**Department of Health and Human Services**
**DEPARTMENTAL APPEALS BOARD**
**Appellate Division**

W. Scott Harkonen, M.D.
Docket No. A-12-78
Decision No. 2485
November 9, 2012

# FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Petitioner W. Scott Harkonen, M.D., appeals the May 14, 2012 decision of Administrative Law Judge (ALJ) Keith W. Sickendick, sustaining Petitioner's exclusion from participating in Medicare, Medicaid, and all other federal health care programs for a period of five years under sections 1128(a)(3) and 1128(c)(3)(B) of the Social Security Act.[1] *W. Scott Harkonen*, DAB CR2541 (2012) (ALJ Decision). The Inspector General (I.G.) of the Department of Health and Human Services excluded Petitioner based on his felony conviction for wire fraud for making materially false or misleading statements about the efficacy of a prescription drug for the treatment of a fatal lung disease that were disseminated in a press release announcing the results of a clinical trial of the drug. On appeal, Petitioner argues that his offense did not occur "in connection with the delivery of a health care item or service" within the meaning of section 1128(a)(3) because there is no evidence that any physician actually prescribed the drug based upon the false statements contained in the press release. Petitioner also contends that the exclusion violates several of his constitutional rights.

For the reasons explained below, we find Petitioner's arguments are without merit and, therefore, sustain the ALJ Decision.

## Legal Background

Section 1128(a)(3) requires the Secretary of Health & Human Services to exclude from participation in any federal health care program—

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

> 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 specifically described in paragraph (1)) operated by or financed in whole or in part by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

Act § 1128(a)(3); *see also* 42 C.F.R. § 1001.101(c) (implementing section 1128(a)(3)). When the Secretary excludes an individual under section 1128(a), it must be for a minimum of five years. Act § 1128(c)(3)(B).

In hearings on exclusions under section 1128(a)(3), the issues before the ALJ are whether there is a basis for the exclusion, and whether the length of exclusion is unreasonable. 42 C.F.R. § 1001.2007(a)(1).

**Case Background**

The following facts are not disputed. Petitioner, a medical doctor, was the Chief Executive Officer of InterMune, Inc. (InterMune) from 1998 until at least June 3, 2003. InterMune was a pharmaceutical company that developed, marketed and sold drugs for lung and liver diseases, including the drug Actimmune. In 2000, Actimmune had been approved by the Food and Drug Administration (FDA) to treat only chronic granulomatous disease and severe malignant osteopetrosis.

In 1999, an Austrian clinical trial concluded that Actimmune's active ingredient was associated with improvement in patients with idiopathic pulmonary fibrosis (IPF), a rare and fatal disease of unknown origin. Median survival of patients with IPF is two to three years after diagnosis. There are approximately 200,000 people in the United States who have IPF, and approximately 50,000 new cases are diagnosed every year.

In response to the Austrian study findings, InterMune undertook its own clinical trial to test whether Actimmune was an effective treatment for IPF. In August 2002, InterMune received the results of its study, which showed that the study missed its primary endpoint, progression-free survival time, as well as all ten secondary endpoints, including survival time.

On August 28, 2002, InterMune issued a press release to the general public with the heading, "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF," with the subtitle, "Reduces Mortality by 70% in Patients with Mild to Moderate Disease." I.G. Ex. 5, at 1. The press release quoted Petitioner as stating:

> We are extremely pleased with these results, which indicate Actimmune may extend the lives of patients suffering from this debilitating disease. . . . Actimmune is the only available treatment demonstrated to have clinical benefit in IPF, with improved survival data in two controlled clinical trials. We believe these 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 . . . .

*Id.*

In an indictment filed on March 18, 2008, in the United States District Court for the Northern District of California, Petitioner was charged with two felony counts. Count One charged Petitioner with committing wire fraud in violation of 18 U.S.C. § 1343 and aiding and abetting in violation of 18 U.S.C. § 2. I.G. Exs. 1-2. The wire fraud count alleged that in furtherance of a scheme and artifice devised by Petitioner to defraud, on or about August 27, 2002, Petitioner caused to be transmitted over wire communication "a press release entitled '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,' which contained materially false and misleading information regarding Actimmune and falsely portrayed the results of the GIPF-001 Phase III trial as establishing that Actimmune reduced mortality in patients with IPF. . . ." I.G. Ex. 2, at 12. Count Two charged Petitioner with "[D]oing acts, with intent to defraud and mislead, resulting in drugs being misbranded while held for sale after shipment in interstate commerce, . . . and aiding and abetting" under 21 U.S.C. §§ 331(k), 333(a)(2), and 352(a), and 18 U.S.C. § 2. *Id.* at 13.

On September 9, 2009, the jury returned a verdict finding Petitioner guilty on the first count charged in the indictment and not guilty on the second count. I.G. Ex. 3, at 1.

By letter dated August 31, 2011, the I.G. notified Petitioner that he was being excluded from Medicare, Medicaid and all other federal health care programs for the mandatory minimum period of five years based on his felony conviction pursuant to section 1128(a)(3) of the Act. I.G. Ex. 6.

Petitioner timely requested a hearing before an ALJ. Petitioner subsequently waived an oral hearing, and the parties agreed that the appeal could be resolved based on the parties' briefs and documentary evidence. The parties thereafter submitted briefs and exhibits, and the ALJ admitted into evidence I.G. Exhibits 1 through 3, 5 and 6, and Petitioner Exhibits 1 through 11.[2]

[2] The ALJ noted that the I.G. did not submit an exhibit marked "I.G. Ex. 4." ALJ Decision at 2, n.3.

**The ALJ Decision**

The ALJ made four numbered Findings of Fact and Conclusions of Law (FFCL):

1. Petitioner's request for hearing was timely, and [the ALJ had] jurisdiction.

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

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.

With respect to FFCL 2, the ALJ determined that all of "the elements necessary for exclusion under section 1128(a)(3)" were satisfied. ALJ Decision at 5. The ALJ explained that Petitioner did not dispute he was convicted of a felony related to fraud that occurred after August 21, 1996, but instead disputed that the offense occurred "in connection with the delivery of a health care item or service" within the meaning of the statute. *Id.* Petitioner argued before the ALJ that "to prove 'delivery' there must be evidence that some physician actually wrote a prescription for Actimmune" as a result of Petitioner's crime and there was no such evidence. *Id.* at 6, *citing* RFH Ex. B, at 13-14; P. Br. at 15-22. Petitioner also argued that in acquitting Petitioner of felony misbranding, the jury had rejected the government's allegation that Petitioner intended to cause or caused an effect upon the delivery of a health care item.

