UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

W. SCOTT HARKONEN, M.D.,

Plaintiff,

v.

KATHLEEN SEBELIUS, Secretary, Department of Health and Human Services,

Defendant.
_____/

No. C 13-0071 PJH

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

The parties' cross-motions for summary judgment came on for hearing before this court on September 11, 2013. Plaintiff appeared by his counsel Mark E. Haddad, and defendant appeared by Assistant United States Attorney Erica Hitchings. Having read the parties' papers and carefully considered their arguments and the relevant legal authority, the court hereby GRANTS defendant's motion and DENIES plaintiff's motion.

INTRODUCTION

This is a case brought under 42 U.S.C. § 1320a-7(f) and 42 U.S.C. § 405(g), seeking review of a decision by the Secretary of the U.S. Department of Health and Human Services ("the Secretary" of "HHS") to exclude plaintiff W. Scott Harkonen, M.D. from participation in federal health care programs for five years.

Dr. Harkonen was formerly the Chief Executive Officer of a company that developed,

marketed and sold a drug known as Actimmune. On March 18, 2008, a grand jury returned an indictment alleging that Dr. Harkonen had knowingly and intentionally devised a scheme to defraud that included the issuance of a press release containing false statements regarding a clinical study of Actimmune, and charging him with two felony counts – wire fraud and felony misbranding.

Following the trial, the jury returned a verdict on September 29, 2009, finding Dr. Harkonen guilty of wire fraud, but acquitting him of felony misbranding. See United States v. Harkonen, No. CR 08-0164 MHP (N.D. Cal.). On December 4, 2009, Dr. Harkonen filed a motion to dismiss the indictment, a motion for judgment of acquittal, and a motion for a new trial. On July 27, 2010, the court issued an order denying the post-trial motions in full. See United States v. Harkonen, 2010 WL 2985257 (N.D. Cal. July 27, 2010).

On November 10, 2010, Dr. Harkonen requested leave to file a motion for reconsideration of the order denying the post-trial motions. On January 7, 2011, Dr. Harkonen filed a motion for a new trial based on alleged Brady violations, and for production of additional Brady evidence. On February 14, 2011, Dr. Harkonen filed another motion for a new trial, based on "newly discovered evidence" contained in an amicus brief relating to the role of statistical evidence in evaluating clinical data, filed by the United States in a case pending before the U.S. Supreme Court.

Sentencing finally went forward on April 13, 2011. Although the prosecution had requested a stiffer sentence, Dr. Harkonen was sentenced to three years' probation, six months' home detention, 200 hours of community service, a $20,000 fine, and a $100.00 special assessment. Judgment was entered on April 18, 2011 (with an amended judgment to correct clerical errors entered on May 26, 2011).

Also on April 18, 2011, the court issued an order denying the two pending motions for a new trial. Dr. Harkonen filed a notice of appeal with the Ninth Circuit on April 25, 2011 (amended notice of appeal filed June 7, 2011), seeking review of the conviction and judgment, the ruling on one of the Secretary's motions in limine, the rulings on the post-trial motions, "and all other adverse orders." On May 12, 2011, the Secretary filed a notice of

appeal of the sentence.

On August 31, 2011, the Office of the Inspector General ("OIG") of HHS notified Dr. Harkonen that, due to his felony conviction for wire fraud, he was being excluded from federal health care programs pursuant to Section 1128(a)(3) of the Social Security Act, 42 U.S.C. § 1320a-7(a)(3), for a period of five years, effective September 20, 2011.

Under § 1128(a) of the Social Security Act, the Secretary is required to exclude from participation in all Federal health care programs any individual or entity convicted of certain types of criminal offenses, listed in four subdivisions of the statute. See 42 U.S.C. § 1320a-7(a)(1)-(4). Of relevance to the present action, subsection (a)(3) provides that the Secretary "shall exclude the following . . . 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 . . . . consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

42 U.S.C. § 1320a-7(a)(3) (emphasis added). Neither the statute nor the implementing regulations provide a definition for "in connection with" or "delivery of."

On October 28, 2011, Dr. Harkonen requested administrative review of the OIG's notice of exclusion. On May 14, 2012, an Administrative Law Judge ("ALJ") in the Civil Remedies Division of HHS' Departmental Appeals Board issued a decision affirming the OIG's exclusion order. Dr. Harkonen appealed the ALJ's decision to the Appellate Division of the Departmental Appeals Board ("DAB"), which affirmed the ALJ's order on November 9, 2012.

Dr. Harkonen filed this action on January 7, 2013, against Kathleen Sebelius, Secretary of HHS, and Daniel R. Levinson, Inspector General of HHS, seeking review of the final exclusion order pursuant to § 1128(f) of the Social Security Act, and 42 U.S.C. § 405(g), and also seeking declaratory and injunctive relief. Mr. Levinson was subsequently dismissed from the case pursuant to stipulation.

On March 12, 2013, the Ninth Circuit issued an unpublished memorandum affirming

Dr. Harkonen's conviction and sentence. See United States v. Harkonen, No. 11-10209, 510 Fed. Appx. 633, 2013 WL 782354 (9th Cir. March 4, 2013) (unpublished decision). Dr. Harkonen sought en banc review; that petition was denied on May 7, 2013. The mandate issued on May 20, 2013. On August 5, 2013, Dr. Harkonen filed a petition with the U.S. Supreme Court seeking a writ of certiorari.

BACKGROUND

Dr. Harkonen served as the CEO of InterMune, Inc. ("InterMune") from February 1998 through June 30, 2003 and was a member of its Board of Directors from February 1998 through September 2003. InterMune developed, marketed and sold drugs, including a drug sold under the brand name Actimmune. Actimmune was approved by the U.S. Food and Drug Administration ("FDA") to treat two rare disorders that primarily affect children, chronic granulomatous disease and severe, malignant osteopetrosis. It was not approved by the FDA to treat idiopathic pulmonary fibrosis (IPF), a fatal lung disease that mainly affects middle-aged people.

In October 2000, InterMune began a Phase III clinical trial – the GIPF-001 trial – to determine whether treating IPF patients with Actimmune was effective. By August 2002, the data from that clinical trial had failed to show that Actimmune was effective in treating IPF. Dr. Harkonen discussed the results of the trial with his staff at InterMune and directed them to conduct additional analyses on subgroups of patients. This analysis suggested a survival trend for patients whose IPF was described by InterMune as "mild to moderate."

