

Trade and Investment Queensland, San Francisco, CA; TruGenomix Health, Inc., dba Polaris Genomics, Gaithersburg, MD; Unveil LLC, Cincinnati, OH; Ursus Medical Designs LLC, Pittsburgh, PA; and Vaxxas Pty, Ltd., Hamilton, AUSTRALIA, have been added as parties to this venture.

Also, ImmersiveTouch, Inc., Chicago, IL; Neuromersive, Inc., Fort Worth, TX; Precisio Biotix Technologies, Dover, DE; and Sepsis Scout, Inc., San Francisco, CA, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and MTEC intends to file additional written notifications disclosing all changes in membership.

On May 9, 2014, MTEC filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on June 9, 2014 (79 FR 32999).

The last notification was filed with the Department on April 2, 2024. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 21, 2024 (89 FR 52090).

**Suzanne Morris,**

*Deputy Director Civil Enforcement Operations, Antitrust Division.*

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## DEPARTMENT OF JUSTICE

### Antitrust Division

#### Notice Pursuant to the National Cooperative Research and Production Act of 1993—America's DataHub Consortium

Notice is hereby given that, on June 28, 2024, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), America's DataHub Consortium (“ADC”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, ADACEN FEDERAL LLC, Albuquerque, NM; AT Worthy Technology, Fairfax, VA; Brightquery, Inc., Irvine, CA; Careplots, Inc., Malvern, PA; CAS a division of American Chemical Society, Columbus,

OH; Data Point LLC, Orange, NJ; Data Products LLC, Chicago, IL; Generative Medical, Inc., Palo Alto, CA; K8R Applications, Inc. dba Future Perfect Engineering, Seattle, WA; Node.Digital, Leesburg, VA; Omnicom Consulting Group, Inc., Tarrytown, NY; Polaron Technologies, Inc., Miamisburg, OH; Prism Lab at Cornell University, Ithaca, NY; and Vistra Communications LLC, Lutz, FL, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and ADC intends to file additional written notifications disclosing all changes in membership.

On November 11, 2021, ADC filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on December 22, 2021 (86 FR 72628).

The last notification was filed with the Department on April 4, 2024. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 21, 2024 (89 FR 52092).

**Suzanne Morris,**

*Deputy Director Civil Enforcement Operations, Antitrust Division.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 23–31]

#### Mary A. Vreeke, M.D.; Decision and Order

On February 13, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Mary A. Vreeke, M.D. (Respondent), of Oxnard, CA. OSC, at 1, 5. The OSC proposed the revocation of Respondent's DEA Certificate of Registration (Registration) No. FV3660037, alleging that Respondent's continued registration is inconsistent with the public interest. *Id.* at 1 (citing 21 U.S.C. 823(g)(1), 824(a)(4)).

A hearing was held before DEA Administrative Law Judge Paul E. Soeffing (the ALJ), who, on October 19, 2023, issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (Recommended Decision or RD). The RD recommended that Respondent's Registration be suspended for six months, and then reinstated with restrictions to ensure that Respondent

remains sober and continues with her current treatment program.<sup>1</sup> RD, at 27. Neither party filed Exceptions to the RD. Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the ALJ's credibility findings,<sup>2</sup> findings of fact, and conclusions of law, and clarifies and expands upon portions thereof herein. However, the Agency has determined that revocation is the appropriate sanction based on the egregiousness of Respondent's conduct, her recidivism, and the Agency's interests in deterring intentional violations of the Controlled Substances Act (CSA).

### I. Findings of Fact

Respondent is an anesthesiologist currently practicing at St. John's Hospital in Oxnard, California. Respondent testified that she has a substance abuse disorder that began with abusing alcohol in her mid-30s. RD, at 18; Tr. 234–35.<sup>3</sup> Respondent later began abusing zolpidem<sup>4</sup> and diazepam<sup>5</sup> which she obtained without a prescription either from a friend or by going into Mexico. Tr. 235. Respondent was arrested and convicted in 2009 for

<sup>1</sup> The restrictions that the ALJ recommends imposing on Respondent's registration require her to: (1) limit her controlled substance administering, prescribing, and dispensing to the practice of anesthesiology; (2) comply with the terms of the Medical Board of California's (MBC's) Stipulated Interim Order imposing restrictions on her Registration; (3) comply with the terms of her probation with the MBC and refrain from seeking early termination of her probation; (4) notify DEA's Los Angeles Field Division of any action taken against her license and immediately surrender her Registration if her California medical license is suspended or revoked; (5) remain in monitoring for substance abuse and submit to regular urine drug screens; (6) provide DEA with copies of all quarterly reports issued by her practice monitor; (7) maintain a detailed record of controlled substances prescribed, administered, or dispensed; (8) report all activity involving Schedule II controlled substances to DEA on a monthly basis; (9) allow DEA personnel to enter her registered location during normal business hours without prior notice or a warrant. RD, at 42–43.

<sup>2</sup> The Agency adopts the ALJ's summary of each of the witnesses' testimonies as well as the ALJ's assessment with respect to each of the witnesses' credibility. RD, at 4–23.

<sup>3</sup> The Agency agrees with the ALJ that Respondent's testimony was “genuine and generally consistent,” despite Respondent having a significant personal interest in the outcome of these proceedings. RD, at 23. The ALJ found that “to the extent that [Respondent's testimony] differs from the testimony of other testifying witnesses, [he would] consider her personal interest in this case, and [he would] give her testimony the weight that it deserves in light of other evidence and testimony presented during the hearing.” *Id.* The Agency agrees with the amount of weight that the ALJ afforded Respondent's testimony.

<sup>4</sup> Zolpidem is a Schedule IV controlled substance sold under the brand name Ambien. The generic name (zolpidem) is used in this decision.

<sup>5</sup> Diazepam is a Schedule IV controlled substance sold under the brand name Valium. The generic name (diazepam) is used in this decision.

transporting zolpidem and diazepam across the United States border with Mexico. RD, at 18; Tr. 235–36. Respondent testified that she transported drugs across the border on approximately ten occasions. RD, at 18 n.25; Tr. 237. In 2013, Respondent was confronted by her employer regarding diversion of controlled substances, and she admitted to diverting fentanyl and midazolam for personal use. RD, at 18; Tr. 239–40.

