

span 987 miles of existing roads: 435 miles in Idaho and 552 miles in Oregon.

Comments on the Draft EIS received from the public and internal BLM review were considered and incorporated as appropriate into the Final EIS. Public comments resulted in the development of Alternative 5, which is within the range of alternatives analyzed in the Draft EIS.

(Authority: 40 CFR 1506.6, 40 CFR 1506.10, and 43 CFR 1610.2)

**Aimee D. K. Betts,**  
*Acting Boise District Manager, Idaho.*

**Donald N. Gonzalez,**  
*Vale District Manager, Oregon/Washington.*  
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2017 and September 13, 2017,<sup>1</sup> which “revealed that [Registrant] was unable to account for large volumes of controlled substances.” *Id.* The Order also alleged that PIC Johnson “engaged in the practice of pharmacy at [Registrant] while under the influence of controlled substances, including some of the same controlled substances for which [one of the audits] showed significant discrepancies.” *Id.* The OSC further alleged that Registrant failed to maintain adequate records in violation of 21 U.S.C. 827(a) and 21 CFR 1304.03-04, 1304.11, 1304.21, and 1305.13(e), and that PIC Johnson placed customers in danger by dispensing controlled substances to a patient without a valid prescription. *Id.* at 2-4.

Based on his “preliminary finding that controlled substances were diverted from [Registrant] in connection with failure to maintain complete records and dispensing controlled substances without a valid prescription,” the former Acting Administrator concluded that Registrant’s registration “is inconsistent with the public interest.” *Id.* at 5. The former Acting Administrator also made the preliminary finding that Registrant’s “continued registration during the pendency of these proceedings would constitute an imminent danger to the public health and safety because of the substantial likelihood of an imminent threat that death, serious bodily harm or abuse of controlled substances will occur in the absence of this suspension.” *Id.* The former Acting Administrator thus concluded that Registrant’s continued registration during the pendency of the proceeding “constitutes an imminent danger to the public health and safety” and suspended its registration “effective immediately.” *Id.* (citing 21 U.S.C. 824(d)). Pursuant to 21 U.S.C. 824(f) and 21 CFR 1301.36(f), the former Acting Administrator authorized the DEA Special Agents and Diversion Investigators serving the OSC on Registrant to place under seal or to remove for safekeeping all controlled substances Registrant possessed pursuant to the immediately suspended registration. *Id.* The former Acting Administrator also directed those DEA employees to take possession of Registrant’s Certificate of Registration AB6785161 and any unused order forms. *Id.*

The OSC notified Registrant of its right to request a hearing on the

allegations or to submit a written statement while waiving its right to a hearing, the procedures for electing either option, and the consequence of failing to elect either option. *Id.* at 5-6 (citing 21 CFR 1301.43).

On October 31, 2017, a DEA Diversion Investigator (DI) personally served the OSC on Brian Johnson, Registrant’s PIC at Registrant’s address. GX 3, at 3. On the same day, Diversion Investigators took custody of Registrant’s DEA Certificate of Registration and removed all controlled substances in Registrant’s possession, pursuant to the Immediate Suspension Order. *Id.* See also GX 3, Appendix 4 (Inventory of Seized Items).

According to the Government, since the date of service of the Order, neither Registrant, nor anyone purporting to represent it, has filed a written statement or made any communication in writing to the Agency since the OSC was served. Request for Final Agency Action (hereinafter, RFAA), at 2; see also GX 3, at 3. Based on the Government’s representation, I find that more than 30 days have now passed and Registrant has neither requested a hearing nor submitted a written statement while waiving its right to a hearing. I therefore find that Registrant has waived its right to a hearing or to submit a written statement, and issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. See 21 CFR 1301.43(e).

On February 25, 2019, I issued an Order taking notice of the Agency’s registration records, which showed that on January 16, 2018, DEA approved the registration of a different retail pharmacy, called “Brewster Marketplace Pharmacy & T.V. Hardware LLC” at the same street address as Registrant. Order dated February 25, 2019 (hereinafter, February Order). The February Order directed the Government “to investigate and to address whether Registrant has discontinued its business practice as a retail pharmacy and whether its DEA registration has thus terminated pursuant to 21 CFR 1301.52.” *Id.* at 2. Additionally, the Order directed the Government to determine whether Registrant has forfeited its right, title and interest in the seized controlled substances. *Id.* at 2-3.

On March 25, 2019, I received the Government’s Reply to Administrator’s February Order (hereinafter, GR), which confirmed that Registrant discontinued business on December 29, 2017, and sold the business to Brewster Marketplace Pharmacy and Hardware, LLC (hereinafter, Marketplace). GR, at 2. The Government asserts that because

<sup>1</sup>The Government did not include any further mention of the September 13, 2017 audit in the record provided to me; therefore, the findings herein are limited to the August 15, 2017 audit.

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Brewster Drug, Inc.; Decision and Order

On October 26, 2017, the DEA Acting Administrator issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter collectively, OSC), to Brewster Drug, Inc. (hereinafter, Registrant), of Brewster, Washington. The OSC informed Registrant of the immediate suspension of its DEA Certificate of Registration AB6785161 and proposed its revocation, the denial of any pending application for renewal or modification of such registration, and the denial of any applications for additional DEA registrations, on the ground that its “continued registration is inconsistent with the public interest.” OSC, at 1 (citing 21 U.S.C. 824(a)(4) and 823(f)).

The OSC alleged that Registrant is a corporate entity in the state of Washington. *Id.* at 2. It further alleged that “Brian Johnson and Nikki Johnson are the [Registrant’s] ‘Governing Persons’—as defined in the Revised Code of Washington (RCW) 23.95.105(12),” and that “Brian Johnson is listed as the Pharmacy’s Registered Agent by the Washington State Corporation commission.” *Id.* It further alleged that Brian Johnson is Registrant’s Pharmacist-in-Charge (hereinafter, PIC). *Id.*

The OSC alleged that “DEA’s investigation [of Registrant] has revealed separate types of misconduct, which, taken together, pose an imminent danger to public health or safety.” *Id.* at 2. Specifically, DEA conducted inspections of Registrant on August 15,

Registrant discontinued professional practice, the regulation states that the registration terminates “without any further action by the Administration.” GR, at 2 (quoting 21 CFR 1301.52). Because Registrant discontinued business, DEA issued a letter on March 15, 2019, notifying Registrant that its DEA-seized controlled substances would be disposed of pursuant to 21 U.S.C. 824(g). *Id.*; GRX 1. On March 20, 2019, DEA received an email from Marketplace claiming an ownership interest in the controlled substances. *Id.* at 3; GRX 2. Therefore, despite the Registrant’s discontinuation of business, the Government requests that I affirm the ISO in order to resolve title to Registrant’s DEA-seized property. *Id.* (citing *ChipRX, L.L.C., d/b/a City Center Pharmacy*, 82 FR 51433 (2017)).

