Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Mel E. Lucas, D.O.,
(OI File No. 7-11-40180-9),

Petitioner,

v.

The Inspector General.

Docket No. C-16-530

Decision No. CR4761

Date: December 15, 2016

DECISION

The Inspector General (IG) of the United States Department of Health and Human Services (HHS) excluded Petitioner, Mel E. Lucas, D.O., from participation in Medicare, Medicaid, and all other federal health care programs based on Petitioner's misdemeanor conviction related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of any health care item or service pursuant to section 1128(b)(1) of the Social Security Act (Act) (42 U.S.C. § 1320a-7(b)(1)). For the reasons discussed below, I conclude that the IG has a basis for excluding Petitioner. I affirm the length of the two-year exclusion, effective March 20, 2016.

I. Background

In a letter dated February 29, 2016, the IG excluded Petitioner from participation in Medicare, Medicaid, and all federal health care programs as defined in section 1128B(f) of the Act, 42 U.S.C. § 1320a-7b(f), for a minimum period of two years, effective 20 days from the date of the letter. IG Exhibit (IG Ex.) 1. The IG explained that Petitioner's exclusion was based on his "conviction as defined in section 1128(i) (42 U.S.C. 1320a-7(i)), in the United States District Court, Eastern District of Missouri, of a misdemeanor offense related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other

financial misconduct in connection with the delivery of any health care item or service" pursuant to section 1128(b)(1) of the Act. IG Ex. 1 at 1. Under Section 1128(b)(1) of the Act, the IG may exclude an individual who has been convicted of a "criminal offense consisting of a misdemeanor related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct . . . in connection with the delivery of a health care item or service." [1] 42 U.S.C. § 1320a-7(b)(1)(A)(i). In his February 29, 2016 letter, the IG informed Petitioner that he imposed a two-year exclusion after considering the mitigating factor that Petitioner was convicted of three or fewer offenses and the entire financial loss to a government program or to other individuals or entities was less than $1,500. IG Ex. 1 at 2; *see* 42 C.F.R. § 1001.201(b)(3).

Petitioner, who is represented by counsel, submitted a timely request for hearing on May 4, 2016. On May 25, 2016, I presided over a telephonic pre-hearing conference, and shortly thereafter, on May 26, 2016, I issued an Order and Schedule for Filing Briefs and Documentary Evidence (Order) that memorialized the discussions in that conference and provided instructions to the parties regarding filings, deadlines, and other substantive matters.

Pursuant to my Order, the IG filed an informal brief (IG Br.) and a reply brief (IG Reply), along with five exhibits. Petitioner filed an informal brief (P. Br.) and supplemental informal brief, along with two exhibits.[2] I admit IG Exs. 1-5 and P. Exs. 1-2. Neither party requested that I convene a hearing in person, and I am therefore deciding this case on the merits based on the parties' written filings.

II. Issues

The issue in this case is whether there is a legal basis for the IG to exclude Petitioner from participation in Medicare, Medicaid, and other federal health care programs. If I

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[1] While there are slight differences in the wording of Section 1128 of the Act and its codification at 42 U.S.C. § 1320a-7, the two authorities are substantively identical and I refer to them interchangeably. I further note that the Secretary of the Department of Health and Human Services (Secretary) has delegated to the IG the authority "to suspend or exclude certain health care practitioners and providers of health care services from participation in these programs." 48 Fed. Reg. 21662 (May 13, 1983); *see also* 42 C.F.R. § 1005.1.

[2] Petitioner also submitted a sur-reply brief. A sur-reply is not contemplated by my Order, and Petitioner did not submit a motion for leave to file a sur-reply brief. Therefore, I have not accepted the sur-reply for filing. However, even if I were to accept Petitioner's sur-reply, it would not affect the outcome of this case.

find a legitimate basis for the exclusion, then I must consider whether a two-year exclusion is reasonable.

III. Jurisdiction

I have jurisdiction to adjudicate this case. 42 U.S.C. § 1320a-7(f)(1); 42 C.F.R. § 1005.2.

