Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

George John Schulte
(OI File No. H-13-4-3161-9),

Petitioner,

v.

The Inspector General.

Docket No. C-14-1867

Decision No. CR3667

Date: February 25, 2015

DECISION

The Inspector General (IG) of the Department of Health and Human Services notified George John Schulte (Petitioner) that he was being excluded from participation in Medicare, Medicaid, and all other federal programs for three years. Petitioner filed a request for hearing (RFH) to dispute the exclusion. For the reasons explained below, I conclude that the IG had a legitimate basis to exclude Petitioner and that a three-year exclusion is reasonable as a matter of law.

I. Background

By letter dated August 29, 2014, the IG notified Petitioner that he was being excluded, effective 20 days from the date of the IG's letter, from participating in Medicare, Medicaid, and all other federal health care programs for three years. The IG cited 42 U.S.C. § 1320a-7(b)(2) as the basis for the exclusion due to Petitioner's conviction of a criminal offense in the Unites States District Court, District of Colorado. RFH, Attached IG Exclusion Letter at 1.

On September 10, 2014, Petitioner filed a timely RFH with 21 exhibits. Petitioner also filed a motion to stay the exclusion with the RFH. On October 8, 2014, I held a telephonic prehearing conference, the substance of which is summarized in my October 8, 2014 Order and Schedule for Filing Briefs and Documentary Evidence (Order). During the conference, I denied Petitioner's motion for a stay of the exclusion since I lacked authority under the regulations to impose such a stay. Order at 2-3. I also stated that I accepted the 21 exhibits submitted with the RFH as Petitioner's proposed exhibits 1-21 (P. Exs. 1-21). I indicated to Petitioner that he did not need to submit exhibits with his prehearing exchange unless they were new ones submitted in addition to those enclosed with the RFH. Order at 3. The IG filed a brief (IG Br.) together with two exhibits (IG Exs. 1-2). Petitioner filed his brief (P. Br.) with three additional exhibits (P. Exs. 22-24). The I.G. filed a reply brief (IG Reply Br.).

II. Issues

1. Whether the IG has a basis to exclude Petitioner from participating in Medicare, Medicaid, and all other federal health care programs under 42 U.S.C. § 1320a-7(b)(2); and

2. Whether the length of the three-year length of exclusion imposed by the IG is unreasonable.

III. Jurisdiction

I have jurisdiction over this case and to decide the issues stated above. 42 U.S.C. § 1320a-7(f); 42 C.F.R. §§ 1001.2007, 1005.2(a).

IV. Evidentiary Ruling

I admit IG Exs. 1-2 and P. Exs. 1-11 and 22-24 without objection from the parties.

The IG objected to P. Exs. 12-21, consisting largely of personal letters from friends, family and colleagues of Petitioner, as irrelevant to the two issues in this matter: whether the IG has the authority to exclude Petitioner and whether the length of the exclusion is reasonable. IG Br at 7.

Petitioner responded as follows:

> The unnecessarily punitive nature of exclusion in this case is further revealed by the character-attesting letters submitted to the U.S. District Court by Mr. Schulte's family and personal and professional contacts. Thus, the representative sample of those letters that Mr. Schulte provided with his Motion for

> Stay, *id*. ¶ 16; P. Exs. 12-21, are properly considered. The I.G.'s position that the letters are irrelevant or immaterial is misplaced.

P. Br at 8.

The regulations require me to exclude irrelevant or immaterial evidence from the record. 42 C.F.R. § 1005.17(c). As stated by the IG, the only issues I may decide in this case are whether the IG had a basis for excluding Petitioner and, if so, whether the length of exclusion imposed is not unreasonable. *Id*. § 1001.2007(a)(1). P. Exs. 12-21, as letters concerning Petitioner's character, are not relevant to the determination of either issue I have jurisdiction to decide. Therefore, I must exclude P. Exs. 12-21 from the record.

