Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

W. Scott Harkonen, M.D.
(O.I. File No. H-11-40892-9),

Petitioner

v.

The Inspector General.

Docket No. C-12-74

Decision No. CR2541

Date: May 14, 2012

DECISION

Petitioner, W. Scott Harkonen, M.D., is excluded from participating in Medicare, Medicaid, and all federal health care programs pursuant to section 1128(a)(3) of the Social Security Act (Act) (42 U.S.C. § 1320a-7(a)(3)), effective September 20, 2011. There is a proper basis for Petitioner's exclusion based upon his felony conviction in a federal court of a criminal offense committed after August 21, 1996, related to fraud in connection with the delivery of an item or service in a health care program, other than Medicare or Medicaid, operated by, or financed in whole or in part by, any federal, state, or local government agency. Petitioner's exclusion for the minimum period of five years is mandatory pursuant to section 1128(c)(3)(B) of the Act (42 U.S.C. § 1320a-7(c)(3)(B)).[1]

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[1] Pursuant to 42 C.F.R. § 1001.3001, Petitioner may apply for reinstatement only after the period of exclusion expires. Reinstatement is not automatic upon completion of the period of exclusion.

I. Background

The Inspector General for the Department of Health and Human Services (I.G.) notified Petitioner by letter dated August 31, 2011, that he was being excluded from participation in Medicare, Medicaid, and all federal health care programs for a period of five years, pursuant to section 1128(a)(3) of the Act, based upon his felony conviction in the United States District Court, Northern District of California, of a criminal offense related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service, or with respect to any act or omission in a health care program (other than Medicare or Medicaid) operated by, or financed in whole or in part, by any federal, state, or local government agency.

Petitioner timely requested a hearing by letter dated October 28, 2011. The case was assigned to me for hearing and decision on November 1, 2011. A telephone prehearing conference was convened on November 22, 2011, the substance of which is memorialized in my order dated November 23, 2011. During the prehearing conference, Petitioner waived an oral hearing. The parties agreed that this matter can be resolved based upon the parties' briefs and documentary evidence, and a briefing schedule was set.

The I.G. filed a brief (I.G. Br.) on December 22, 2011,[2] with I.G. exhibits (I.G. Exs.) 1 through 3. Petitioner filed his brief on January 27, 2012 (P. Br.), with Petitioner's exhibits (P. Exs.) 1 through 10. The I.G. filed a reply brief on February 15, 2012 (I.G. Reply), with I.G. Exs. 5 and 6.[3] On February 29, 2012, Petitioner filed a Motion for Leave to File Supplemental Reply, accompanied by a supplemental reply brief (P. Reply) and P. Ex. 11. On March 20, 2012, I issued an Order accepting Petitioner's supplemental reply for filing and gave the I.G. an opportunity to file any objections to the admissibility of P. Ex. 11. The I.G. had no objection to P. Ex. 11. No objections have been filed to my consideration of I.G. Exs. 1 through 3, 5 and 6, and P. Exs. 1 through 11, and they are admitted as evidence.

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[2] The I.G. filed a motion for summary judgment and a brief titled "The Inspector General's Brief in Support of Motion for Summary Judgment on the Written Record." Petitioner waived an oral hearing and both parties agreed during the prehearing conference that this case may be decided on the documents and written briefs and that there is no need for oral testimony. Therefore, there is no need to apply the summary judgment procedures or standards in this case.

[3] The I.G. did not submit an exhibit marked "I.G. Ex. 4."

II. Discussion

A. Applicable Law

Petitioner's rights to a hearing by an administrative law judge (ALJ) and judicial review of the final action of the Secretary of Health and Human Services (the Secretary) are provided by Section 1128(f) of the Act (42 U.S.C. § 1320a-7(f)).

Pursuant to section 1128(a)(3) of the Act, the Secretary must exclude from participation in any federal health care program:

> Any individual or entity that has been convicted for an offense which occurred after [August 21, 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 subject to section 1128(a)(1) of the Act] 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.