According to the Controlled Substances Act (hereinafter, CSA), the controlled substances inventory that DEA seized from Registrant’s registered location on the date DEA served the OSC “shall be forfeited to the United States” and “[a]ll right, title, and interest in such controlled substances shall vest in the United States upon a revocation order becoming final.” 21 U.S.C. 824(f). Disposition of Registrant’s seized controlled substances inventory remains outstanding even though Registrant discontinued business, and, therefore, its registration is terminated. 21 CFR 1301.52. I shall, therefore, adjudicate this OSC to finality as required by 21 U.S.C. 824(f). *See also Jeffrey D. Olsen, M.D.*, 84 FR 68474 (2019) (declining to dismiss an immediate suspension order as moot when the registrant allowed the registration subject to the ISO to expire before final adjudication of the ISO).<sup>2</sup>

I make the following findings.

## Findings of Fact

### Registrant’s DEA Registration

Registrant, a retail pharmacy, was a corporate entity organized under the laws of Washington State. OSC, at 2. It was registered with the DEA as a retail pharmacy authorized to dispense controlled substances in schedules II–V pursuant to Registration AB6785161, with a registered address at 811 US Highway 97, P.O. Box 798, Brewster, Washington 98812. GX 1 (Certificate of Registration). Registrant’s registration would have expired by its terms on July 31, 2020; however, it appears that the

Registrant discontinued business on December 29, 2017. *Id.*; GR, at 2.

According to the DI in charge of this investigation, at the time of the investigation, Brian Johnson and Nikki Johnson were listed as Registrant’s “Governing Persons,” under the Revised Code of Washington, which defines “Governor” as “a director of a business corporation . . . or any other person under whose authority the powers of an entity are exercised and under whose direction the activities and affairs of the entity are managed pursuant to the organic law and organic rules of the entity.” GX 3, at 2 (Declaration of Diversion Investigation) (citing Wash. Rev. Code Ann. § 23.95.105(12) (West 2019)); *see also* GX 3, Appendix 1 (copy of web page entitled “Corporations: Registration detail” obtained from Washington Secretary of State website, [www.sos.wa.gov/corps/search\\_detail](http://www.sos.wa.gov/corps/search_detail)). The same web page also listed Brian Johnson as the Registered Agent for Registrant.<sup>3</sup>

According to the DI, Brian Johnson worked as Registrant’s PIC and is married to Nikki Johnson. GX 3, at 2. Agency registration records show that Brian Johnson is the contact for Registrant’s DEA registration.<sup>4</sup>

### Investigation by Washington State Pharmacy Investigator

The Government’s evidence includes a sworn Declaration, dated March 15, 2018, by an investigator (hereinafter, Investigator V.) employed by the Washington State Pharmacy Quality Assurance Commission, Washington State Department of Health (DOH).<sup>5</sup> GX 4. According to the Declaration, the investigation into dispensing practices at Registrant was initiated by a physician’s complaint to the DOH, which alleged that a patient (hereinafter, Patient M.R.) had obtained multiple dispensings of oxycodone based on a single prescription presented to

<sup>3</sup> The website currently lists the business status as “administratively dissolved.”

<sup>4</sup> Under the Administrative Procedure Act (APA), an agency “may take official notice of facts at any stage in a proceeding—even in the final decision.” U.S. Dept. of Justice, *Attorney General’s Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA’s regulations, Registrant is “entitled on timely request to an opportunity to show to the contrary.” 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). To allow Registrant the opportunity to refute the facts of which I take official notice, Registrant may file a motion for reconsideration within fifteen calendar days of service of this order which shall commence on the date this order is mailed.

<sup>5</sup> The Government’s evidence includes the Declarations of the State Investigator and Dr. F., including attachments, but does not explain how it obtained them, nor how this Agency became aware of the State’s investigation.

Registrant. GX 4, at 1 (Declaration of Investigator V.).

According to the Government’s evidence, a physician practicing in Wenatchee, Washington (hereinafter, Dr. F.) averred in a sworn declaration that, while she was treating Patient M.R. on February 17, 2017, the patient showed her three bottles of oxycodone filled by Registrant. GX 5 (Declaration of Dr. F.), at 1. Patient M.R. told Dr. F. that he had obtained them from Registrant, and that he did not know how much he had received, but “recalled the first bottle was for a smaller amount than on the prescription as they did not have enough pills to fill as written” and that “[h]e later received the remainder from that prescription.” *Id.* Dr. F. stated, “[e]ach of the bottles had a sticker indicating that the bottle was for patient M.R.” and “[o]ne of the bottles was labeled for oxycodone 30 mg, and the other two for oxycodone 15 mg.” *Id.* Dr. F. then “reviewed M.R.’s patient record from a prior visit” and found that the records showed that a nurse practitioner at her practice (N.P.) had issued a single prescription for 182 tablets of oxycodone 30mg to M.R. on January 20, 2017. *Id.* The doctor also compared M.R.’s patient record with the Washington state Prescription Drug Monitoring Program (hereinafter, PMP), which showed that Registrant reported three transactions of dispensing oxycodone to M.R. in early February 2017, after the prescription written by N.P. *Id.* at 1–2.

Dr. F. stated that she telephoned Registrant on February 17, 2017, and asked the PIC to find out how much oxycodone had been provided to patient M.R., but the PIC was unable to tell her. *Id.* Dr. F. then submitted a complaint to the Washington Pharmacy Commission. GX 4, at 1.