The ALJ rejected Petitioner's arguments as without merit, concluding that he "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" to uphold the exclusion. *Id.* at 6. "Rather," the ALJ determined, "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." *Id. citing Erik D. DeSimone, R.Ph.,* DAB No. 1932, at 4 (2004). Here, the ALJ found, the press release on which Petitioner's wire fraud conviction was based was sufficient to establish that there was such a "nexus or common sense connection." ALJ Decision at 6-7. Specifically, the ALJ reasoned that the language in the press release "touting the virtues of Actimmune had a potential impact upon the delivery of health care in the community . . . ." *Id.* at 6. Statements in the press release attributable to Petitioner, the ALJ found, "establish[] that a purpose of the press release was to encourage victims of IPF and their physicians to use Actimmune for the treatment of IPF," and that it was "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." *Id.* at 7-8.

The ALJ also rejected Petitioner's arguments that his exclusion violated the Fifth Amendment's Double Jeopardy Clause and Due Process Clause, as well as the Eighth Amendment's prohibition against excessive fines and cruel and unusual punishment. The ALJ initially noted that he is "bound to follow the federal statutes and regulations," and has "no authority to declare them unconstitutional." *Id.* at 8, *citing Susan Malady, R.N.*, DAB No. 1816 (2002); 42 C.F.R. § 1005.4(c)(1). While the ALJ acknowledged that he is required to construe and apply the Act and regulations consistent with constitutional principles, he concluded that Petitioner's arguments were "only an attack upon the Act and the regulations on constitutional grounds" and that "Petitioner has preserved his issues for appeal" to federal court. ALJ Decision at 8.

## Proceedings before the Board

Petitioner timely appealed the ALJ Decision to the Board. Following the submission of the parties' briefs, the Board held an oral argument on September 13, 2012 at Petitioner's request and without objection by the I.G. The transcript of the oral argument is included in the administrative record.[3]

## Standard of Review

The standard of review on a disputed issue of law is whether the ALJ decision is erroneous. 42 C.F.R. § 1005.21(h). The standard of review on a disputed issue of fact is whether the ALJ decision is supported by substantial evidence in the record as a whole. *Id*. Substantial evidence is "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401 (1971), *quoting Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). Under the substantial evidence standard, the reviewer must examine the record as a whole and take into account whatever in the record fairly detracts from the weight of the evidence relied on in the decision below. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951).

## Analysis

In Part I of our analysis, we address Petitioner's argument that the offense for which he was convicted did not occur in connection with the delivery of any health care item or service under section 1128(a)(3). We first describe Petitioner's exceptions to the ALJ's construction of the statute. We then discuss the meaning of the language of section

[3] At the oral argument, counsel for the I.G. discussed an April 18, 2011 memorandum and order issued by the district court in Petitioner's criminal case denying Petitioner's motions for a new trial. Tr. at 29-32. The document is publicly available and was referenced in the I.G.'s brief but was not previously made a part of the record. *Id.* To ensure the administrative record is complete and without objection by Petitioner, the Board has included a copy of the document in the case record as Departmental Appeals Board Exhibit 1. *Id.*

1128(a)(3), the Board's application of the statute in prior cases, and the statute's legislative history. We explain why the ALJ's analysis is free from legal error and why his application of the provision is supported by substantial evidence on the record as a whole. We further describe why we reject Petitioner's arguments that the ALJ Decision contradicts the record of the criminal proceedings.

Part II of our analysis addresses Petitioner's constitutional challenges to his exclusion. We describe Petitioner's contentions that the exclusion constitutes double jeopardy under the Fifth Amendment, violates the Eighth Amendment's protections against excessive fines and cruel and unusual punishments, and violates the Due Process Clause's protection against arbitrary government action. We then explain why these arguments are without merit and do not provide a basis for the Board to reverse the ALJ Decision.

## I. The ALJ's determination that Petitioner's exclusion is required by section 1128(a)(3) of the Act is free from legal error and supported by substantial evidence in the record as a whole.

*Petitioner's contention that the ALJ misconstrued the exclusion statute*

Petitioner argues that his conviction for wire fraud was not a proper basis for exclusion because the offense did not occur "in connection with the *delivery* of a health care item" under section 1128(a)(3). P. Br. at 16-17 (emphasis added by Petitioner). According to Petitioner, the ALJ construed the statute "to allow exclusion based upon his own findings of an intent to cause a speculative, 'potential impact' on delivery." *Id.* at 16; Notice of Appeal, ¶ 5, *citing* ALJ Decision at 6. Petitioner argues that by "requiring that the offense be connected not just with any health care item or service, but with its '*delivery*,' Congress limited exclusion to offenses that harm patients or insurers, the statute's beneficiaries." P. Br. at 16.

Petitioner acknowledges that the Board has construed the statute "to encompass certain offense[s] involving 'unsuccessful or thwarted' attempts to engage in 'fraud or one of the other enumerated offenses.'" P. Br. at 21, *quoting* ALJ Decision at 6; *see also* Tr. at 4-5. But here, Petitioner asserts, the ALJ's "limitless" and "novel construction effectively strikes 'delivery' from the statute" and would support an exclusion based on a crime where "the requisite connection" is missing. P. Br. at 17-18, 20. According to Petitioner, the press release on which the wire fraud conviction was based "did not propose any transaction to deliver Actimmune, and it was not directed to patients, physicians, or insurers." *Id.* at 20. Petitioner alleges that "the 'potential impact' speculated by the ALJ would materialize only if multiple contingencies occurred" and "is far too attenuated to satisfy the exclusion statute." *Id.;* P. Reply at 6.

*The language, prior application and legislative history of section 1128(a)(3)*

The starting point for our analysis is the language of section 1128(a)(3), which provides in relevant part that the Secretary shall exclude an individual who has been "convicted for an offense which occurred . . . in connection with the delivery of a health care item or service . . . ." Analyzing the wording of the statute in prior cases, the Board has 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. *See, e.g., Ellen L. Morand*, DAB No. 2436, at 9 (2012); *Charice D. Curtis*, DAB No. 2430, at 5 (2011). Reading the statute's language to require a rational link between the facts or circumstances underlying the crime and the delivery of health care items or services is consistent with the ordinary meaning of the phrase "in connection with," which "is used to capture a very wide variety of different relationships," is noted for its "vagueness and pliability," and usually "expresses some relationship or association, one that can be satisfied in a number of ways such as a causal or logical relation or other type of relationship." *United States v. Loney*, 219 F.3d 281, 283-84 (3d Cir. 2000) (evaluating the meaning of "in connection with" in the context of United States Sentencing Guidelines), *citing, inter alia*, Fowler's Modern English Usage 172 (R.W. Burchfield ed., 3d ed. 1996); 1 Oxford English Dictionary 520 (compact ed. 1971); American Heritage Dictionary of the English Language 400 (3d ed. 1992); Webster's Ninth New Collegiate Dictionary 278 (1990).