The Secretary has promulgated regulations implementing these provisions of the Act. 42 C.F.R. § 1001.101(c).

Section 1128(c)(3)(B) of the Act provides that an exclusion imposed under section 1128(a) will be for a period of not less than five years. Pursuant to 42 C.F.R. § 1001.102(b), the period of exclusion may be extended based on the presence of specified aggravating factors. Only if the aggravating factors justify an exclusion of longer than five years are mitigating factors considered as a basis for reducing the period of exclusion to no less than five years. 42 C.F.R. § 1001.102(c). No aggravating factors are cited by the I.G. in this case, and the I.G. does not propose to exclude Petitioner for more than the minimum statutory period of five years.

The standard of proof is a preponderance of the evidence, and there may be no collateral attack of the conviction that provides the basis of the exclusion. 42 C.F.R. § 1001.2007(c), (d). Petitioner bears the burden of proof and the burden of persuasion on any affirmative defenses or mitigating factors, and the I.G. bears the burden on all other issues. 42 C.F.R. § 1005.15(b).

B. Issues

The Secretary has by regulation limited my scope of review to two issues:

> Whether the I.G. has a basis for excluding Petitioner from participating in Medicare, Medicaid, and all other federal health care programs; and
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> Whether the length of the proposed exclusion is unreasonable.

42 C.F.R. § 1001.2007(a)(1).

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold followed by the pertinent findings of fact and analysis.

1. Petitioner's request for hearing was timely, and I have jurisdiction.

2. Petitioner's exclusion is required by section 1128(a)(3) of the Act.

a. Facts

According to court documents from the United States District Court, Northern District of California offered as evidence by Petitioner, Petitioner was the Chief Executive Officer of InterMune, Inc. (InterMune) from 1998 until through at least June 3, 2003. InterMune was a California-based pharmaceutical company that developed, marketed, and sold drugs for lung and liver diseases. One of the drugs InterMune sold was Actimmune. InterMune purchased the rights to Actimmune from the company that developed the drug. In 2000, Actimmune had only been approved by the Food and Drug Administration (FDA) for the treatment of chronic granulomatous disease and severe, malignant osteopetrosis. In 1999, a small Austrian clinical trial showed that Actimmune might be a promising treatment for idiopathic pulmonary fibrosis (IPF). The cause of IPF is unknown. IPF sufferers generally die within two to three years. There are approximately 200,000 people in the United States who suffer from IPF and 50,000 new cases are diagnosed every year. InterMune undertook its own study of Actimmune's effectiveness for the treatment of IPF. In August 2002, InterMune received the results of its study. On August 28, 2002, InterMune issued a press release claiming that data from its study showed that Actimmune reduced mortality in patients with IPF. The press release and other conduct by Petitioner and InterMune formed the bases for the grand jury indictment. The indictment filed on March 18, 2008, in the United States District Court, Northern District of California, charged Petitioner in two counts. Count One charged Petitioner with committing wire fraud, in violation of 18 U.S.C. § 1343, and aiding and abetting the wire fraud, in violation of 18 U.S.C. § 2. Count Two charged

Petitioner with felony misbranding of a drug in violation of 21 U.S.C. §§ 331(k), 333(a)(2), 352(a). P. Ex. 1, at 1-2.

On September 29, 2009, a jury found Petitioner guilty of wire fraud and not guilty of felony misbranding. P. Ex. 1, at 3; I.G. Exs. 1, 3. The wire fraud charge of which Petitioner was convicted alleged that the press release "contained materially false and misleading information regarding Actimmune" and "falsely portrayed the results" of the InterMune study of Actimmune as showing "that Actimmune reduces mortality in patients with IPF." P. Ex. 1, at 2-3; I.G. Ex. 2, at 12. On April 13, 2011, Petitioner was sentenced: to three years probation; to pay an assessment of $100; to pay a fine of $20,000; to six months of home detention without electronic monitoring (stayed until further notice pending appeal); and to serve 200 hours of community service. I.G. Ex. 1; P. Ex. 8, at 19.

b. Analysis

Section 1128(a)(3) of the Act requires the Secretary to exclude from participation in any federal health care program an individual or entity convicted of a felony offense under federal or state law that occurred after August 21, 1996, if the offense was related to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct, and if the offense was 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 Medicare or Medicaid and the program was operated or financed in whole or in part by any governmental agency.