After admitting to diversion in 2013, Respondent entered treatment at the Loma Linda behavioral unit, and then moved to a 95-day inpatient program at the Betty Ford Center. RD, at 18; Tr. 240. The Medical Board of California (MBC) required Respondent to participate in a recovery program for one year before formally putting her on probation. RD, at 18; Tr. 241–42. This program included undergoing monitoring with the Pacific Assistance Group (PAG),<sup>6</sup> attending PAG support meetings twice weekly, attending Alcoholics Anonymous (AA) meetings, getting an AA sponsor, engaging in individual therapy, and attending meetings and programming through Betty Ford. RD, at 18; Tr. 240–41.

After a year of monitoring, the MBC and Respondent reached an agreement that resulted in restrictions being placed on Respondent's medical license for seven years. RD, at 18; Tr. 242–43. The conditions included "all of the conditions that [she] was currently doing and then a few more." RD, at 18; Tr. 243, 246–47; RX 2. Respondent testified that she was "100 percent" compliant with the terms of her probation. RD, at 19; Tr. 247–48. After approximately four years on probation, her probation agent suggested that she apply for early termination. *Id.* Respondent testified that she delayed her application for early termination because she was very comfortable in the routine that she had developed with PAG and AA, and she felt safe having their support. RD, at 19; Tr. 250–51. However, Respondent eventually applied for early termination, and her probation terminated on December 31, 2020. RD, at 19; Tr. 249, 252; RX 4.

During the time that Respondent was on probation with the MBC, she also entered into a Memorandum of Agreement (MOA) with DEA that allowed her to retain authority in Schedules II–V as long as she abided by the MBC's restrictions, which included limiting her registration to prescribing

and administering controlled substances in a perioperative or obstetric setting. RD, at 19; Tr. 252–53; RX 3. Respondent testified that she fully complied with the DEA restrictions, which terminated in December of 2020 along with her MBC probation. RD, at 19; Tr. 254–56.

In January of 2021, less than 30 days after the MBC's and DEA's restrictions were lifted, Respondent relapsed and resumed diverting controlled substances from her employer for personal use.<sup>7</sup> RD, at 19; Tr. 256–57. Respondent's relapse lasted from January 2021 to March 2021, and she recalled diverting fentanyl, midazolam, and hydromorphone on at least ten occasions for intravenous use. RD, at 19; Tr. 257–58. Respondent testified that she diverted mostly "waste" controlled substances that were not used during a procedure and should have been discarded.<sup>8</sup> *Id.* Respondent deceived the nurses by telling them that she was disposing of the "waste" substances, when instead she was disposing of saline. *Id.* On other occasions, Respondent overprescribed controlled substances to patients, or falsely documented that she had administered a controlled substance to a patient, and retained the excess for herself.<sup>9</sup> RD, at 19–20; Tr. 300. Respondent used the diverted controlled substances at home or in the call room where she worked at St. John's hospital. RD, at 20; Tr. 258. On March 26, 2021, Respondent was found unconscious in the hospital bathroom after having unintentionally overdosed on fentanyl, midazolam, and propofol that she had falsely

<sup>7</sup> Respondent testified that the circumstances that precipitated her relapse included stress related to the second wave of the COVID-19 pandemic, wanting to spend more time with her family, sporadic shifts, and mounting anger and resentment towards her boss relating to his scheduling decisions. RD, at 20; Tr. 258–59, 296–97. Respondent also testified that around the time of her relapse, she was attending AA meetings via Zoom video conferencing, not in person, due to COVID-related stress. RD, at 20; Tr. 259. Respondent testified that she "basically had no accountability" with the lack of a "solid" AA program. RD, at 20; Tr. 259–60. Respondent testified that on the day of her overdose, she received a text message from her boss that he would not give her future shifts if she did not cancel a long-scheduled vacation. RD, at 20–21; Tr. 260–61, 298. Additionally, her last case of the day involved a "code crimson," where hospital staff must engage in a hasty blood transfusion. RD, at 21; Tr. 299.

<sup>8</sup> Respondent testified that she never took medication that was necessary to treat a patient. RD, at 19; Tr. 300.

<sup>9</sup> Respondent admitted that overprescribing controlled substances to a patient and diverting the excess could have an impact on the actions of another doctor reviewing the patient's file at a later time. RD, at 20; Tr. 335–36. However, she testified that it is standard practice for anesthesiologists to titrate the dose until the desired respiratory rate is achieved, which would mitigate the potential harms of overprescribing. *Id.*

documented that she had given to a patient during her shift.<sup>10</sup> RD, at 20–21; Tr. 298–300.

Respondent's testimony about the restrictions that the MBC placed on her registration after her 2021 relapse is summarized below. *See infra* III.B.

## II. Discussion

### A. The Five Public Interest Factors

Under the CSA, "[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 his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a). In making the public interest determination, the CSA requires consideration of the following factors:

- (A) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (B) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.
- (C) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (D) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1).

The Agency considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15,227, 15,230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. Drug Enft Admin.*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 FR 37,507, 37,508 (1993).

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1), the Government's evidence in support of its *prima facie* case for revocation of

<sup>10</sup> DEA Diversion Investigator Yekaterina Blissard (DI) testified that DEA received an anonymous tip in August of 2022 alleging that Respondent was found unconscious in a hospital bathroom in March of 2021 "with an IV still attached to her hand" and controlled substances on her person. RD, at 4; Tr. 16.

DI's testimony primarily focused on the introduction of the Government's documentary evidence and her interactions with Respondent following the anonymous tip. RD, at 5. The Agency agrees that DI's testimony was "generally consistent," that "there was no indication that she harbors any animosity towards the Respondent," and that she has no personal stake in this proceeding. *Id.*

<sup>6</sup> PAG is a support group for "impaired healthcare professionals" that is "designed to help healthcare professionals provide treatment that is safe for the public [and] that is ethical and within the bounds of each of their practices." RD, at 6; Tr. 55–56.