IV. Findings of Fact, Conclusions of Law, and Analysis[3]

1. ***Petitioner pleaded guilty to Count Two of a misdemeanor information and admitted that he received misbranded prescription drugs in interstate commerce in violation of 21 U.S.C. §§ 331(c), 333(a)(1), 352(f), and 18 U.S.C. § 2, from approximately April 2009 through approximately September 2011.***

2. ***Petitioner was convicted of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.***

Section 1128(b)(1)(A)(i) of the Act authorizes the Secretary to permissively exclude an individual or entity from participation in any federal health care program under certain circumstances, to include:

> **(1) Conviction relating to fraud**
>
> Any individual or entity that has been convicted for an offense which occurred after August 21, 1996, under Federal or State law—
>
> (A) of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct--
>
> (i) in connection with the delivery of a health care item or service . . . .

42 U.S.C. § 1320a-7(b)(1). The Secretary has promulgated regulations implementing these provisions of the Act. 42 C.F.R. § 1001.201(a). Pursuant to 42 U.S.C. § 1320a-

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

7(c)(3)(D), the exclusion will be for a period of three years, unless the IG determines, in accordance with regulations, that a shorter period is appropriate because of mitigating circumstances or that a longer period is appropriate because of aggravating circumstances. 42 C.F.R. § 1001.201(b)(2) and (3).

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

The Departmental Appeals Board (Board) has held that "section 1128(b)(1) of the Act 'does not restrict exclusions to only offenses constituting or consisting of fraud, but requires merely that the offense at issue be one 'relating to fraud.'" *Richard E. Bohner*, DAB No. 2638 at 10 (2015), *aff'd, Bohner v. Burwell*, Civ. A. No. 15-4088 (E.D. Pa. Dec. 2, 2016); quoting *Paul v. Goldenheim, M.D., et al.*, DAB No. 2268 at 10 (2009). The U.S. Court of Appeals for the District of Columbia, in evaluating arguments that a "strict liability" misdemeanor offense cannot form a basis for exclusion under section 1128(b)(1), remarked that section 1128(b)(1) has a "broad scope" and held that it authorizes the Secretary to exclude from participation in federal health care programs "an individual convicted of a misdemeanor if the conduct underlying that conviction is *factually* related to fraud." *Friedman v. Sebelius*, 686 F.3d 813 at 820, 824 (D.C. Cir. 2012) (emphasis added). Thus, I need not determine that Petitioner's conviction, itself, was for committing fraud; I need only determine that the offense was *related to* fraud.

The IG argues that it properly excluded Petitioner from all federal health care programs based on his conviction for receiving misbranded prescription drugs in interstate commerce. A superseding information filed on May 15, 2015, in the United States District Court for the Eastern District of Missouri, and on the same day as Petitioner entered into a written plea agreement, charged that Petitioner and an employee of his practice, along with his practice (which was named as a separate co-defendant), violated various federal laws. With respect to Petitioner and his employee, both were charged with violating 21 U.S.C. §§ 331(c), 333(a)(1), 352(f), and 18 U.S.C. § 2 based on their receipt of misbranded drugs in interstate commerce. IG Ex. 4.

On May 15, 2015, Petitioner, along with his counsel, signed a 12-page plea agreement with the United States Attorney's Office in which he agreed to enter a plea of guilty to Count Two of the superseding criminal information filed that same day. Petitioner acknowledged the elements of the offense to which he was pleading guilty, which the plea agreement set forth as follows:

a. Defendant received prescription drugs in interstate commerce;

b. The prescription drugs were misbranded.

IG Ex. 2 at 2. Count Two of the information charged the following:

> Defendants herein, received in interstate commerce a quantity of the prescription drug Aclasta, imported from Canada, via the United Kingdom, that was misbranded within the meaning of the Food, Drug, and Cosmetic Act in that (a) the drug's labeling failed to bear adequate directions for use in that the drug's labeling was in the Turkish or Italian language, 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5, and (b) the Aclasta came from Novartis, a foreign drug establishment located in Switzerland, and Aclasta was not annually listed with the FDA by Novartis as one of the drugs which was being manufactured for commercial distribution in the United States.
>
> In violation of Title 21, United States Code, Sections 331(c), 333(a)(1), 352(f), and Title 18, United States Code, Section 2.