The evidence before me shows that the elements necessary for exclusion under section 1128(a)(3) of the Act are satisfied in this case. There is no dispute that Petitioner was convicted by a federal court of felony wire fraud that occurred after August 21, 1996. Based on my review of the evidence, the conduct for which Petitioner was convicted was in connection with the delivery of health care items or services. Accordingly, I conclude that there is a basis to exclude Petitioner pursuant to section 1128(a)(3) of the Act.

Petitioner argues that his conviction did not trigger a mandatory exclusion pursuant to section 1128(a) of the Act. Request for Hearing (RFH) at 2; RFH Exhibit B, at 9-16; P. Br.; P. Reply. Petitioner does not deny that he was convicted of the offense of wire fraud based upon the false press release. Petitioner does not deny that the offense of which he was convicted occurred after August 21, 1996. Petitioner does not argue that the offense of which he was convicted is fraud or other financial misconduct within the meaning of section 1128(a)(3) of the Act. Petitioner acknowledges that his conviction and the bases for his conviction are not subject to review by me. P. Br. at 13, n.9. Petitioner argues that his offense was not in connection with the delivery of a health care item or service and it was not based on any act or omission in a health care program. Petitioner's arguments are without merit.

Petitioner concedes that Actimmune is a health care item (RFH Exhibit B, at 13; P. Br. at 1). But Petitioner argues the evidence does not show that the offense for which he was convicted involved delivery. P. Br. at 1, 14-19. Petitioner argues that the I.G. does not meet its burden of persuasion to establish a bases for exclusion pursuant to section 1128(a)(3) of the Act, because the I.G. failed to show a connection or nexus between the offense and "delivery" as required by the Act. Section 1128(a)(3) requires that Petitioner's offense be "in connection with the delivery of a health care item or service." *Erik D. DeSimone, R.Ph.*, DAB No. 1932, at 4 (2004). Petitioner argues that to prove "delivery" there must be evidence that some physician actually wrote a prescription for Actimmune. RFH Exhibit B, at 13-14; P. Br. at 15-19. Petitioner reasons that the language of section 1128(a)(3) shows that Congress specifically intended mandatory exclusion when the criminal offense was related to the delivery of a health care item or service and not just any health care-related offense. P. Br. at 15-17. Petitioner correctly characterizes the legislative history as showing Congress' intent to exclude individuals or entities that have been convicted of defrauding patients and care insurers. Petitioner does not explain how or why he concluded that Congress did not also seek to exclude those who also engaged in fraud or one of the other enumerated offenses but were unsuccessful or thwarted in their attempt prior to completion. P. Br. at 17. Petitioner departs somewhat from his original theory by subsequently arguing that section 1128(a)(3) of the Act requires "some impact on the delivery of an item or service, even if indirectly and not as a part of the offense." P. Reply at 11-13. I need not find that any prescriptions for Actimmune were actually written, that the treatment was actually used, or that there was some actual effect upon the delivery of a health care item or service. In none of the cases cited by either the I.G. or Petitioner has it been found that an actual impact or effect is required to be proved. Rather, it is sufficient that there be a nexus or common sense connection between the offense and the delivery of a health care item or service. *Erik D. DeSimone, R.Ph.*, DAB No. 1932, at 4. In this case, Petitioner's press release touting the virtues of Actimmune had a potential impact upon the delivery of health care in the community and there is a sufficient nexus.[4]

Petitioner argues that there is no evidence that he was convicted for intending that the press release have an impact upon the delivery of Actimmune. P. Br. at 20-22. Petitioner argues that the jury and trial court found no actual effect on the sale of Actimmune as a result of the press release and the jury did not convict Petitioner on the