Investigator V. reported that he “obtained a copy of the original prescription written by N.P. for Patient M.R. from [Registrant],” which “has a fill sticker from [Registrant] reflecting prescription number N1133568” and indicates the “prescription was filled on February 11, 2017.” *Id.* “The initials ‘BJ’ are on the fill sticker indicating that the prescription was filled by PIC Brian Johnson.” *Id.* at 1; GX 4, Appendix 1. The Investigator attached a true and correct copy of the prescription to his Declaration. *Id.* at 1; GX 4, Appendix 1. The prescription notes “Dispense as Written: No” and includes a “Start Date” of January 20, 2017, but

<sup>6</sup> The Registrant’s PIC’s name is Brian Johnson (B.J.).

<sup>2</sup> My implementation of these statutory and regulatory provisions also provides transparency given Marketplace’s claim of an ownership in the controlled substances inventory that DEA seized in conjunction with its service of the OSC.

the “End Date” is blank and there are “0 (Zero)” refills. GX 4, Appendix 1.

The Investigator obtained a copy of the Washington state PMP report for Patient M.R. “to identify what [Registrant] reported to the PMP” regarding the controlled substance prescriptions it filled for M.R. *Id.* He noted that “a Pharmacy is required to report to the Washington State PMP every instance where a controlled substance is dispensed to a patient.” *Id.* He reported and included a record demonstrating that Patient M.R.’s PMP report showed that in February 2017, Registrant reported three dispensings of oxycodone prescribed by N.P.:

(1) 364 tablets oxycodone 15mg on February 1 under prescription #1132787, a 14 day supply;

(2) 182 tablets oxycodone 30mg on February 11 under prescription #1133568, a 14 day supply;

(3) 364 tablets oxycodone 15mg on February 11 under prescription #1132787, a 14 day supply.

*Id.* at 1–2; GX 4, Appendix 3 (PMP database printout). The Investigator stated that these were the only reports made by Registrant to the PMP, and all were associated with the single prescription issued by N.P. to Patient M.R. on January 20, 2017. GX 4, at 2; accord GX 5 (Declaration of Dr. F.). In consideration of the DI’s attestation regarding the report’s authenticity as a true and correct copy of the Washington State PMP, and in the absence of any evidence to the contrary, I find that this report represents a true copy of the Washington State PMP and accurately reflects what Registrant reported as its dispensings of oxycodone to M.R. on the dates listed.

The Investigator also obtained Registrant’s patient profile for Patient M.R. for the time period February 1—February 28, 2017, which shows Registrant’s internal dispensing record of prescriptions it filled for M.R. GX 4, at 2. A copy of this report was submitted to the Government’s evidentiary record. GX 4, Appendix 2. The patient profile records two oxycodone dispensings on February 11, 2017, showing prescription number 1132787 for 364 tablets of oxycodone 15mg, and prescription number 1133568 for 182 tablets of oxycodone 30 mg. *Id.* at 1. Registrant’s patient profile does not show any oxycodone dispensing to Patient M.R. on February 1, 2017. *Id.*

According to the Investigator, Dr. F. sent him photocopies of the three prescription bottles patient M.R. brought to his appointment. GX 4, at 2. “She [ ] informed me that her patient, M.R., had three bottles of various

strength oxycodone that [he] reported [he] obtained from Registrant based on the single prescription from [N.P.].” *Id.*; see also GX 4, Appendix 4. The photocopies attached to the Investigator’s report are poor quality but include four pages, each showing three prescription bottles, each from a slightly different angle, depicting:

1) One bottle labeled RX#N113278[ ]<sup>7</sup> for 364 tablets of oxycodone dated February 1, 2017, issued to [M.R.] by Dr. [N.P.], with the initials “BJ”<sup>8</sup> on the label.

(2) One bottle labeled RX#N1132787 for 364 tablets of oxycodone dated February 1, 2017, issued to [M.R.] by Dr. [N.P.], with the initials “BJ” on the label, and

(3) One bottle labeled RXN#113356[], for 182 tablets of oxycodone, dated February 11, 2017, issued to [M.R.] by [N.P.], with the initials “BJ” on the label.

GX 4, Appendix 4, at 1–4.<sup>9</sup> The three bottles appear to bear the name “Brewster Drug;” however, corresponding dosage units are not clearly shown on any of the copies. *Id.*

Investigator V. further attested that he spoke with PIC Brian Johnson regarding the Registrant’s dispensing multiple bottles of various strength oxycodone on the basis of a single prescription, and he memorialized the conversation in a Memorandum, dated June 13, 2017. GX 4, Appendix 5. He reported, “PIC Johnson explained that he may have filled the prescription for 30 mg oxycodone tablets with 15 mg tablets because he did not have enough supply on hand,” but he “was not sure when or what quantities he dispensed to patient M.R., and he could not account for prescription RX#1133568, shown in the PMP.” GX 4, at 2. Investigator V. further stated he “confronted PIC Johnson on the fact that he had only a record of the single issued prescription corresponding with prescription number 1132787,” and “he

<sup>7</sup> The last digit is unclear from the photocopy, but the declarations indicate that this prescription was for RX #1132787 and I find that it is probable that the missing number is a 7.

<sup>8</sup> The evidence demonstrates that BJ is PIC Brian Johnson. *See* GX 4.

<sup>9</sup> The PMP demonstrates that there were three prescriptions, one on February 1st, and two on February 11th, but the copies of bottle labels provided by Dr. F. demonstrate two bottles on February 1st and one on February 11th. This discrepancy is not further described in the Government’s evidence; however, the PMP is clearly inaccurate, so the bottle labels seem to represent a more accurate depiction of what Registrant actually filled. Regardless of which is more accurate, the evidence is clear that Registrant filled one prescription in three different ways on two different dates and did not appropriately maintain records, as further described herein.

acknowledged that he had made no record of partial fills or substitute fills and had no other explanation” for M.R.’s three prescription bottles. *Id.*; see also GX 4, Appendix 5 (Investigator V.’s Memorandum of Conversation with PIC).