On August 27, 2002, Dr. Harkonen and other InterMune employees spoke with the FDA about the results of the GIPF-001 Phase III trial and additional subgroup analyses of patient deaths. The FDA medical reviewer staff advised Dr. Harkonen that the trial data were not sufficient to gain FDA approval for Actimmune to treat IPF and that further clinical testing would be required to determine whether Actimmune could delay death for IPF patients.

Nevertheless, on August 28, 2002, InterMune issued a press release announcing the results of the GIPF-001 Phase III clinical trial ("the Press Release"). The headline

stated, "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF," with the subheading "Reduces Mortality by 70% in Patients With Mild to Moderate Disease." Administrative Record ("AR") 515. Dr. Harkonen wrote the headline and subheading and controlled the content of the entire Press Release; and also caused the Press Release to be posted on InterMune's website and to be sent to a wire service for release to news outlets nationwide.

Among other things, the Press Release stated that InterMune had announced that

> preliminary data from its Phase III clinical trial of Actimmune® (Interferon gamma-1b) injection for the treatment of idiopathic pulmonary fibrosis (IPF), a debilitating and usually fatal disease for which there are no effective treatment options, demonstrate a significant survival benefit in patients with mild to moderate disease randomly assigned to Actimmune versus control treatment ($p = 0.004$). . . .
>
> Importantly, Actimmune also demonstrated a strong positive trend in increased survival in the overall patient population, and a statistically significant survival benefit in patients with mild to moderate IPF. . . .

AR 515, 516.

In March 2008, Dr. Harkonen was indicted for wire fraud in violation of 18 U.S.C. § 1343, and felony misbranding of a drug in violation of 21 U.S.C. §§ 331(k), 333(a)(2), and 352(a). AR 501-513. Both counts were based on the same set of facts and allegations, which included a detailed recitation of Dr. Harkonen's and InterMune's marketing strategy, and Dr. Harkonen's fraudulent scheme to induce doctors to prescribe, and patients to take, Actimmune to treat IPF.

While the indictment did not allege that the data were falsely reported, it did challenge the interpretation and presentation of the data in the study, specifically asserting that the Press Release "contained materially false and misleading information regarding Actimmune and falsely portrayed the results of a GIPF-001 Phase III trial as establishing that Actimmune reduces mortality in patients with IPF." AR 509.

On September 29, 2009, the jury convicted Dr. Harkonen of wire fraud and acquitted him of felony misbranding. The district court and Ninth Circuit opinions describe the evidence supporting the jury's finding that Dr. Harkonen knowingly participated in a

scheme to defraud, as charged. See Harkonen, 2010 WL 2985257 at *14 ("sufficient evidence for the jury to find beyond a reasonable doubt that Harkonen acted with the intent to defraud"); Harkonen, 2013 WL 782354 at *1-2 (jury justified in finding specific intent to defraud). The district court also noted evidence of "extensive, coordinated efforts by InterMune to disseminate the Press Release to doctors and patients," AR 362, as well as to pharmacies, AR 358 (April 18, 2011 order denying motions for a new trial); see also Harkonen, 2013 WL 782354 at *3.

Other evidence presented at trial indicated that Dr. Harkonen had a motivation to commit fraud, since he and InterMune stood to benefit financially if Actimmune sales increased, AR 387; see also Harkonen, 2013 WL 782354 at *2 (discussing Dr. Harkonen's financial motivation to find a positive result in the face of GIPF-001's failure); and evidence that Dr. Harkonen prevented individuals at InterMune – include some knowledgeable regarding the data – from reviewing the Press Release before it was issued, AR 387-88; see also Harkonen, 2013 WL 782354 at *1. Both the district court and the Ninth Circuit upheld the jury's finding of materiality, holding that the Press Release had the capacity to influence the targeted audience of doctors and patients, AR 362; Harkonen, 2013 WL 782354 at *3 (evidence that Press Release was capable of misleading some addressees).

On August 31, 2011, the Secretary (through the OIG) notified Dr. Harkonen that he was being excluded from federal health care programs pursuant to § 1128(a)(3) of the Social Security Act for a period of five years based on the wire-fraud conviction. Dr. Harkonen requested administrative review on October 28, 2011, arguing that his conviction did not trigger a mandatory exclusion because his offense was not "in connection with the delivery of a health care item or service" and was not based on any act or omission in a health care program.

The ALJ affirmed the exclusion order on May 14, 2012, finding that § 1128(a)(3) did not require proof 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." AR 6. Instead, the ALJ held that it was sufficient "that there

be a nexus or common sense connection between the offense and the delivery of a health care item or service." AR 6 (citing Erik D. DeSimone, R.Ph., DAB No. 1932, 2004 WL 1764746 (H.H.S. July 20, 2004)).

The ALJ also found no requirement under § 1128(a)(3) that there be proof that the defendant intended to cause, or did cause, an effect upon the delivery of a health care item or service. AR at 7. He noted that the standard in the matter before him was preponderance of the evidence, and stated that he had "no trouble concluding based on the language of the press release that the intent of the release and [Dr. Harkonen's] statements therein were to increase the sales of Actimmune." AR at 7. Dr. Harkonen appealed the ALJ's decision to the DAB, which, on November 9, 2012, affirmed the ALJ's order based on the same reasoning. AR 10-30.

The DAB addressed each of Dr. Harkonen's arguments in turn, explaining, with citations to the record, why the exclusion was fully supported by both the jury's findings and the district court's findings at sentencing. First, consistent with the plain language and purpose of the statute, the DAB read "the word 'delivery' together with the key modifying language in the phrase, 'in connection with,' to require a 'common sense connection' or 'nexus' between the underlying facts and circumstances of the offense and the delivery of health care items or services to individuals for their health care needs." AR 16.

Apart from this, the DAB found that § 1128(a)(3) "does not require proof of an actual impact or effect on the delivery of a health care item or service" – and that, in this case, there was no need for proof that the false or fraudulent statements in the August 28, 2002 Press Release caused a particular prescription of Actimmune. AR 19. The DAB further explained that, when reviewing an exclusion, the ALJ is to consider not only the "evidence of the conviction," but also the "circumstances underlying the offense." Id.

The DAB found that the "ALJ reasonably determined that the language used in the press release itself showed that the intent of the release and [Dr. Harkonen's] statements therein were to increase the sale of Actimmune and thereby have an impact on delivery of the drug" and "that the claims in the press release had the potential to encourage patients

to seek, and doctors to prescribe, Actimmune." AR 21 (quotations omitted). The DAB also noted that "even absent any intent by [Dr. Harkonen], the press release's claims about the drug could reasonably be viewed . . . as part of the delivery process." AR 21.