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[4] There is impact for example, if Actimmune is prescribed based upon information from the press release in lieu of other medications or treatment or based upon an erroneous understanding of potential benefits indicated in the press release versus the potential risks.

misbranding charge. P. Br. at 20-21; P. Reply at 1-11. Petitioner is in error to the extent he suggests that section 1128(a)(3) of the Act is only triggered if the jury found Petitioner intended to cause or caused an effect upon the delivery of a health care item or service. The Act and regulations impose no such limitation. The I.G. has the burden of proving the elements of its prima facie case before me and that proof is not limited to the findings and conclusions in the trial court. Rather, I consider evidence of the conviction and any other evidence presented to resolve whether or not the elements of section 1128(a)(3) of the Act are satisfied. The standard of proof in criminal court is beyond a reasonable doubt. Before me, the standard of proof is a preponderance of the evidence, i.e., more likely true than not. Thus, while the jury might not have been able to find beyond a reasonable doubt, I have no trouble concluding based on the language of the press release that the intent of the release and Petitioner's statements therein were to increase the sale of Actimmune.[5]

Petitioner argues that the evidence before me does not show that he had the intent to affect the delivery of the health care item Actimmune. P. Br. at 22-24. Petitioner's argument is proven false by the press release itself. The language of the press release establishes that a purpose of the press release was to encourage victims of IPF and their physicians to use Actimmune for the treatment of IPF.[6] The press release contains the following statements attributed to Petitioner: "Actimmune may extend the lives of patients suffering from this debilitating disease," and "Actimmune is the only available treatment demonstrated to have clinical benefit in IPF, with improved survival data in two controlled clinical trials." The press release also quotes Petitioner as stating that the study results will "support use of Actimmune and lead to peak sales in the range of $400-$500 million per year, enabling us to achieve profitability in 2004 as planned." I.G. Ex. 5, at 1. These statements, attributed to Petitioner, establish that the purpose of the press

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[5] Petitioner is correct that an indictment generally need only be supported by probable cause, a lesser standard than a preponderance of the evidence. Thus, as a general matter, an indictment alone would not be sufficient evidence to meet the standard applicable in this proceeding. P. Br. at 22. Consideration of other evidence, such as the record of conviction in addition to the indictment, may be sufficient to constitute a preponderance of the evidence. However, in this case, the evidence relied upon to show that there was an intent or purpose to affect delivery is the actual press release, the content of which is not disputed in any respect by Petitioner.

[6] Of course, there are likely a number of business purposes for the press release that I need not list. However, it would be naïve not to recognize that a pharmaceutical company's business is better when patients want and doctors prescribe the pharmaceuticals produced by the company.

release and its false representation regarding the effectiveness of Actimmune was intended to cause sales of Actimmune for the treatment of IPF. It is reasonable to infer that both physicians who could prescribe Actimmune and patients who suffer IPF and could ask for prescriptions were targets of the false press release.