Respondent's registration is confined to Factors B and D. RD, at 26–31; *see also id.* at 26 n.33 (finding that Factors A, C, and E do not weigh for or against revocation).<sup>11</sup> Having reviewed the record and the RD, the Agency adopts the ALJ's analysis, and agrees that the Government's evidence satisfies its *prima facie* burden of showing that Respondent's continued registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4); RD, at 25–31.

### B. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. *See Sualesh Ashraf, M.D.*, 88 FR 1095, 1097 (2023); *Kareem Hubbard, M.D.*, 87 FR 21,156, 21,162 (2022). In the current matter, the Government has alleged that Respondent violated numerous federal and state laws regulating controlled substances. OSC, at 1–2. Specifically, federal law requires that "[a] prescription for a controlled

substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a).<sup>12</sup> California law provides that "no person shall knowingly prescribe, administer, dispense, or furnish a controlled substance to or for any person . . . not under his or her treatment for a pathology or condition." Cal. Health & Safety Code § 11154(a). California law also provides that "no person shall prescribe, administer, or furnish a controlled substance for himself." *Id.* at § 11170. Further, California law defines unprofessional conduct to include "[p]rescribing, dispensing, or furnishing [controlled substances] without an appropriate prior examination and a medical indication" and "commi[tting] [] any act involving dishonesty or corruption that is substantially related to the qualifications, functions, or duties of a physician and surgeon." Cal. Bus. & Prof. Code §§ 2242(a), 2234.

In the current matter, Respondent admitted that she diverted controlled substances for her own personal use on at least ten occasions between January 2021 and March 2021. The parties stipulated that these acts of diversion occurred and that Respondent's conduct weighs against her under Factors B and D.<sup>13</sup> As Respondent's conduct displays clear violations of the federal and state regulations described above, the Agency agrees with the ALJ and finds that Respondent repeatedly violated federal and state law relating to controlled substances. RD, at 41. Accordingly, the Agency agrees with the ALJ and finds that Factors B and D weigh in favor of revoking Respondent's registration, and thus finds Respondent's continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1).

### III. Sanction

Where, as here, the Government has established sufficient grounds to revoke Respondent's registration, the burden shifts to Respondent to show why she can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18,882, 18,904 (2018). When a registrant has committed

acts inconsistent with the public interest, she must both accept responsibility and demonstrate that she has undertaken remedial measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195*, 77 FR 62,316, 62,339 (2012). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations, the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.*, 86 FR 33,738, 33,746 (2021).

#### A. Acceptance of Responsibility

Here, the Agency agrees with the ALJ that Respondent unequivocally accepted responsibility for her conduct and expressed genuine remorse for her actions. RD, at 31–35. Respondent fully accepted responsibility for the allegations outlined in the OSC, as well as her misconduct in 2009 and 2013, and agreed that she violated state and federal law. *Id.* at 22, 33; Tr. 332, 327. Respondent testified that, for her, accepting responsibility means making "living amends" and not "minimizing" her actions. RD, at 33; Tr. 345–46. She feels "profound regret" for her relapse, but she is "trying to use [that regret] as a tool for good." RD, at 22; Tr. 326–27. Respondent testified that her actions were egregious because she was dishonest, she "violated the trust of patients and nurses," she "potentially" hurt patients, she knew better, and she failed to use her available resources to get help. RD, at 23; Tr. 346. Respondent's willingness to reflect on her battle with addiction in a public forum is admirable, and the Agency agrees with the ALJ that Respondent unequivocally accepted responsibility for her misconduct. RD, at 31–35.

#### B. Remedial Measures

Having found that Respondent has unequivocally accepted responsibility for her conduct, the Agency considers whether Respondent has implemented sufficient remedial measures to demonstrate that she will not engage in future misconduct and can be trusted with a registration. *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 463 (2009). The Agency has acknowledged that "[i]n self-abuse cases, . . . successful rehabilitation efforts are an important consideration in determining whether a respondent can be trusted with a registration." *Trenton F. Horst, D.O.*, 80 FR 41,079, 41,091 (2015); *see also Abbas E. Sina, M.D.*, 80 FR 53,191, 53,201

<sup>11</sup> Respondent argues that Factor A weighs in her favor because the MBC considered her misconduct and put her on probation rather than revoking her state medical license. ALJ Exhibit (ALJX) 29, at 29. Prior Agency decisions have considered two forms of recommendations from state licensing entities: "(1) A recommendation to DEA directly from a state licensing board or professional disciplinary authority . . . , which explicitly addresses the granting or retention of a [Registration]; and (2) the appropriate state entity's action regarding the licensure under its jurisdiction on the same matter that is the basis for the DEA OSC." *John O. Dimowo, M.D.*, 85 FR 15,800, 15,810 (2020). Here, the MBC has not made a direct recommendation to DEA, but the MBC has considered the same misconduct alleged in the OSC and entered into a Stipulated Interim Order (Interim Order) with Respondent substantially restricting her registration. The Interim Order is not a final decision by the MBC, it does not contain final legal conclusions or factual findings, and it clarifies that any admissions regarding Respondent's conduct are not admissible in administrative proceedings. RX 12, at 3 ("The parties stipulate that the admissions made by Respondent as to the alleged conduct . . . are solely for the purpose of this stipulated Interim Order Imposing License Restrictions only, and shall not be used in any other proceeding before the [MBC], and shall not be admissible in any other criminal, civil, and/or administrative proceeding."). Moreover, the Order does not analyze whether Respondent's continued registration is consistent with the public interest under the CSA, which is a determination that the Agency must make in deciding whether to sanction a registrant. *Id.* at 15,810 (citing *Ajay S. Ahuja, M.D.*, 84 FR 5479, 5490 (2019)). Thus, the Agency finds that this Order is not determinative.