Finally, the DAB concluded that Dr. Harkonen's exclusion "comports with the remedial purpose" of the exclusion statute because "the evidence relating to the crime for which he was convicted . . . shows that [he] was untrustworthy in representations he made or caused to be made about the efficacy of a health care item tested, marketed and sold by the pharmaceutical company of which he was the Chief Executive Officer." AR 31.

Having engaged in a detailed review of the Press Release, the March 2002 indictment, the jury instructions and verdict, and the district court's memoranda addressing the post-trial motions, the DAB concluded that substantial evidence in the record as a whole supported a finding that Dr. Harkonen's wire fraud conviction was in connection with the delivery of a health care item or service. AR 20-26. The DAB's decision represents the Secretary's final decision. See 42 C.F.R. § 1005.21(j).

Dr. Harkonen brought this action to challenge the Secretary's decision, alleging in the first and second causes of action that the Secretary's decision is contrary to law, is arbitrary and capricious, and is not based upon substantial evidence; and in the third, fourth, and fifth causes of action that the exclusion violates his rights under the Fifth and Eighth Amendments of the U.S. Constitution.[1] See Cplt ¶¶ 58-75. The parties have submitted the matter for summary judgment based on the administrative record.

The basic dispute between the parties is whether the wire fraud for which Dr. Harkonen was convicted was perpetrated "in connection with the delivery of a healthcare item or service."

STANDARD OF REVIEW

Under § 1128(f) of the Social Security Act (providing for notice, hearing, and judicial review with regard to Secretary's decision to exclude individual from participation), and 42

[1] These constitutional claims were not adjudicated in the proceeding before the ALJ, as the ALJ does not have the authority to grant relief on claims of constitutional violations.

U.S.C. § 405(g), (h) (judicial review and finality of decision by Commissioner of Social Security), the district court has the power to review and reverse the Secretary's exclusion decisions. See Aukland v. Massanari, 257 F.3d 1033, 1035 (9th Cir. 2001).

Review pursuant to § 405(g) is "highly deferential," Valentine v. Commissioner Social Sec. Admin., 574 F.3d 685, 690 (9th Cir. 2009), requiring affirmance of the Secretary's decision so long as the record as a whole contains substantial evidence to support the Secretary's findings of fact, and so long as the Secretary applied the correct legal standard. 42 U.S.C. § 405(g); see also Matney v. Sullivan, 981 F.2d 1016, 1019 (9th Cir. 1992).

"Substantial evidence" means "more than a mere scintilla, but less than a preponderance." Valentine, 574 F.3d at 690 (citation omitted); see also Travers v. Shalala, 20 F.3d 993, 996 (9th Cir. 1994). On factual issues, the Secretary bears the burden of proof in establishing the basis for an exclusion. 42 C.F.R. § 1001.15(b). To be supported by "substantial evidence," the agency's decision requires "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion;" it may not be affirmed "simply by isolating a specific quantum of supporting evidence." Hill v. Astrue, 698 F.3d 1153, 1159 (9th Cir. 2012) (quotation omitted).

When evaluating the Secretary's interpretation of 42 U.S.C. § 1320a-7, courts routinely apply the principles laid out in Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). A two-step review procedure is used in such situations. First, the court begins with the statute's "'language itself [and] the specific context in which that language is used.'" Resisting Envtl. Destruction on Indigenous Lands, REDOIL v. U.S. Envtl. Prot. Agency, 716 F.3d 1155, 1161 (9th Cir. 2013) (quoting McNeill v. United States, 131 S.Ct. 2218, 2221 (2011)). That is, the court should apply "the ordinary tools of statutory construction" to determine whether congressional intent is clear and the agency's interpretation "is based on a permissible construction of the statute." City of Arlington, Tex. v. F.C.C., 133 S.Ct. 1863, 1868 (2013). If the expressed intent of Congress is clear, then the court and the agency must give effect to that unambiguously expressed intent.

REDOIL, 716 F.3d at 1161 (citing Chevron, 467 U.S. at 842-43).

If, however, Congress has not directly addressed the precise question at issue, the court must not simply impose its construction on the statute, as it would in the absence of an administrative interpretation, but rather ask "whether the agency's answer is based on a permissible construction of the statute." Id. (quoting Chevron, 467 U.S. at 843). If the Secretary's construction is "'rational and consistent with the statute,' it is a permissible construction" and will be upheld. Zinman v. Shalala, 67 F.3d 841, 845 (9th Cir. 1995) (quoting N.L.R.B. v. United Food & Commercial Workers Union, 484 U.S. 112, 123 (1987)); see also Haro v. Sebelius, __ F.3d __, 2013 WL 4734032 at *12 (9th Cir. Sept. 4, 2013). The court defers to the Secretary's reasonable interpretation of a statute she administers. See, e.g., Friedman v. Sebelius, 686 F.3d 813, 818 (D.C. Cir. 2012).

THE CROSS-MOTIONS

A. Legal Standard

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The judicial review standard set forth in 42 U.S.C. § 405(g) is expressly incorporated in 42 U.S.C. § 1320a-7(f), the statute under which Dr. Harkonen seeks review.

B. The Cross-Motions

Dr. Harkonen seeks summary judgment that the final agency decision excluding him from participation in federal health care programs pursuant to 42 U.S.C. § 1320a-7(a)(3) is contrary to law, arbitrary and capricious, and unsupported by substantial evidence; and/or that his exclusion violates his rights under the Fifth and Eighth Amendments to the United States Constitution. The Secretary seeks summary judgment that the decision to exclude Dr. Harkonen from federal health care programs was based on application of the correct legal standard and is supported by substantial evidence on the record as a whole; and that the decision is in accord with the Fifth and Eighth Amendments.

The court finds that the Secretary's decision must be affirmed. The record as a

whole contains substantial evidence to support the Secretary's findings of fact, and the Secretary's construction of the statute is reasonable. Dr. Harkonen has not shown that the exclusion was based on an erroneous or impermissible interpretation of the statute.

1. Whether the Secretary applied the correct legal standard and whether the decision is supported by substantial evidence

The primary dispute between the parties is whether Dr. Harkonen was convicted of a crime committed "in connection with the delivery of a health care item or service." In evaluating the Secretary's interpretation of § 1128(a)(3), the court first employs "traditional tools of statutory construction," City of Arlington, 133 S.Ct at 1863, beginning with the text and structure of the statute, and "the assumption that the ordinary meaning of that language accurately expresses the legislative purpose," Park 'N Fly, Inc. v. Dollar Park & Fly, Inc., 469 U.S. 189, 194 (1985).