According to the Investigator, PIC Johnson “confirm[ed] that it was he who was the responsible pharmacist on each of the dispensing[s],” but that “he was sure the patient wasn’t given more medication than the doctor had prescribed but doesn’t recall the exact amount in each bottle.” GX 4, Appendix 5. He also told the Investigator that “he [didn’t] recall the exact events,” but believed he “either didn’t have enough, or any, of the 30 mg Oxycodone so he gave him a partial quantity of the 15 mg tablets” and that he “didn’t document how much he gave him at this time.” *Id.* Further, according to the Memorandum, PIC Johnson told Investigator V. that “when the patient returned for the remainder of the prescription he believe[d] he again didn’t have enough of the 30mg tablets to complete the order so he provided a combination of both 15mg and 30 mg tablets” and that “the patient has been on this drug for quite some time and he believe[d] the patient [was] knowledgeable enough to take the correct bottle and dose and not to overdose himself.” *Id.*

Additionally, Investigator V.’s Memorandum reported that Johnson stated that “he wasn’t sure how the patient received a bottle dated [February 1, 2017] as he doesn’t recall giving him that one and it’s not listed in his computer,” but he acknowledged that the prescription was entered into the system on February 1, 2017. *Id.* The Memorandum further reported that PIC Johnson “recognize[d] that he failed to keep records of each time and quantity given to the patient.” *Id.* The Investigator finally reported that he asked a pharmacy employee to retrieve the hard copy prescriptions for Rx#1132787 [364 oxycodone 15mg] and Rx#1133568 [182 oxycodone 30mg], but #1132787 was not located. *Id.* According to the Memorandum, PIC Johnson also attempted to retrieve them and did not locate them. *Id.*

Investigator V.’s Memorandum also stated that PIC Johnson “identified the partial adhesives near the back tag label applied to the [ARNP’s] prescription, which he opined may have been the previous label [RX 1132787 for 364 oxycodone 15mg] that he put on the prescription and then must have removed it when he filled the 30mg tablets.” *Id.* According to the Memorandum, PIC Johnson admitted to Investigator V., “Boy I guess I shouldn’t

have done that”<sup>10</sup> and “I guess I [f-ed] this one up. I quit. Do you know anybody who wants to buy a pharmacy?” *Id.*

*The Diversion Investigator’s Investigation*

The DI reported, in a sworn Declaration dated March 19, 2018, that he conducted an accountability audit for Registrant on August 15, 2017. GX 3, at 2. As part of the audit, he conducted a physical count and review of some, but not all, controlled substances on hand at Registrant, and “compared that count with the [Registrant’s] biennial inventory records, dispensing logs, DEA 222 forms, and invoices compared with shipping records, which [he] had subpoenaed from pharmacy suppliers McKesson and Amerisource Bergen.” *Id.* According to the DI, the results of his audit showed that Registrant was short 10,594 oxycodone 30 mg tablets and 11,125 Carisprodol 350 mg tablets, and had overages of hydrocodone/apap 10/325 mg by 3,717 tablets, and overages of Tramadol 50 mg by 5,018 tablets.<sup>11</sup> *Id.* The DI’s declaration explained that when he began the audit on August 15, 2017, “DEA was not aware that PIC Johnson had tested positive for amphetamines, and did not select amphetamines as a controlled substance to audit.” *Id.*

The DI stated that he issued an administrative subpoena to Three Rivers Hospital in Brewster, Washington to obtain PIC Johnson’s patient file. *Id.* According to the DI, the records show that PIC Johnson had tested positive in urine drug screens for oxycodone and amphetamines on July 29, 2017, and October 7, 2017, and that he had “made various admissions regarding his drug abuse during the course of his treatment for drug overdose.” *Id.*; *see also* GX 3, Appendix 2 (subpoenaed Three Rivers Hospital records).

The DI also obtained Emergency Medical Service records from the Douglas Okanogan County Fire Department,<sup>12</sup> which demonstrated that on July 29, 2017, and October 7, 2017, Emergency Medical Services (hereinafter, EMS) were dispatched to

<sup>10</sup> Ellipses omitted from quote.

<sup>11</sup> The Government’s evidence does not include any evidence of the DI’s audit calculations, beginning or ending inventories, dispensing records, receiving records, DEA 222 order forms, invoices or a computation chart. The DI’s declaration touches on some of this information, and there is no evidence to contradict it, so I am sustaining those allegations that are adequately explained in the DI Declaration.

<sup>12</sup> The subpoenaed Fire Department records in Appendix 3 also included an emergency dispatch on September 29, 2017, which was not included in the DI’s declaration.

Registrant to attend to PIC Johnson. GX 3, at 3 (citing GX 3, Appendix 3 (EMS records)).

The DI also reported that during an interview with PIC Johnson on October 31, 2017, which included two of his DEA colleagues, “PIC Johnson admitted that he was diverting controlled substances from the pharmacy and was, on average, taking approximately 4–5 oxycodone 30 mg tablets at a time, twice a day,” but he “could not recall . . . how long he had been diverting controlled substances from the pharmacy.” *Id.* Further, PIC Johnson admitted that he had abused oxycodone on the previous night and “admitted that he abused amphetamines which he diverted from Registrant, but not as often as he abused diverted oxycodone.” *Id.* Further, according to the DI, PIC Johnson told them during the interview that in spite of his regular diversion, abuse and impairment, “it would be more dangerous to have a new pharmacist who does not know the community operating [Registrant] than it would be for [him] to continue operating [it].” *Id.*

The DI also interviewed PIC Johnson’s wife, Nikki Johnson, who told them that she began noticing that PIC Johnson was using controlled substances “about a year prior,” and that “he would ‘plan ahead’ and bring home controlled substance pills [from Registrant] in his pockets and she would occasionally find controlled substances pills in his pockets at home.” *Id.*

*PIC Brian Johnson’s Treatment for Substance Abuse*

In particular, the Government’s evidence includes a copy of a medical incident report obtained by the DI from the Douglas Okanogan County Fire Department on July 29, 2017.<sup>13</sup> GX 3, Appendix 3. The incident report states that EMS responded to a call for “Heat/Cold Exposure” at Registrant’s location at 811 Highway 97, Brewster, where the Emergency Medical Technicians (EMTs) found PIC Johnson suffering from “possible heat stroke,” “confused/disoriented,” and displaying symptoms of “Cognitive-Confusion/Disorientation.” *Id.* at 1–2. The report states, “[I]t is known to EMS crew that patient has recently been to rehab for opioid drug use.” *Id.* at 2. The EMTs

<sup>13</sup> The Government’s evidence does not include a subpoena for the medical reports obtained from Douglas Okanogan County Fire Department, nor is there a corresponding attestation of authenticity to those records, however, the DI attests that that all information included in his Declaration is true and correct, and specifically states that he attached the records obtained from the subpoenas in Appendix 2; therefore, I find that these records appear to be authentic.

administered Narcan (Naloxone) and transported him to the local hospital. *Id.*

PIC Johnson’s patient records from Three Rivers Hospital (TRH) show that on July 29, 2017, PIC Johnson was treated in the emergency room after EMS documented “[c]oncern for heatstroke vs. drug OD?” GX 3, Appendix 2, at 2. The results of an administered urine drug test were positive for amphetamines and oxycodone. *Id.* at 20. The “Nurses Notes” in the hospital record state that prior to discharge from the hospital a “brief intervention [was] done regarding drug use.” *Id.* at 7.