V. Decision on the Record

The IG offered no witnesses and indicated that an in-person hearing is unnecessary. IG Br. at 6. Petitioner did not offer any witnesses to testify at a hearing, but suggested that oral argument would provide the parties an opportunity to further explain their positions, clarify any misunderstandings, and address questions. P. Br. at 6. Because neither party seeks to present witness testimony, an evidentiary hearing is not necessary in this case. Further, after review of the record, I do not believe that oral argument is necessary for me to decide the issues in this case. Therefore, I deny Petitioner's request for oral argument.

VI. Findings of Fact, Conclusions of Law, and Analysis[1]

The IG may exclude any individual from participation in any federal health care program, as defined in 42 U.S.C. § 1320a-7B(f), who is "convicted, under Federal or State law, in connection with the interference with or obstruction of any investigation into any criminal offense described in [42 U.S.C. § 1320a-7(a) or (b)(1)]." 42 U.S.C. § 1320a-7(b)(2); 42 C.F.R. § 1001.301(a).

A. The IG had a legitimate basis for excluding Petitioner under 42 U.S.C. § 1320a-7(b)(2).

1. Petitioner was convicted of an offense under federal law.

Relevant to this case, an individual is considered "convicted" for exclusion purposes when either of the follow occur:

[1] My findings of fact and conclusions of law are set forth in italics and bold font.

> (1) when a judgment of conviction has been entered against the individual or entity by a Federal, State, or local court, regardless of whether there is an appeal pending or whether the judgment of conviction or other record relating to criminal conduct has been expunged; [or]
> (2) when there has been a finding of guilt against the individual or entity by a Federal, State, or local court.

42 U.S.C. § 1320a-7(i)(1), (2).

Petitioner does not dispute that he was convicted of a criminal offense. P. Br. at 1-2. Petitioner was charged with twelve counts of offenses under federal law. P. Ex. 2. On March 1, 2012, a jury found Petitioner guilty of Count Two, which involved a violation under 18 U.S.C. § 1001(a)(2) for knowingly and willfully making materially false statements to an investigative agent of the Food and Drug Administration (FDA). P. Ex. 2 at 22-23; P Ex. 3 at 1. On May 31, 2012, the United States District Court for the District of Colorado entered a Judgment in a Criminal Case in which the court noted Petitioner was guilty of an offense under 18 U.S.C. § 1001, sentenced Petitioner to one year of probation, and ordered Petitioner to pay a $5,000 fine. P. Ex. 8 at 1-2, 4. Therefore, based on the evidence of record, I conclude that Petitioner was convicted of a criminal offense under federal law.

2. Petitioner's conviction was in connection with the interference of an investigation into a criminal offense relating to fraud in connection with the delivery of a health care item or service.

The statute at 42 U.S.C. § 1320a-7(b)(2) requires that the excluded individual be convicted of interfering with an investigation into an offense described in 42 U.S.C. § 1320a-7(a) or (b)(1). The IG argues that Petitioner was convicted of a criminal offense of interfering with an investigation into a criminal offense described in 42 U.S.C. § 1320a-7(b)(1). IG Br. at 3. Crimes under 42 U.S.C. § 1320a-7(b)(1) include fraud related to the delivery of a health care item or service. The IG argues that this is precisely why Petitioner was being investigated:

> Here, [Spectranetics Corporation] knowingly imported unapproved medical devices, did not properly declare them to Customs, and then distributed them to physicians for use in patients. I.G. Ex. 1 at 9-10. This conduct has a common-sense nexus to fraud and is directly related to the delivery of a health care item or service.

IG Br at 4.

Petitioner contends that although he was convicted of making false statements, that fact alone is not sufficient to authorize exclusion under 42 U.S.C. § 1320a-7(b)(2); the IG also must prove that the false statements were material to interfering with an investigation. P. Br. at 2. Petitioner cites *Subramanya K. Prasad, M.D.*, DAB No. 2568, at 8–9 (2014), for the proposition that simply because an individual is convicted of a false statement under 18 U.S.C. § 1001, it does not follow that such a conviction is grounds for exclusion under 42 U.S.C. § 1320a-7(b)(2) unless the IG shows additional evidence that the false statement actually interfered with an investigation. RFH at 12-13. Petitioner argues that the false statements made to the FDA investigator, which resulted in his conviction, did not impact the FDA's investigation because the investigator knew, at the time Petitioner made the statements, that they were false. RFH at 5. Petitioner also avers that he corrected his false statements shortly after his interview with the FDA investigator. RFH at 6-11; P. Exs. 5-7.