In this case, the text and structure of § 1128(a)(3) provide a clear indication that Congress intended to mandate a five-year-minimum exclusion for anyone convicted of a felony relating to one of the enumerated offenses. See 42 U.S.C.A. § 1320-7(a)(3); see also Travers, 20 F.3d at 998 ("[t]he Secretary shall exclude" in § 1128(a) is mandatory not discretionary; where the OIG finds that a conviction falls within the category of offense listed in the statute, the Secretary has "no choice but to impose the mandatory 5-year exclusion").

What is not entirely clear from the face of the statute is how to determine whether a felony was committed "in connection with the delivery of" a health care item or service. Where the court is faced with an ambiguous statutory term, Chevron requires that the court defer to the construction given the term by the agency charged with the statute's administration, provided the interpretation is a permissible construction of the statute. Donchev v. Mukasey, 553 F.3d 1206, 1216 (9th Cir. 2009).

Where, as here, a word or phrase is not defined by statute, the court normally construes it "in accord with its ordinary or natural meaning." Smith v. United States, 508 U.S. 223, 228 (1993) (citation omitted). The word "delivery" is used to refer to formal acts

of transferring or conveying, as in the "delivery" of deeds or title to real property. See, e.g., Black's Law Dictionary (7th ed. 1999) at 440. However, "delivery" has also acquired a more informal meaning of "providing." See Bryan A. Garner, A Dictionary of Modern Legal Usage (Oxford, 2d ed. 1995), at 263. "Provision" (or "providing") refers generally to the "act of supplying," or "furnishing" or "purveyance." See William C. Burton, Burton's Legal Thesaurus (Macmillan, 3d ed. 1998) at 437.

In addition, the phrases "in connection with," "in relation to," or "related to" are generally interpreted expansively. See Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 739 (1985) ("relate to" has a "broad common-sense meaning" and a statutory provision containing the phrase therefore has "broad scope"); see also Morales v. Trans World Airlines, Inc., 504 U.S. 374, 383 (1992); United States v. Loney, 219 F.3d 281, 283-84 (3d Cir. 2000).

In affirming the ALJ's decision, the DAB read the word "delivery" together with the phrase "in connection with" to require a "common sense connection" or "nexus" between the underlying facts and circumstances of the offense and the delivery of health care items or services to individuals for their health care needs. See AR 16. This interpretation has been applied by the DAB in numerous decisions. See, e.g., Ellen L. Morand, DAB No. 2436, at 9, 2012 WL 369634 (H.H.S. Jan. 17, 2012) (theft of money from pharmacy by pharmacy employee); Charice D. Curtis, DAB No. 2430, at 5, 2011 WL 7444589 (H.H.S. Dec. 21, 2011) (theft of money from employer by in-home nursing services administrator); Kenneth M. Behr, DAB No. 1997 at n.5, 2005 WL 2835001 (H.H.S. Sept. 28, 2005) (attempted embezzlement by theft of drugs by pharmacist); DeSimone, 2004 WL 1764746 (theft of controlled substance by pharmacist from employer for his own use).

The same interpretation has also been approved by federal courts reviewing exclusion decisions. See, e.g., Friedman v. Sibelius, 755 F.Supp. 2d 98, 108 (D.D.C. 2010) ("common sense connection" or "nexus" standard was consistent with ordinary meaning of phrase "related to"), rev'd on other grounds, 686 F.3d 813, 820-23 (C.A.D.C. 2012); Ellicott v. Leavitt, 2008 WL 4809610 at *3 (S.D. Ga. Nov. 4, 2008); Quayum v. U.S.

Dept. of Health and Human Servs., 34 F.Supp. 2d 141, 143 (E.D.N.Y. 1998).

The Secretary asserts that a common sense nexus is present here because Dr. Harkonen's wire fraud conviction was based on (among other things) the issuance of a press release that misrepresented the effectiveness of a health care item (the prescription drug Actimmune) with the intent of persuading doctors to prescribe, and patients to take, Actimmune for IPF, and which was capable of influencing the decision of doctors to prescribe, or patients to seek, prescriptions of Actimmune.

However, Dr. Harkonen takes issue with the Secretary's analysis, arguing that such a standard is arbitrary and capricious, and leads to inconsistent results. He relies heavily on the decision in Kabins v. Sibelius, 2012 WL 4498295 (D. Nev. Sept. 28, 2012), where the court suggested that the Secretary's "common sense nexus" test is of questionable utility because it is susceptible to discretionary and arbitrary enforcement.

Both the facts and procedural history of the Kabins case are distinguishable from the facts and issues in this case. For example, the court in Kabins found that the petitioner had at best a "minor role" in the offense, whereas here, it is undisputed that Dr. Harkonen was the "controlling force" behind the Press Release.

It is true that the district court in Kabins reversed the determination of the Secretary with regard to the plaintiff, Dr. Kabins, and did so based on a finding that the felony for which Dr. Kabins had been connected was not committed "in connection with the delivery of a health care product or service." However, Dr. Kabins pled guilty to misprision (failure to report alleged crime of others) for helping cover up misdeeds of two attorneys, which led the court to conclude that the offense was best viewed as being in connection with the delivery of legal, not medical, services. See id., 2012 WL 4498295 at *2.

In the present case, by contrast, Dr. Harkonen was convicted of wire fraud in connection with false statements regarding the clinical trials of a prescription drug, which statements were likely to influence a person to part with money or property (to purchase the drug). The Kabins court's comments regarding the "common sense nexus" test appear in a footnote, and are dicta at best. See id. at *3 & n.1. Moreover, Dr. Harkonen's

exclusion is not contrary to the Kabins court's statement that an exclusion should not be "premised on what is a remote relatedness to some health care delivery," id., 2012 WL 4498295 at *3, because in this case the connection is not "remote" – Dr. Harkonen issued a false press release misrepresenting the efficacy of a prescription drug which was available at that time for doctors to prescribe and patients to take.

Dr. Harkonen also asserts that the mandatory exclusion criteria cannot be satisfied in this case because the underlying conviction was not based on "delivery" in the form of a physician writing a prescription for Actimmune, and because there was no showing that Actimmune was actually used by a patient as part of treatment for IPF. That is, he contends that "in connection with the delivery of a health care item" can refer only to conduct that occurs in the delivery process itself, and that where conduct – such as the issuance of a press release – is not itself part of the delivery process, and there is no showing that the conduct had a proximate impact on delivery because there was no direct connection to the drug's distribution or sale in commerce, it is too remote or peripheral for the mandatory exclusion to apply.

