Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

George John Schulte
Docket No. A-15-55
Decision No. 2649
August 7, 2015

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

George John Schulte (Petitioner), the former Chief Executive Officer of a medical device company, appeals the February 25, 2015 decision of an Administrative Law Judge (ALJ) sustaining the Inspector General's (I.G.) determination to exclude Petitioner from participation in Medicare, Medicaid, and all other federal health care programs for three years. *George John Schulte*, DAB CR3667 (2015) (ALJ Decision). The I.G. acted under Social Security Act (Act) provisions permitting the exclusion of any individual or entity convicted "in connection with the interference with or obstruction of any investigation or audit related to" offenses relating to fraud that are "in connection with the delivery of a health care item or service." Act §§ 1128(b)(2), 1128(b)(1)(A)(i). The I.G. excluded Petitioner based on his conviction for making false statements to a special agent of the Food and Drug Administration (FDA) who was investigating Petitioner's company for importing unapproved medical devices and providing them to physicians for use in humans. Petitioner argues that his exclusion should be reversed because the record does not show that the false statements for which he was convicted interfered with the FDA investigation. For the reasons explained below, we sustain the ALJ Decision.

Applicable Legal Authority

Section 1128(b)(2) of the Act,[1] 42 U.S.C. § 1320a–7(b)(2), "Conviction relating to obstruction of an investigation or audit," authorizes the Secretary of Health and Human Services to exclude, from participation in any federal health care program–

> Any individual or entity that has been convicted, under Federal or State law, in connection with the interference with or obstruction of any investigation or audit related to—
>
> (i) any offense described in paragraph (1) or in subsection (a); [or]

[1] The current version of the Social Security Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact-toc.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section.

> (ii) the use of funds received, directly or indirectly, from any Federal health care program . . . .

See 42 C.F.R. § 1001.301 (implementing regulation). As relevant here, offenses "described in paragraph (1)" include misdemeanor offenses "relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct" that are "in connection with the delivery of a health care item or service." Act § 1128 (b)(1)(A)(i), 42 U.S.C. 1320a–7(b)(1)(A)(i).

The I.G. excluded Petitioner under section 1128(b)(2) based on his conviction for an offense under 18 U.S.C. § 1001(a)(2). That statute makes it illegal to knowingly and willfully make "any materially false, fictitious, or fraudulent statement or representation" in "any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States."

An exclusion under section 1128(b)(2) is for three years "unless the Secretary determines in accordance with published regulations that a shorter period is appropriate because of mitigating circumstances or that a longer period is appropriate because of aggravating circumstances." Act § 1128(c)(3)(D); *see* 42 C.F.R. § 1001.301(b) (implementing regulation). Neither party alleged the existence of aggravating or mitigating factors here.

Factual Background[2]

Petitioner was Chief Executive Officer of Spectranetics, a Colorado corporation that manufactured medical lasers and related devices physicians use in procedures to remove blockages in coronary and peripheral arteries to ease blood flow. I.G. Ex. 2, at 2-3; P. Ex. 2, at 2-3; ALJ Decision at 5. The events that led to Petitioner's exclusion involve Spectranetics' efforts to import and add to its product line two medical devices produced by other manufacturers: a guidewire designed to unblock arteries manufactured by Future Medical Design Co., Ltd., a Japanese company (FMD guidewire) and a "balloon angioplasty catheter" manufactured by Bavaria Medizin Technologie, a German company (BMT balloon). I.G. Exs. 1, at 9-10; 2 at 2-3. Neither device had received the FDA approval that was required to market the devices in the United States for use in humans. I.G. Exs. 1, at 10; 2, at 3-5; ALJ Decision at 5-6.

In July 2008, former and current Spectranetics employees alleged to the FDA that Spectranetics had been using the unapproved devices in patients. I.G. Ex. 2, at 5-6. On September 4, 2008, agents from the FDA and from U.S. Immigration and Customs Enforcement executed a federal search warrant at the Spectranetics corporate

[2] This summary derives from the undisputed facts in the ALJ Decision and the record and is intended to provide context for our discussion and is not intended to present new findings of fact. We refer the reader to the ALJ Decision for a detailed narrative of the facts.

headquarters in Colorado Springs, Colorado. I.G. Ex. 1, at 10. During the search, an FDA special agent interviewed Petitioner, with his agreement, regarding the importation, and the distribution to physicians, of the unapproved devices. P. Ex. 2, at 22-24; I.G. Ex. 2, at 6-8; ALJ Decision at 5-6.