A document titled “ER Note” for PIC Johnson on that date states that his chief complaint was “altered mental status” and that “he denies taking any medications,” and “denies recreational drug use”; however, the reviewing doctor’s assessment was “Narcotic overdose.” *Id.* at 19–21.

The records attached to the DI’s Declaration show that on September 29, 2017, the EMS responded to an emergency call on Highway 97, Pateros, Washington, where they encountered PIC Johnson sitting “in a car along the road [ ] shaking and non-responsive to [rescue personnel] on the scene.” GX 3, Appendix 3, at 4. The EMTs reported that he “kept saying that he was late and needed to get to work.” *Id.* The EMTs assessed him with “altered mental status” and transported him to the hospital. *Id.* at 3. The corresponding hospital report states that he “[denies] any drug use in the past 30 days.” GX 3, Appendix 2, at 41. According to the report, during his treatment in the emergency room, police “received orders from a judge to obtain labs,” and he was discharged into police custody and “taken to jail for DUI.” *Id.* at 45. The reviewing doctor’s report states that he “reports a history of narcotic dependence in the past and though he denies dependency now he admits to abuse.” *Id.* at 46. No urine drug screen was performed at the hospital but the treating doctor’s report was amended to state, “The main issue will be withdrawal from narcotics which may happen in the next 24 hours.” *Id.* at 48.

On October 7, 2017, the EMS responded to a call at Registrant in response to a complaint of PIC Johnson “shaking, possibly having seizure while standing.” GX 3, Appendix 3, at 8. The EMT’s report states that, upon arrival, they encountered PIC Johnson and the field assessment of him was “Substance Abuse—Opioid.” *Id.* at 10.

According to the hospital patient records for PIC Johnson on that date, a urine drug screen showed positive results for amphetamines and

oxycodone. GX 3, Appendix 2, at 69, 77. The treating physician's report states that PIC Johnson "admits during ER course to problem with using drugs and wishes to stop but declines admission and states he knows how to get off drugs with Methadone or Suboxone" and that he planned to enter rehab when "able to be free from his pharmacy business for at least a [three] week period." *Id.* at 72. He also admitted he "has no prescribed medication from a provider . . . [h]e states he is a pharmacist and has access to medications." *Id.* The treating physician's impression was "drug intoxication, mixed substance abuse, narcotics and amphetamine, acute, recurrent. Illicit drug use." *Id.*

*Allegation That PIC Johnson Abused Registrant's Registration To Fuel His Drug Addiction*

The Government has demonstrated that PIC Johnson used the Registrant's registration to procure drugs for his own addiction. By his own admission to the DI, PIC Johnson was "diverting controlled substances from the pharmacy and was, on average, taking approximately 4–5 oxycodone 30 mg tablets at a time, twice a day." GX 3, at 3. His wife, and co-owner of Registrant, confirmed this admission in stating to the DI that PIC Johnson "would 'plan ahead' and bring home controlled substance pills [from Registrant] in his pockets." *Id.* The evidence is clear that Registrant was enabling this drug addiction by dispensing to PIC Johnson without a prescription and without maintaining required records. Although I believe that the Government has provided substantial evidence regarding PIC Johnson's abuse of Registrant's registration through PIC Johnson's admission, this violation was not alleged in the OSC; therefore, I will not ultimately consider this violation as a basis for sanction in this case. Had this case gone to hearing, the violation would have likely been adequately noticed during the prehearing phase.<sup>14</sup> In this case, I believe that there is enough evidence that Registrant's registration is inconsistent with the public interest without it.

*Allegation That PIC Johnson Was Impaired While Working as Pharmacist In-Charge*

Based on the declaration of the DI and the records from EMS and Three Rivers Hospital, I find that the Government has

<sup>14</sup> In this case, the Government has provided no evidence or legal arguments regarding its provision of due process to the Registrant related to the allegation not charged in the OSC that would allow me to consider PIC Johnson's admission as a basis for sanction.

established that PIC Johnson was impaired on at least two occasions, while working as the Pharmacist in Charge. GX 3, Appendix 2 & 3. Particularly, EMS was dispatched on July 29, 2017, and October 7, 2017, to Registrant to attend to PIC Johnson. GX 3, at 3 (citing GX 3, Appendix 3). Laboratory tests conducted at the hospital on those two occasions demonstrated that PIC Johnson tested positive for oxycodone and amphetamines. GX 3, Appendix 2, 20; *id.* at 69, 77.

*Allegation That Registrant Failed To Keep Accurate Records*

Based on the uncontested declaration of the DI, I find that Registrant failed to maintain adequate records of its controlled substances.<sup>15</sup> GX 3, at 2. I find that an accountability audit conducted on August 15, 2017, demonstrated that Registrant was short 10,594 oxycodone 30 mg tablets and 11,125 Carisoprodol 350 mg tablets, and had overages of hydrocodone/apap 10/325 mg by 3,717 tablets, and overages of Tramadol 50 mg by 5,018 tablets.<sup>16</sup><sup>17</sup> *Id.*

Regarding the multiple fillings of Patient M.R.'s prescription, I find that the Government's evidence substantially indicates that on more than one occasion, PIC Johnson dispensed varying dosages of Oxycodone to Patient M.R. on the basis of a single prescription. Although the evidence is unclear as to how many bottles were filled on February 1, 2017, it appears that the PMP entries for the prescription were inaccurate, because it shows only one prescription filled on February 1, for the full prescription. See GX 4, Appendix 1 (PMP data for February 1, 2017 and February 11, 2017) (showing three dispensings on two different dates, one of which is for the full prescription). I find that both the State PMP and the labels on the bottles show that the Registrant filled a prescription for a prescription number that was entirely invented (no record from the

<sup>15</sup> The Government also alleged in the OSC that Registrant failed to record the date and quantity of controlled substances received on multiple copies of DEA Form 222; however, the DI's sworn declaration did not include confirmation of this allegation; therefore, this allegation is not sustained.

