estimated for an average respondent to respond: An estimated 2,000 respondents will provide information to complete this form once annually, and it will take approximately 5 minutes to complete the form.

(6) An estimate of the total public burden (in hours) associated with the collection: The estimated annual public burden associated with this collection is 167 hours, which is equal to 2,000 (total respondents) * 1 (# of response per respondent) * .833333 (5 minutes or the time taken to prepare each response).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Mail Stop 3.E-405A, Washington, DC 20530.

Dated: May 13, 2022.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. 19-31]

Eric David Thomas, M.D.; Denial of **Application**

On March 25, 2020, a former Assistant

I. Introduction

Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Eric David Thomas, M.D., (hereinafter, Applicant) of Helena, Montana. OSC, at 1. The OSC proposed the denial of Applicant's DEA registration application No. W18015986C and "any other application(s) for a DEA registration" on the grounds that he "materially falsified" that application "in violation of 21 U.S.C. 824(a)(1)," and "also pursuant to 21 U.S.C. 824(a)(4) and 823(f)," alleging that his being registered "would be inconsistent with the public interest as that term is defined in 21 U.S.C. 823(f) for violations of applicable Federal Law." Id.

The substantive grounds for the proceeding, as more specifically alleged in the OSC, are, first, that Applicant's DEA registration application No. W18015986C "does not set forth that . . [he] previously surrendered . . . [his registration] No. FT2321797 for cause" even though he was "aware of

that fact, as evidenced by . . . [his] agreement to surrender . . . [it] by signing and dating a Form DEA-104 on or about May 20, 2015." Id. at 5. The second substantive ground alleged in the OSC is that, although he did not have authority from DEA or New Jersey, Applicant issued at least eleven controlled substance prescriptions between about June 2, 2015, and August 17, 2015. Id. at 5-7 (citing 21 U.S.C. 822(a)(2), 841(a)(1), 843(a)(2), 802(10) and 21 CFR 1306.03(a)(2)). The third substantive ground alleged in the OSC is lack of candor based on Applicant's alleged provision of "false or misleading statements" and alleged "fail[ure] to answer questions candidly" in "multiple conversations and interviews with DEA personnel," and the submission of another, subsequently withdrawn, "falsified" registration application (No. W16055629C) to DEA. Id. at 7-10 (citing prior Agency decisions and 21 U.S.C. 824(a)(1)).

The OSC notified Applicant of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. Id. at 10-11 (citing 21 CFR 1301.43). The OSC also notified Applicant of the opportunity to file a corrective action plan (hereinafter, CAP). Id. at 11-12 (citing 21 U.S.C.

824(c)(2)(C)).

Applicant requested a hearing. Request for Hearing for "Eric Robert Thomas, MD," dated March 30, 2020; see also Order for Prehearing Statements dated March 31, 2020, at 1 (regarding "Eric Thomas, M.D."). The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge (hereinafter, ALJ) Mark M. Dowd. The hearing took place by video teleconference from the DEA Hearing Facility in Arlington, Virginia from June 15, 2020 through June 17, 2020. See Transcript (hereinafter, Tr.) 4.

The ALJ's Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, RD) is dated September 29, 2020. The RD notes thirty-eight stipulations agreed upon by the parties and includes them in its found facts. RD, at 91–96; infra, section II.A. The RD finds that Applicant materially falsified his DEA registration application, prescribed controlled substances without an active DEA registration on eleven occasions, and exhibited a lack of candor during DEA's investigation and during the proceeding, thus concluding that it would be inconsistent with the public interest for

me to grant Applicant's pending DEA registration application. RD, at 138–42 (citing 21 U.S.C. 823).

Applicant filed exceptions to the RD. [Applicant's] Exceptions to Decision of September 29, 2020 dated October 19, 2020 (hereinafter, Appl Exceptions). The Government sought, and eventually received, leave to respond to Appl Exceptions. Government's Responses to [Applicant's] Exceptions to Recommended Decision, Findings of Fact, and Conclusions of Law dated October 29, 2020 (hereinafter, Govt Exceptions).