Regarding Factor C, the Agency does not consider Respondent's 2009 felony conviction as part of the public interest analysis because the Government did not allege that the conviction was a basis for revocation. RD, at 26 n.33. Finally, regarding Factor E, the absence of evidence of "other conduct which may threaten the public health and safety" does not militate for or against a finding that Respondent's registration is inconsistent with the public interest. *Id.*

<sup>12</sup> The Agency need not adjudicate the criminal violations alleged in the instant OSC. *Ruan v. United States*, 142 S. Ct. 2370 (2022) (decided in the context of criminal proceedings).

<sup>13</sup> RD, at 2; Stipulation 3, 4 ("[Respondent] acknowledges that her conduct reflects negative experience in dispensing with respect to controlled substances in violation of 21 U.S.C. 823(g)(1)(B)."), 5 ("[Respondent] failed to comply with applicable federal and state laws relating to controlled substances in violation of 21 U.S.C. 823(g)(1)(D)."), 6.

(2015) (“[T]he risk of relapse becomes critical in determining what steps are warranted when determining the public interest.”)

Respondent testified at length about the measures that she has taken, and will continue to take, to remain sober. These measures were implemented after Respondent was caught diverting from her employer in 2021, and they are mandatory under the terms of her agreements with the MBC and/or St. John’s Hospital (her current employer), which diminishes their weight as remedial evidence.<sup>14</sup> However, the Agency appreciates that the measures that Respondent is required to take under her agreements with the MBC and St. John’s hospital are extensive, leaving little room for Respondent to implement additional voluntary measures. The Agency also appreciates that Respondent has made a sincere commitment to remaining sober for herself, and not just for her employer. Tr. 341. Thus, the Agency considers Respondent’s remedial measures in determining whether Respondent can be trusted with a DEA registration.

#### Summary of Respondent’s Remedial Measures

After her overdose in March of 2021, Respondent was put on a medical leave of absence and began a new 30-day inpatient treatment program at the Betty Ford Center. RD, at 21; Tr. 302–04. Following her discharge from Betty Ford in May of 2021, she completed another three-month outpatient addiction program. RD, at 21; Tr. 304–05, 307–09.

On August 2, 2023, Respondent entered into a restrictive agreement with the MBC (the 2023 MBC Agreement) that allows her to continue practicing anesthesia as long as she: (1) abstains from using drugs and alcohol, (2) enlists a licensed physician to monitor her at work, (3) remains enrolled in the PAG program, (4) attends weekly substance abuse support group meetings, (5) receives psychotherapy, (6) submits to

<sup>14</sup> The Agency has held that remedial measures are given “limited-to-no-weight” when they are implemented after enforcement begins. *See, e.g., Morris & Dickson Co., LLC*, 88 FR 34,523 (2023) (citing *Mireille Lalanne, M.D.*, 78 FR 47,750, 47,777 (2013) (“The Agency has recognized that a cessation of illegal behavior only when ‘DEA comes knocking at one’s door,’ can be afforded a diminished weight borne of its own opportunistic timing.”); *Southwood Pharmaceuticals, Inc.*, 72 FR 36,487, 36,503 (2007) (giving no weight to respondent’s “stroke-of-midnight decision” to cease supplying suspect pharmacies with controlled substances and to employ a compliance officer). This principle applies in even greater force here, where the remedial measures that Respondent has implemented appear to be mandatory under an agreement with the state medical board rather than voluntary.

regular biological fluid testing (drug testing), and (7) notifies all of her employers about the MBC Agreement. RD, at 21–22; Tr. 323–24; RX 12, at 4–10. The MBC agreement allows Respondent to order, prescribe, and dispense controlled substances in a perioperative setting. RD, at 22; Tr. 324; RX 12 at 4.

Respondent testified that she currently attends AA meetings five times per week and PAG meetings twice per week (more than is required by the MBC Agreement). RD, at 21; Tr. 309. Respondent has completed the AA 12-Step Program and remains in the “maintenance steps,” 10, 11, and 12.<sup>15</sup> RD, at 21; Tr. 309.

Respondent’s return to work following her relapse began in November of 2021 at UrgentMed urgent care, where she worked through the spring of 2023.<sup>16</sup> RD, at 21; Tr. 168, 315. In August of 2022, Respondent resumed practicing as an anesthesiologist at St. John’s Hospital, where her continued employment is conditioned upon compliance with a Return to Practice Agreement (the St. John’s Practice Agreement). RD, at 21; Tr. 315–18; RX 9. In addition to the requirements outlined above in the 2023 MBC Agreement, the St. John’s Practice Agreement also requires Respondent to continue treatment with naltrexone (or an equivalent medication), to notify the hospital of any outside employment, and to maintain records of controlled substances ordered, prescribed, dispensed, administered, or possessed. RX 9, at 1–3. The St. John’s Practice Agreement also included restrictions that remained in place for a limited period of time, including proctoring for at least three cases, limitations on the number of shifts and hours worked, and evaluation by a board-certified addiction physician.<sup>17</sup> *Id.* Respondent is

<sup>15</sup> Respondent described the “maintenance steps” as steps to avoid complacency by focusing on recognition of present feelings and emotions, faith and meditation, and outreach to others in recovery and service. RD, at 21; Tr. 309–10.

<sup>16</sup> The Medical Director of UrgentMed, Dr. Peter Chung, testified that there were no complaints about Respondent’s treatment of patients and she received only positive feedback from patients and colleagues. RD, at 14; Tr. 175. The Agency agrees with the ALJ that Dr. Chung’s testimony was “genuine and generally consistent, though the subject matter of his testimony is of limited relevance to these proceedings.” RD, at 13. The ALJ stated that “where relevant[,] [he would] give [Dr. Chung’s] testimony the weight that it deserves in light of other evidence and testimony presented during the hearing.” *Id.* The Agency agrees with the amount of weight that the ALJ afforded Dr. Chung’s testimony.

<sup>17</sup> Dr. James Golden, a California-licensed physician who is Board certified in addiction medicine, evaluated Respondent following her relapse in 2021. RD, at 11–12; Tr. 124–26. Dr.

currently working a full 40-hour per week schedule. RD, at 21; Tr. 318–19.