The IG responded to Petitioner's argument by citing the appellate decision from the United States Court of Appeals for the Tenth Circuit in which that court affirmed Petitioner's conviction by rejecting a similar argument to the one Petitioner makes in this proceeding (i.e., Petitioner's false statements to the FDA investigator did not have an impact on the FDA's investigation since the FDA investigator knew those statements were false and because Petitioner corrected the false statements promptly). The IG asserts that the Tenth Circuit decision is sufficient evidence that Petitioner's false statements interfered with the FDA investigation. Further, the IG argues that Petitioner misinterprets *Prasad* and points out that Petitioner's arguments, which are essentially the same as the ones made during his criminal case, may be viewed as impermissible collateral attacks on the Petitioner's conviction. IG Reply Br. at 2-3.

I am persuaded that the IG is correct and that it has met its burden of proof in this case. Petitioner was the Chief Executive Office of Spectranetics Corporation (SPNC), a corporation located in Colorado that manufactured medical lasers and related devices associated with them such as catheters. IG Ex. 2 at 2; P. Ex. 2 at 2-3. In 2008, the United States investigated SPNC for, among other things, the importation and provision to physicians of certain medical devices which were not approved by the FDA, but which were nonetheless used in humans.[2] IG Ex. 1 at 8-11; IG Ex. 2 at 2-9; P. Ex. 2 at 5-22. As

[2] The FDA is responsible for enforcing the provisions of the Federal Food, Drug, and Cosmetic Act (FDCA). P. Ex. 2. The FDA's responsibilities include regulating the manufacture, labeling and distribution of medical devices shipped or received in interstate commerce. Medical devices which are defined under the FDCA must be either cleared or approved by the FDA for each intended use prior to being distributed in interstate commerce, unless they are exempt from clearance or approval. The United States Customs and Border Protection (CBP), an agency of the Department of Homeland Security, is responsible for assessing duties, collecting duties on imported goods and preventing the smuggling of goods into the United States. P. Ex. 2 at 2. By agreement

part of the investigation, the United States executed a search warrant on the SPNC facilities. IG Ex. 2 at 6-9; P. Ex. 23. During the execution of the search warrant, and as part of its investigation, an FDA investigator conducted an interview with Petitioner during which he made certain statements. IG Ex. 2 at 6-8; P. Ex. 23.

In this case, the exclusion is based on Petitioner's conviction for making false statements pursuant to 18 U.S.C. § 1001. The jury found Petitioner guilty of making materially false statements to an FDA investigator during the investigation of SPNC by the United States Government and interfering with that investigation. The United States Court of Appeals for the Tenth Circuit affirmed the conviction concluding that Petitioner's statements were material and, as they were given during the course of an investigation, could have influenced the government's actions.

> The FDA, charged with protecting citizens' health, was trying to ascertain the number and type of unapproved devices placed into human patients. Schulte's statements misdirected the focus of the investigation from a company policy soliciting clinical trials to the possible, but unknown activities of individual employees. . . . Given Schulte's position in the company and his ability to explain the purpose and use of the devices prior to FDA approval, the jury was provided sufficient evidence to find, beyond a reasonable doubt, Schulte's statements could have influenced the agency.

IG Ex. 2 at 23-24.