Dr. Harkonen's suggestion that the "delivery" of a drug only occurs at the point when a prescription is filled and paid for, and that because his company merely "delivered" the drug to a middleman (the distributor), he cannot be deemed to have participated in the "delivery" of the drug or to have made any misrepresentation regarding the drug during its "delivery," is contrary to the language and purpose of § 1128(a)(3), as shown by the legislative history of the statute and the broadly-described felonies encompassed therein. Moreover, it also departs from DAB precedent. See, e.g., Scott D. Augustine, DAB 2043, 2006 WL 2751080 (H.H.S. Sept. 14, 2006) (misrepresentation in connection with sale of medical equipment to a distributor was part of process of delivery to medical facility or patient, supporting exclusion under § 1128(a)(2)).

Courts have interpreted the phrases "in connection with" and "in relation to" as encompassing the very type of "potential" effect that Dr. Harkonen contends is an impermissible stretch of the statutory language. See, e.g., Smith, 508 U.S. at 238 (firearm

deemed to have been used "in relation to" a drug trafficking offense if it had "the potential of facilitating" the offense); United States v. Routon, 25 F.3d 815, 819 (9th Cir. 1994) (firearm deemed have been used or possessed "in connection with" a felony offense even if the firearm only "potentially facilitated" or had "some potential emboldening role" in the crime).

Dr. Harkonen asserts that the legislative history of § 1128 demonstrates that the purpose of the statute is to protect Medicare, Medicaid, and other Federal programs and their beneficiaries from financial misconduct and the provision of inadequate or improper care – and that it was for this reason that Congress included the provisions allowing or requiring excluding individuals and certain entities for certain conduct that it described in the Senate Report as "related to the delivery of health care." He suggests that because "theft," "embezzlement," and "financial misconduct" are specifically listed in the statute and necessarily occur in connection with a program's "delivery" of items and services, it is those types of actions which constitute offenses that if done in connection with Medicare or Medicaid, would constitute stealing from the government, and which can support exclusion under § 1128(a)(3).

Congress enacted the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), of which 42 U.S.C. § 1320-7(a)(3) is a part, "to combat waste, fraud, and abuse in health insurance and health care delivery." Pub.L. No. 104-191, 110 Stat.1936, 1936 (1996). The legislative history regarding the statute as originally enacted indicates that it was intended to protect federal programs from untrustworthy individuals and to "provide a clear and strong deterrent against the commission of criminal acts." S. Rep. 100-109, at 5 (1987), reprinted in 1987 U.S.C.C.A.N. 682, 686.

The court finds, however, that there is nothing in the language of § 1128(a)(3) or the legislative history that requires that the conviction have been for an act equivalent to "stealing from the government" – such as defrauding Medicare. Moreover, subsection (a)(1) of the statute mandates a minimum five-year exclusion for anyone convicted of "program-related crimes" – i.e., "a criminal offense related to the delivery of an item or

service" under Medicare or Medicaid. Thus, subsection (a)(3) must be directed at a different type of conviction.

The offenses enumerated in subsection (a)(3) are felonies "relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct." Dr. Harkonen's interpretation would read out everything except theft and embezzlement, and some aspects of "other financial misconduct." The statute does not require that the "fraud" be fraud perpetrated against the government – just that it be "fraud" and that it be "in connection with the delivery of a health care item or service."

The DAB's decision affirming the ALJ is the product of formal adjudication that merits Chevron deference. See Arizona Health Care Cost Containment Sys. v. McClellan, 508 F.3d 1243, 1249 (9th Cir. 2007). Prescription drugs are "health care items." See 42 C.F.R. § 1001.101(b) (regulation interpreting subsection (a)(1) refers to health care item or service as "any item or service to an individual to meet his or her physical, mental, or emotional needs or well-being").

The connection argued by the Secretary – that the issuance of a press release containing false information about the efficacy of a prescription drug was designed to encourage more sales of that drug, and can be considered fraud in the "delivery" of that prescription drug in that it was issued in order to persuade doctors to prescribe, and patients to seek, prescriptions for that drug – is a permissible interpretation and is not unreasonable. Thus, under the Chevron standard, the court must defer to this reasonable interpretation.

Dr. Harkonen also argues that the Secretary's exclusion decision fails the substantial evidence test, both because he was acquitted on the misbranding count, and also based on the district court's findings at sentencing. He contends that the wire fraud count was for a "transmittal" to the general public that was not part of the drug's distribution (or "delivery"), and the jury was not required to find any actual or specifically intended impact on sales. By contrast, in Dr. Harkonen's view, the misbranding count – on which he was acquitted – was expressly a charge of misrepresentations in connection with the

drug's sales.

That is, Dr. Harkonen claims that because he was acquitted on the charge that would have involved a connection to the delivery of Actimmune (misbranding) and was convicted of the charge that did not (wire fraud), there is no basis for concluding that his "intent" in issuing the Press Release was to defraud physicians into prescribing, and patients into purchasing, Actimmune. He argues that because there was no clear connection between his conviction and the delivery of a prescription drug, the Secretary's decision is arbitrary and capricious.

As an initial matter, the court finds that the DAB correctly concluded that Dr. Harkonen's acquittal on the misbranding charge has no impact on the analysis in the exclusion proceedings, which are based on a fraud conviction. The inquiry for the misbranding count in the criminal case required a finding that Actimmune bore false or misleading labeling. Such a finding is entirely different from the standard in the present civil action. In particular, "labeling" is far more limited in its breadth than "in connection with." See 21 U.S.C. § 321(m) (defining "labeling" as all labels or printed matter on any article or its containers, or accompanying such article). Thus, a press release can be issued "in connection with the delivery of a health care item or service" while at the same time not qualifying as labeling – which is the case here.

Moreover, the underlying facts and circumstances of Dr. Harkonen's offense – as set forth in the district court opinions, the Ninth Circuit opinion, and the DAB opinion – show that the issuance of the press release was connected to the delivery of health care items to individuals. As Dr. Harkonen concedes in his moving papers, "delivery" can also mean "distribution or sale in commerce." Dr. Harkonen was the CEO of a business dedicated to the development and manufacture of drugs for health care delivery. He committed his crime as part of operating that business. The jury instructions, as well as the guilty verdict on the wire fraud count, establish that Dr. Harkonen's conviction is "in connection with the delivery of a health care item or service."

