determines that any aggravating factor is present and justifies extending the exclusion period beyond five years, he may consider whether any mitigating factors are present that would reduce the exclusion period to no less than five years. Section 1001.102(c). Only the mitigating factors listed in section 1001.102(c) may be considered when reducing an exclusion period. *Id.*

When the I.G. excludes an individual or entity, that individual or entity may request a hearing before an ALJ. 42 C.F.R. §§ 1001.2007(a), 1005.2(a). The ALJ's review is limited to whether the "basis for the imposition of the sanction exists" and whether the "length of exclusion is unreasonable." Section 1001.2007(a)(1). Any party dissatisfied with the ALJ's decision may appeal to the Board. Section 1005.21(a).

Case Background

The facts of this case are undisputed. Petitioner is a physician licensed in California and board-certified in oncology and primary care.[3] Petitioner provides medical services in Upland (San Bernardino County), California. Petitioner claims, and the I.G. does not dispute, that Petitioner is the only oncologist in the Upland area who provides cancer treatment to indigent patients.

On May 8, 2009, a jury sitting in the United States District Court for the Central District of California convicted Petitioner of numerous criminal offenses arising from his scheme to smuggle misbranded and unregulated cancer medications from other countries, including India and Honduras, then distribute those medications to Petitioner's patients in the United States.[4] I.G. Ex. 2 (Judgment & Probation Order), at 1. As part of Petitioner's scheme, he often did not charge patients for the misbranded medication, but "when reimbursement was available," he would seek reimbursement for the misbranded medication through the Medicare and California Medicaid (Medi-Cal) programs. P. Ex. 2 (tr. of sentencing hr'g), at 59. Petitioner's scheme lasted for approximately three years, from 2005 to mid-2008. P. Br. at 3; I.G. Br. at 8. On September 24, 2009, the District Judge sentenced Petitioner to nine months of home detention, five years of probation, and ordered Petitioner to pay $1,313,634.10 in restitution to the Centers for Medicare and Medicaid Services (CMS) and Medi-Cal collectively. P. Ex. 2, at 83-87; I.G. Ex. 2, at 1.

On November 19, 2010, Dr. David Maxwell-Jolly, in his capacity as Director of the California Department of Health Care Services, wrote to the Special Agent in Charge in the I.G.'s San Francisco office and requested that the I.G. grant a waiver pursuant to 42 C.F.R. § 1001.1801(b) of any exclusion the I.G. may impose against Petitioner. P. Ex. 8

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[3] On August 26, 2010, the Medical Board of California revoked Petitioner's medical license, but stayed the revocation pending Petitioner's successful completion of a five-year probation period. P. Ex. 3 (Medical Board Decision), at 19. The Medical Board's decision authorizes Petitioner to practice medicine subject to the conditions of his probation. *Id.* at 19-25.

[4] The jury convicted Petitioner of one count of conspiracy, 18 U.S.C. § 371; two counts of introducing misbranded drugs into interstate commerce, 21 U.S.C. §§ 331(a), 333(a)(2), 352(c), 352(f)(1); two counts of smuggling goods into the United States (drugs purchased in India) contrary to law, 18 U.S.C. § 545; one count of knowingly and intentionally aiding, abetting, counseling, commanding, inducing, procuring, and causing the fraudulent and knowing importation and bringing into the United States goods contrary to law (drugs purchased in Honduras), 18 U.S.C. §§ 2(a)-(b), 545; one count of criminal forfeiture, 18 U.S.C. § 982(a)(2)(B), 21 U.S.C. § 853(p); and one count of civil forfeiture, 18 U.S.C. § 981(a)(1)(C), 28 U.S.C. § 2461(c), 21 U.S.C. § 853(p). *See* I.G. Ex. 2, at 1.

(letter from Director), at 1. Citing favorable comments from the District Judge as well as the State ALJ in the medical license hearing, the Director asserted that Petitioner was "the only oncologist to treat the poor and indigent cancer patients in his area" and that the Director "had [Petitioner's] assurance that he will respect and follow all rules and regulations related to continued participation in Federal health care programs in the future." *Id.* at 1-2.

By letter dated June 30, 2011, the I.G. excluded Petitioner from all federal health care programs for 23 years, but granted Petitioner a limited waiver in response to the request from Director Maxwell-Jolly. The I.G. waived Petitioner's exclusion only with respect to "oncological items and services [Petitioner] provides in Upland, California for as long as the California Department of Health Care Services determines that such need exists." I.G. Ex. 1 (exclusion notice letter), at 2. The I.G. stated that the length of the exclusion from all federal health care programs not covered by the waiver was based on the presence of three aggravating factors: (1) the acts resulting in the conviction caused losses to Government programs of more than $5,000; (2) the acts resulting in the conviction were committed over a period of more than one year; and (3) the sentence imposed by the court included a period of incarceration. *Id.* Petitioner appealed the exclusion to the ALJ, arguing that the length of the exclusion imposed was unreasonable. Petitioner did not challenge the basis of the exclusion or that he was subject to the five-year minimum exclusion period for an exclusion imposed under section 1128(a) of the Act. *See* ALJ Decision at 2.