In December 2009, Spectranetics entered into a non-prosecution agreement with the FDA and the U.S. Attorney's Office in which Spectranetics admitted it had imported the unapproved FMD guidewires and BMT balloons into the United States and distributed them to physicians for use in humans, knowing that the devices lacked the required FDA approval. I.G. Ex. 1. Spectranetics also admitted it had not accurately declared or classified the imported devices to U.S. Customs as medical devices or medical equipment, and that "[c]ertain Spectranetics officers, managers, agents, and other employees" involved in the distribution of the devices were aware that the physicians were using them and that the devices had not been approved by the FDA for use in humans. *Id*. at 10.

In May 2011, the United States filed a 12-count indictment against Petitioner and three others (two company executives who reported to Petitioner and a contractor representative) charging them with various offenses including conspiring to defraud the government, receiving illegally imported merchandise, and introducing into and receiving from interstate commerce adulterated and misbranded medical devices. P. Ex. 2. One count alleged that Petitioner knowingly and willfully made five materially false statements to the FDA special agent during their interview in violation of 18 U.S.C. § 1001(a)(2). *Id*. at 22-24; ALJ Decision at 6-7. In those five statements, Petitioner stated that he did not bring FMD guidewires to the U.S. from Japan, that Spectranetics gave FMD guidewires to physicians but not for use in humans, that he did not know that Spectranetics employees gave FMD guidewires and BMT balloons to physicians for use in humans, and that he had never seen an evaluation form that Spectranetics gave to the physicians to report on their use of the balloons in humans. P. Ex. 2, at 22-24. The indictment also alleged that, among other acts, Petitioner had brought FMD guidewires from Japan, was aware that the FMD guidewires and BMT balloons had been given to physicians who used them in patients, had reviewed the physicians' evaluation of both devices and had reviewed and approved a form on which the physicians supplied clinical feedback about the BMT balloons. *Id*. at 6, 11-14, 19-21.

On March 1, 2012, a jury found Petitioner guilty of the false statement count (Count II) under 18 U.S.C. § 1001(a)(2) and acquitted him of the other 11 counts. I.G. Ex. 2, at 9-10; P. Ex. 2, at 22-23; P. Ex. 3; ALJ Decision at 4. The jury acquitted one of the two other Spectranetics defendants of all counts and the United States dropped the charges against the other defendant. P. Ex. 9, at 8; P. Ex. 4. According to Petitioner, the fourth defendant, the contractor representative, pled guilty to a single count of misprision of a felony. P. Request for ALJ Hearing at 4; P. Appellate Brief (P. Br.) at 4. Petitioner was sentenced to one year of probation and ordered to provide 100 hours of community

service and to pay a special assessment of $100 and a fine of $5,000. P. Exs. 8, at 1-4; 9, at 29-32. The U.S. Court of Appeals for the Tenth Circuit affirmed the conviction in *U.S. v. Schulte*, 741 F.3d 1141 (10th Cir. 2014) (I.G. Ex. 2), and on August 29, 2014 the I.G. excluded him for three years, the period provided in the statute in the absence of aggravating or mitigating factors.[3] ALJ Decision at 1.

Petitioner appealed the exclusion. The ALJ received the parties' exhibits and granted the I.G.'s objections to some of Petitioner's exhibits comprising character testimony, which the ALJ found not relevant to the issues before him by regulation: whether the I.G. had a basis to exclude Petitioner and whether the length of the exclusion was reasonable. *Id*. at 2-3. The ALJ ruled that an evidentiary hearing was not necessary because neither party sought to present witness testimony, and he denied Petitioner's request for oral argument. *Id*.

The ALJ Decision

The ALJ concluded that "[t]he IG had a legitimate basis for excluding Petitioner under 42 U.S.C. § 1320a-7(b)(2)" (Act § 1128(b)(2)) because "Petitioner was convicted of an offense under federal law" and "Petitioner's conviction was in connection with the interference [with] an investigation into a criminal offense relating to fraud in connection with the delivery of a health care item or service." ALJ Decision at 3-4. The ALJ relied on the Tenth Circuit's decision affirming Petitioner's conviction, on the indictment's description of the company's and Petitioner's conduct in the medical device scheme, and on the context of Petitioner's false statements to the FDA special agent underlying Petitioner's conviction. *Id*. at 5-7. The ALJ found that the record "is sufficient to show Petitioner's false statements to the FDA investigator interfered with the FDA's investigation." *Id*. at 7. The ALJ quoted the Tenth Circuit's findings that Petitioner had "misdirected the focus of the investigation" and that the jury that convicted Petitioner "was provided sufficient evidence to find, beyond a reasonable doubt" that his statements "could have influenced" the FDA. *Id*. at 6, citing I.G. Ex. 2, at 23-24. The ALJ also noted that Petitioner made his false statements "to a federal investigator during the execution of a search warrant involving more than 30 federal agents" and found that "[a]ny material false statements to the investigator would tend to interfere with that investigation." *Id*. at 7. The ALJ also concluded that "[b]ecause neither the IG nor Petitioner proved that there were any aggravating or mitigating factors in this case, Petitioner must be excluded for three years." *Id*.