Having considered the record in its entirety, I conclude that the Government failed to establish by clear, unequivocal, and convincing evidence that Applicant violated 21 U.S.C. 824(a)(1). I further conclude that there is uncontroverted, substantial record evidence, including Applicant's admission, that Applicant issued eleven controlled substance prescriptions when he had neither federal nor state authority to do so. I also conclude that the record evidence about whether Applicant exhibited candor in his interactions with the Agency and Agency investigators is not conclusive and, accordingly, that the record does not include substantial evidence of Applicant's OSC-alleged lack of candor.

I conclude, based on the entire record before me, that Applicant did not unequivocally accept responsibility for the egregious violations of prescribing controlled substances eleven times when he lacked federal and state authority to do so. Accordingly, based on the entire record before me, I decline to entrust Applicant with a DEA registration at this time and I deny DEA registration application No. W18015986C.

I set out the parties' stipulations of fact, adopting them as the ALJ recommended, and I make additional findings.

II. Findings of Fact

A. Stipulations of Fact

As already discussed, the parties agreed to thirty-eight stipulations of fact. The ALJ recommended that they be accepted as fact. I agree and I adopt as fact the parties' thirty-eight stipulations of fact, copied verbatim below. RD, at

- 1. [Applicant] was licensed in the State of New Jersey, Medical License No. 25MA08851700.
- 2. [Applicant's] New Jersey medical license, License No. 25MA08851700,

¹ The RD proposes, if I were considering granting Applicant's application, that I limit Applicant's authority to Schedule V. RD, at 142 n.35.

was temporarily suspended by the State of New Jersey, State Board of Medical Examiners, and the Order so doing took effect on December 4, 2015. Order of 25MA08851700, State of New Jersey, Department of Law & Public Safety, Division of Consumer Affairs, State Board of Medical Examiners (filed Nov. 25, 2015; effective date Dec. 4, 2015).2

3. [Applicant] entered into a final consent order in the state board case involving his New Jersey medical license, License No. 25MA08851700, that was issued, on or about, February 22, 2018. Consent Order, In the Matter of the Suspension or Revocation of the License of Eric Thomas, M.D. License No. 25MA08851700, State of New Jersey, Department of Law and Public Safety, Division of Consumer Affairs, State Board of Medical Examiners (filed Feb. 22, 2018).3 Pursuant to the Order, [Applicant] agreed "to retire his license to practice medicine and surgery in the State of New Jersey, with such retirement to be deemed a permanent suspension." Id. at 2.

4. [Applicant] previously had a Controlled Dangerous Substance ("CDS") registration in the State of New Jersey, Registration No. DO9767000. On or about May 20, 2015, [Applicant] signed a Consent Order that temporarily suspended his New Jersey CDS registration. Consent Order of Temporary Suspension of NJ CDS Registration, In the Matter of the Temporary Suspension of the NJ CDS Registration of Eric Thomas, M.D., State of New Jersey, Department of Law & Public Safety, Division of Consumer Affairs (filed May 21, 2015). Pursuant to the final consent order entered the [sic] in the state board case involving [Applicant's]'s New Jersey medical license, License No. 25MA08851700, [Applicant's]'s New Jersey CDS registration also was surrendered. Consent Order, In the Matter of the Suspension or Revocation of the License of Eric Thomas, M.D. License No. 25MA08851700, State of New Jersey, Department of Law and Public Safety, Division of Consumer Affairs, State Board of Medical Examiners (filed Feb. 22, 2018) at 2,4

5. [Applicant] was issued a medical 49958, by the State of Montana, on or about, June 20, 2016. The License was issued under his name and the business name of Medical Associates of Montana.

6. [Applicant] was registered with DEA as a practitioner authorized to handle controlled substances in Schedules II-V under DEA COR number FT2321797 at 44 Ridge Road, North Arlington, NJ 07031.5 On or about May 20, 2015, [Applicant] voluntarily surrendered COR FT2321797 by submitting a Form DEA-104 that he signed and dated.

7. On or about June 22, 2016, [Applicant] submitted an application for a DEA COR to handle controlled substances in Schedules II-V, with Application No. W16055629C, at 1001 South Main Street, Suite 49, Kalispell, MT 59901.6 [Applicant] withdrew this application, on or about, January 24, 2018.