Respondent offered eight witnesses to testify about Respondent’s commitment to remaining sober, her success in remaining sober from 2013 to 2020 while being monitored by PAG, and their belief that there is a high likelihood that Respondent will remain sober under her current monitoring program. RD, at 6–17; Tr. 50–217.

Tracy Zemansky, Ph.D., is a clinical psychologist and one of seven practitioners who owns and operates PAG.<sup>18</sup> RD, at 6; Tr. 50, 55–56. Dr. Zemansky was accepted as an expert in psychology, specializing in the field of physician impairment, evaluation, and recovery. RD, at 6; Tr. 57–58. Dr. Zemansky has known Respondent since November of 2013, when Respondent initially enrolled in PAG after being caught diverting drugs from her employer the first time. RD, at 6; Tr. 58, 61. Dr. Zemansky has also been involved in monitoring Respondent since her relapse in 2021.

Dr. Zemansky testified that, in her expert opinion, Respondent remains safe to practice as a physician and safe to prescribe controlled substances. RD, at 9; Tr. 84–85, 94, 107–08. Dr. Zemansky testified that the stressors that led to Respondent’s relapse in 2021 are a new focus of her recovery plan, and that her commitment to recovery is

Golden testified that he initially determined that Respondent was fit to work twenty or thirty hours a week, because she has a “propensity to have problems when she [feels] overwhelmed.” RD, at 12; Tr. 124–29. After additional meetings with Respondent, Dr. Golden has increased his recommended limitation to forty hours per week. RD, at 12; Tr. 130. Dr. Golden agreed that even physicians being monitored can relapse, but testified that relapse is less likely the longer a physician is in recovery and subject to monitoring. RD, at 12; Tr. 132–33. Dr. Golden further testified that Respondent “stands out [to him] as someone who is very committed” to her recovery program with a “willingness to continue with recovery.” RD, at 12; Tr. 135–36. Dr. Golden expressed support for the Respondent’s continued DEA registration and medical practice “so long as she is being monitored under the terms imposed by the Medical Board of California.” RD, at 12; Tr. 137.

The Agency agrees with the ALJ that Dr. Golden’s testimony was “was genuine and generally consistent, though the bases for his recommendations and conclusions were not addressed in much detail.” RD, at 12. The ALJ determined that Dr. Golden’s testimony was “credible and [he would] give it appropriate weight.” *Id.* The Agency agrees with the amount of weight that the ALJ afforded Dr. Golden’s testimony.

<sup>18</sup> The Agency agrees with the ALJ that Dr. Zemansky “presented credible testimony that was internally consistent and generally logically persuasive” and that she “presented an objective analysis” despite her “close therapeutic relationship with the Respondent.” RD, at 11. The Agency also agrees with the ALJ that Dr. Zemansky’s testimony is entitled to significant weight. *Id.*

sincere. RD, at 7–8, 11; Tr. 80, 101–04. Although Dr. Zemansky agreed that new and unforeseen stressors could cause a future relapse, she opined that having already gone through an extremely stressful situation resulting in relapse, Respondent now has additional tools that will help her remain sober. RD, at 11; Tr. 104–05. Dr. Zemansky testified that Respondent is being monitored closely by St. John's well-being committee, and that PAG provides St. John's with monthly compliance reports. RD, at 9; Tr. 81–82. Dr. Zemansky testified that Respondent has not had any positive drug tests or missed any appointments since resuming monitoring with PAG, and that Respondent has been sober since March of 2021. RD, at 7–8; Tr. 69–72, 74. Dr. Zemansky also highlighted that Respondent was fully compliant with her probation during her initial eight years of monitoring with PAG from 2013 to 2020, and that she “went above and beyond what was required in terms of her attitude . . . [and] involvement in outside recovery.” RD, at 6–7, 9; Tr. 62–64; Tr. 84–85, 99–100.

Dr. Zemansky opined that physicians in monitoring are “actually safer than physicians” who are not being monitored, because “we don't know what [the unmonitored physicians] are doing.” RD, at 9; Tr. 81–82. However, Dr. Zemansky acknowledged that there is “always” a chance for relapse, and that relapse can occur even with monitoring, though rare. RD, at 9; Tr. 87–88.

Dr. Zemansky testified that she supported Respondent's request for early termination of her probation in December of 2020. RD, at 9–10; Tr. 86–87, 105–06. At that time, Dr. Zemansky offered testimony on Respondent's behalf in front of the MBC stating that she believed that Respondent had an excellent prognosis for continued success and that she had no reservations about terminating Respondent's probation. Tr. 86–87. At the DEA hearing, Dr. Zemansky acknowledged that she regrets her decision to support the removal of all monitoring requirements in December of 2020, and she characterized Respondent's relapse in January of 2021 as “brief but quite severe.” Tr. 87, 106–07. Dr. Zemansky testified that she “wish[es] that [she] had been able to foresee differently.” Tr. 107.

Dr. W. Lee Wan,<sup>19</sup> a California-licensed ophthalmologist and Chair of

the Well-Being Committee at St. John's, testified that the Well-Being Committee has assumed an active role in monitoring Respondent since her 2021 relapse.<sup>20</sup> RD, at 16; Tr. 205–06. Dr. Wan testified that Respondent has remained compliant with the St. John's Practice Agreement. RD, at 17; Tr. 215. Dr. Wan supports Respondent's continued ability to practice as an anesthesiologist and continued DEA registration, and testified that he believes Respondent remains fit for duty. RD, at 17; Tr. 217, 221–22. However, Dr. Wan agreed that there is always a chance that an “addicted physician” will relapse. Tr. 217–18.<sup>21</sup>

Based on this evidence, the ALJ found that Respondent had “produced significant, un rebutted evidence

deserves in light of other evidence and testimony presented during the hearing.” *Id.* The Agency agrees with the amount of weight that the ALJ afforded Dr. Wan's testimony.