[3] The parties in referring to the Tenth Circuit decision consistently refer to the copy in the record at I.G. Exhibit 2, and so we do the same in citing to the decision.

Petitioner's Argument on Appeal

On appeal, Petitioner does not dispute that a jury convicted him of knowingly and willfully making a materially false statement to an investigative agent of the FDA under 18 U.S.C. § 1001(a)(2). He also does not contest that the FDA was investigating possible offenses "relating to fraud" that were "in connection with the delivery of a health care item or service," offenses that are listed in section 1128(b)(1) and incorporated as offenses forming a basis for exclusion by section 1128(b)(2). Transcript of Oral Argument (Tr.) at 6-7, 9; P. Br. at 15-17. He also does not assert that mitigating factors should reduce the length of the exclusion. We accordingly affirm without further discussion the ALJ's determinations that Petitioner's conviction involved "an investigation into a criminal offense relating to fraud in connection with the delivery of a health care item or service" and that the three-year exclusion the I.G. imposed is required by statute and thus reasonable as a matter of law. ALJ Decision at 4, 8.

Petitioner's argument on appeal is that there was no basis for the exclusion because the record, contrary to the ALJ's conclusion, does not support a conclusion that Petitioner's false statements to the FDA special agent interfered with the FDA investigation. The issue before us, therefore, is limited to whether substantial evidence supports the ALJ's conclusion that Petitioner's conviction was in connection with the interference with the FDA investigation. Petitioner also raises an issue of law – whether section 1128(b)(2) requires a showing of actual interference, an issue that we address below but conclude we need not decide.

Standard of Review

Our standard of review of an exclusion imposed by the I.G. is established by regulation. We review a disputed issue of fact as to "whether the initial decision is supported by substantial evidence on the whole record," and we review a disputed issue of law as to "whether the ALJ decision is erroneous." 42 C.F.R. § 1005.21(h). Substantial evidence is "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401 (1971), citing *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

Analysis

For the reasons explained below, we find that substantial evidence supports the ALJ's determination that Petitioner was convicted of a crime "in connection with" the interference with the FDA criminal fraud investigation and that the ALJ's determination was free of legal error.

A. Petitioner's reliance on the Board's Prasad *decision is misplaced since contrary to Petitioner's assertion, that decision does not hold that as a matter of law, actual interference with an investigation is required for an exclusion under section 1128(b)(2) of the Act.*

The ALJ concluded that the I.G. was authorized to exclude Petitioner because his false statement conviction under 18 U.S.C. § 1001(a)(2) was "in connection with the interference [with the FDA] investigation" of Spectranetics' importation, distribution and testing of the unapproved medical devices. ALJ Decision at 4; Act § 1128(b)(2). Petitioner argues that he could not be excluded because his false statements were not "in connection with the interference with the investigation of" Spectranetics since, he contends, his false statements "did not actually interfere with the investigation." Tr. at 7, 9; *see also* P. Br. at 1 (arguing that his false statements did not "rise to the level of interference sufficient to support exclusion"). For this position, Petitioner relies heavily on the Board decision in *Subramanya K. Prasad, M.D.*, DAB No. 2568 (2014). In *Prasad*, the Board reversed an ALJ decision that had overturned a section 1128(b)(2) exclusion that the I.G. took based on a conviction under the same statute at issue here. The Board concluded "that the I.G. met its burden of establishing that Petitioner's offense was in connection with the interference with or obstruction of an investigation . . . ." *Id*. at 8. While it reversed the ALJ decision and, thus, reinstated the exclusion, the Board rejected the I.G.'s position that the petitioner's conviction under 18 U.S.C. § 1001 for making a material false statement "amounts *per se* to proof that [he] obstructed the . . . investigation" in that case. *Id*. at 8. Citing this statement, Petitioner argues that under *Prasad* the I.G. must "show a connection between the false statements and an actual interference" and "come forward with … evidence of interference." Tr. at 11.