IG Ex. 4 at 7-8. Count Two, in describing the offense conduct committed by Petitioner and his employee, a nurse practitioner, provided the following discussion:

> 10. Dr. Lucas used his Bank of America/American Express credit card to pay for Aclasta, which was shipped by Parcel Force Worldwide (located in the United Kingdom) to Patterson Medical.
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> 11. In her capacity as an employee of Patterson Medical, Defendant [R.L.] infused patients with Zoledronic Acid which was provided by Patterson Medical under the brand name Reclast and which was approved by the FDA. Defendant [R.L.] also infused patients with Zoledronic Acid which was provided by Patterson Medical under the brand name Aclasta which was not approved by the FDA.
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> 12. On or about April 10, 2013, federal agents recovered ten boxes of Aclasta from Patterson Medical. The word "Aclasta" was prominently displayed on the bottles of Aclasta. The bottles also had Italian or Turkish language on them, a clear indication that the drug was not intended for use in the United States.

IG Ex. 4 at 7. Petitioner agreed to the following facts in his plea agreement:

> 1. Petitioner is a doctor of osteopathic medicine, licensed to practice in Missouri.
> 2. Petitioner is the owner of Patterson Medical Clinic, Inc.
> 3. Petitioner is the only doctor practicing at Patterson Medical Clinic.

4. Petitioner has been a participating physician in Medicare and TRICARE,[4] along with several insurance companies, to include Anthem Blue Cross Blue Shield and Blue Shield of Missouri (Blue Cross).
5. Aclasta is a brand name for Zoledronic Acid, and that brand name is not approved by the Food and Drug Administration (FDA) for use in the United States.
6. Aclasta may not legally be imported, prescribed, or dispensed in the United States.
7. Reclast is the brand name for Zoledronic Acid approved by the FDA for use in the United States.
8. Only a licensed medical practitioner may lawfully prescribe or dispense Zoledronic Acid under the brand name Reclast.
9. Petitioner repeatedly purchased Aclasta from two online Canadian pharmacies in or about April 2009 and in or about September 2011.
10. When Petitioner ordered Aclasta from outside of the United States, he paid several hundred dollars less than the price of a bottle of Reclast purchased in the United States.
11. Petitioner had the Aclasta shipped via Parcel Force Worldwide (located in the United Kingdom) to Patterson Medical Clinic.
12. Federal agents recovered 10 boxes of Aclasta from Patterson Medical Clinic.
13. The bottles recovered from Patterson Medical by federal agents had Italian or Turkish language on them and that was a "clear indication that the drug was not intended for use in the United States."
14. The Aclasta's labeling failed to bear adequate directions for use.

IG Ex. 2 at 2-5.

Petitioner entered a plea of guilty to Count Two of the information, "Receipt of Misbranded Prescription Drugs From Interstate Commerce," in violation of 21 U.S.C. § 331(c), 21 U.S.C. § 333(a)(1), 21 U.S.C. § 352(f) and 18 U.S.C. § 2, and the remaining counts were dismissed. IG Ex. 3 at 1. On September 2, 2015, a United States District Judge imposed a sentence of three years of probation with various special conditions of supervision. IG Ex. 3 at 1-2. Petitioner's probation was terminated after one year. P. Ex. 2.

On the same day as Petitioner entered a plea of guilty on May 15, 2015, co-defendant R.L, his employee, entered a plea of guilty to Count Two of the information and received

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[4] TRICARE is the health insurance program that serves active and retired military servicemembers and their families.

a sentence of a two-year term of probation. IG Ex. 5 at 1-2. Count Two of the indictment had charged that R.L. "infused patients with Zoledronic Acid which was provided by Patterson Medical Clinic under the brand name Aclasta, but which was not approved by the FDA." IG Ex. 4 at 7.