In *Erik D. DeSimone, R.Ph.*, DAB No. 1932, the Board sustained the exclusion of a pharmacist based on his guilty plea to felony theft of a controlled substance from his employer. The Board concluded that the circumstances underlying the offense – that petitioner's employer obtained controlled substances for the purpose of delivering them to individuals to meet their health care needs, and that petitioner interfered with that delivery by taking the substances for his own use under the guise of performing his professional responsibilities – were sufficient to show that there was a "common sense connection" between the offense and the delivery of health care items to support the exclusion. *Id.* at 5.

Similarly sustaining the exclusion of a pharmacist who pleaded guilty to attempted embezzlement of prescription drugs from his employer, the Board in *Kenneth M. Behr*, DAB No. 1997 (2005), reasoned the petitioner's employer was a medical center that obtained drugs "for the purpose of delivering them to individuals in order to meet those individuals' health needs," and the "petitioner's responsibilities necessarily involved participating in delivery of drugs to the patients served" by his employer. *Id.* at 8. The Board also noted that the petitioner was able to attempt to embezzle those drugs because he had access to them as part of performing his professional duties and his attempted

embezzlement occurred under cover of performing those duties. These facts, the Board concluded, were sufficient to establish a "common sense connection" between the offense of which Petitioner was convicted and the delivery of a health care item or service. *Id.*

The Board in *Behr* also expressly rejected the argument that section 1128(a)(3) applies only where an element of the underlying criminal offense involves the actual delivery (i.e., transmission, distribution or administration) of a health care item or service: "Simply because Petitioner failed [in his attempt] to embezzle the drugs at issue and therefore did not 'deliver' them farther in the chain of commerce does not mean his offense did not 'occur in connection with the delivery of an item or service[.]'" *Id.* While "financial misconduct generally is not part of the actual delivery of the item or service," the Board explained, it "is related, for example, to payment for (or misappropriation of) an item or service that was delivered, that was fraudulently claimed to have been delivered, or that was intended to be delivered." *Id.* at 9. The Board also noted that its construction of the statutory language was "consistent with the regulations implementing section 1128(a)(3), which provide that an offense occurring in connection with the delivery of a health care item or service includes 'the performance of management or administrative services relating to the delivery of such items or services.'" *Id.* at 8; 42 C.F.R. § 1001.101(c)(1). The regulation reasonably interprets section 1128(a)(3) "to include offenses . . . which occur in the context of an individual's participation in the chain of delivery of health care items or services even if the individual's offense does not involve his/her personally delivering an item or service as an element of the offense." *Id.* at 8-9.

More recently, in *Morand*, the Board rejected a petitioner's argument that her theft of money from the evening deposits of her employer, a pharmacy, did not occur "in connection with the delivery of a health care item or service." DAB No. 2436. The Board explained that "the conduct underlying the criminal offense does not necessarily have to involve actual delivery (or the interruption of same) of a health care item or service to the patient or beneficiary" for the Secretary to exclude an individual under section 1128(a)(3). *Id.* at 9, *citing Curtis*, DAB No. 2430, at 5 (administrator's fraudulent theft of money from her employer, a provider of nursing services, was connected to the delivery of health care items or services where petitioner's employment status gave her access to the funds and the money stolen was "derived from and could have otherwise been used to fund the provision of health care items or services."). In *Morand*, the Board concluded, the fact that the evening deposits included revenue from the sale of health care items, and the fact that the petitioner had "diverted money that could have otherwise been used [to furnish] health care items or services," were "sufficient to demonstrate a common-sense connection between" the offense and the "delivery of a health care item or service." DAB No. 2436, at 10. Thus, the Board has held that frauds or thefts that are linked in a rational way to the delivery of a health care item or service do fall within the ambit of the statute.

The Board's interpretation of the language of section 1128(a)(3) is consistent with its construction of similar language in section 1128(a)(1), which requires the exclusion of individuals who have been convicted of an offense "related to the delivery of an item or service under title XVIII or under any State health care program."[4] In multiple cases involving section 1128(a)(1), the Board has found that offenses committed by petitioners were "related to the delivery of an item or service" where the crimes were rationally linked to, but did not directly involve or result in, the delivery of a health care item or service under title XVIII or a State health care program. For example, the Board determined that submitting false Medicaid claims was "related" to the delivery of an item or service under title XVIII or a State health care program, *Jack W. Greene*, DAB No. 1078 (1989), *aff'd, Green v. Sullivan*, 731 F. Supp. 835 (E.D. Tenn. 1990); *Michael Travers, M.D.*, DAB No. 1237 (1991), *aff'd, Travers v. Sullivan*, 791 F. Supp. 1471, 1481 (E.D. Wash. 1992) and *Travers v. Shalala*, 20 F.3d 993 (9th Cir. 1994); that the unlawful diversion of a Medicare reimbursement check was related to the delivery of an item under title XVIII, *Napoleon S. Maminta*, M.D., DAB No. 1135, at 7 (1990); and that there was a sufficient nexus between conspiring to commit bribery to reduce the amount of Medicare overpayments owed by a defendant and the delivery of a health care item or service to support exclusion. *Salvacion Lee, M.D.*, DAB No. 1859, at 4 (2002).

The Board's application of the phrases "in connection with the delivery of a health care item or service" and "related to the delivery of an item or service under title XVIII or under any State care health care program" effectuates the twin purposes of section 1128(a): 1) to protect federal health care programs and their beneficiaries from individuals who have been shown to be untrustworthy; and 2) to deter health care fraud.[5] *Jeremy Robinson*, DAB No. 1905, at 3 (2004), *citing* S. Rep. No. 109, 100th Cong., 1st Sess. (1987), *reprinted in* 1987 U.S.C.C.A.N. 682, 686; *cf. S.E.C. v. Zandford*, 535 U.S. 813 (2002) (sustaining the Securities and Exchange Commission's "broad reading" of the phrase "in connection with the purchase or sale of any security" under section 10(b) of the Securities Exchange Act of 1934 to effectuate the statute's remedial purposes).

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[4] Section 1128(a)(1) was enacted in 1987 under Public Law No. 100-93, § 2. Section 1128 (a)(3) was added in 1996 under Public Law No. 104-191, § 211. There is no legislative history that indicates Congress intended the wording "in connection with" to require something more than a nexus between an offense and the delivery of a health care item or service. Though Congress's use of different words may give rise to an inference that Congress meant something different, it appears that Congress used "in connection with" to avoid confusion, because it had already used the term "relating to" in section 1128(a)(3) to require that the offense "consist[ed] of a felony relating to . . . embezzlement . . . or financial misconduct." *Kenneth M. Behr*, DAB No. 1997, n.5. The Board has also previously rejected an argument that the use of "related to" in some parts of the exclusion statute and "in connection with" in other parts should mean the terms are to be interpreted differently. *Chander Kachoria, R.Ph.*, DAB No. l380, at 4-5 (1993). The Board examined section 1128 of the Act as a whole and concluded that "Congress intended no difference" in meaning between the two phrases. *Id*. at 5.