Petitioner misreads *Prasad*. The Board in *Prasad* did not hold, as Petitioner asserts, that, as a matter of law, the I.G. is required to prove that a petitioner's false statements actually interfered with an investigation to show that the conviction was "in connection with" interference with or obstruction of an investigation. In *Prasad*, the Board merely recognized, correctly, that a conviction for false statements under 18 U.S.C. § 1001 is not per se grounds for exclusion under section 1128(b)(2) because section 1001, unlike the exclusion statute, relates to false statements in government matters generally, not specifically to false statements in the context of interference with or obstruction of government investigations. This recognition is reflected in the Board's statement that while Prasad's "conviction [under section 1001] establishes that Petitioner's false statement was material to at least some matter within the Government's jurisdiction, section 1001 itself does not require any finding that the false statement was material to interfering with an investigation." DAB No. 2568, at 8-9 (emphasis in original). Thus, the Board concluded that it would need to look to the evidence of record surrounding the investigation to determine whether the false statement "was material to interfering with

an investigation." After discussing that evidence, the Board concluded that "the only reasonable inference that could be drawn from the record as a whole in this case is that Petitioner's false statement was *in connection with* the interference with or obstruction of the … investigation." *Id.* at 9 (emphasis added).

Petitioner's reliance on *Prasad* also overlooks the Board's discussion and application in that decision of long-standing Board precedent in exclusions under section 1128 for offenses "in connection with" or "relating to" specified actions. In concluding that the I.G. had met its burden in *Prasad*, the Board relied on its decisions interpreting the phrase "in connection with" as used in section 1128 "as requiring only a 'common sense connection or nexus'" between a conviction and the action or conduct specified in section 1128. *Id.* at 7 (citations omitted). The Board has applied this approach in determining whether convictions were for criminal offenses committed "in connection with" the delivery of a health care item or service, or for offenses "relating to" fraud, theft, embezzlement, breach of fiduciary responsibility, as required for exclusions under sections 1128(a)(3) and 1128(b)(1)(A)(i), (B) of the Act. *Richard E. Bohner*, DAB No. 2638 (2015); *Lyle Kai, R.Ph.*, DAB No. 1979 (2005), *aff'd*, *Kai v. Leavitt*, Civ. No. 05-00514 BMK (D. Haw. July 17, 2006); *Erik D. DeSimone, R.Ph.*, DAB No. 1932 (2004).

The Board has held, for example, that the requirement in section 1128(a) and (b) that an offense be committed "in connection with" the delivery of a health care item does not require actual delivery of the item, and that the requirement that an offense be one "relating to fraud" does not require the excluded individual to have been convicted of fraud. In *Kenneth M. Behr*, DAB No. 1997 (2005), the Board held that the fact that the petitioner, excluded under section Act § 1128(a)(3) based on conviction for attempted embezzlement of drugs from a medical center, "failed 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.'" DAB No. 1997, at 8. In *Bohner*, DAB No. 2638, at 10-15 and in *Paul D. Goldenheim, M.D., et al.*, DAB No. 2268, at 10-12 (2009), *aff'd sub nom. Friedman v. Sebelius, 755 F. Supp. 2d 98 (D.D.C. 2010), rev'd and remanded* 686 F.3d 813 (D.C. Cir. 2012) (sustaining the exclusion but remanding for further consideration of the length of the exclusion), the Board concluded that the petitioners' misdemeanor convictions, under the responsible corporate officer doctrine for introducing misbranded devices into interstate commerce, were for offenses "relating to" fraud, even though fraud was not an element of either those offenses or the misbranding offenses of which the corporations were convicted. In affirming this aspect of the Board's decision in *Goldenheim*, the D.C. Circuit held that the I.G. could look beyond the generic criminal offense with which a petitioner is charged and consider the facts underlying his particular conviction in determining whether the conviction is "related to fraud." *Friedman v. Sebelius* at 818-24.

Consistent with this long-standing precedent, the Board in *Prasad* did not hold, contrary to Petitioner's assertion, that, as a matter of law, the I.G. is required to prove that a

petitioner's false statements actually interfered with an investigation to show that the conviction was "in connection with" interference with an investigation. Tr. at 7, 9, 11. Instead, the Board examined the facts surrounding Prasad's conviction and concluded that "the only reasonable inference that could be drawn from the record as a whole in this case is that Petitioner's false statement was *in connection with* the interference with or obstruction of the … investigation." *Prasad* at 9 (emphasis added).

In addition to misreading *Prasad* and ignoring the Board's discussion of the precedent discussed above, Petitioner has not attempted to explain how the plain language of section 1128(b)(2), which does not include the word "actual" in the broadly framed phrase "in connection with the interference," can reasonably be read as requiring evidence that the convicted individual's misconduct resulted in actual interference with the investigation. In the final analysis, however, we do not need to decide this legal issue because, as discussed below, we conclude that substantial evidence supports the ALJ's finding that Petitioner's false statements did interfere with the FDA investigation even under Petitioner's construction of section 1128(b)(2).