Petitioner does not deny that he was convicted of the criminal offense addressed above, yet he contends that he was not convicted of an offense for which exclusion is authorized. Petitioner's contention that the IG was not authorized to exclude him is not supported by the relevant facts or the law, and his conviction meets the elements set forth in section 1128(b)(1)(A)(i) of the Act. By entering a plea of guilty to Count Two of the information, Petitioner admitted that he purchased misbranded prescription drugs in interstate commerce. Petitioner acknowledged that a drug is "misbranded if the labeling fails to bear adequate directions for use or fails to bear adequate warnings where use of the drug may be dangerous to the health of users. 21 U.S.C. §§ 352(f)(1), 352(f)(2)." IG Ex. 2 at 4. He further acknowledged that he received in interstate commerce misbranded drugs with labeling that "failed to bear adequate directions for use in that the drug's labeling was in the Turkish or Italian language" and that "Aclasta was not annually listed with the FDA by Novartis as one of the drugs which was being manufactured for commercial distribution in the United States." IG Ex. 2 at 5. Petitioner also admitted that he purchased misbranded drugs at a substantial discount compared to the FDA-approved version of the drugs. IG Ex. 2 at 5.

I conclude that the IG had a basis to exclude Petitioner pursuant to section 1128(b)(1)(A)(i) of the Act. All elements required to exclude an individual under that section of the Act are present here. Petitioner was convicted within the meaning of 1128(i) of the Act when the District Court accepted his guilty plea to Count Two of the information filed on May 15, 2015, and Petitioner's criminal conduct occurred well after August 21, 1996. IG Ex. 3 at 1. Furthermore, Petitioner's offense was in connection with the delivery of a health care item or service, as evidenced by the fact that Petitioner "repeatedly purchased" Aclasta for more than two years and had those shipments delivered to and stored at his medical practice. Additionally, the evidence supports that Aclasta was infused to patients at his office. IG Exs. 4, 5. Finally, as I will discuss below, Petitioner's conviction is related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

Petitioner contends that "[t]he evidence in the record does not support a finding that Petitioner provided Aclasta to his patients, much less that he defrauded them . . . ." P. Br. at 5. Petitioner argues that he was not convicted of distributing or providing the medications to patients, and there "can only be fraud involved in the delivery or dispensing of misbranded drugs, and then only with a knowing misrepresentation or concealment of material fact, of which Petitioner was not convicted." P. Br. at 6. Petitioner contends that he "was only convicted of receipt of misbranded medications in interstate commerce, and as such, whether or not the instructions were in English or

another language is irrelevant." P. Br. at 12-13. Petitioner further states that "even if [his] conviction involved the administration of Aclasta to his patients, there is no evidence that Petitioner or his staff required instructions on how to administer this common medication." P. Br. at 13.

Regardless of whether Petitioner administered Aclasta himself in his medical practice, the undisputed evidence demonstrates that he repeatedly purchased Aclasta from two different online Canadian pharmacies over a nearly two and a half year period, and he paid several hundred dollars less for each bottle of Aclasta than he would have paid for each bottle of Reclast if lawfully purchased in the United States. IG Ex. 2 at 5. Petitioner had the bottles of Aclasta shipped to his medical practice, and ten boxes of Aclasta were found by federal agents at his practice.[5] IG Ex. 2 at 5. Further, Petitioner's employee, R.L., entered a guilty plea to Count Two of the information, which charged that she "infused patients with . . . Aclasta." IG Ex. 4 at 7. Even though the IG alleged in his brief that Petitioner provided his patients with Aclasta and "subjected them to non-FDA approved drugs," Petitioner does not refute this allegation anywhere in his 19-page brief, in that he does not affirmatively state that he *did not* provide Aclasta to his patients. IG Br. at 6. Rather, Petitioner emphasizes that his conviction was not for administering Aclasta to patients, but instead, was only for receiving the misbranded Aclasta in interstate commerce. P. Br. at 5-6. Petitioner further argues that "the evidence in the record does not support a finding that Petitioner provided Aclasta to his patients," yet he ultimately does not deny that he did provide Aclasta to his patients. P. Br. at 5. Instead, he spends considerable effort arguing that "Reclast and Aclasta are the same medication" and "the chemical formula of Aclasta is identical to that of Reclast." P. Br. at 9. In support of these arguments regarding the purported similarity of Aclasta and Reclast, Petitioner submitted evidence from the Center for Drug Evaluation and Research.[6] P. Ex. 1.

Petitioner has identified no reason why he repeatedly purchased Aclasta from outside of the United States for approximately $749 per bottle over a period of nearly two and a half years, and had those bottles shipped to, and stored at, his medical practice. Despite having the opportunity to do so in his brief, Petitioner gave no explanation, in response to the IG's allegations, why he expended large sums of money to have illegal drugs shipped to and stored at his medical practice. In fact, in his background discussion, he admits that

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[5] The evidence does not show how many bottles of Aclasta are contained in a box.