[5] Federal courts and this Board "have repeatedly held that a section 1128 exclusion is civil and remedial rather than criminal and punitive." Joann Fletcher Cash, DAB No. 1725, at 12 (2000) (citations omitted). The deterrent goal of the exclusion provision does not transform this civil remedy into a criminal or punitive sanction. *Id.* at 11.

Indeed, the Board has previously noted, "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 . . . .'" *Jeremy Robinson*, DAB No. 1905, at 3-4, *citing* H.R. Rep. 496(I), 104th Cong., 2nd Sess. (1996), *reprinted in* 1996 U.S.C.C.A.N. 1865, 1886. The United States Court of Appeals for the 11th Circuit has concluded, moreover, that the "legislative history [associated with section 1128(a)], taken as a whole, demonstrates that the primary goal of the legislation is to . . . protect the public. . . ." *Manocchio v. Kusserow*, 961 F.2d 1539, 1541–42 (11th Cir. 1992), *citing* S.Rep. No. 109, 100th Cong., 1st Sess. 1-2, 5 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682, 686. Another federal court has observed that a narrow interpretation of the statute "would limit the deterrent effect intended by Congress." *Morgan v. Sebelius* No. 3:09-1059, 2010 WL 3702608, at 6 (S.D.W.Va. 2010), *aff'd, Morgan v. Sebelius*, 694 F.3d 535 (4th Cir. 2012).

*The ALJ's conclusion is free from legal error and supported by substantial evidence.*

In light of the language of section 1128(a)(3), prior Board decisions interpreting the statute, and the statute's legislative history, we conclude that the ALJ's construction of the exclusion provision is free from legal error. As the ALJ correctly stated, the wording of the statute read in its entirety requires "that there be a nexus or common sense connection between the offense and the delivery of a health care item or service," but does not require proof of "an actual impact or effect" on the delivery of a health care item or service (in this case, according to Petitioner, proof that the false or fraudulent statements in the August 28, 2002 press release caused physicians to prescribe and patients to take Actimmune). ALJ Decision at 6, *citing Erik D. DeSimone, R.Ph.*, DAB No. 1932, at 4. Rather, an ALJ considers the circumstances underlying the offense, taking into account, for example, whether the offence "related to an item or service that was delivered, that was fraudulently claimed to have been delivered, or that was intended to be delivered." *Kenneth M. Behr*, DAB No. 1997, at 9. In evaluating whether the circumstances underlying the offense are rationally linked to the delivery of a health care item or service, the ALJ correctly explained, an ALJ may "consider evidence of the conviction and any other evidence presented . . ." ALJ Decision at 7; *see* 42 C.F.R. § 1005.17 (governing the admissibility of evidence in the ALJ proceedings).[6]

[6] The Board has held that it "does not follow from the derivative nature of the exclusion that all elements of the exclusion must be contained in the necessary elements of the criminal offense or referenced in the process leading to the conviction." *Narendra M. Patel, M.D.*, DAB No. 1736, at 12 (2000), *aff'd Patel v. Thompson*, 319 F.3d 1317 (11th Cir. 2003). "[W]hether a particular conviction meets all the elements required for exclusion depends instead on the facts and circumstances surrounding the underlying conduct which constituted the offense leading to the actual conviction." *Id.* Thus, the Board has explained, "extrinsic evidence . . . is admissible where reliable and credible to show the underlying facts of the specific conduct which did in fact form the basis of the conviction from which the exclusion authority derives, regardless of whether that evidence (or evidence of all the facts and circumstances relevant to the exclusion authority) formed part of the criminal process. *Id.*

We further conclude that substantial evidence in the record as a whole supports the ALJ's determination, based on the language contained in the August 2002 press release, that there was a rational, common sense connection between the occurrence of the felony for which Petitioner was convicted and the delivery of a health care item. As noted above, Count One of the indictment charged Petitioner with wire fraud and aiding and abetting, in violation of 18 U.S.C. §§ 1343 and 2. The indictment alleged that "[o]n or about August 27, 2002 . . . having devised and intending to devise a scheme and artifice to defraud by means of materially false and fraudulent pretenses, representations and promises," Petitioner caused to be transmitted:

> a press release entitled "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," which contained materially false and misleading information regarding Actimmune and falsely portrayed the results of the GIPF-001 Phase III trial as establishing that Actimmune reduced mortality in patients with IPF . . . .

I.G. Ex. 2, at 12, ¶ 26.

The jury instructions on the wire fraud count provided that to find Petitioner guilty of that offense, the jury was required to find beyond a reasonable doubt that each of the following elements were met: 1) Petitioner "made up a scheme or plan to defraud by making false or fraudulent statements . . . [which] may include deceitful statements, half-truths, or statements which omit material facts . . . with the intent to deceive;" 2) Petitioner "knew that the statements made in the August 28, 2002 press release were false or fraudulent at the time they were made;" 3) "the statements were material; that is, they had a natural tendency to influence, or were capable of influencing, a person to part with money or property;" 4) Petitioner "acted with the intent to defraud" (i.e., "act[ed] knowingly with the specific intent to deceive or cheat, ordinarily for the purpose of either causing some financial loss to another or bringing about some financial gain to one's self"); and 5) Petitioner "used or caused to be used, the interstate wires to carry out or attempt to carry out the scheme." P. Ex. 5, at 1, 4; *see also* I.G. Ex. 1, at 1; I.G. Ex. 3, at 1.[7] Thus, the indictment, the jury instructions, and the jury's guilty verdict on the wire fraud count establish that false or fraudulent statements in the August 28, 2002 press release, which Petitioner knew to be false or fraudulent and made or directed with the intent to deceive, and which had a natural tendency to influence a person to part with money or property, were central to Petitioner's offense.

[7] Petitioner objected to the inclusion in the jury instructions of "half-truths or statements which omit material facts" as forms of false or fraudulent statements; the court overruled this objection. P. Ex. 2, at 7-8, 12.