8. For Application No. W16055629C, [Applicant] answered "Y" or "Yes" for liability question 3. [Applicant] also provided the following information for question 3:

Incident Nature[:] THERE WAS CONCERN THAT DURING THE COURSE OF DR. THOMAS' SEEING, **EXAMINING AND TREATING** VARIOUS PATIENTS WITH VARIED MEDICAL PROBLEMS, THERE MAY HAVE BEEN A VERY FEW PATIENTS' MISUSE OF PRESCRIPTIONS PROVIDED FOR THEIR ALLEGED PAIN CONTROL. NONE OF THIS MISUSE WAS ANTICIPATED IN ANY WAY BY ME IN MY ADMINISTRATION OF PROVIDING PROPER HEALTH CARE TREATMENT TO MY PATIENTS.

Incident Result[:] IN CONSIDERATION OF THIS PENDING ACCUSATION, I VOLUNTARILY SUSPENDED MY DEA LICENSE 13 MONTHS AGO IN GOOD FAITH IN ORDER TO RESPECT THE ACCUSATIONS THAT HAD BEEN MADE. DESPITE MY BEST EFFORTS TO PROVIDE APPROPRIATE HEALTH CARE AND TREATMENT. THESE ACCUSATIONS BY THE NJ MEDICAL BOARD RESULTED IN THE TEMPORARY SUSPENSION OF MY MEDICAL LICENSE PENDING THE CONSIDERATION STILL TO BE MADE BY A PROPER AND MORE APPROPRIATE, YET STILL UNSCHEDULED, "PLENARY HEARING".

9. On or about February 21, 2018, [Applicant] submitted an application for a DEA COR to handle controlled substances in Schedules II-V, with Application No. W18015986C, at 2620

Colonial Drive, Helena, MT 59602.7 This application is currently pending, and is the subject of this Order.

10. For Application No. W18015986C, [Applicant] answered "Y" or "Yes" for liability question 2. [Applicant] also provided the following information for question 2:

Incident Nature[:] THERE WAS CONCERN BY THE CONTROLLED DRUG DIVISION (CDS) THAT THERE WAS INAPPROPRIATE PRESCRIBING OF CONTROLLED SUBSTANCES BY DR. THOMAS FROM HIS MEDICAL OFFICE. OF THE 1,000 CHARTS OF [sic] DR. THOMAS HAD, SIX MEDICAL RECORDS WERE REQUESTED FOR REVIEW BY THE DEPUTY ATTORNEY GENERAL. AT THIS TIME, DR. THOMAS COMPLIED WITH ALL REQUESTS AND VOLUNTARILY SURRENDERED HIS CDS REGISTRATION PRIVILEGES WHILE THE CHART INSPECTION WAS BEING CONDUCTED.

Incident Result[:] THE NJ MED BOARD HELD A HEARING WHERE THE CHARTS OF DR THOMAS WERE INCOMPLETELY COPIED AND GIVEN TO ANOTHER DR WHO INCORRECTLY CONCLUDED THAT DR THOMAS DIND'T [sic] PROVIDE GOOD MEDICAL CARE WHILE PRESCRIBING CDS MEDS. DR THOMAS AND LAWYER CONTACTED ANOTHER MEDICAL DR—TRIPLE BOARD CERTIFIED—WHO REVIEWED THE ENTIRE CHARTS AND CONCLUDED MEDICAL CARE GIVEN BY DR THOMAS MET OR EXCEEDED STANDARD PRACTICES. A CONSENT ORDER WAS THEN AGREED UPON W/ DR THOMAS DENYING ANY WRONG DOING, NO CIVIL PENALTY MADE.

11. On or about December 4, 2018, [Applicant] submitted an application for a DEA COR to handle controlled substances in Schedule V, with Application No. W18128011C, at 400 Conley Lake Road, Deer Lodge, MT 59722-8708.8 [Applicant] withdrew this application on or about March 15, 2019.

12. [Applicant] has not had a DEA Registration to handle controlled substances since he surrendered COR No. FT2321797 for cause, on or about, May 20, 2015.

13. On or about June 2, 2015, [Applicant] issued to a patient with the initials T.P. a controlled substance prescription for Sonata 10 mg capsules (20 count).9

Temporary Licensure Suspension, In the Matter of Eric Thomas, M.D. License No.

license, License No. MED-PHYS-LIC-

² This document is Government Exhibit (hereinafter, GX) 3, admitted without objection. Tr.

³ This document is GX 4, admitted without objection. Tr. 88-89.

⁴This document is GX 2, admitted without objection. Tr. 36-38.

⁵ This document is GX 1a, admitted without objection. Tr. 98-99.