The United States charged Petitioner not only with making false statements pursuant to 18 U.S.C. § 1001, but also with, among other things, knowingly conspiring to defraud the United States under 18 U.S.C. § 371 for the purpose of impeding, impairing, obstructing, and defeating their lawful government functions of inspecting, taxing, approving, evaluating and clearing medical devices imported into the United States, and medical devices distributed in the Unites States in interstate commerce. P. Ex. 2 at 5. The indictment further charged that as part of the conspiracy, Petitioner imported medical devices into the United States by false declarations regarding the description, value or uses for which the medical devices were imported, thereby defeating the lawful government functions of CBP and FDA; introduced and delivered for introduction into interstate commerce medical devices that were adulterated and misbranded in that they were not approved nor cleared by the FDA nor exempt from approval or clearance, defeating the lawful government functions of the FDA; unlawfully delivered unapproved

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with the FDA, CBP also cooperates in the enforcement of provisions of the FDCA relative to the importation of medical devices. *Id.*

and uncleared medical devices for use in humans, and concealed his conduct from internal investigators at SPNC and investigators from the FDA and Department of Homeland Security. P. Ex. 2 at 5.

I find that the record, including the Tenth Circuit's decision, is sufficient to show Petitioner's false statements to the FDA investigator interfered with the FDA's investigation. IG Ex. 2 at 23-24. It is important to note the context in which Petitioner made his false statements. Petitioner was not providing false information to a federal agency under normal circumstances, rather, Petitioner made false statements to a federal investigator during the execution of a search warrant involving more than 30 federal agents. Any material false statements to the investigator would tend to interfere with that investigation. Based on the record in the criminal case, the Tenth Circuit came to this conclusion when it found that Petitioner's "statements misdirected the focus of the investigation from a company policy soliciting clinical trials to the possible, but unknown activities of individual employees" and that "the jury was provided sufficient evidence to find, beyond a reasonable doubt, Schulte's statements could have influenced the agency." IG Ex. 2 at 23-24.

Further, Petitioner interfered with an investigation involving, in part, an effort to determine if Petitioner or SPNC were conspiring to defraud the United States Government by importing medical devices for the insertion in human patients.[3] IG Ex. 1 at 9-11; P. Ex. 2 at 4-22. Thus, I concluded that the offense for which Petitioner was convicted involved the interference of an investigation into a criminal offense under 42 U.S.C. § 1320a-7(b)(1). Therefore, the I.G. had a legitimate basis for excluding Petitioner pursuant to 42 U.S.C. § 1320a-7(b)(2).

B. Because neither the IG nor Petitioner proved that there were any aggravating or mitigating factors in this case, Petitioner must be excluded for three years.

For an exclusion under 42 U.S.C. § 1320a-7(b)(2), "the period of the exclusion shall be 3 years, unless the Secretary determines in accordance with published regulations that a shorter period is appropriate because of mitigating circumstances or that a longer period is appropriate because of aggravating circumstances." 42 U.S.C. § 1320a-7(c)(3)(D). The IG did not assert that there were any aggravating factors and set the length of Petitioner's exclusion as three years.

In order to reduce this length of exclusion, Petitioner has the burden of proving that one or more of the mitigating factors specified in the regulations exist. 42 C.F.R.

[3] While Petitioner was found not guilty with respect to the charge of defrauding the government, the charge is nonetheless evidence that the investigation by the FDA and CBP involved fraud related to the medical devices. P. Exs. 2 and 8.

§§ 1001.301(b)(3), 1005.15(c); Order at 2. Only the following can serve as mitigating factors in this case:

> (i) The record of 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;
>
> (ii) The individual's or entity's cooperation with Federal or State officials resulted in—
>
> (A) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,
>
> (B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or
>
> (C) The imposition of a civil money penalty against others; or
>
> (iii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

42 C.F.R. §§ 1001.301(b)(3).

Petitioner has not asserted or proven that any of the mitigating factors listed above are present in his case. Therefore, I conclude that the three-year length of exclusion that the IG imposed is required by statute and thus reasonable as a matter of law.

VII. Conclusion

For the foregoing reasons, I affirm the I.G.'s determination to exclude Petitioner from participating in Medicare, Medicaid, and all other federal health care programs for three years.

/s/
Scott Anderson
Administrative Law Judge