Applying section 1128(a)(3) to the circumstances underlying Petitioner's conviction, the ALJ reasonably determined that the language used in the press release itself showed that "the intent of the release and Petitioner's statements therein were to increase the sale of Actimmune" and thereby have an impact on delivery of the drug. ALJ Decision at 7. The press release stated that InterMune's clinical trial "demonstrate[ed]" a "survival benefit of Actimmune in IPF," characterized Actimmune as the "only available treatment demonstrated to have clinical benefit in IPF" for this "debilitating and usually fatal disease," and reported that Actimmune "reduces mortality by 70% in patients with mild to moderate" IPF. I.G. Ex. 5, at 1. The language of the press release thus implied that statistically significant data from a clinical trial showed that the drug caused patients with mild to moderate IPF to live longer when, in fact, Petitioner had been informed that the actual data did not establish such a causal connection. P. Ex. 1, at 18-19. Moreover, in quoting Petitioner to have stated that "*these results will support use of Actimmune"* and, in turn, enable InterMune to "achieve profitability," the press release conveyed an expectation that the outcome of the study should, and would, lead to increased use of the drug for patients with IPF and financially benefit those producing or selling the drug. I.G. Ex. 5, at 1 (emphasis added). Furthermore, because of the very subject of the press release and its widespread circulation to the general public, including patients and health care practitioners, the ALJ reasonably inferred "that both physicians who could prescribe Actimmune and patients who suffer IPF and could ask for prescriptions were targets of the false press release." ALJ Decision at 8.

Thus, Petitioner misrepresents the ALJ's reasoning by characterizing the decision as based upon the ALJ's "own findings of an intent to cause a speculative, 'potential impact' on delivery." P. Br. at 16. Rather, the ALJ reasonably looked at the language of the press release and concluded that the claims in the press release had the potential to encourage patients to seek, and doctors to prescribe, Actimmune. The ALJ could reasonably infer that Petitioner's intent in issuing the press release encompassed affecting the delivery of a health care item, regardless of whether a physician actually prescribed the drug based on the press release. Moreover, even absent any intent by Petitioner, the press release's claims about the drug could reasonably be viewed by the ALJ as part of a delivery process.

Accordingly, we conclude that the ALJ properly applied section 1128(a)(3) and reasonably determined that Petitioner's crime occurred in connection with the delivery of a health care item. We also note that as the Chief Executive Officer of a business dedicated to developing and manufacturing drugs for health care delivery, Petitioner committed his crime in the context and under the cover of carrying out that business.

*Petitioner's arguments that the ALJ's findings lack substantial evidentiary support are unpersuasive.*

Petitioner argues that no "reasonable mind" could support the ALJ's reading of the press release. P. Br. at 29. According to Petitioner, "the wire fraud conviction was based on only certain statements – the *interpretation* that the study data demonstrated a survival benefit." *Id.* (emphasis in original). The actual data, Petitioner asserts, "were accurately reported in the press release and were made publicly available within just days of the press release's initial transmission." *Id.* Petitioner states that as a medical doctor he knows that "physicians have a professional and ethical duty to exercise 'independent judgment' about whether to prescribe a drug, based on actual data," and the press release itself indicated "the expectation physicians would 'evaluate [the study] when making treatment decisions for their patients.'" *Id.* at 29-30, *citing Transue v. Aesthetech Corp.*, 341 F.3d 911, 916-19 (9th Cir. 2003); I.G. Ex. 5, at 3. "As someone intimately familiar with the realities of drug sales," Petitioner argues, he "knew that the press release headlines would not influence prescribing decisions, and could not have intended otherwise." P. Br. at 31-32; *see also* Tr. at 12-13, 26-27 ("Doctors don't prescribe based on press releases. It's against their professional duty to do so. There's no evidence that they do so. They never did so."). Petitioner also asserts that his statement that the study results would support use of Actimmune and lead to peak sales "reflected his belief" that after the full study data were presented, discussed and analyzed by the medical community, "doctors would have a sufficiently favorable clinical view . . . to support the years of future sales he projected," and the statement was merely to "communicate[] that belief to the markets." P. Br. at 30.

Petitioner's claims that his wire fraud conviction was based *only* on statements in the press release interpreting the study data, on which doctors would not rely, and that the data doctors would have independently assessed were accurately reported in the press release, are contradicted by the material facts pled in the indictment, the district court's assessment of the evidence introduced at trial, and the district court's enumeration of the possible bases for the jury's verdict. As quoted above, Count One of the indictment identified the press release by its title and subheading, which interpreted the study data, and described the document generally to have "contained materially false and misleading information regarding Actimmune and falsely portrayed the results of the GIPF-001 Phase III trial as establishing that Actimmune reduced mortality in patients with IPF . . . ." I.G. Ex. 2, at 12. Thus, the government's charge that the press release contained false or fraudulent statements was not limited to statements in the document interpreting the study data. Furthermore, in denying Petitioner's post-trial motion, the district court explained that at trial the prosecution introduced evidence 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. P. Ex. 1, at 13.

On review of that evidence and in response to Petitioner's post-trial motion, the court explained that Petitioner 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 contained in the press release [including the headline interpreting the study data] were false or fraudulent." *Id.* at 13-14. The court observed that the jury "could have concluded that the press release, as a whole, was false or fraudulent" because it described the study "as a success" while the "overwhelming, undisputed evidence at trial was that the . . . study was a failure." *Id.* at 15. The court further explained that "the basis of the jury's finding of falsity" also could have been the press release's wording together with "*omissions of critical information* – especially given that at the time of the press release there was no publicly available data for the [study] such that *interested individuals* could verify the results . . . ." *Id.* at 15 (emphases added). In particular, the court pointed out, the "jury heard credible testimony that in clinical trials with multiple endpoints" such as InterMune's GIPF-001 study, "where the primary endpoint is missed, and where researchers conduct post-hoc, subgroup analyses, p-values are unreliable." *Id.* at 14. "Thus," the court stated, "depending on the context, sub-0.05 p-values do not 'demonstrate,' prove, establish or indicate anything." *Id.* InterMune's press release completely omitted "any mention that the only results with a p-value less than 0.05 – the subgroup analysis of patients with mild to moderate IPF – were observed only after InterMune engaged in retrospective analysis." *Id.* at 15. The press release also failed to explain that the study protocol set out ten secondary endpoints – of which survival time was ranked as only the seventh most clinically relevant – and that all ten failed to produce statistically meaningful results." *Id.* These omissions of the context in which the data reported in the press release were derived, the evidence showed, were critical to interpreting the data. *Id.* at 14-15.

The documentation in the record relating to the criminal proceedings does not establish on which of these grounds the jury found the press release false or fraudulent. The court's memorandum makes clear, however, that there was sufficient evidence at trial to conclude that Petitioner's conviction could have been based on the press release as a whole, including its material omissions of critical information that "interested individuals," such as medical doctors, would need to know to independently assess the study results, as well as the false or fraudulent statements in the press release interpreting the study data. Accordingly, the evidence does not support Petitioner's assertion that his conviction was based only on statements in the press release interpreting the study data and not on any other aspect of the press release.