In her decision, the ALJ found that Petitioner did not dispute the presence of the three aggravating factors cited by the I.G. in the exclusion letter. *Id.* at 6. The ALJ also found that no mitigating factors were present, rejecting Petitioner's assertion that his "altruism" was a basis for shortening the exclusion period. *Id.* at 6-7. The ALJ stated that altruism is not a "mental, emotional, or physical condition" and so did not constitute a mitigating factor under section 1001.102(c)(2). *Id.* at 7.

The ALJ discussed the background of Petitioner's scheme, and stated that she recognized Petitioner was "not typical of the convicted felons excluded from program participation." *Id.* at 7. The ALJ then stated that it was "well established by the record before me" that Petitioner "was motivated by misguided altruism." *Id.* Nevertheless, the ALJ stated that she could not "disregard the significant aggravating factors in this case," and rejected Petitioner's request to reduce the exclusion to five years. *Id.* The ALJ then concluded:

> On the other hand, I agree with [the District Judge] and [the State ALJ]: Petitioner poses less of a risk to program integrity than many of those subject to a minimum period of exclusion. Given the totality of the circumstances in

> this case, I find a 23-year exclusion unreasonably harsh and reduce that period to 12 years, which I consider within a reasonable range.

Id.

Petitioner timely appealed the ALJ Decision to the Board, arguing that the 12-year exclusion period is unreasonable.

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). Substantial evidence is "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401 (1971) (citing *Consolidated Edison Co. v. N.L.R.B.*, 305 U.S. 197, 229 (1938)). We review a disputed issue of law as to "whether the initial decision is erroneous." 42 C.F.R. § 1005.21(h).

Analysis

Petitioner's sole argument on appeal is that the 12-year exclusion imposed in this case is unreasonable. Petitioner asserts that the three aggravating factors upon which the I.G. relied "are barely present and do not support an exclusion for more than the minimum statutory period." P. Br. at 3. Citing letters of praise offered from his patients and state politicians, Petitioner argues that "the amount of support he has received due to his long history of humanitarianism and altruism should not be shunned in determining a reasonable length of exclusion." *Id.* Petitioner also claims he "swiftly paid restitution," and argues that this payment demonstrates that his conduct was motivated by "altruism" rather than greed. *Id.* In addition, Petitioner argues that the limited exclusion waiver granted by the I.G. shows the ongoing need to have Petitioner participating in federal health care programs, and lessens the need to protect these programs from him. *Id.*

The I.G. did not appeal the ALJ Decision. Although the I.G. notes that he "continues to believe that a 23-year length of exclusion is reasonable when considering the systematic fraud perpetrated on the Federal health care programs by [Petitioner]," I.G. Br. at 6, n.4, he does not take exception to the ALJ's conclusions regarding the length of the exclusion. The I.G. argues that "a 12-year exclusion is reasonable and is supported by the law and substantial evidence on the whole record," and requests that the Board "affirm the ALJ's decision upholding [Petitioner's] 12-year exclusion under sections 1128(a)(1) and 1128(a)(3) of the Act." *Id.* at 14.

Based on the circumstances surrounding the three undisputed aggravating factors and Petitioner's failure to show the existence of any mitigating factors, we agree with the I.G. and the ALJ that an exclusion period longer than the statutory minimum is warranted here. *See* 57 Fed. Reg. 3298, 3315 (Jan. 29, 1992) ("An aggravating factor is one that does not automatically exist in every case, but when it does exist, justifies a longer period of exclusion."). As we discuss below, an exclusion period of 12 years is reasonable in this case.

A. The three undisputed aggravating factors present in this case support the 12-year exclusion imposed by the ALJ.

The Board has stated that when determining whether an exclusion period "falls within a reasonable range, the ALJ must weigh the aggravating and mitigating factors," and "must evaluate the quality of the circumstances surrounding these factors." *Jeremy Robinson*, DAB No. 1905, at 11 (2004) (citing *Keith Michael Everman, D.C.*, DAB No. 1880, at 10 (2003)). Other than noting that nine months of home detention without electronic monitoring was a "comparatively light jail sentence," the ALJ here did not explain how she weighed each of the aggravating factors or evaluated the quality of the circumstances surrounding them in determining that a 12-year exclusion period was within a reasonable range. As explained below, however, we conclude that an exclusion of at least 12 years is amply supported given the circumstances surrounding the three aggravating factors present in this case.