<sup>20</sup> Dr. Wan testified that Respondent was not being formally monitored by the Well-Being Committee when she relapsed in 2021. RD, at 16; Tr. 206–07. Dr. Wan is not aware of any patient complaints or other issues in the seven or eight years that Respondent worked at St. John's prior to relapsing. *Id.*

<sup>21</sup> Respondent offered the testimony of four additional colleagues and friends who support the continuation of her registration: Kathleen Van Daalen Wetter, Kimrae McDonald, Dr. Karen Simon, and Dr. Bahram Namdari. Ms. Wetter has been Respondent's AA sponsor for the past two years and interacts with her daily. RD, at 13. Ms. Wetter believes that Respondent has the “perfect attitude needed to continue to stay clean and sober,” and “[s]he remains open, willing, and honest about her recovery.” *Id.*; Tr. 147. Ms. McDonald, a nurse who works with Respondent at St. John's, testified that Respondent has a stellar reputation and she unequivocally supports Respondent's ability to continue practicing as an anesthesiologist. RD, at 13; Tr. 150–159. Dr. Simon, another colleague at St. John's, testified that she has known Respondent for 15 years, but was unaware of Respondent's substance abuse history until these proceedings. RD, at 15; Tr. 193–97. Dr. Simon testified that since 2021 she has not observed Respondent appear impaired while at work, and that she and Respondent have “an excellent working relationship.” RD, at 15; Tr. 198. Dr. Simon testified that Respondent's practice at St. John's is very busy and regularly involves emergency care, and that Respondent's performance is “excellent” under those stressful conditions. RD, at 15–16; Tr. 199. Dr. Namdari, a California-licensed anesthesiologist, testified that he has worked with Respondent at St. John's since 2015 and interacts with her nearly every workday as her workplace monitor. RD, at 15; Tr. 183–89. Dr. Namdari testified that since returning to work at St. John's following her relapse, Respondent has had no issues, she is “doing a great job,” and “patients are happy.” RD, at 15; Tr. 188. Dr. Namdari supported Respondent's ability to continue administering controlled substances with monitoring in place. RD, at 15; Tr. 189.

The Agency agrees with the ALJ that the testimony of Ms. Wetters, Ms. McDonald, Dr. Simon, and Dr. Namdari was “genuine and generally consistent[,] though the subject matter of [their] testimony is of minimal relevance to these proceedings.” RD, at 13–16. The Agency agrees with the amount of weight that the ALJ afforded these witnesses' testimony.

showing that she is capable of complying with the terms of licensing restrictions and monitoring,” and concluded that the Agency can trust Respondent to handle controlled substances as long as these rehabilitative measures remain in place. RD, at 35, 38–39. The ALJ did observe, however, that the length of time between the end of Respondent's probation in December of 2020 and her relapse in January of 2021 was “especially concerning.” *Id.* at 39.

The Agency agrees with the ALJ that the likelihood of Respondent relapsing is reduced if Respondent remains under strict monitoring. However, the record in this case establishes that relapse is always possible.<sup>22</sup> Respondent's expert witness, Dr. Zemansky, acknowledged this, and even admitted that she did not foresee Respondent's severe relapse in 2021. Thus, in assessing the adequacy of Respondent's remedial measures, the Agency must weigh the reduced risk of relapse against the serious and unmitigable risk that Respondent poses to the public if she relapses on the job again. Respondent works with patients while they are heavily sedated or unconscious—in their most vulnerable state. The practice of anesthesia requires careful focus and continuous monitoring, as Respondent testified that medication is titrated during a procedure in small doses until the desired respiratory rate is achieved. RD, at 20 n.30; Tr. 335–39. During Respondent's previous episodes of abuse and diversion, she treated patients for months at a time while under the influence, deceiving her colleagues and falsifying patient records to obtain more drugs. Although there was no evidence demonstrating that Respondent harmed any patients during her previous relapses, Respondent concedes that her conduct put patients at risk and could have caused harm. RD, at 20; Tr. 327–28, 337.

The Agency finds that Respondent has presented substantial evidence of remedial measures and acknowledges that Respondent has taken admirable steps towards continued sobriety; but continued sobriety is not guaranteed. Moreover, the agency has long held that “past performance is the best predictor of future performance.” *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995). Here, where Respondent had a “severe” relapse one month after the prior

<sup>22</sup> Several of Respondent's witnesses acknowledged that relapse is possible (although rare) when physicians are being monitored for substance abuse. *See* RD, at 9–10; Tr. 87–88, 106–07 (Dr. Zemansky's testimony); *see also* RD, at 12; Tr. 132–33 (Dr. Golden's testimony); RD, at 17; Tr. 217–18 (Dr. Wan's testimony).

<sup>19</sup> The Agency agrees with the ALJ that Dr. Wan's testimony was “generally credible and consistent.” RD, at 17. The ALJ found that, “where relevant [he would] give his testimony the weight that it

restrictions to her controlled substances authority were lifted, the Agency is not confident that it can trust Respondent with the continuation of her registration even with the remedial measures in place.

### C. Deterrent Effect and Egregiousness

Acceptance of responsibility and remedial measures are assessed in the context of the “egregiousness of the violations and the [DEA’s] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.” *Daniel A. Glick, D.D.S.*, 80 FR 74,800, 74,810 (2015); *OakmontScript Limited Partnership*, 87 FR 21,546, 21,545 (2022). Here, although Respondent accepted responsibility and expressed a genuine commitment to ensuring that she does not relapse again, she has a long history of violating federal and state laws related to controlled substances. DEA has shown leniency in the past by allowing Respondent to retain her registration after her previous offenses, but Respondent reverted back to intentionally diverting from her employer less than 30 days after DEA’s and the MBC’s restrictions were lifted, and she continued diverting for several months until she was caught. Thus, the Agency finds that considerations of specific deterrence weigh in favor of revocation. The Agency also finds that the interests of general deterrence support revocation. A decision to maintain Respondent’s registration after repeated behavior of intentionally diverting from her employer and violating other controlled substance laws would send a message to the registrant community that repeated acts of intentional diversion can be overlooked or excused as long as the Respondent accepts responsibility when confronted.