In returning a conviction on the wire fraud count, the jury necessarily found each of

the five elements of the crime proven beyond a reasonable doubt – that Dr. Harkonen had "made up a scheme or plan to defraud by making false or fraudulent statements;" that Dr. Harkonen knew that the statements in the August 28, 2002 Press Release were false or fraudulent at the time they were made; that "the statements were material" – that is, that "they had a natural tendency to influence, or were capable of influencing, a person to part with money or property;" that Dr. Harkonen had "acted with the intent to defraud;" and that Dr. Harkonen had "used, or caused to be used, the interstate wires to carry out or attempt to carry out the scheme." See AR 443.

The Press Release was designed to increase sales of a prescription drug that was already in the stream of commerce. Thus, the sales of Actimmune and its use by patients were part of the delivery process, and both were clearly referenced in the Press Release. The fact that Dr. Harkonen's conviction required a finding that the fraudulent statements or omissions in the Press Release (or the Press Release as a whole) "had a natural tendency to influence, or were capable of influencing, a person to part with money or property," as set forth in the wire fraud jury instruction, further illustrates the link between the conviction and the commercial prescription drug market.

In denying Dr. Harkonen's post-trial motions, the district court noted that the prosecution had introduced evidence at trial not only that numerous statements in the Press Release were false or fraudulent, but also that the Press Release "as a whole" was false or fraudulent. Harkonen, 2010 WL 2985257 at *9.

Among other things, the court found that Dr. Harkonen was the "controlling force" behind the content of the Press Release, and that there was sufficient evidence for the jury to conclude beyond a reasonable doubt that multiple statements in the Press Release (including the headline) were false or fraudulent. In particular, the Press Release described the study as "a success," but the overwhelming evidence at trial was that it was a failure. The court also concluded that the basis of the jury's finding of falsity could have been the Press Release's wording together with "omissions of critical information," especially given that there was no other independent source at the time from which

interested individuals could have verified the results. See AR 21-26; see also Harkonen, 2010 WL 2985257 at *9-12.

A fraud that occurs in the "chain of delivery" qualifies for exclusion. See, e.g., Augustine, 2006 WL 2751080. Here, the DAB legitimately concluded that the Press Release's claims about Actimmune "could reasonably be viewed by the ALJ as part of a delivery process." See AR 21. Moreover, Dr. Harkonen's misrepresentation occurred before, during, and after his company's delivery of the health care item Actimmune, and in addition was intended to, and likely did, impact the decisionmaking process of doctors and patients as to whether to prescribe/take the drug. For this reason, Dr. Harkonen's offense occurred in the "chain of delivery of a health care item or service."

The district court concluded that the scheme to defraud underlying the wire fraud conviction encompassed the false promotion of Actimmune to physicians and patients, and was not limited to the issuance of the Press Release, but included "extensive, coordinated efforts by InterMune to disseminate the press release to doctors and patients." See AR 358, 362; U.S. v. Harkonen, CR-08-0164 MHP (N.D. Cal.), Memorandum & Order re Defendant's Motions for a New Trial, unpub. decision, at 8, 12.

The district court found in its post-trial memorandum that the fact that a press release is not the type of scientific data consulted by physicians in making treatment decisions does not mean that the statements contained in the Press Release are not material. The Ninth Circuit subsequently arrived at the same conclusion – that there was sufficient evidence to support a finding that the statements (or omissions) in the Press Release carried the capacity to affect treatment decisions. See AR 360, 362.

The district court also found that the Press Release had some influence on IPF patients and/or their family members, as the court referred to letters from members of the public, including one written by the son of an IPF patient, requesting that the VA prescribe Actimmune for his father. Furthermore, the court concluded that the Press Release itself was written in such a way as to tout its own significance. The district court characterized Dr. Harkonen's crime as involving the coordinated decisionmaking between doctors and

IPF patients to prescribe and take Actimmune, and found extensive evidence introduced at trial from which the jury could infer the materiality of statements in the Press Release. See AR 358, 362, 365.

Similarly, the DAB's found that the Press Release was part of and in connection with the delivery process. The Press Release quoted Dr. Harkonen as saying that he believed the results being reported "will support use of Actimmune and lead to peak sales in the range of $400-$500 million per year." AR 515. The DAB found that Dr. Harkonen, as the CEO of a business dedicated to developing and manufacturing drugs for health care delivery, committed his crime in the context and under the cover of carrying out that business, as the sale of a drug and its use by a patient are both necessary parts of the delivery process and both were clearly referenced in the Press Release. See AR 21.

Dr. Harkonen's second principal contention is that the Secretary unjustifiably ignored the district court's findings at sentencing – specifically the finding that there was no evidence that Dr. Harkonen intended to cause any loss. In a related argument, he contends that the government asked for, and the district court rejected, an enhancement based not merely on actual loss, but also on intended loss (citing AR 464, 485-87; U.S. v. Harkonen, 510 Fed. Appx. 633, 2013 WL 782354 at *4). He asserts that when the district court rejected the proposed enhancement for intended loss as lacking any reasonable basis, the court was applying essentially the same evidentiary standards that the ALJ was required to apply in determining whether the Secretary had met her burden of demonstrating a sufficient connection to the delivery of health care services.

The court finds, however, that the DAB reasonably concluded that nothing in the sentencing proceeding conflicted with the finding that Dr. Harkonen's fraud conviction was "in connection with the delivery of a health care item or service." The question at sentencing was whether the government had met its burden with regard to the imposition of a sentencing enhancement that was based on the amount of the loss caused by the conduct underlying the conviction. See U.S.S.G. § 2B1.1, n.2(A)(i) (2001 rev.) – "[a]ctual loss" means "reasonably foreseeable pecuniary harm that resulted from the offense"); id.

§ 2B1.1, n.2(A)(ii) – "[i]ntended loss" means "pecuniary harm that was intended to result from the offense."

Thus, the court's inquiry was whether "an amount of loss" caused (or intended to be caused) by the Press Release could be determined with a sufficient degree of accuracy. The court found that it was "unable to determine with a sufficient degree of accuracy that . . . there is a loss as a result of the conduct reflected in the wire fraud count." AR 464-65. The fact that the district court was unable to determine that there was an amount of loss caused by the Press Release does not constitute an affirmative finding that in committing wire fraud, Dr. Harkonen did not intend to cause any loss, or did not intend to encourage patients to use and doctors to prescribe Actimmune. Moreover, this conclusion is bolstered by the court's failure to apply a "mass marketing" enhancement during the same hearing.