Further undercutting Petitioner's contention that it was implausible for him to have intended the press release to influence doctors to prescribe Actimmune because doctors have a professional responsibility to independently assess study data, the indictment states that in August 2002, InterMune commissioned a marketing research firm to find

out whether the press release would have an impact on doctors' decisions to prescribe Actimmune for patients with IPF. I.G. Ex. 2, at 10. The indictment also states that in September 2002, the firm reported to InterMune that a survey had found that the August 2002 press release "had a positive impact on pulmonologists and increased their likelihood to use Actimmune to treat IPF." *Id.*[8] InterMune's decision to hire the marketing research firm and the firm's survey results show that, regardless of whether physicians have a professional duty to assess objective clinical data before making treatment decisions, a press release interpreting study data and characterizing a failed drug trial as a success may nevertheless influence the prescribing decision. The trial court stated in an April 18, 2011 memorandum and order denying Petitioner's motions for a new trial, "That a press release is not the type of scientific data consulted by physicians in making treatment decisions does not mean that the statements made therein are not material – i.e., that the information conveyed by the press release carries the capacity to affect the relevant decision." Board Ex. 1, at 10. Indeed, the press release itself quotes an executive of InterMune stating, "We felt we had an ethical obligation to get this important news out about the survival benefit of Actimmune so physicians can evaluate it when making treatment decisions for their patients." Thus, a "reasonable mind" could conclude, as the ALJ correctly did here, that the press release was intended to encourage physicians to prescribe the drug. I.G. Ex. 5, at 3.

InterMune's commissioning of the marketing research firm to evaluate whether the press release would influence physicians' decisions to prescribe Actimmune for IPF also undercuts Petitioner's contention that the purpose of the press release was merely to comply with federal securities laws and to communicate to "the markets" that physicians ultimately "would have a sufficiently favorable clinical view . . . to support the years of future sales [Petitioner] projected." P. Br. at 30; *see also* P. Reply at 1. As the ALJ noted, there are likely multiple business purposes for a press release, and "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." ALJ Decision at 7, n.6. Moreover, Petitioner does not dispute that the press release was posted on InterMune's website and broadly circulated to the public via a wire service that released it to news outlets across the country. I.G. Ex. 2, at 10. Widely-circulated to the general public, the press release undeniably would have been of great interest to those who suffer from IPF, as well as to those physicians who treat such patients.

[8] While Petitioner asserts that these "unproven" allegations reference a report "that was not even introduced at trial, let alone credited by the jury," Petitioner has not denied that InterMune hired the firm or the results of the firm's study. P. Reply at 5.

The March 2008 criminal indictment against Petitioner also supports the ALJ's determination. The indictment based both the wire fraud and misbranding counts on the same set of general factual allegations, which were expressly "realleged and incorporated by reference" under both the first and second counts "as if fully set forth herein." I.G. Ex. 2, at 12-13. Paragraphs 22-24 of the indictment's general allegations described Petitioner's "Scheme to Defraud" and provided in part:

> 22. . . . [Petitioner] did knowingly and intentionally devise a scheme and artifice to defraud, and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, well knowing that the pretenses, representations, and statements were materially false when made, ***in order to induce doctors to prescribe, and patients to take, Actimmune to treat IPF.***
>
> 23. It was part of the scheme to defraud that [Petitioner] . . . caused the general public media and InterMune's sales force to communicate information about the GIPF-001 Phase III trial results that falsely portrayed Actimmune as an effective treatment for IPF by helping IPF patients live longer.
>
> a. On August 28, 2002, InterMune publicly announced the results of the . . . clinical trial of Actimmune for the treatment of IPF in the form of a press release. The press release contained false and misleading information regarding Actimmune and falsely portrayed the results of the . . . trial as establishing that Actimmune helped IPF patients live longer. . . .
>
> b. On or about August 28, 2002, [Petitioner] caused the press release to be posted on InterMune's own website, hosted by a company located in San Francisco, and caused the press release to be sent to a wire service located in New York for release to news outlets nationwide.

I.G. Ex. 2, at 9-10 (emphasis added). As noted above, to satisfy the first element of wire fraud, the prosecution was required to prove beyond a reasonable doubt that the defendant "made up a scheme or plan to defraud by making false or fraudulent statements . . . with the intent to deceive." P. Ex 5, at 1. Stating that the central purpose of the fraudulent scheme devised by Petitioner was "to induce doctors to prescribe, and patients to take, Actimmune to treat IPF," the indictment thus describes that in carrying out wire fraud, Petitioner intended to increase use – that is, delivery – of Actimmune for patients with IPF. I.G. Ex. 2, at 9. The indictment further states that the "scheme to defraud" included the August 28, 2002 issuance of the press release, its posting on InterMune's website, and the nation-wide circulation of the press release via wire service to the general public.

In light of the language of the press release, the March 2002 indictment, the jury instructions and verdict, and the district court's memoranda addressing Petitioner's post-trial motions, we conclude that the ALJ's findings are supported by substantial evidence on the record as a whole.

*We reject Petitioner's arguments that the ALJ Decision impermissibly exceeds the jury's findings and contradicts the district court's findings at sentencing.*

Petitioner asserts that "the ALJ's finding of a potential and intended impact on delivery" was merely speculative and "impermissibly contradict[s] the record of the criminal proceedings." P. Br. at 22-24. While both counts of the indictment "recite a perfunctory incorporation of all foregoing allegations," Petitioner contends, "the two counts are based on distinct sets of allegations," and the indictment "must be viewed in light of the jury's split verdict and the jury instructions." P. Br. at 6; P. Reply at 2. Petitioner argues that the "wire fraud count alleged that [Petitioner] directed the transmission of the press release," cited the heading and subtitle of the press release and "charged that these statements 'falsely portrayed the results of the GIPF-001 Phase III trial as establishing that Actimmune reduced mortality in patients with IPF.'" P. Br. at 7, *citing* I.G. Ex. 2, at 9-10, 12. Petitioner asserts that the "transmission of those statements in the press release '[o]n or about August 27, 2002' consummated the conduct alleged as wire fraud." *Id*. Petitioner avers that "the jury was not required to find intended or actual effect on delivery on the wire fraud count." P. Br. at 22. Moreover, Petitioner argues, the press release "wasn't directed at doctors and patients and it was not likely to influence doctors to prescribe the drug, and in fact, it did not influence them." Tr. at 5.