<sup>16</sup> The OSC also alleged that the audit showed shortages of morphine immediate release, morphine extended release and meperidine; however, the DI's sworn declaration did not include confirmation; therefore, this allegation is not sustained.

<sup>17</sup> The Government's evidence does not include any evidence of the DI's audit calculations, beginning or ending inventories, dispensing records, receiving records, DEA 222 order forms, invoices or a computation chart; however, there is no information to contradict the DI's sworn declaration, so I will find the facts as presented therein.

prescriber or at the pharmacy), and also filled the full amount of the single prescription twice. *Id.*; GX 5, at 2.<sup>18</sup>

## Discussion

### Public Interest Analysis

The Government asserts that Registrant's registration should be revoked because its continued registration is inconsistent with the public interest, and requests that I issue a final order affirming the Order of Immediate Suspension issued on October 26, 2017. RFAA, at 1. According to the Government, Registrant's pharmacist in charge "circumvented the CSA's prescription requirement by leapfrogging the doctor-patient component of the CSA's closed system, obtained [sic] a DEA Registration, and used the Pharmacy to order wholesale quantities of controlled substances for his abuse." RFAA, at 7. It also contends that PIC Johnson dispensed controlled substances to patient M.R. contrary to the CSA's prescription requirement, and that the PIC's repeated drug overdoses, while working as the Pharmacist-in-Charge at the Registrant, demonstrates conduct which may threaten the public health and safety.

In addition, the Government requests that all controlled substances seized from Registrant on October 31, 2017, pursuant to the Order of Immediate Suspension be forfeited to the United States. *Id.* at 1.

Section 304(a) of the CSA provides that "[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). In the case of a "practitioner," which is defined in 21 U.S.C. 802(21) and includes a pharmacy, the CSA requires that the Agency consider the following factors in making the public interest determination:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

<sup>18</sup> The evidence also demonstrates that Registrant engaged in unlawful dispensing to PIC Johnson, which would provide further evidence of recordkeeping violations, but as explained herein, I am not ultimately considering violations related to PIC Johnson's self-dispensing in my sanction determination, because these violations were not included in the OSC, nor was Registrant otherwise provided with notice that they would be a basis for sanction.

(2) The applicant's experience in dispensing . . . controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the . . . distribution[ ] or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003).

According to Agency decisions, I "may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether" to revoke a registration. *Id.*; see also *Jones Total Health Care Pharmacy, LLC v. Drug Enft Admin.*, 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi v. Drug Enft Admin.*, 841 F.3d 707, 711 (6th Cir. 2016); *MacKay v. Drug Enft Admin.*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman v. Drug Enft Admin.*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. Drug Enft Admin.*, 419 F.3d 477, 482 (6th Cir. 2005)). Moreover, while I am required to consider each of the factors, I "need not make explicit findings as to each one." *MacKay*, 664 F.3d at 816 (quoting *Volkman*, 567 F.3d at 222); see also *Hoxie*, 419 F.3d at 482. "In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct." *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821.

Also, pursuant to section 824(d), "[t]he Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety." 21 U.S.C. 824(d)(1). Congress has defined "the phrase 'imminent danger to the public health or safety' [to] mean[ ] that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under [the CSA], there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." *Id.* at (d)(2).

Under the Agency's regulation, "[a]ny hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to . . . 21 U.S.C. 824(a) . . . are satisfied." 21 CFR 1301.44(e). In this matter, I have considered all of the factors and find that the Government's evidence with respect to factors two, four and five establishes that Registrant, through its corporate principal and pharmacist-in-charge, has committed acts which render its registration "inconsistent with the public interest" and which support the revocation of its registration. 21 U.S.C. 824(a)(4). I further find that the Government's evidence, supports my initial finding and further establishes that Registrant's misconduct satisfies the imminent danger standard of 21 U.S.C. 824(d), in that, Registrant's failure "to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under" the CSA created "a substantial likelihood of an immediate threat that . . . abuse of a controlled substance will occur in the absence of an immediate suspension of [its] registration." *Id.*

*Factors Two and/or Four—The Registrant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances*

The Government has established that Registrant unlawfully dispensed controlled substances to Patient M.R. The definition of "dispense" under the CSA is "to deliver a controlled substance to an ultimate user . . . pursuant to the lawful order of, a practitioner." *Id.* at § 802(10); see also 21 CFR 1300.01(a) ("Prescription means an order for medication which is dispensed to or for an ultimate user . . . .")

Factor Four is demonstrated by evidence that a registrant has not complied with laws related to controlled substances, including violations of the CSA, DEA regulations, or other state or local laws regulating the dispensing of controlled substances. The Government's case relies primarily on the actions of Registrant's PIC and co-owner. "Agency precedent has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee." *Perry County Food & Drug*, 80 FR 70084, 70109 (2015) (citing *EZRX, LLC*, 69 FR 63178, 63181 (1988); *Plaza Pharmacy*, 53 FR 36910, 36911 (1988)).

Under the CSA, it is "unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter." 21 U.S.C. 844(a). While PIC Johnson was authorized to order controlled substances for the pharmacy and to possess controlled substances in his capacity as the Registrant's PIC, he was authorized to do so only for the purpose of dispensing the controlled substances to patients "pursuant to the lawful order of a practitioner," in this case, a prescription. 21 U.S.C. 822(b) ("Persons registered by the Attorney General under this subchapter to . . . dispense controlled substances . . . are authorized to possess . . . distribute, or dispense such substance . . . to the extent authorized by their registration and in conformity with the other provision of this subchapter.") (emphasis added); 21 U.S.C. 823(f); see also *ChipRX, L.L.C.*, d/b/a *City Center Pharmacy*, 82 FR 51433, 51437 (2017).