B. Substantial evidence supports the ALJ's finding of interference with the investigation of Spectranetics.

We agree with the ALJ that the record in this case "is sufficient to show Petitioner's false statements to the FDA investigator interfered with the FDA's investigation" of Spectranetics and that his conviction "was in connection with the interference [with] an investigation into a criminal offense relating to fraud in connection with the delivery of a health care item or service." ALJ Decision at 4, 7. The FDA special agent's trial testimony, the Tenth Circuit decision affirming Petitioner's conviction, and the context of Petitioner's statements constitute substantial evidence supporting the ALJ's determination.

1. The FDA special agent's testimony shows that Petitioner's false statements to him interfered with the FDA's investigation of Spectranetics.

Petitioner filed excerpts of the special agent's trial testimony in which the special agent explained why it "was important to [him] that [Petitioner] tell [him] the truth" during their interview:

> I was a little over a month into this investigation, and I wanted to find out exactly what had gone on. Really, it was important. I mean, we're -- how many of these devices were used, how many patients were affected, what doctors were involved, was it just limited to the information I had obtained from the whistleblowers. So at this point, I'm in the information gathering

> stage, and I need to find out the scope of, you know, what exactly is going on here. … After the discussion regarding [the devices], I didn't believe he was being truthful with me, based -- it wasn't comporting with the information I had received from the whistleblowers.

P. Ex. 1, at 7. Implicit in the special agent's explanation of why it was important that Petitioner give him truthful information is support for the ALJ's finding that by instead giving the special agent untruthful information, Petitioner hampered or impeded the investigation and, thus, interfered with it. Petitioner's statements hampered or impeded the agent's efforts to test and develop, or potentially reject, the information he had obtained from whistleblowers. Those statements also hampered the special agent's attempts to ascertain the specific acts the company committed in importing the unapproved devices and providing them to physicians to test in human patients and who at the company had directed or committed those actions. *See* ALJ Decision at 7 ("Petitioner interfered with an investigation involving, in part, an effort to determine if Petitioner or [Spectranetics] were conspiring to defraud the United States Government by importing medical devices for the insertion in human patients.").

Petitioner suggests that the agent's statements in this and other excerpts Petitioner chose to submit are not sufficient to show interference simply because the investigator does not specifically state that the false information Petitioner gave interfered with his testimony. *See, e.g.*, Tr. at 20 (arguing that there was no testimony by the agent "that if the answers to the questions . . . would have been different, he would have done anything differently . . . ."). We reject this suggestion. Since the complete transcript is not in the record, it is impossible for us to determine whether the excerpts Petitioner has provided reflect the full extent of the agent's testimony. However, assuming the selected excerpts or the transcript as a whole show that the agent never specifically stated that the false statements interfered with the investigation, neither do they state that Petitioner's false statements did not interfere with the investigation. The description of the agent's need for truthful information at the stage of the investigation when his interview of Petitioner occurred at a minimum implies that Petitioner's provision of false and misleading information instead had an important negative impact on the course of his investigative work. Thus, the omission to which Petitioner points does not undercut our conclusion that Petitioner's false statements interfered with the FDA investigation.

We also find no merit in Petitioner's arguments that his statements to the FDA special agent did not interfere with the investigation because the FDA special agent testified at trial that he knew the answers to his questions before asking them and "knew when he interviewed [Petitioner] that some of [his] statements were inaccurate." P. Br. at 5, 17, citing P. Ex. 1, at 1901, 1962-63.[4]

[4] Petitioner cited to page numbers on the trial transcript excerpts rather than to the numbers that Petitioner used to number the pages of the exhibit containing the trial transcript excerpts. The corresponding exhibit pagination is P. Ex. 1, at 7, 13-14.

With respect to Petitioner's assertion that the agent knew at the time of the interview that "some" of Petitioner's statements "were inaccurate," even assuming that is true, that is not evidence that the special agent knew all of Petitioner's statements were inaccurate or that any of them were outright untrue at that point in the investigation. Indeed, since the excerpt quoted above shows that the interview occurred during the early "information gathering" stage of the investigation, it is more reasonable to assume that while the agent may have had reason to doubt the accuracy of some of Petitioner's information based on the whistleblower information, he was still in the process of testing all of Petitioner's statements against that other information.

Meritless for similar reasons is Petitioner's citation to the agent's testimony that he "didn't believe [Petitioner] was being truthful with me" and the fact that before the interview ended the agent gave Petitioner a warning about the potential for a false statements charge. P. Br. at 5, citing P. Ex. 1, at 1901. The agent's mere "belief" does not show that he had decided with any certainty the truth or falsity of Petitioner's testimony. Petitioner also omits from the excerpt he cites the agent's statement of the basis for his belief, which was that Petitioner's testimony "wasn't comporting with the information I had received from the whistleblowers." P. Ex. 1, at 7. In its proper context, the statement Petitioner relies on reflects nothing more than the agent's skepticism about Petitioner's testimony at that point in time given contradictory testimony he had received from other sources, a skepticism that prompted him to give the warning about false statements.