In contrast, Petitioner contends, the misbranding count, of which he was acquitted, "*did* actually include an intent to impact delivery as an element." P. Br. at 22 (emphasis in original). According to Petitioner, the misbranding count "alleged that [Petitioner] violated provisions of the Food Drug & Cosmetics Act, not by distributing the initial press release to the public at large, but by authorizing subsequent distributions of the press release to patients and doctors." P. Br. at 7, citing I.G. Ex. 2, at 11-13. The second count, Petitioner states, "asked the jury to find that [Petitioner] 'caused . . . Actimmune [to] be [] misbranded' by virtue of the press release becoming 'labeling' when it was sent to 'prospective and actual patients and doctors.'" P. Br. at 24, citing P. Ex. 5, at 3-4; I.G. Ex. 2, at 11-12. The jury instructions defined "labeling" as labels or other printed or graphic matter that is "'textually related' to the drug and is shipped to 'a common destination (<u>such as prospective and actual patients and doctors</u>.)'." P. Reply at 3, citing P. Ex. 5, at 3 (emphasis added by Petitioner). Thus, Petitioner argues, if "the jury had believed that [Petitioner] intended to send the 'false' press release to prospective and actual patients and doctors, it would have convicted him of the misbranding charge." P. Reply at 3. Under these circumstances, Petitioner argues, "the acquittal on the misbranding charge establishes a key limitation on the scope of [his] conviction." P. Reply at 3.

In support of this argument, Petitioner cites to one Board decision and one ALJ decision. First, Petitioner relies upon the Board's statement in *Bruce Lindberg, D.C.*, that "it is not sufficient to show that Petitioner was *charged* with a criminal offense 'relating to . . . abuse of patients. . . .' Instead, it must be established that Petitioner was *convicted* of such an offense." P. Reply at 3, *citing* DAB No. 1280 (1991)(emphasis added by Petitioner). Second, Petitioner relies on the ALJ decision in *Gregory Vagshenian*, wherein the ALJ stated that "the I.G. may *not* consider accusations of which Petitioner was explicitly acquitted" to support his position. P. Reply at 3, *citing* DAB CR1457 (2006)(emphasis added by Petitioner).

The evidence in the administrative record relating to the criminal proceedings does not comport with Petitioner's characterization of the "narrow nature" of Petitioner's wire fraud conviction or the meaning of his acquittal on the second count. As discussed above, the jury instructions and verdict show that in finding Petitioner guilty of wire fraud, the jury found each of the five elements of the crime proven beyond a reasonable doubt, including that Petitioner engaged in a "scheme to defraud." Indeed, the transcript from the criminal proceedings shows that while the government's attorney agreed that the underlying evidence of the wire fraud count was the press release, he stated, "The scheme to defraud certainly goes beyond the press release." P. Ex. 2, at 7.

Furthermore, the first paragraph in the section of the indictment describing Petitioner's "Scheme to Defraud" (paragraph 22), which was expressly "realleged and incorporated by reference as if fully set forth" in the first paragraph of the wire fraud count, plainly stated that the purpose of Petitioner's "scheme to defraud" was "to induce doctors to prescribe, and patients to take, Actimmune to treat IPF." I.G. Ex, 2, at 9, 12. The indictment also describes the "scheme to defraud" to have included both the public announcement by InterMune of the results of the study "in the form of a press release" and Petitioner's actions causing the press release to be posted on InterMune's website and sent to a wire service for release to news outlets nationwide. I.G. Ex. 2, at 9-10. Because the jury found Petitioner guilty on the first count, the I.G. properly relied on all of the factual allegations set forth in the indictment under that count in considering whether the offense occurred in connection with the delivery of a health care item. Thus, even if we were to accept Petitioner's contention that the wire fraud charge did not encompass the subsequent, *direct transmission* of the press release and other promotional materials to prospective and actual patients and doctors as alleged in the indictment, this would not alter the fact that Petitioner's "scheme to defraud" in committing wire fraud involved the widespread circulation of the press release to the general public (including potential and actual IPF patients and doctors) or that the intent of the fraudulent scheme was to encourage doctors to prescribe, and patients to take, Actimmune to treat IPF.

Moreover, even if the jury was not *required* to find that Petitioner intended to induce doctors to prescribe, and patients to take, Actimmune in order to convict Petitioner of wire fraud, this would not preclude the ALJ from determining, based on the underlying circumstances of the crime (including the language of the press release), that the wire fraud "occurred in connection with" such intended delivery under section 1128(a)(3). As explained in detail above, the ALJ is not bound by the formal elements of a crime in analyzing whether the offense occurred in connection with the delivery of a health care item or service under section 1128(a)(3). Rather the ALJ may look beyond the formal elements of the crime and consider extrinsic evidence of the underlying circumstances of the offense in determining whether there is a basis to exclude an individual under section 1128 of the Act. Indeed, the Board decision cited by Petitioner, *Bruce Lindberg, D.C.*, so held: "[E]ven if there is nothing on the face of the counts of which Petitioner was convicted or in related court documents which establishes that section 1128(a)(2) applies, other evidence is certainly admissible to establish this." DAB No. 1280, at 4.

We also reject Petitioner's argument that in acquitting Petitioner of felony misbranding, the jury expressly rejected the allegation that Petitioner intended the press release to influence sales of Actimmune to treat IPF. The jury instructions show that the felony misbranding count was made up of multiple complex elements and a multipart definition of the term "labeling." P. Ex. 5, at 2-3. In order to find Petitioner guilty of felony misbranding, the jury was required to find proof beyond a reasonable doubt that each of the elements of the crime were met and that "labeling" occurred within the legal definition. Contrary to Petitioner's characterization, the evidence before us that relates to the criminal proceedings does not show which element(s) of the misbranding charge the jury determined were not proven beyond a reasonable doubt. Moreover, it was not necessary for the jury to find Petitioner did not intend the press release to influence doctors and patients to use Actimmune for IPF in order to acquit Petitioner on the misbranding charge. Accordingly, we reject Petitioner's contention that in acquitting Petitioner of misbranding the jury "refused to find that [Petitioner] intended the charged statements in the press release to affect the delivery of Actimmune to doctors and patients." P. Br. at 25.

The acquittal on the misbranding charge also does not undercut the ALJ's analysis of whether the offense for which Petitioner *was* convicted occurred in connection with the delivery of a health care item under section 1128(a)(3). As the ALJ noted, the standard of proof for the jury in determining whether Petitioner committed felony misbranding required the jury to find evidence "beyond a reasonable doubt" that each element of the offense was met. In contrast, the evidentiary standard governing the ALJ's analysis under section 1128(a) required him to determine whether Petitioner's commission of wire fraud occurred in connection with the delivery of a health care item based on the "preponderance of the evidence." 42 C.F.R. § 1001.2007(c). In this case, where the very

language of the press release underlying the wire fraud conviction was released to the general public and encouraged increased use of Actimmune by leading consumers to believe that Actimmune was an effective treatment for IPF, the ALJ reasonably concluded that the preponderance of the evidence showed that the offense was committed in connection with the delivery of a health care item.