The egregiousness of Respondent’s conduct also supports a sanction of revocation.<sup>23</sup> Respondent engaged in

<sup>23</sup> The ALJ concluded that Respondent’s conduct was egregious, but found that there were two factors that mitigated the egregiousness: first, that Respondent’s addiction problems “greatly impacted her decision-making leading to her deceptive actions,” and second, that the record is devoid of evidence that Respondent directly harmed her patients. RD, at 37–38. The Agency agrees that the first factor could be mitigating in certain circumstances, but finds that the weight of the evidence supports a sanction of revocation, as discussed throughout this Order. Regarding the second factor, the Agency does not consider the lack of evidence of harm to be a mitigating factor because of the significant risk to public health and safety that Respondent posed while treating patients under the influence. The Agency has repeatedly held that it is not necessary for the Agency to find patient harm to revoke a registration and has declined to consider a lack of harm as evidence of positive prescribing experience. *See*,

prolonged and repeated acts of intentional diversion, involving deception, theft, and falsifying patient records, that “strike[] at the CSA’s core purpose.” *Samuel Mintlow, M.D.*, 80 FR 3630, 3653 (2015). In this case, the Agency believes that revocation of Respondent’s registration would encourage the general registrant community to seek help as soon as possible upon experiencing substance abuse problems, in order to avoid violating the Agency’s trust by engaging in repeated and intentional diversion.

Respondent agrees that her misconduct was egregious, but she cites in her Post-Hearing Brief to several cases where the Agency has allowed physicians to retain restricted registrations despite intentional and egregious violations of the CSA. ALJX 29, at 34–36. However, most of the cases that Respondent cites were decided more than 20 years ago, before the opioid epidemic surged.<sup>24</sup> The Agency has since departed from some of its more lenient sanction policies, citing the need to protect the public from abuse and diversion. For example, in *Jayam Krishna-Iyer*, the Agency noted that “[b]ecause of the grave and increasing harm to public health and safety caused by the diversion of prescription controlled substances,” it would no longer allow registrants who intentionally diverted controlled substances to retain their registrations if they declined to accept responsibility. *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 463 (2009). In *Southwood* and *Gaudio*, the Agency further clarified that it would consider the deterrent effect of a potential sanction, in addition to requiring registrants to accept responsibility and demonstrate that they could be trusted with a registration. *Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36504 (2007); *Joseph Gaudio, M.D.*, 74 FR 10083, 10094 (2009). Although the Agency has issued decisions within the past decade maintaining or granting restricted

*e.g.*, *Larry C. Daniels, M.D.*, 86 FR 61630, 61660–61 (2021) (“Waiting for a controlled substance to be found coursing through a person’s bloodstream before holding the registrant accountable is wholly at odds with the DEA’s responsibility to protect the public interest under 21 U.S.C. 823(f).”); *Jeanne E. Germeil, M.D.*, 85 FR 73786, 73799 n.32 (2020) (“I decline to consider that ‘no reported overdoses or deaths’ is an indicator of positive dispensing experience and there is no legal authority for the proposition that I must find death or an overdose before I may suspend or revoke a registration.”).

<sup>24</sup> *See* ALJX 29, at 34–36 (citing *Judy L. Henderson, D.V.M.*, 65 FR 5672 (2000); *Theodore Neujahr, D.V.M.*, 65 FR 5680 (2000); *Jimmy H. Conway, Jr., M.D.*, 64 FR 32271 (DEA 1999); *Robert G. Hallermeier, M.D.*, 62 FR 26,818 (1997); *Karen A. Kruger, M.D.*, 69 FR 7016 (2004) *Jeffrey Martin Ford, D.D.S.*, 68 FR 10750 (2003)).

registrations notwithstanding intentional and egregious violations of the CSA,<sup>25</sup> the Agency considers the unique facts of each case in determining the appropriate sanction. In this case, there are significant factors weighing against continuing Respondent’s registration, including the recurrent nature of her misconduct, the severity of her relapse, the substantial danger that she will pose to the public if she relapses again, the high level of deception involved in her diversion, and the speed with which Respondent resumed her unlawful behavior after DEA and the MBC lifted their restrictions in December of 2020.

Respondent also argues that revocation is not necessary for purposes of deterrence, and that revoking Respondent’s registration would “send[] the wrong message to impaired physicians” that “if you are open, honest, and admit to abusing or diverting controlled substances and seek help, you may have your DEA registration revoked.” ALJX 29, at 36. However, this record establishes that DEA did show leniency to Respondent previously, in 2013, which should give addicted registrants hope that by accepting responsibility and remedying their actions they too may be shown leniency for CSA violations. Rather, this decision is meant to encourage recovering registrants to continue to follow the CSA and avoid diversion even after DEA lifts any restrictions. Moreover, Respondent did not admit to abusing or diverting controlled substances and seek help until after she was confronted by her employer in both 2013 and 2021. If she had immediately sought help after relapsing in January of 2021, rather than diverting from her employer for several months until getting caught, Respondent’s argument regarding deterrence may have been more persuasive.

In sum, Respondent has not offered sufficient credible evidence on the record to rebut the Government’s case for revocation and Respondent has not demonstrated that she can be entrusted

<sup>25</sup> *See, e.g., Abbas E. Sina, M.D.*, 80 FR 53191 (2015) (physician with a long history of abusing alcohol, controlled substances, and illicit drugs allowed to retain a restricted registration, despite repeated acts of issuing unlawful prescriptions, because he unequivocally accepted responsibility for his misconduct and demonstrated that he had successfully complied with substance abuse monitoring for four years); *Trenton F. Horst, D.O.*, 80 FR 41079 (2015) (physician with a history of self-abuse granted a restricted registration, despite repeatedly issuing unlawful prescriptions and possessing methamphetamine without a prescription, after expressing true remorse for his actions and demonstrating compliance with a substance abuse treatment plan for seven months).



with the responsibility of registration. Accordingly, the Agency will order that Respondent's registration be revoked.

### 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. FV3660037 issued to Mary A. Vreeke, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Mary A. Vreeke, M.D. to renew or modify this registration, as well as any other pending application of Mary A. Vreeke, M.D., for additional registration in California. This Order is effective October 16, 2024.