In sum, Petitioner's arguments ignore the fact that the special agent clearly stated in his testimony that he interviewed Petitioner early in the investigation when the scope of the company's actions remained undetermined and his understanding of the alleged fraud at that point was based largely on unconfirmed reports. *Id*. As the Tenth Circuit aptly stated, Petitioner's argument that his statements did not interfere with the investigation "fails to account for the nascent quality of the investigation" at the time of the interview. I.G. Ex. 2, at 23. At the very least, even assuming the special agent did not trust Petitioner's statements when he made them, those statements burdened that agent and/or the other investigators with the additional investigative task of determining the extent to which Petitioner had attempted to mislead them. We also note that Petitioner has offered no reason why he would give false information to the FDA special agent other than to mislead the agent about the company's admittedly illegal importation, distribution and testing of the devices and his own role in that activity. *See Prasad* at 8 (reversing the ALJ's reversal of the exclusion because, in part, the ALJ "gave no reason why Petitioner would make" his false statement to federal agents "other than in an attempt to influence the investigators' evaluation of his culpability and the state of knowledge of the conspirators").

For all of these reasons, we conclude that substantial evidence in the record as a whole supports the ALJ's finding that Petitioner's false statements interfered with the FDA investigation into the fraudulent activities of Spectranetics.

2. Petitioner's alleged attempts to clarify or correct some of his untrue statements after the interview do not undercut the ALJ's or our finding of interference with the investigation.

Petitioner's indictment under Count II, the count on which he was convicted, listed five specific alleged untrue statements made to the special agent. P. Ex. 2, at 22-24. Addressing the first three statements, Petitioner conceded at oral argument that "there's evidence in the record, which I think this [Board] can conclude that the statements were inaccurate when they were made." Tr. at 14. Nonetheless, Petitioner argues that these statements could not have interfered with the investigation because they were either corrected or clarified in letters from his attorney following the interview. P. Br. at 6-7; Tr. at 13. We find no merit in this argument. We begin by noting that the Tenth Circuit rejected essentially the same argument when Petitioner made it to dispute that he "knowingly and willingly provided false statements to the FDA." I.G. Ex. 2, at 7, 18-24. The court essentially found that Petitioner's claimed corrections and clarifications were of limited value and failed to admit the extent of his knowledge of the company's actions. *Id*. at 7, 22 (finding that "none of his 'prompt recantations' included an admission he knew his employees gave the BMT balloons to the doctors at his direction"). We also note that the three letters Petitioner cites were sent, respectively, one day, two weeks, and over four months after the day he made the false statements to the special agent. P. Br. at 6-7, citing P. Exs. 5-7. Thus, even if Petitioner's claimed corrections and clarifications had been truly candid about Petitioner's role in the company's conduct (contrary to the Tenth Circuit's finding), that would not eliminate the effect of his original false statements which, as the Tenth Circuit stated, "misdirected the focus of the investigation from a company policy soliciting clinical trials to the possible, but unknown activities of individual employees." I.G. Ex. 2, at 23-24, quoted in ALJ Decision at 7. At best, any belated truth-telling might have helped investigators to re-direct their investigation at a later point. At worst, they would simply have caused further confusion and further hampered the investigation by causing investigators to wonder which version of Petitioner's facts they could trust.

3. Petitioner's assertion at oral argument that the I.G. was required to identify which of the five statements was untrue but had not done so raises an argument that is not properly before us and, in any event, is unsupported.

As indicated above, Petitioner's indictment under Count II, the count on which he was convicted, listed five alleged untrue statements. While conceding that the first three statements were "inaccurate," Petitioner argues that statements 4 and 5 could not have

interfered with the investigation because they were "literally true" or "technically correct." P. Br. at 6-8; Tr. at 14 (asserting that Statement 4 was not untrue because he made it in response to an incorrect question and that Statement 5 was "technically correct" because while Petitioner later recalled he had seen the product evaluation form, he had not seen the filled-out version shown him by the special agent). At oral argument, Petitioner added that because the jury verdict form did not indicate which or how many of his five statements it found to be false, the I.G. cannot show which statement interfered with the investigation.[5] Tr. at 11-12. Petitioner further asserted that "the I.G. must establish – it's their burden of proof – they must establish which statement was false" but that "they hadn't even taken up that issue, let alone to show how the statement that they allege to be false actually interfered with the FDA's investigation." Tr. at 12; *see also* Tr. at 12, 14, 23 (questions and comments by the Presiding Board Member relating to whether the issue had been raised).