Petitioner asserts that his exclusion raises serious constitutional problems and would violate the Fifth Amendment's double jeopardy clause and guarantee of due process, as well as the Eighth Amendment's prohibition against excessive fines and cruel and unusual punishment. P. Br. at 26-36. As a general rule, I am bound to follow the federal statutes and regulations, and have no authority to declare them unconstitutional. *Susan Malady, R.N.*, DAB No. 1816 (2002); 42 C.F.R. § 1005.4(c)(1). Petitioner correctly notes that in construing and applying the Act and regulations, I must do so consistent with Constitutional principles. P. Reply at 14-16. No matter how well argued by Petitioner, there is no issue of interpretation for me in this case – only an attack upon the Act and the regulations on Constitutional grounds. Petitioner has preserved his issues for appeal to the federal courts but his arguments have been rejected by the courts before. Exclusions imposed by the I.G. are civil sanctions, remedial in nature and not punitive and criminal. Because exclusions are remedial sanctions, they do not violate the double jeopardy clause or the prohibition against cruel and unusual punishment. *Manocchio v. Kusserow*, 961 F.2d 1539 (11th Cir. 1992); *Greene v. Sullivan*, 731 F.Supp. 838 (E.D. Tenn. 1990); *Joann Fletcher Cash*, DAB No. 1725 (2000); *Douglas Schram, R. Ph.*, DAB No. 1382 (1992); and *Janet Wallace, L.P.N.*, DAB No. 1126 (1992).[7] Arguments that the exclusion provisions are anything but remedial have been found to be without merit. *Manocchio* , 961 F.2d 1539; *Greene*, 731 F.Supp. 838. Petitioner contends that the five-year exclusion amounts to an arbitrary government action that affects his ability to pursue his chosen profession, infringing upon his property and liberty interests. The federal courts have rejected claims that the Secretary's exclusion procedures amount to a deprivation of due process, finding no constitutionally-protected property or liberty interests. *Rodabaugh v. Sullivan*, 943 F.2d 855 (8th Cir. 1991); *Lavapies v. Bowen*, 883 F.2d 465 (6th Cir. 1989); *Hillman Rehab. Ctr. v. U.S. Dep't of Health & Human Servs.*,

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[7] The exclusion remedy serves twin congressional purposes: the protection of federal funds and program beneficiaries from untrustworthy individuals and the deterrence of health care fraud. S. Rep. No. 109, 100th Cong., 1st Sess. 1-2 (1987), reprinted in 1987 U.S.C.C.A.N. 682, 686 ('clear and strong deterrent'); *Joann Fletcher Cash*, DAB No. 1725, at 18 (discussing trustworthiness and deterrence). When Congress added section 1128(a)(3) in 1996, it again focused upon the desired deterrent effect: "greater deterrence was needed to protect the Medicare program from providers who have been convicted of health care fraud felonies . . . ." H.R. Rep. 496(I), 104th Cong., 2nd Sess. (1996), reprinted in 1996 U.S.C.C.A.N. 1865, 1886.

No. 98-3789 (GEB), slip op. at 16, 1999 WL 34813783, at 16 (D.N.J. May 13, 1999); *Travers v. Sullivan*, 801 F.Supp. 394, 404-05 (E.D. Wash. 1992), *aff'd, Travers v. Shalala*, 20 F.3d 993 (9th Cir. 1994). Of course, Petitioner's exclusion does not prohibit him from engaging in any employment. Petitioner's exclusion precludes him from participation in Medicare, Medicaid, and all federal health care programs and payment for his services through those programs.

3. Pursuant to section 1128(c)(3)(B) of the Act, five years is the minimum period of exclusion under section 1128(a).

4. Petitioner's exclusion for five years is not unreasonable as a matter of law.

I have concluded that there is a basis for Petitioner's exclusion pursuant to section 1128(a)(3) of the Act. Five years is the minimum period authorized for a mandatory exclusion pursuant to section 1128(a). Act § 1128(c)(3)(B). Accordingly, Petitioner's five-year exclusion is not unreasonable as a matter of law.

The Secretary's regulation provides that an exclusion is effective 20 days from the date of the I.G.'s written notice of exclusion to the affected individual or entity. 42 C.F.R. § 1001.2002(b). The Secretary's regulations do not give me discretion to change the effective date of Petitioner's exclusion and I may not refuse to follow the Secretary's regulations. 42 C.F.R. § 1005.4(c)(1); *Thomas Edward Musial, R.Ph.*, DAB No. 1991 (2005). Consequently, the effective date of Petitioner's exclusion is September 20, 2011, twenty days after the August 31, 2011 I.G. notice of exclusion.

III. Conclusion

For the foregoing reasons, Petitioner is excluded from participation in Medicare, Medicaid, and all other federal health care programs for the minimum statutory period of five years, effective September 20, 2011.

/s/
Keith W. Sickendick
Administrative Law Judge