[6] Petitioner's submission is incomplete, in that he did not submit the majority of the pages referenced in the table of contents. In particular, Petitioner did not submit the section entitled "Labeling and Package Insert" that is referenced at page 7 of P. Ex. 1.

he purchased Aclasta from approximately April 2009 through September 2011 (P. Br. at 2), and then explains how Aclasta and Reclast have different brand names but "are administered in the same fashion and are equally as potent, safe, and effective." P. Br. at 3. In so doing, Petitioner appears to justify his actions to obtain a misbranded drug that indisputably led R.L. to administer Aclasta to Petitioner's patients. While Petitioner disputes the IG's allegation that he used the Aclasta in his practice, Petitioner has not refuted the IG's allegations. Nor has Petitioner reconciled the fact that his employee entered a guilty plea based on her conduct of infusing patients with the Aclasta that Petitioner, the owner of Patterson Medical and its sole doctor, purchased. In fact, Petitioner makes the bald statement that "there is no evidence in the record that any patient received Aclasta from Petitioner." P. Br. at 9. As the sole owner of Patterson Medical and the sole doctor supervising R.L. at the practice, such a claim is beyond belief and is undermined by the evidence.

Even though Petitioner has not admitted as much, I can make no other conclusion than Petitioner purchased the Aclasta for use in his practice. Petitioner repeatedly purchased the non-FDA compliant version of the drug Zoledronic Acid over a lengthy period of time and at a substantial discount, and there appears to be no other logical reason why he would stockpile such a medication that is "used primarily to treat osteoporosis," other than to obtain at a deep discount medication to infuse to his patients.[7] *See* IG Ex. 2 at 4. Both Petitioner, who purchased the Aclasta, and his employee R.L., who infused the Aclasta, were co-defendants charged in the same count of the superseding information, and both individuals entered guilty pleas to the charges presented in Count Two of the information. IG Exs. 3, 4, 5.

Petitioner acknowledged in his plea agreement that a drug is misbranded if the labeling fails to bear adequate direction for use or fails to bear adequate warnings where the use of the drug may be dangerous to the health of users. 21 U.S.C. §§ 352(f)(1), 352(f)(2). Along those lines, the FDA has imposed numerous requirements for the content and labeling for prescription drugs in the United States. These requirements pertain to:

- product names
- boxed warnings

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[7] The IG has not submitted evidence regarding Petitioner's treatment and billing for patients who were administered Aclasta or Reclast. Therefore, I cannot ascertain whether Petitioner, his patients, and/or insurance companies were the beneficiaries of the cost savings yielded through the administration of Aclasta versus Reclast. However, being that Aclasta cannot be legally imported, prescribed or dispensed in the United States (IG Ex. 2 at 4), it is highly unlikely that any insurance company would knowingly provide reimbursement for the infusion of Aclasta.

- recent major changes
- indications and usage
- dosage and administration
- dosage forms and strengths
- contraindications, warnings and precautions
- adverse reactions
- drug interactions (to include significant interactions with other prescription and over-the-counter drugs, classes of drugs, foods)
- use in specific populations (to include pregnancy, lactation, females and males of reproductive potential, pediatric use, and geriatric use)
- patient counseling information
- drug abuse and dependence
- overdosage
- clinical pharmacology (to include mechanism of action, pharmacodynamics, and pharmacokinetics)
- nonclinical toxicology
- clinical studies
- references
- drug storage and handling; and
- the revision date of the most recent revision of the labeling.