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The regulations provide, "The [Board] will not consider any issue not raised in the parties' briefs, nor any issue in the briefs that could have been raised before the ALJ but was not." 42 C.F.R. § 1005.21(e). The Board's Guidelines, a copy of which Petitioner received with the ALJ Decision, cite this regulation and similarly provide that the Board "will not consider issues not raised in the notice of appeal or in the opposing party's response, nor issues which could have been presented to the ALJ but were not." *Guidelines – Appellate Review of Decisions of Administrative Law Judges in Cases to Which Procedures in 42 C.F.R. Part 1005 Apply* (Guidelines).[6] Although Petitioner recited in his Request for Hearing, and again in his appeal brief, the fact that the jury verdict form did not indicate which of the five statements formed the basis of the jury's verdict, P. Request for ALJ Hearing at 10; P. Br. at 10, Petitioner did not make in either pleading the argument he made at oral argument that to exclude him under section 1128(b)(2), the I.G. must identify which of the five statements interfered with the investigation. Nor do we find such an argument in any other pleading filed in the ALJ proceeding or any evidence in the ALJ Decision that such an argument was made.

In any event, Petitioner presents no support for this argument. For example, Petitioner points to no language in section 1128(b)(2) (or the language of section 1128(b)(1) incorporated therein) that requires the I.G. to show that the "conviction" underlying the exclusion was based on more than one false statement or, where there was more than one false statement, to identify which of those false statements interfered with the investigation. Indeed, the exclusion statute does not even require a false statement but only requires that the criminal conduct for which an excluded petitioner was convicted

[5] The verdict form did not specify which statement or statements the jury found untrue because neither party had requested a special verdict form. I.G. Ex. 2, at 10.

[6] The Guidelines are available at http://www.hhs.gov/dab/divisions/appellate/guidelines/procedures.html.

occurred "in connection with the interference with . . . any investigation . . . ." Act § 1128(b)(2). As we have already concluded, the record shows that the criminal conduct for which Petitioner was convicted (knowingly and willingly making any materially false statement in any federal government matter) was in connection with the interference with an investigation into fraud by Spectranetics in connection with the unapproved use of medical devices. Whether the interference can be attributed to one or more of the false statements in particular is not material. In addition, we note that the Tenth Circuit found that the record did not support Petitioner's arguments that statements 4 and 5 were not untruthful. The court found that Petitioner's arguments "ignore[] the contextual evidence" and were contradicted by "an abundance of evidence" including the testimony of "[n]umerous witnesses." I.G. Ex. 2, at 18, 21.

C. Petitioner's other argument are without merit.[7]

1. The ALJ did not err in relying, in part, on the Tenth Circuit decision.

Petitioner objects to the ALJ's reliance on the Tenth Circuit's decision as evidence that his false statements interfered with the investigation. We note first that Petitioner erroneously states that the ALJ "relied entirely on the Tenth Circuit's decision . . . ." Tr. at 16. The ALJ specifically stated that his conclusion on the interference issue was based on the whole "record, including the Tenth Circuit's decision." ALJ Decision at 7 (emphasis added). Moreover, the ALJ's discussion shows that in addition to the Tenth Circuit decision, the ALJ relied on the indictment and the context of Petitioner's false statements to the FDA special agent. *Id*. at 5-7. But Petitioner's mischaracterization aside, there is nothing wrong with the ALJ's (or the Board's) reliance on the Tenth Circuit Decision.

It is well-settled that an ALJ (and the Board) may look to all of the circumstances surrounding a conviction, including intrinsic evidence, to determine whether the elements needed to exclude are present. *E.g. Narendra M. Patel, M.D.*, DAB No. 1736 (2000), *aff'd sub nom. Patel v. Thompson*, No. 00-00277-CV-HLM-4 (N.D. Ga. 2002), *aff'd*, 319 F.3d 1317 (11th Cir. 2003). As part of the legal history of the conviction, an appellate court decision qualifies as a circumstance surrounding the conviction.

Moreover, the rationale Petitioner gives for his objection is baseless. He argues that reliance on the Tenth Circuit decision is improper because the court was applying a standard of materiality that required it to determine only "whether [Petitioner's] statements were 'capable of influencing' the FDA," and did not require it to determine "whether any false statement actually was in connection with the interference with the investigation," a determination Petitioner asserts is required to exclude him. P. Reply at

[7] In addition to the arguments discussed below, Petitioner makes a number of complaints about the process in the criminal investigation. *See* P. Br. at 17-20; Tr. at 20-22. These complaints are clearly collateral attacks on the conviction and, as such, are beyond our review authority.