### Signing Authority

This document of the Drug Enforcement Administration was signed on September 10, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

### Heather Achbach,

*Federal Register Liaison Officer, Drug Enforcement Administration.*

[FR Doc. 2024-20939 Filed 9-13-24; 8:45 am]

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 23-48]

### Awesome Care Pharmacy, Inc.; Decision and Order

On June 1, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Awesome Care Pharmacy, Inc., (Respondent) of Houston, Texas. OSC/ISO, at 1. The OSC/ISO informed Respondent of the immediate suspension of its DEA Certificate of Registration Number FA2332346 (registration), pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes "an imminent danger to the public health or safety." *Id.* at 1 (quoting

21 U.S.C. 824(d)).<sup>1</sup> The OSC/ISO also proposed the revocation of Respondent's registration, alleging that Respondent's continued registration is inconsistent with the public interest. *Id.* (citing 21 U.S.C. 824(a)(4)).

A hearing was held before DEA Administrative Law Judge Paul E. Soeffing (the ALJ), who, on February 6, 2024, issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (Recommended Decision or RD), which recommended revocation of Respondent's registration. RD, at 59. Following the issuance of the RD, Respondent filed exceptions.<sup>2</sup> Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, credibility findings,<sup>3</sup> findings of fact, conclusions of law, sanctions analysis, and recommended sanction as found in the RD and summarizes and clarifies portions thereof herein.<sup>4</sup>

<sup>1</sup> Respondent argues in its Exceptions to the Recommended Decision (Exceptions) that the ISO "led to the 'wrongful takings' of its DEA license" because the hearing established that no diversion occurred and there was "no imminent harm, no harm, and no damage, threat or harm to the 'public interest.'" Exceptions, at 1 (citing Tr. 8, 14, 52-53, 55, 69, 179-81, 192). However in this case, the evidence showed that Respondent repeatedly dispensed dangerous combinations of controlled substances that posed serious risks to patients without first resolving blatant red flags of drug abuse and diversion. Respondent's repeated dispensing of controlled substances outside the usual course of the professional practice and in violation of federal and state law established "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 Respondent's registration. 21 U.S.C. 824(d). Thus, the Agency finds that at the time the Government issued the OSC/ISO, there was clear evidence of imminent danger. Moreover, the immediate suspension aspect of the Government's case was final as of the date the OSC/ISO was issued by the Administrator, and is not the subject of these proceedings. 21 U.S.C. 824(d)(1) ("A[n immediate] suspension . . . shall continue in effect until the conclusion of [administrative enforcement] proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction."); 21 CFR 1301.36(h) ("Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction.").

<sup>2</sup> The Agency has reviewed and considered the Respondent's exceptions and addresses them herein, but ultimately agrees with the ALJ's recommendation.

<sup>3</sup> The Agency adopts the ALJ's summary of each witness' testimony, as well as the ALJ's assessment of each witness' credibility, except as clarified herein. See RD, at 4-53.

<sup>4</sup> Respondent argues in its Exceptions that the ALJ was biased towards the Government. Respondent's only record support for this assertion is a citation to the transcript where the ALJ thanks the Government for printing certain documents in large enough font for him to read. Exceptions, at 3 (citing Tr. 46-47). Respondent cites no authority

## I. Findings of Fact

### *Texas Standard of Care*

Katherine Salinas testified as the Government's expert regarding the standard of care for pharmacy practice in the State of Texas. RD, at 6; Tr. 96-97. Ms. Salinas has been licensed as a pharmacist in Texas for over thirty years and has dispensed medications in retail pharmacies since 1992. RD, at 6; Tr. 89-91, 167. Ms. Salinas served as a Compliance Officer with the Texas Board for approximately nine years, where she inspected approximately 2,700 pharmacies, and she currently works as the Medication Safety and Drug Diversion Supervisor for the University of Texas Medical Branch. RD, at 6-7; Tr. 93-95.<sup>5</sup>

Dr. Okpala, Respondent's owner and Pharmacist-in-Charge (PIC), testified on Respondent's behalf. Dr. Okpala testified that he has been licensed as a pharmacist in Texas since 1993. RD, at 20; Tr. 373, 376-77; RX 2, at 2.<sup>6</sup> The Agency agrees with the ALJ that Dr. Okpala has a significant personal interest in the outcome of these proceedings. RD, at 24. Additionally, the Agency finds that Dr. Okpala's testimony at times contradicted the language of Texas's regulations. Therefore, to the extent that Dr. Okpala's testimony diverges from the Texas regulations and the testimony of Ms. Salinas, the Agency will credit Ms. Salinas's testimony.<sup>7</sup>

Ms. Salinas testified that the standard of care in Texas is informed by DEA regulations and Texas laws and regulations, including Texas Administrative Code § 291.29(b), which requires pharmacists to "make every reasonable effort to ensure that any prescription drug order . . . has been issued for a legitimate medical purpose by a practitioner in the course of medical practice." 22 Tex. Admin. Code § 291.29(b); RD, at 7-8; Tr. 98-100. Ms.

suggesting that the ALJ's expression of appreciation for a chosen font size reflects bias especially where, as here, the ALJ thanked both parties at the end of the hearing for their zealous advocacy. Tr. 522.

<sup>5</sup> For Ms. Salinas's full qualifications, see RD, at 6-7, Government Exhibit (GX) 10.

<sup>6</sup> The Agency incorporates herein the entire summary of Dr. Okpala's testimony. RD, at 19-24.

<sup>7</sup> The ALJ found Dr. Okpala's testimony to be "generally credible," while noting that Dr. Okpala failed to lay an adequate foundation for his testimony that the patients in this case suffered from chronic pain. RD, at 24. The ALJ determined that "[t]o the extent that [Dr. Okpala's] testimony differs from the testimony of other testifying witnesses, I will consider his personal interest in this case, and I will give his testimony the weight it deserves in light of other evidence and testimony presenting during the hearing." *Id.* The Agency agrees with the amount of weight that the ALJ afforded Dr. Okpala's testimony, except as clarified herein.