⁶ This document is GX 1b, admitted without objection. Tr. 94-95.

⁷ This document is GX 1c, admitted without objection. Tr. 96-97.

⁸ This document is GX 1d, admitted without objection. Tr. 97-98.

⁹The controlled substance prescriptions referenced in Stipulations 13 through 23 are

- 14. On or about June 2, 2015, [Applicant] issued to a patient with the initials A.G. a controlled substance prescription for Sonata 10 mg capsules (30 count).
- 15. On or about June 2, 2015, [Applicant] issued to a patient with the initials M.M. a controlled substance prescription for Sonata 10 mg capsules (30 count).
- 16. On or about June 2, 2015, [Applicant] issued to a patient with the initials E.G. a controlled substance prescription for Sonata 10 mg capsules (30 count).
- 17. On or about June 2, 2015, [Applicant] issued to a patient with the initials R.B. a controlled substance prescription for Sonata 10 mg capsules (30 count).
- 18. On or about June 12, 2015, [Applicant] issued to a patient with the initials M.W. a controlled substance for Qsymia 7.5–46 mg capsules (30 count).
- 19. On or about June 22, 2015, [Applicant] issued to a patient with the initials J.E. a controlled substance prescription for Lomotil 2.5–0.025 mg tablets (60 count).
- 20. On or about July 22, 2015, [Applicant] issued to a patient with the initials M.G. a controlled substance prescription for Lomotil 2.5–0.025 mg tablets (40 count).
- 21. On or about July 27, 2015, [Applicant] issued to a patient with the initials DC a controlled substance prescription for Belviq 10 mg tablets (30 count).
- 22. On or about August 13, 2015, [Applicant] issued to a patient with the initials M.C. a controlled substance prescription for phenobarbital 64.8 mg tablets (30 count).
- 23. On or about August 17, 2015, [Applicant] issued to a patient with the initials H.G. a controlled substance prescription for Restoril 22.5 mg tablets (30 count).
- 24. Sonata is the brand name for zaleplon, a Schedule IV controlled substance that is often used to treat insomnia.
- 25. Qsymia contains phentermine and topiramate, and is a Schedule IV controlled substance that is often used to treat obesity.
- 26. Lomotil is the brand name for diphenoxylate-atropine, a Schedule V controlled substance that often is used to treat irritable bowel syndrome and diarrhea.
- 27. Belviq is the brand name for lorcaserin, a Schedule IV controlled substance that often is used to treat obesity.

28. Phenobarbital is a Schedule IV controlled substance that often is used to treat certain types of epilepsy.

- 29. Restoril is the brand name for temazepam, a Schedule IV controlled substance that often is used to treat insomnia.
- 30. On or about July 26, 2018, [Applicant] participated in a face-to-face interview with DEA personnel.
- 31. On or about September 28, 2018, [Applicant] participated in a telephonic call with DEA personnel.
- 32. On or about October 3, 2018, [Applicant] participated in a telephonic call with DEA personnel. [Applicant] participated in a follow-up call with DEA personnel the following day, on or about, October 4, 2018.
- 33. On or about March 25, 2019, [Applicant] participated in a telephonic call with DEA personnel.
- 34. On or about April 9, 2019, [Applicant] participated in a face-to-face interview with DEA personnel. [Applicant] provided a handwriting exemplar to DEA personnel during this interview.
- 35. On or about April 26, 2019, [Applicant] participated in a telephonic call with DEA personnel.
- 36. Government Exhibit 2 is a true and correct copy of Consent Order of Temporary Suspension of NJ CDS registration, In the Matter of the Temporary Suspension of the NJ CDS Registration of Eric Thomas, M.D., State of New Jersey, Department of Law & Public Safety, Division of Consumer Affairs (May 21, 2015).
- 37. Government Exhibit 3 is a true and correct copy of Order of Temporary Licensure Suspension, *In the mater of Eric Thomas, M.D. License No.* 25MA08851700, State of New Jersey, Department of Law & Public Safety, Division of Consumer Affairs, State Board of Medical Examiners (filed Nov. 25, 2015; effective date Dec. 4, 2015).
- 38. Government Exhibit 4 is a true and correct copy of Consent Order, In the Matter of the Suspension or Revocation of the License of Eric Thomas, M.D. License No. 25MA08851700, State of New Jersey, Department of Law and Public Safety, Division of Consumer Affairs, State Board of Medical Examiners (filed Feb. 22, 2018).