21 C.F.R. §§ 201.56, 201.57. Additionally, labeling information must be in accordance with specific type face and font size requirements. *Id.* In discussing these requirements, the FDA has explained that "[a]ll drugs approved in the United States, regardless of where they are made, must be in compliance with . . . product label requirements." *http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194989.htm* (last visited December 9, 2016). While Petitioner contends that "there is no evidence that Petitioner or his staff required instructions on how to administer this common medication" (P. Br. at 12), in the absence of FDA-compliant labeling and content, he ignores the essential purpose of the FDA's drug labeling requirements: "*The labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug.*" 21 C.F.R. § 201.56(a)(1) (emphasis added). Petitioner oversimplifies the reason for FDA-approved labeling in the United States, which is not merely to provide "required instructions on how to administer" a medication. The "how to" for the administration of a medication is only a very small component of the FDA's labeling requirements. While Petitioner believes it is only necessary to know "how to administer" a misbranded medication that was not produced for the United States market, he overlooks that, as a physician, the correct labeling is required in order for the prescriber to be aware of such issues as contraindications, adverse reactions, drug interactions, patient counseling information, and proper storage of the drugs. 21 C.F.R. §§ 201.56, 201.57.

I conclude that Petitioner purchased the Aclasta for use in his practice; even if the limited evidence before me does not demonstrate that Petitioner actually administered Aclasta to his patients himself, it is clear that Petitioner purchased the Aclasta for that purpose. Further, the evidence shows that his employee, R.L, infused patients with Aclasta and entered a guilty plea to the offense of receiving misbranded drugs in interstate commerce on the same day as Petitioner entered his plea. IG Ex. 5. Further, Petitioner purchased prescription drugs that did not contain the FDA-mandated packaging information, in that the drugs were labeled in Turkish or Italian. In fact, Petitioner admitted in his plea agreement that the foreign language on the labeling was "a clear indication that the drug was not intended for use in the United States." IG Ex. 2 at 5. Owing to the fact that Petitioner admitted that he paid several hundred dollars less than United States prices per bottle, and had a clear indication the Aclasta was not intended for use in the United States, I conclude that Petitioner purchased the drugs from online Canadian pharmacies in order to obtain a deep discount on the medications he stocked and administered at this practice. Petitioner treated Medicare and TRICARE beneficiaries, along with privately insured patients, and these patients expected, and deserved, to be treated by a licensed doctor who administered FDA-approved medications in an informed and appropriate manner. Contrary to Petitioner's arguments that Reclast and Aclasta are identical, these drugs are not identical: Reclast has been approved by the FDA for use in the United States, and Aclasta has not been approved for use in the United States.[8] One drug, Reclast, comes with FDA-compliant labeling that is intended to provide a prescribing doctor "a summary of the essential scientific information needed for the safe and effective use of the drug," and one drug may or may not have such labeling. 21 C.F.R. § 201.56(a)(1). In purchasing a non-FDA approved drug for use in his practice, Petitioner looked out for monetary interests, rather than the medical interests of his patients. Even if no harm actually occurred to any patients, Petitioner exposed his patients to the possibility of harm through the administration of an unapproved drug and without having the labeling information required by the FDA. The facts of this case support that Petitioner's offense is related to fraud. While Petitioner had an obligation to provide each patient with an FDA-approved drug, he illegally purchased an unapproved drug in order to obtain it at a lower price. When a patient visits his or her doctor for a

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[8] I note that while the two drugs may have an identical formula, as Petitioner alleges, the evidence does not show whether they are manufactured in identical facilities that have been inspected and approved by the FDA. Nor does the evidence demonstrate whether Aclasta and Reclast have the same shelf life (i.e., expiration date). Further, even if the drugs are identical, the FDA has noted there are risks inherent in purchasing drugs from foreign websites. *See, e.g.*, The Possible Dangers of Buying Medicines Over the Internet *http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048396.htm* (last visited December 9, 2016) (FDA informing the public of various risks, to include counterfeit, old, unlabeled, and improperly stored and shipped drugs).

medication infusion, the patient expects that he or she will receive a legal, safe, and FDA-compliant drug. Providing a patient a misbranded drug that cannot legally be sold in this country, if not fraud, is undoubtedly related to fraud. Simply stated, when a doctor, for the sake of saving money, purchases a cheap and illegal substitute to use in place of an approved medication, he is acting in a fraudulent manner. Every patient should rightfully expect that his or her doctor will prescribe legally obtained medications that are not misbranded.