The court finds that substantial evidence in the record as a whole supports the finding that Dr. Harkonen's offense was in connection with the delivery of a health care item or service. InterMune disseminated the Press Release to doctors, patients, and pharmacies, and Dr. Harkonen's "scheme to defraud" extended over a period of time and entailed both the issuance of a Press Release containing false and misleading information about Actimmune, but also the dissemination of the misinformation in the Press Release to pharmacies that sold Actimmune to patients and doctors.

2. Whether construing § 1128(a)(3) as mandating exclusion would result in violations of Dr. Harkonen's constitutional rights.

Dr. Harkonen argues that upholding the Secretary's decision would result in a violation of his rights under the Fifth and Eighth Amendments to the United States Constitution.

a. Double jeopardy

Dr. Harkonen contends that exclusion constitutes double jeopardy in violation of the Fifth Amendment's Double Jeopardy Clause, because even though the mandatory exclusion resembles a civil penalty, it effectively constitutes a criminal penalty, and

therefore amounts to a double punishment.

The Double Jeopardy Clause, which provides that no "person [shall] be subject for the same offence to be twice put in jeopardy of life or limb," is violated when multiple punishments are imposed for the same offense. Schiro v. Farley, 510 U.S. 222, 229 (1994). Thus, it may be violated when a defendant, punished in a criminal prosecution, is penalized by a subsequent punitive civil sanction. Hudson v. United States, 522 U.S. 93, 98-99 (1997). However, it protects only against the imposition of multiple criminal punishments for the same offense. Id. at 99.

In determining whether a penalty is criminal or civil, the court must first ask whether the legislature, in establishing the penalizing mechanism, indicated either expressly or impliedly a preference for one label or the other. United States v. Reveles, 660 F.3d 1138, 1140 (9th Cir. 2011) (citing Rivera v. Pugh, 194 F.3d 1064, 1068 (9th Cir. 1999)); see also Hudson, 522 U.S. at 99. Even where the legislature has indicated an intention to establish a civil penalty, the court inquires further whether the statutory scheme is so punitive either in purpose or effect as to transform what was clearly intended as a civil remedy into a criminal penalty. Reveles, 660 F.3d at 1140.

To determine whether a remedy denominated "civil" is actually a punitive criminal penalty subject to the prohibition of double jeopardy, a court may consider whether the sanction (1) involves an affirmative disability or restraint; (2) has historically been regarded as punishment; (3) requires a finding of scienter; (4) will promote retribution and deterrence; (5) applies to behavior that is already a crime; (6) can have an alternative purpose; and (7) appears excessive in relation to the alternative purpose. Id.; see also Kennedy v. Mendoza-Martinez, 372 U.S. 144, 168-69 (1963).

These factors, which "provide useful guideposts," Hudson, 522 U.S. at 99, should be considered "in relation to the statute on its face, and only the clearest proof will suffice to override legislative intent and transform what has been denominated a civil remedy into a criminal penalty." Reveles, 660 F.3d at 1143 (citations and quotations omitted). "With this very high burden, even a showing that most of the relevant factors weigh in favor of

considering a punishment criminal in nature may be insufficient to transform it into a criminal punishment." Id. In particular, "no one factor should be considered controlling." Hudson, 522 U.S. at 101.

The court finds that the Double Jeopardy Clause does not preclude application of the exclusion. Section 1128(a)'s statutory scheme is not so punitive in purpose or effect so as to transform what was clearly intended as a civil remedy into a criminal penalty.

First, the exclusion does not involve confinement or another form of restraint. While it does preclude individuals and entities from participating in Federal health care programs, it does not impose any physical restraint. Second, there is no indication one way or another as to whether exclusion has historically been regarded as a punishment. Third, while scienter is certainly an element of the convictions that trigger the exclusion, exclusion does not require a finding of scienter, as exclusion may be imposed regardless of the convicted individual's state of mind.

Fourth, as for whether operation of the exclusion promotes deterrence and retribution, there appears to be an element of deterrence in the penalty, but the court finds no indication that its purpose is retribution. Moreover, it is undisputed that deterrence can be a legitimate aim of any civil sanction without transforming it into a criminal sanction. See id. at 102. Fifth, while exclusion is triggered by a conviction for certain felonies, and can in that sense be said to apply to behavior that is already a crime, the offenses listed in the statute also can form the basis of civil actions – fraud, various forms of theft, financial misconduct.

Sixth, the exclusion clearly serves an alternative purpose, and it does not appear excessive when compared to that purpose. The legislative history of the five-year minimum mandatory exclusion period in § 1128(a) establishes that the sanction is civil and remedial. The Senate Finance Committee report indicates that the purpose of the Medicare and Medicaid Patient and Program Protection Act is to "improve the ability of the Secretary and the Inspector General of [HHS] to protect Medicare, Medicaid, [and other social services programs] from fraud and abuse," and also to "protect the beneficiaries of

those programs from incompetent practitioners and from inappropriate or inadequate care." S. Rep. No. 109, 100th Cong., 1st Sess., at 1-2 (1987), reprinted in 1987 U.S.C.C.A.N. 682.

In addition, the Committee report states that the law "should provide a clear and strong deterrent against the commission of criminal acts." Id. at 5, 1987 U.S.C.C.A.N. at 686. While the desire to provide a deterrent may also be a punitive goal, the legislative history demonstrates that the primary goal of the legislation is to protect present and future Medicare beneficiaries from the abusers of these programs.

Therefore, given that the legislative intent of the exclusionary period is to protect the public, the court finds that the sanction should be viewed as civil and remedial, not punitive. See Manocchio v. Kusserow, 961 F.2d 1539, 1543 (11th Cir. 1992) (exclusionary period provided by § 1128(a) is remedial, not punitive).

The Double Jeopardy Clause protects only against the imposition of multiple criminal punishments for the same offense, and does not prohibit the imposition of additional sanctions that could, in common parlance, be considered "punishment." See Hudson, 522 U.S. at 98-99. On balance, the court finds that the Kennedy factors overwhelmingly favor a finding that the exclusion of Dr. Harkonen – which is remedial in purpose – cannot give rise to a claim of violation of the Double Jeopardy Clause.

b. Excessive fines and cruel and unusual punishment

Dr. Harkonen argues that the exclusion is grossly disproportionate to the nature of his offense, and that upholding the Secretary's decision would result in a violation of his Eighth Amendment right to be free from excessive fines and cruel and unusual punishment. He contends that the five-year exclusion is excessive in comparison to his "minor" felony offense, which he characterizes as providing a "misleading" interpretation of clinical data, with no impact on Actimmune delivery.