B. The Investigation of Applicant

According to the Government's first witness, a Diversion Investigator (hereinafter, NJ DI) assigned to the New York Division Office whose DEA work is primarily in New Jersey, he received a telephone call from his New Jersey Enforcement Bureau investigator counterparts on May 20, 2015. Tr. 55–

56, 33. NJ DI testified that his counterparts told him they were "in the process of temporarily suspending. [Applicant's New Jersey Controlled Dangerous Substances (hereinafter, CDS)] registration, and they asked if we could come out to obtain his DEA registration." 10 Id. at 33-34; see also GX 2 (New Jersey Division of Consumer Affairs Consent Order of Temporary Suspension of N[ew] J[ersey] CDS Registration dated May 20, 2015), at 1 ("This matter was opened . . . upon receipt of information that . . [Applicant] was engaged in the prescribing of . . . [CDS] in the usual course of professional practice, without some ET 5/20/15 legitimate medical purpose in violation of N.J.A.C. 13:45H-7.4."), GX 2, at 2 ("Through the course of the investigation, it was determined that . . . [Applicant] had been prescribing CDS without some ET 5/20/ 15 legitimate medical purpose, notably highly addictive narcotics, to his patients and had knowingly prescribed CDS to known drug addicts, known felons and patients testing positive for Suboxone and illegal street drugs.").11 NJ DI testified that "typically when . . . [a New Jersey] administrative action occurs, in this case the suspension of a registration, we're contacted so that way we can follow suit . . . and make sure there is clarity for the person in question so that way they don't view it as having one license that's active and one that's not." Tr. 41. NJ DI testified that this notification process occurs "basically to protect the registrant holder." Id. NJ DI elaborated by stating that, "[b]ecause . . . [Applicant] was suspending his CDS registration, he was no longer going to be in good standing with the DEA" and "as a result, we were seeking a surrender of his DEA registration at that time." Id.; see also id. at 46-47, 54-55.

NJ DI's testimony described his encounter with Applicant on May 20, 2015. NJ DI testified that, since he "was in the office when . . . [he] received the phone call from the state investigators," he "had the time to put in the information to make . . . [a typed Form DEA-104 Voluntary Surrender of Controlled Substances Privileges form] more legible." *Id.* at 47–48. He testified that he, not Applicant, checked the first box on the Form DEA-104, the one that states "[i]n view of my alleged failure to comply with the Federal requirements

¹⁰ NJ DI testified that a New Jersey CDS registration "allows the doctor to prescribe specifically controlled substances whereas the medical license allows them to actually practice medicine overall." Tr. 35.

¹¹ The italicized material in these two quotes is handwritten above the noted text of GX 2.

compiled in GX 8. Tr. 130–32. GX 8 was admitted without objection. *Id.* at 132.

pertaining to controlled substances, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part." *Id.* at 44; GX 5, at 1. NJ DI and another DI traveled to Applicant's office after Applicant "had already signed the [Temporary New Jersey CDS Registration Suspension] Order" and "asked him to surrender his DEA registration, and presented a DEA Form[-]104." Tr. 42; *see also* GX 5 (Signed Form DEA—104 (Voluntary Surrender of Controlled Substances Privileges) dated May 20, 2015), at 1; Tr. 65, 73.

NJ DI testified that the two DIs met with Applicant, "explained who we were and explained the purpose of us being there, . . . that we were there seeking a surrender of his DEA registration because . . . he no longer possessed a CDS registration . . . in good standing, and as a result, the DEA was no longer going to be valid." Tr. 43. NJ DI testified that he read the Form DEA-104 to Applicant "so that way he knew what he was signing" because he "no longer had a CDS registration in good standing." Id. NJ DI testified that Applicant signed the DEA-completed Form DEA-104 and dated it May 20, 2015. Id. at 44-45. NJ DI testified that obtaining the voluntary surrender form from Applicant was the "final action for us" and that neither he nor anyone else at the New Jersey office of whom he is aware conducted any subsequent investigation of Applicant. Id. at 65–66.