3. Petitioner's exclusion for a period of two years is not unreasonable.

The period of exclusion under section 1128(b)(1) is three years, unless aggravating or mitigating factors justify lengthening or shortening that period. 42 U.S.C. § 1320a-7(c)(3)(D); 42 C.F.R. § 1001.201(b)(1). Only the mitigating factors authorized by 42 C.F.R. § 1001.201(b)(3) may be considered in order to reduce the period of exclusion. The IG has the discretion to impose an exclusion longer than the minimum period when there are aggravating factors present. *See* 42 C.F.R. § 1001.201(b)(2). The notice letter states that the IG considered one mitigating factor, that Petitioner was convicted of one misdemeanor offense and that the entire amount of financial loss to a government program or to other individuals or entities was less than $1500.[9] 42 C.F.R. § 1001.201(b)(3)(i); IG Ex. 1 at 2.

Petitioner argues with little specificity why "a two-year exclusionary period is unreasonable." P. Br. at 15. Petitioner repeats his argument that "Aclasta is identical in all respects to the FDA-approved medication, Reclast, and the only reason Aclasta was illegal to receive in the first place was due to the name the manufacturer chose to give it." P. Br. at 15. Petitioner could not be more mistaken: Petitioner admitted that he received Aclasta "that was misbranded within the meaning of the Food, Drug, and Cosmetic Act in that (a) the drug's labeling failed to bear adequate directions for use in that the drug's labeling was in the Turkish or Italian language . . . and (b) the Aclasta came from Novartis, a foreign drug establishment based in Switzerland and Aclasta was not annually listed with the FDA by Novartis as one the drugs which was being manufactured for commercial distribution in the United States." IG Ex. 2 at 5.

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[9] The IG argues the presence of an aggravating factor, that the duration of Petitioner's offense was one year or more, in his brief. IG Br. at 9-10. That aggravating factor is not listed in the IG's notice letter. IG Ex. 1. Even without consideration of this aggravating factor, a minimum period of exclusion of at least two years is warranted.

While Petitioner argues that the two-year period of exclusion is not reasonable because the mitigating factors were not weighed heavily enough, I disagree.[10] P. Br. at 15. Petitioner's characterization that a "hyper-technical violation of the FDCA that required no showing of fraud or *mens rea* and that was not (and cannot be) shown to have resulted in harm or risk to patients was not weighed heavily enough, if at all" is misguided and is not a basis for mitigation. P. Br. at 16. Further, such a basis, even if true, is not permitted by regulation and shows Petitioner's lack of recognition for the risks associated with prescribing a misbranded medication. 42 C.F.R. § 1001.201(b)(3). Furthermore, the financial savings received from purchasing a heavily discounted drug demonstrates there was a *mens rea* in his conduct, even if *mens rea* is not a required element of the offense for which he was convicted. *See Friedman*, 686 F.3d at 820, 824 (noting conduct underlying the conviction warrants exclusion if it is factually related to fraud, even if the elements of the offense do not require *mens rea*).

In weighing the mitigating factors, the IG reduced the period of exclusion by one year, or a third. While the IG considered the sole mitigating factor that Petitioner had a single misdemeanor conviction and the financial loss was less than $1500, I note that Petitioner admitted in his plea agreement that he "repeatedly" purchased Aclasta online from Canadian companies over a lengthy time period. Thus, Petitioner has admitted to committing repeated offenses of receiving misbranded drugs in interstate commerce, even if he has a single conviction. Likewise, while the loss to health care programs is under $1500, the monetary gain to Petitioner did not necessarily arise from a loss from health care programs or entities, but rather, by providing a cheaper and illegal drug to his patients. The IG's reduction of the three-year period of exclusion to two years is reasonable, if not overly generous, and Petitioner has not shown that a one third reduction in the period of exclusion based on the mitigating factor listed at 42 C.F.R. § 1001.201(b)(3)(i) was inappropriate.

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[10] While it may be appropriate to increase the length of the minimum period of exclusion in this case, I will limit my discussion to whether the length of the two-year exclusion determined by the IG was reasonable. *See* 42 C.F.R. § 1005.20(b) (stating an administrative law judge may "affirm, increase or reduce the penalties, assessment or exclusion proposed or imposed by the IG, or reverse the imposition of the exclusion.")

V. Conclusion

For the foregoing reasons, I affirm the IG's exclusion of Petitioner from participation in Medicare, Medicaid, and all other federal health care programs for a period of two years, effective March 20, 2016.

/s/
Leslie C. Rogall
Administrative Law Judge