The Government asserts that not only does PIC Johnson's misconduct in dispensing to himself violate 21 U.S.C. 844(a) (unauthorized possession of controlled substances), but that such possession demonstrates the Registrant's violation of § 829(a) and (b) (requiring a prescription to dispense controlled substances). RFAA, at 8. Further, it alleges that the Registrant's conduct violates federal regulations mandating that a pharmacist may dispense scheduled drugs only pursuant to a written prescription signed by the practitioner. 21 CFR 1306.11 (schedule II) and 1306.21 (schedules III–V). *Id.* The evidence shows that Registrant's PIC was diverting narcotic controlled substances from Registrant's pharmacy stock for his own misuse—taking approximately 4–5 oxycodone 30 mg tablets at a time, twice a day. *See* GX 3, at 3. His wife, Registrant's co-owner, also informed the DIs that he would bring home controlled substance pills from Registrant in his pockets, which demonstrated that she had knowledge of Registrant's unlawful activity and permitted it to continue. Although there is substantial evidence that PIC Johnson violated multiple laws in dispensing to himself, these allegations were not noticed in the OSC, and therefore, I am not relying on the violations of law associated with them in my sanction determination.

There is substantial evidence that Registrant violated the recordkeeping requirements of the CSA. Recordkeeping is one of the CSA's principal tools for preventing the diversion of controlled substances. *Grider Drug 1 & Grider Drug 2*, 77 FR 44070, 44100 (citing *Paul H. Volkman*, 73 FR 30630, 30644 (2008)). Under the Act, "every registrant . . . dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance . . . received, sold, delivered, or otherwise disposed of by him." 21 U.S.C. 827(a). Further, DEA decisions have explained that "a registrant's accurate and diligent adherence to [its recordkeeping] obligations is absolutely essential to protect against the diversion of controlled substances." *Volkman*, 73 FR at 30644. Here, the Government alleged, in its Order to Show Cause, that an audit conducted by the Diversion Investigators of Registrant showed shortages of more than 10,000 oxycodone 30 mg tablets and more than 11,000 carisoprodol 350 mg tablets. OSC, at 2. In addition, the Government alleged that the audit showed overages for hydrocodone/apap 10/325 and tramadol. *Id.* (citing 21 CFR 1304.03, 1304.04, 1304.11, 1304.21);<sup>19</sup> see also GX3, at 2 (DI's Declaration). It is clear from such overages and shortages that Registrant was not maintaining required records.

In addition, as found herein, the Government's evidence substantially indicates that PIC Johnson filled multiple prescriptions for varying dosages of Oxycodone to Patient M.R. on the basis of a single prescription. Registrant filled the single Schedule II oxycodone prescription on more than one occasion in violation of 21 U.S.C. 841(a). Further, it is clear that Registrant did not maintain adequate records regarding its dispensing to Patient M.R.

On the basis of these unrefuted facts I find that Registrant, through its PIC, failed to maintain accurate records of its dispensing activities to M.R., violated federal law in dispensing to M.R. without a valid prescription, and Registrant's inventory overages and shortages further demonstrate violations of federal law and regulations. Such findings weigh against entrusting Registrant with a registration.

<sup>19</sup> Although the OSC alleged that Registrant had also violated 21 CFR 1305.13(e), I found no mention of the underlying violations in the DI Declaration nor in the RFAA, so I am not sustaining that violation. See OSC, at 2; GX 3; RFAA. Additionally, I am not sustaining a violation of 21 CFR 1304.22 as alleged in the RFAA, because it was not alleged in the OSC and the Government has not provided me with a basis for considering it.

#### Factor Five—Such Other Conduct Which May Threaten Public Health and Safety

Although factor five is broad, DEA decisions have qualified its breadth by limiting the considerations made under that factor to those where there is "a substantial relationship between the conduct and the CSA's purpose of preventing drug abuse and diversion." *Zvi H. Perper, M.D.*, 77 FR 64131, 64141 (2012), citing *Tony T. Bui*, 75 FR 49979, 49988 (2010). DEA caselaw has held that registrants who self-abuse controlled substances may endanger public health and safety. See *Tyson D. Quy, M.D.*, 78 FR 47412 (2013); *Bui*, 75 FR at 49988; *Kenneth Wayne Green, Jr.*, 59 FR 51453 (1994). In particular, PIC Johnson abused oxycodone and amphetamines on two documented occasions, while acting as the Pharmacist-in-Charge at Registrant to such an extent that EMS had to take him to the hospital for a potential overdose. A practitioner, who is under the influence of controlled substances while practicing, places public health and safety in jeopardy. See *Quy*, 78 FR at 47418 (holding that a physician who reported to work at a hospital while under the influence endangered public health and safety, because "the fact that he was willing to risk such harm is inconsistent with the requirements of a DEA registrant.").

In this case, Registrant is a corporation, not an individual, but "misconduct of an entity's principal is properly considered in determining whether to revoke the entity's registration." *ChipRX, L.L.C., d/b/a City Center Pharmacy*, 82 FR 51438 (citing *G&O Pharmacy of Paducah*, 68 FR 43752, 43753 (2003)). Although PIC Johnson's dispensing to Patient M.R. fortunately did not result in harm to the patient, it demonstrates a dangerous lack of attention to detail and violations of law, which resulted in PIC Johnson filling "this single prescription three times,"<sup>20</sup> providing patient M.R. with three different prescription bottles with various dosage strengths, for a total of 910 oxycodone tablets." OSC, at 4. As the Agency has previously held, "[c]areless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration or the denial of an application for a registration." *Lon F. Alexander, M.D.*, 82 FR 49704, 49725 n.43 (2017) (quoting *Paul J. Caragine, Jr.*, 63 FR 51592, 51601 (1998)).

<sup>20</sup> As explained herein, he appeared to fill the prescription twice in three bottles.

Additionally, on September 29, 2017, EMS and hospital records demonstrate that PIC Johnson showed signs of drug abuse while operating his vehicle on his way to work. See GX 3, Appendix 3, at 4. The hospital records show that he was subsequently arrested for Driving Under the Influence. GX 3, Appendix 2, at 45. Once again, it appears that PIC Johnson was planning to practice as the Pharmacist-in-Charge while dangerously intoxicated, and additionally, he demonstrated an extreme lack of judgment and a reckless disregard for the safety of others by driving his car in such a state.

#### Summary of Factors Two, Four and Five and Imminent Danger

Having considered all of the factors, I conclude that the evidence pertinent to factors two, four and five demonstrate a *prima facie* showing that Registrant "has committed such acts as would render [its] registration . . . inconsistent with the public interest." 21 U.S.C. 824(a)(4). I further conclude that Registrant has not rebutted the Government's *prima facie* case.