The first aggravating factor in this case is that the "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." 42 C.F.R. § 1001.102(b)(1). The undisputed amount of loss to the government programs here was $1,313,634.10. ALJ Decision at 6; I.G. Ex. 2, at 1. The amount of loss here is over 262 times larger than the $5,000 required to increase the minimum exclusion period. The Board has described the financial loss to a government program as an "exceptional aggravating factor" when, such as here, the loss is "very substantially greater than the statutory minimum." *Robinson* at 11 (determining a $205,000 loss warranted weight sufficient to support a 15-year exclusion period); *Donald A. Burstein, Ph.D.*, DAB No. 1865, at 12 (2003) (determining a $1.7 million loss was an "exceptional aggravating factor"); *see also Paul D. Goldheim, M.D., et al.*, DAB No. 2268, at 28 (2009), *aff'd sub nom. Friedman v. Sebelius*, 755 F. Supp. 2d 98 (D.D.C. 2010) (upholding ALJ's finding that the loss in that case was "astronomical," which supported a 15-year exclusion, but reducing the exclusion to 12 years on other grounds). Based on the scope of the loss here, this aggravating factor should be accorded substantial weight. While no rigid formula applies, the exclusion period in this case must be large enough to reflect the significant program loss and the need "to protect federally-funded health care programs from untrustworthy individuals." *Burstein* at 12 (citing *Patel v. Thompson*, 319 F.3d 1317 (11th Cir. 2003); *Mannocchio v. Kusserow*, 961 F.2d 1539 (11th Cir. 1992)). Thus, the

substantial amount of program loss supports a significant increase in the five-year minimum exclusion period.

The second aggravating factor in this case is that the "acts that resulted in the conviction, or similar acts, were committed over a period of one year or more." 42 C.F.R. § 1001.201(b)(2). It is undisputed that Petitioner's scheme continued from 2005 to mid-2008. ALJ Decision at 6. The length of Petitioner's scheme was three times the amount of time required to increase an exclusion period. The Board has said that the purpose of this aggravating factor "is to distinguish between petitioners whose lapse in integrity is short-lived from those who evidence a lack of such integrity over a longer period . . . ." *Burstein* at 8. The three-year scheme in this case demonstrates Petitioner's ongoing lack of integrity. Thus, this aggravating factor also supports a substantial increase in the five-year minimum exclusion period.

The third aggravating factor in this case is that the "sentence imposed by the court included incarceration." 42 C.F.R. § 1001.102(b)(5). Here, the court sentenced Petitioner to nine months of home detention without electronic monitoring. ALJ Decision at 6; I.G. Ex. 2, at 1. The ALJ correctly stated that "home detention" constitutes "incarceration," which the applicable regulation defines as "imprisonment or any type of confinement with or without supervised release, including, but not limited to, community confinement, house arrest, and home detention." ALJ Decision at 6 (citing 42 C.F.R. § 1001.2(d)). Petitioner argues that this factor should not be accorded much weight because the court sentenced him to the "lightest sentence possible." *See* P. Br. at 2. We do not find this argument persuasive. First, Petitioner does not cite any record support for his assertion that the court's sentence was in fact the "lightest sentence possible." Second, although home detention is a less severe form of "incarceration" than imprisonment, it still constitutes an aggravating factor under the regulations. Petitioner's incarceration, therefore, supports an increase to the exclusion period, although this factor under the circumstances of this case carries less weight than the other two aggravating factors.

Far from being "barely present" as Petitioner asserts, the aggravating factors in this case are "significant," as the ALJ held. ALJ Decision at 7. In fact, the first two aggravating factors discussed above are so significant that these two factors combined amply support a 12-year exclusion period and would most likely support a lengthier exclusion period as well. As discussed above, these two particular aggravating factors demonstrate Petitioner's profound untrustworthiness and the future risk he poses to the Medicare and

Medi-Cal programs.[5] Moreover, when all three aggravating factors are taken together, they are more than sufficient to support the 12-year exclusion imposed by the ALJ.

Accordingly, we conclude that a 12-year exclusion period is within a reasonable range in light of the circumstances of the three aggravating factors present in this case.

B. Petitioner's arguments as to the motivation behind his crimes, the speed with which he paid restitution, and the support of his patients are unpersuasive and irrelevant to our analysis of whether a 12-year exclusion is unreasonable.

We concluded above that the three aggravating factors support lengthening the period of exclusion to 12 years. Petitioner does not argue that any of the mitigating factors listed in section 1001.102(c) are present here. Thus, there is no basis in the regulations for reducing the period of exclusion below 12 years. Petitioner nevertheless argues that a 12-year exclusion is unreasonable on other grounds. As discussed below, most of these arguments are based on faulty premises, and all of these arguments are irrelevant because the factors they identify are not mitigating factors under the regulations.