2; P. Br. at 15. We note once again that Petitioner has not cited support for the distinction he is attempting to make between potential and actual interference as it may affect the I.G.'s exclusion authority under section 1128(b)(2). Putting that aside, however, that the Tenth Circuit may not have been required to conclude that Petitioner's statements were in connection with the interference with an investigation in order to affirm the conviction under section 1001, did not preclude the court from finding interference. Indeed, while the court found on the one hand that "the jury was provided sufficient evidence to find . . . [Petitioner]'s statements could have influenced the agency[]" the court also found, as we previously noted, that Petitioner's statements "misdirected the focus of the investigation . . . ." I.G. Ex. 2, at 23-24. Misdirection of an investigation is interference with an investigation regardless of whether actual interference, as opposed to potential interference, is a necessary element of a section 1001 conviction. In any event, the Board has rejected the proposition that the exclusion statutes "require[] that the necessary elements of the criminal offense must mirror the elements of the exclusion authority . . . ." *Narendra M. Patel, M.D.*, DAB No. 1736, at 10. Although *Patel* involved an exclusion under section 1128(a), we see no reason why the rejection of this proposition would not apply equally to section 1128(b) exclusions.

2. The ALJ did not "improperly rel[y] on charges of which [Petitioner] was acquitted."

Petitioner argues that reversal of the ALJ Decision is compelled because the ALJ "improperly relied on charges of which [Petitioner] was acquitted" by referring to descriptions of his conduct contained in counts of the indictment for which he was acquitted. P. Br. at 16. The ALJ did not improperly rely on those charges. The ALJ specifically stated that although Petitioner was charged with twelve counts, he was found guilty only of Count II. ALJ Decision at 4. As Petitioner acknowledges, the ALJ also specifically stated that the jury found Petitioner not guilty on the charge of defrauding the government. P. Br. at 16, citing ALJ Decision at 7 n.3. Petitioner complains that after acknowledging he was found not guilty on the defrauding charge, the ALJ added that "the charge is nonetheless evidence that the investigation by the FDA and [U.S. Customs and Border Protection] involved fraud related to the medical devices." ALJ Decision at 7 n.3, citing P. Exs. 2 (the indictment) and 8 (the judgment in Petitioner's case). This complaint is baseless. The ALJ clearly was referring to the charge in question solely as evidence of the nature of the fraud investigation that underlay Petitioner's charge as well as the other charges. The general description of the fraudulent conduct by Spectranetics set forth in the indictment provided necessary context for the false statement charge of which Petitioner was convicted, since the jury's determination that the statements were false depended on that context.

We also note that the Board, citing the legislative history and purpose of the exclusion statutes, has broadly construed the evidence on which an ALJ may rely in determining whether the I.G. had a basis for an exclusion. For example, in *Narendra M. Patel, M.D.*, DAB No. 1736, at 6-8, the Board held that an ALJ may rely on evidence extrinsic to the criminal court proceeding to prove an element of the I.G.'s exclusion authority, in that case a sworn affidavit by a victim of the excluded physician in a state licensing proceeding submitted as evidence that the abuse of which the doctor was convicted occurred in connection with delivery of a health care item or service. In addition, descriptions of Petitioner's conduct and the overall fraud scheme for which Spectranetics was being investigated that are similar those in the indictment appear in the Tenth Circuit decision affirming Petitioner's conviction and in the non-prosecution agreement. Thus, even if the ALJ's reference to the fraud allegations in the indictment was error (and it is not), the reference would not be reversible error.[8]

Conclusion

For all of the foregoing reasons, we affirm the ALJ Decision. .

/s/
Constance B. Tobias

/s/
Susan S. Yim

/s/
Sheila Ann Hegy
Presiding Board Member

[8] Also not error is the ALJ's statement that "[t]he jury found Petitioner guilty of making materially false statements to an FDA investigator during the investigation of [Spectranetics] by the United States Government *and interfering with that investigation*." P. Br. at 16, quoting ALJ Decision at 6 (emphasis added by Petitioner). In context, given the immediately following quote from the Tenth Circuit decision, it appears the ALJ's reference to "interfering with that investigation" was not a reference to the jury verdict itself, as Petitioner suggests, but to the Tenth Circuit's assessment of the evidence before the jury on the Count II charge and what the jury could reasonably conclude with respect to the materiality of Petitioner's false statements based on that evidence. In any event, given our conclusion that the record as a whole supports the ALJ's finding that Petitioner's conviction was "in connection with the interference [with] an investigation," any error by the ALJ would be harmless.