This case is thus distinguishable from the Board and ALJ decisions cited by Petitioner in support of his arguments. In *Lindberg*, the Board vacated an ALJ finding and remanded the case involving a chiropractor's exclusion under section 1128(a)(2) (patient abuse). The Board found that there was "no evidence in the record . . . from which it [could] reasonably be inferred" that the victims were patients of the petitioner or that the abuse occurred in connection with the delivery of health care services. DAB No. 1280, at 3. In contrast, the record here contains substantial evidence to support the inference drawn by the ALJ from the language of the press release that in committing wire fraud, Petitioner intended to encourage the use of Actimmune to treat IPF and thereby increase sales of the drug. In addition, as we noted earlier, *Lindberg* supports the ALJ's looking beyond the formal elements of the offense and considering extrinsic evidence of the underlying circumstances to determine whether the crime occurred in connection with the delivery of a health care item or service.

The ALJ decision in *Vagshenian* involved exclusion under section 1128(a)(2) where the petitioner was charged with felony sexual assault but was convicted of a lesser offense included in the offense of felony sexual assault. We first note that ALJ decisions are not binding on the Board, though they may provide useful reference on issues of first impression. In addition, the issue in *Vagshenian* was not whether the elements to exclude the petitioner under section 1128(a)(2) were satisfied, the proposition for which Petitioner cites the decision but, rather, whether an aggravating factor applied to lengthen the exclusion period was supported by the circumstances surrounding the petitioner's conviction. Thus, the ALJ decision in *Vagshenian* is inapposite here. Moreover, unlike Vagshenian, who was convicted of a lesser-included offense than that charged, the crime for which Petitioner in this case was convicted, wire fraud, was not a lesser offense included in the felony misbranding charge. Rather, the wire fraud and misbranding counts were two separately charged offenses, each with different elements, and there was substantial evidence on the record as a whole supporting the inference drawn by the ALJ that the circumstances of the crime for which Petitioner was convicted involved the delivery of a health care item.

Petitioner also argues that the ALJ Decision "ignores and contradicts the district court's findings at sentencing." P. Br. at 27. Petitioner contends that during the sentencing proceedings, the prosecution sought to enhance the sentence given Petitioner by trying to prove that Petitioner intended the press release to cause, and that the press release did in fact cause, doctors to write prescriptions for Actimmune. Petitioner argues that the prosecution was unable to prove either allegation by a preponderance of the evidence.

Petitioner further asserts, the government was unable to provide even a "rough estimate" of the amount of prescriptions written as a result of the press release. Tr. at 11-12. According to Petitioner, the court determined that there was no connection between the press release and the writing of prescriptions, and that the Board must defer to the court's determination. Tr. at 10-12, *citing* 42 C.F.R. § 1001.2007(d).

We disagree. The transcript of the sentencing proceedings does not demonstrate that the court found Petitioner had not intended to encourage patients to use and doctors to prescribe Actimmune in committing wire fraud. Rather, the transcript shows that the judge denied the government's motion to enhance Petitioner's sentence based upon harm to the program because the government failed to prove there was "a *loss as a result of the conduct reflected in the wire fraud count."* P. Ex. 8, at 9 (emphasis added). However, there is nothing in the language of section 1128(a)(3) that requires a finding of actual harm to federal health care programs or a finding of monetary loss caused by the crime in order to determine that a petitioner should be excluded. *Cf. Paul R. Scollo, D.P.M.*, DAB No. 1498, at 9 (1994) (stating that no showing of harm to a protected program was necessary in order for an offense to be related).[9] Nor, as applied in this case, does section 1128(a)(3) require proof that any prescriptions were written as a result of the press release in order to establish the common sense nexus between the occurrence of the offense and the delivery of a health care item.

Accordingly, we reject Petitioner's arguments that the ALJ Decision impermissibly exceeds the jury's findings and contradicts the district court's findings at sentencing.

**II. Petitioner's contentions that exclusion would result in violations of Petitioner's constitutional rights do not form a basis for the Board to reverse the ALJ Decision.**

Petitioner argues that affirming his exclusion "would 'raise serious constitutional problems.'" P. Br. at 32, *citing Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988). Petitioner contends that "the five-year exclusion amounts to a second punishment" for Petitioner's wire fraud offense and therefore "violates the Fifth Amendment's Double Jeopardy Clause." P. Br. at 32-33, *citing Hudson v. United States*, 552 U.S. 93 (1997). Petitioner further argues that his "exclusion violates the Eighth Amendment's protections against excessive fines and cruel and unusual Punishment," because "it is 'grossly disproportional to the gravity' of his 'offense.'" P. Br. at 36-37, *citing United States v. Bajakajian*, 524 U.S. 321 (1998).

[9] We note that the I.G. may use such a loss, if it exists, as an aggravating factor in determining the length of exclusion. 42 C.F.R. § 1001.102(b)(1). The exclusion in this case, however, was for the mandatory minimum of five years. Accordingly, the issue of the amount of any program loss that resulted from the offense for which Petitioner was convicted is not relevant here.

Finally, Petitioner contends, his exclusion "violates the Due Process Clause's protection against arbitrary government action." P. Br. at 38.

The regulations governing this matter expressly preclude the ALJ (and hence the Board in its review of the ALJ Decision) from finding "invalid or refusing to follow Federal statutes or regulations," including the five-year minimum period for a mandatory exclusion pursuant to sections 1128(a)(3) and 1128(c)(3)(B) of the Act. 42 C.F.R. § 1005.4(c)(1). Petitioner's contentions that his exclusion would violate his constitutional rights under the Fifth and Eighth Amendments constitute an attack upon the Act and regulations on which neither the ALJ nor the Board may rule.

Nevertheless, as the ALJ correctly observed, federal courts and the Board have rejected similar arguments before. Because exclusions under section 1128(a) are remedial in nature, they do not violate the Double Jeopardy Clause or the prohibition against cruel and unusual punishment. ALJ Decision at 8, *citing 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). The ALJ also did not err in rejecting Petitioner's contention that the five-year exclusion constitutes an arbitrary government action affecting his ability to pursue his chosen profession, infringing upon his property and liberty interests. The ALJ observed here that "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." ALJ Decision at 8, *citing 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.*, 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).

Finally, as explained above, the purposes of the exclusion provisions are to protect federal health care programs and their beneficiaries from individuals who have been shown to be untrustworthy and to deter health care fraud. A provider who has been convicted of a crime described in section 1128(a) is presumed by Congress to be untrustworthy and a threat to federal health care programs and their beneficiaries and recipients. Contrary to Petitioner's characterizations, the evidence relating to the crime for which he was convicted, discussed in detail above, shows that Petitioner 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. Accordingly, we conclude, Petitioner's exclusion comports with the remedial purpose of the Act.

Conclusion

For the reasons discussed, we affirm the ALJ Decision.

/s/
Sheila Ann Hegy

/s/
Leslie A. Sussan

/s/
Stephen M. Godek
Presiding Board Member