We are not persuaded by Petitioner's claim that the I.G.'s limited waiver of Petitioner's exclusion shows that Petitioner is not a risk to and should participate in federal health care programs. The I.G. granted a waiver in this case in order to assure that program beneficiaries in Upland, California received essential specialized services that could not be provided by other providers. *See* 42 C.F.R. § 1001.1801(b) (stating that a waiver will only be considered if the individual "is the sole community physician or the sole source of essential specialized services in a community"). Petitioner does not point to any evidence in the record demonstrating that the I.G. granted the waiver because he considered Petitioner to be trustworthy or a low risk to federal health care programs. Rather, the 23-year exclusion imposed by the I.G. shows that he considered Petitioner to be a substantial risk to federal health care programs. Thus, we do not find the I.G.'s limited waiver supports Petitioner's position or is relevant to our determination of whether a 12-year exclusion period is unreasonable.

Petitioner further argues that his actions were based on his "misguided altruism," a notion that the ALJ stated was "well-established by the record before me." *See* ALJ Decision at 7; P. Br. at 2. The ALJ cited no record support for this statement, and we do not find "well-established" support in the record for this characterization of Petitioner's conduct. Billing government programs $1,313,634.10 for smuggled medications that were not

[5] We note, but are not persuaded by, the ALJ's assertion, "I agree with [the District Judge] and [the State ALJ]: Petitioner poses less of a risk to program integrity than many of those subject to a minimum period of exclusion." ALJ Decision at 7. In our view, operating a three-year prescription-drug smuggling scheme that resulted in a $1,313,634.10 loss to federal health care programs and resulted in beneficiaries receiving misbranded and unregulated chemotherapy drugs is strong evidence of the high level of untrustworthiness Petitioner has demonstrated through his prolonged scheme. We also do not find clear support in the record for the District Judge's and State ALJ's opinions that Petitioner is unlikely to commit such fraud again.

approved by the Food and Drug Administration (FDA) and providing these medications to cancer patients without disclosing that the medications were not FDA-approved is hardly evidence of altruism.[6] Although Petitioner provided the medications to some patients without charge, these unregulated medications had the potential to harm the very people Petitioner alleges he was helping. *See* P. Ex. 2, at 29-30 (describing trial testimony that medication that should have been refrigerated was smuggled into the United States at room temperature); *id.* at 72 (statement of Assistant United States Attorney explaining the basis for federal drug regulations is to promote safety of medication introduced into interstate commerce). Even if we accepted that Petitioner's scheme was legitimately based on his "misguided altruism," we agree with the ALJ that altruism is "not a mental or emotional 'condition' within the meaning of [section 1001.102(c)(2)]." ALJ Decision at 7. Thus, we conclude that Petitioner's alleged "altruism" is not a mitigating factor that lessens the substantial weight accorded to the aggravating factors in this case.

Petitioner also argues that he "swiftly paid the restitution" in this case and so should not be excluded for more than five years.[7] P. Br. at 3. However, section 1001.102(b)(1) states that the "entire amount of financial loss to such programs . . . will be considered regardless of whether full or partial restitution has been made." Also, prompt payment of restitution is not a mitigating factor recognized in section 1001.102(c). Therefore, the speed with which Petitioner paid restitution is not a basis for reducing the length of the exclusion.

Moreover, Petitioner's argument that the "amount of support he has received . . . should not be shunned in determining a reasonable length of exclusion," P. Br. at 3, is without merit because public support is not recognized as a mitigating factor and serves no basis for reducing the exclusion period in this case. *See* 42 C.F.R. § 1001.102(c).

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[6] In this regard, we note the following comment by the Ninth Circuit:

> Patwardhan told his staff not to give patients foreign medicine for at-home use after a patient's mother expressed concern about one label, which was written in Hindi. Patwardhan never informed his patients that the drugs administered to them during in-office treatments were not FDA-approved. To the contrary, the IV bags used to administer the foreign medicine contained only the names of the FDA-approved counterparts. Additionally, there was evidence that Patwardhan's staff hid foreign medicine during an audit, and used the codes corresponding to the FDA-approved drugs, not the foreign medicines that had actually been used, when billing Medicare for reimbursement.

422 Fed. App'x at 616-17.

[7] While the I.G. does not dispute that Petitioner has repaid all of the restitution ordered in the underlying criminal proceedings, the record calls into question Petitioner's claim that he paid the entire $1,313,640.10 within six months of his sentencing. The Medical Board of California, which issued its decision nearly one year after Petitioner had been sentenced and ordered to pay restitution, asserted that "it is highly unlikely [Petitioner] will be able to make full restitution by the time his criminal probation expires." P. Ex. 3, at 18.

Conclusion

We affirm the ALJ's 12-year exclusion of Petitioner from participation in all federal health care programs with the exception of the limited waiver already granted by the I.G.

/s/
Judith A. Ballard

/s/
Leslie A. Sussan

/s/
Sheila Ann Hegy
Presiding Board Member