The limitations of the Excessive Fines Clause of the Eighth Amendment to the Constitution are applied only to fines "directly imposed by, and payable to, the government" and only to fines constituting punishment. See, e.g., Austin v. United States, 509 U.S. 602,

607 (1993) (citation omitted); see also Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc., 492 U.S. 257, 264-65 (1989) (excessive fines clause is implicated only when a party must make "a payment to a sovereign as punishment for some offense").

Here, to the extent that the exclusion can be considered a "fine" – in the sense that an individual or entity that is excluded from participation in Federal health care programs will lose money, which is not quite the same as paying money to the government as a sanction – the question is whether it is excessive.

Dr. Harkonen asserts that because the district court could not identify a clear "victim," and did not grant the government's request for a lengthy prison sentence, and because in his view his offense was "minor," consisting of nothing more than a simple "misrepresentation" of some clinical data, and because the government was unable to prove any "actual loss," the five-year exclusion is "excessive" and violates the Eighth Amendment.[2]

As explained above, however, exclusions imposed by the OIG are civil sanctions, designed to protect beneficiaries of Federal health care programs from "untrustworthy" providers and others involved in the delivery of health care items and services, and are thus remedial in nature rather than primarily punitive or deterrent. Thus, the exclusion is not subject to the Excessive Fines Clause. Moreover, even if the exclusion has some punitive aspect, it is not a sanction that is "grossly disproportionate" to the gravity of the underlying offense. See, e.g., United States v. Bajakajian, 524 U.S. 321, 334 (1998) ("The amount of forfeiture must bear some relationship to the gravity of the offense that it is designed to punish.").

Federal courts have repeatedly held that a § 1128 exclusion is civil and remedial rather than criminal and punitive, and numerous DAB decisions have concurred. See AR

---

[2] Dr. Harkonen appears to be suggesting that there was no substantive merit to the wire fraud charge for which he was convicted. However, as set forth above, the Ninth Circuit has affirmed his conviction and sentence. Moreover, he was precluded from collaterally attacking the basis for the underlying conviction on either procedural or substantive grounds in the proceeding before the DAB. See 42 C.F.R. § 1001.2007(d); see also Travers, 20 F.3d at 998.

18 (citing Johann Fletcher Cash, DAB No. 1725, at 12, 2000 WL 710697 (H.H.S. May 23, 2000)); see also Manocchio, 961 F.2d at 1541-43 (legislative history of § 1128(a) establishes that the sanction is civil and remedial); Greene v. Sullivan, 731 F.Supp. 838, 839-40 (E.D. Tenn. 1990) (same); Donna Rogers, DAB No. 2381, 2011 WL 3251326 (H.H.S. May 23, 2011); Douglas L. Reece D.O., DAB No. 1448, 1993 WL 719939 (H.H.S. Nov. 15, 1993). The exclusion does not pose a concern under the Eighth Amendment, as it is not "grossly disproportionate" to the gravity of the underlying offense. See Bajakajian, 524 U.S. at 324.

In any event, § 1128(a)(3) gives the Secretary no discretion with regard to the minimum five-year period. Conviction of a felony involving fraud or other financial misconduct in connection with the delivery of a health care item or service is the triggering event that mandates that the Secretary impose a minimum five-year exclusion. The language – "the Secretary shall exclude" – is clearly not discretionary. See 42 U.S.C. § 1320a-7(a). There is no dispute here that Dr. Harkonen was convicted of wire fraud as a result of his involvement in the issuance of the Press Release. Thus, because the wire fraud was perpetrated in connection with the delivery of a health care item or service, the Secretary is required to exclude him from participation in federal health care programs for a minimum period of five years.

c. Due process

Dr. Harkonen argues further that the exclusion violates the Fifth Amendment's guarantee of due process, because there is no rational connection between the exclusion and any governmental interest – i.e., his offense had no impact on federal health care programs or patients, as the fraudulent statements involved only interpretation of data, not the presentation of false data – and the HHS's own sponsored-entity (the National Institute of Health - "NIH") committed a similar, though more egregious, act of "press release fraud" in 2009 in connection with the release of information regarding a medication to treat HIV, yet was not disciplined. He also contends that the exclusion violates his rights to substantive due process, because the Secretary acted arbitrarily in excluding him but failing

to discipline NIH employees who issued a similarly misleading press release in connection with a drug for treatment of HIV.

As explained above, the statute permits the Secretary no discretion is deciding whether to exclude an individual or entity from participating in Federal health care programs, once the requirements of § 1128(a) have been satisfied. Thus, because the Secretary had no discretion to exercise, her actions cannot be viewed as arbitrary and capricious.

The exclusion is rationally related to the government's interests in deterring fraud in the delivery of health care and health care items and services, and in protecting federal health care programs and their beneficiaries from individuals who have behaved in an untrustworthy manner. See Friedman, 686 F.3d at 820, 824; Morgan, 694 F.3d at 538; Manocchio, 961 F.2d at 1541-42. "Untrustworthiness" is not a separate element that the OIG must establish in order to support an exclusion. Nevertheless, Congress has reasonably determined that a felony conviction for fraud in connection with the delivery of a prescription drug is sufficient grounds for the government to "refuse to deal further with" an individual, Friedman, 686 F.3d at 824; AR 31 – or, in any event, for at least the statutory five-year period.

Nor does Dr. Harkonen's exclusion constitute an arbitrary government action in violation of the Fifth Amendment based on the NIH press release. As noted above, § 1128(a)(3) provides no discretion for the Secretary to exert – whether fairly, or in an arbitrary, capricious, or selective manner – because it mandates exclusion upon conviction of a charge of fraud in connection with the delivery of a health care product or service. Conversely, without an underlying conviction, the Secretary does not have the authority to exclude, except in certain specific situations (which do not apply to either NIH or the press release about which Dr. Harkonen complains). Since Dr. Harkonen has made no showing that any of the NIH-affiliated individuals was criminally prosecuted, he cannot prevail in this claim that his substantive due process rights have been violated because he was treated differently than the NIH employees.

CONCLUSION

In accordance with the foregoing, defendant's motion for summary judgment is GRANTED, and plaintiff's motion is DENIED.

IT IS SO ORDERED.

Dated: October 22, 2013

PHYLLIS J. HAMILTON
United States District Judge