For purposes of the imminent danger inquiry, my findings also lead to the conclusion that Respondent has "fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant" under the CSA. 21 U.S.C. 824(d)(2). The uncontested, substantial evidence that Respondent was severely impaired while working or heading to work, as evidenced by his emergency room treatments for potential overdose three times in the course of three months, establishes that there was "a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance . . . [would] occur in the absence of the immediate suspension" of Registrant's registration. *Id.*; see also, *ChipRX, L.L.C. d/b/a City Center Pharmacy*, 82 FR 51433, 51439 (2017).

#### Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Registrant's continued registration is inconsistent with the public interest, the burden shifts to the Registrant to show why it can be entrusted with a registration. *Garrett Howard Smith, M.D.*, 83 FR 18882, 18910 (2018) (collecting cases).

The CSA authorizes the Attorney General to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. 871(b). This authority

specifically relates “to ‘registration’ and ‘control,’ and ‘for the efficient execution of his functions’ under the statute.” *Gonzales*, 546 U.S. at 259. “Because ‘past performance is the best predictor of future performance, *ALRA Labs, Inc. v. Drug Enf’t Admin.*, 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant’s] actions and demonstrate that [registrant] will not engage in future misconduct.’” *Jayam Krishna-Iyer*, 74 FR at 463 (quoting *Medicine Shoppe*, 73 FR 364, 387 (2008)); *see also Jackson*, 72 FR at 23853; *John H. Kennedy, M.D.*, 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.*, 60 FR 62884, 62887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant; therefore, the Agency looks at factors, such as the acceptance of responsibility, and the credibility of that acceptance as it relates to the probability of repeat violations or behavior, and the nature of the misconduct that forms the basis for sanction, while also considering the Agency’s interest in deterring similar acts. *See Arvinder Singh, M.D.*, 81 FR 8247, 8248 (2016).

Here the Registrant failed to respond to the Government’s Order to Show Cause and Immediate Suspension Order and did not avail itself of the opportunity to refute the Government’s case. PIC Johnson did arguably accept responsibility on two occasions, one by admitting to the DI that he was diverting controlled substances, and the other when he admitted to the state investigator that he “shouldn’t have done that.” GX 3, at 3; GX 4, Appendix 5. However, he also told the DI that “it would be more dangerous to have a new pharmacist who does not know the community operating [Registrant] tha[n] it would be for [him] to continue operating the Pharmacy notwithstanding his regular diversion, abuse, and impairment.” GX 3, at 3. This statement undercuts any acceptance of responsibility and also highlights PIC Johnson’s lack of judgment in believing that it would benefit the community to have a pharmacist under the influence of controlled substances. Furthermore, because neither PIC Johnson nor anyone else testified nor presented any evidence on behalf of the Registrant in this proceeding, the Registrant has not provided any assurances that it has implemented remedial measures to

ensure such conduct is not repeated. Such silence weighs against the Registrant’s continued registration. *Zvi H. Perper, M.D.*, 77 FR at 64142 (citing *Medicine Shoppe*, 73 FR at 387); *see also Samuel S. Jackson*, 72 FR at 23853.

Accordingly, I find that the factors weigh in favor of sanction and I shall order the sanctions the Government requested, as contained in the Order below.

### Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. AB6785161 issued to Brewster Drug, Inc. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Brewster Drug, Inc. to renew or modify this registration, as well as any other pending application of Brewster Drug, Inc. for additional registrations in Washington. Pursuant to the authority vested in me by 21 U.S.C. 824(f), as well as 28 CFR 0.100(b), I further order that all controlled substances seized pursuant to the Order of Immediate Suspension of Registration are forfeited to the United States. This Order is effective May 4, 2020.

Dated: March 13, 2020.

**Uttam Dhillon,**

*Acting Administrator.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### [Docket No. 19-35]

#### **Gregory L. Molden, M.D.; Decision and Order**

On June 28, 2019, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Gregory L. Molden, M.D. (hereinafter, Respondent) of New Orleans, Louisiana. OSC, at 1. The OSC proposed the revocation of Respondent’s Certificate of Registration No. BM0671481. *Id.* It alleged that Respondent is mandatorily excluded from participation in Medicare, Medicaid, and all Federal health care programs for a minimum period of fifteen years. *Id.* at 1-2 (citing 21 U.S.C. 824(a)(5)). The OSC further alleged that Respondent is without “authority to practice medicine or handle controlled substances in the State of Louisiana, the

state in which [Respondent is] registered with DEA.” *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that on or about September 25, 2018, Respondent was convicted in the United States District Court for the Eastern District of Louisiana on one count of “Conspiracy to Commit Health Care Fraud,” in violation of 18 U.S.C. 1349, one count of “Conspiracy to Pay and Receive Illegal Health Care Kickbacks,” in violation of 18 U.S.C 371, and eleven counts of “Health Care Fraud,” in violation of 18 U.S.C 1347. *Id.* According to the OSC, based on Respondent’s conviction, the U.S. Department of Health and Human Services, Office of Inspector General, by letter dated March 29, 2019, mandatorily excluded Respondent from participation in Medicare, Medicaid and all Federal health care programs for a minimum period of fifteen years effective April 18, 2019, pursuant to 42 U.S.C 1320a-7(a). *Id.*

Additionally, the OSC alleged that the Louisiana State Board of Medical Examiners issued an Interim Consent Order for Suspension of Medical License on May 13, 2019. OSC, at 2. This Order, according to the OSC, indefinitely suspended Respondent’s Louisiana medical license leaving Respondent without authority to practice medicine or handle controlled substances in Louisiana—the state in which Respondent is registered with DEA. *Id.*

The OSC notified Respondent of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2-3 (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. OSC, at 3 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated August 7, 2019, Respondent timely requested a hearing.<sup>1</sup> Request for Hearing, at 1. According to the Hearing Request, Respondent sought to “reset/delay” any action on the OSC for a period of six months to allow Respondent time to appeal his criminal conviction. *Id.* Respondent stated that the criminal conviction, which he was appealing, was the basis for revoking his

<sup>1</sup> The Hearing Request was filed on August 7, 2019. Order Denying Continuance Request and Directing the Filing of Government Evidence Regarding its Lack of State Authority Allegation and Briefing Schedule, at 1. I, thus, find that the Government’s service of the OSC was adequate.