Regarding NJ Dl's credibility, I agree with the RD, and I find that NJ Dl's testimony is fully credible. RD, at 110. I shall fully credit it. Tr. 29–76. Accordingly, I find uncontroverted, substantial, clear, unequivocal, and convincing record evidence that Applicant surrendered his DEA registration (No. FT2321797) and signed a DEA-completed Form DEA–104 on May 20, 2015. See also supra, section II.A., infra, section II.D.

NJ DI's testimony relates to action by the New Jersey State Board of Medical Examiners (hereinafter, NJMB) concerning Applicant's New Jersey medical license and CDS registration. Supra, section II.A. According to GX 4, the final Consent Order between Applicant and the NJMB filed on February 22, 2018, Applicant agreed to retire his medical license and surrender his CDS registration, and he agreed "not to reapply for a New Jersey medical license or to seek a CDS registration in the State of New Jersey in the future." GX 4, at 2–4. According to this Consent Order, after a hearing on the application for the temporary suspension of Applicant's medical license and the

"consideration of all evidence and testimony presented," the NJMB "found" that Applicant's "continued practice of medicine presented a clear and imminent danger to the public health[,] safety, and welfare, and therefore temporarily suspended his license to practice medicine." *Id.* at 1-2. The Consent Order also states that Applicant "agrees to the terms of this Consent Order as a settlement of a disputed matter" and "denies any and all wrongdoing." *Id.* at 2. Accordingly, I find uncontroverted record evidence that Applicant denied "any and all wrongdoing" about which the NJMB found his "continued practice of medicine . . . [to present] a clear and imminent danger to the public health" and about which he agreed never again to apply to practice medicine in New Jersey.

C. The Government's Case

In addition to NJ DI's testimony, the Government offered the testimonies of another DI and a Group Supervisor, and successfully moved thirteen exhibits into the record. ¹² The Government also called, obtained the testimony of, and cross-examined Applicant.

The Government's second DI witness testified that she is assigned to DEA's office in Billings, Montana (hereinafter, MT DI) and that she is the lead investigator on DEA registration application No. W18015986C, the registration application that is the subject of the OSC.13 Tr. 79, 81; see also id. at 93-102. MT DI testified that Liability questions are part of the DEA registration application. Id. at 82; see also id. at 102. Her testimony described these Liability questions as asking applicants about state and federal license "trouble," such as revocation, suspension, and denial, and about "any legal troubles with controlled substances . . . of some sort." Id. at 82. 103-105. MT DI testified that affirmative responses to a Liability question prompt a DEA investigation, and that the failure of an applicant to submit an affirmative response when the true response to the question is in the affirmative "could . . . [mean that the application is] inadvertently approved." Id. at 82, 103, 105-06. MT DI testified that it is important for DEA registration applicants to complete the

Liability question narratives directly, truthfully, and honestly because it is their "chance to basically tell what happened . . . so that we can trust that . . . [they are] telling the truth." *Id.* at 105.

MT DI testified that Applicant truthfully answered Liability questions 2 and 3 in the affirmative on the DEA registration application about which the OSC was issued. Id. at 107; GX 1c, at 1, 3. She also testified, however, that Applicant's narrative response to Liability question 2 is not accurate, is false, and exhibits a lack of candor to DEA. Tr. 109, 118. Regarding this Liability question, MT DI specifically testified that Applicant's narrative response is not accurate because the Liability question is about a federal controlled substance registration but Applicant's narrative response does not "mention anything federal in any of the narrative whatsoever," including that Applicant surrendered his DEA registration.¹⁴ Id. at 109. MT DI testified that this failure of Applicant's narrative response for Liability question 2 "actually [to] give any of the details of him surrendering that federal DEA number" is "not full disclosure of everything that has happened" and, therefore, is a lack of candor. 15 Id. at

By querying New Jersey's Prescription Drug Monitoring Program, MT DI testified, she identified eleven controlled substance prescriptions that Applicant issued when he had neither

 $^{^{12}\,\}mbox{Three}$ of the Government's Exhibits, GX 1, GX 12, and GX 13, have subparts.

¹³ MT DI testified about her investigation of Applicant's pending DEA registration application. Among other things, she testified that she ascertained from the Montana Department of Labor and Industry website that Applicant has a Montana medical license. Tr. 83; GX 6. GX 6 was admitted without objection. Tr. 83–85.

¹⁴ MT DI testified that Applicant was aware that he surrendered his DEA registration because NJ DI gave him a copy of the Form DEA-104 (Voluntar Surrender of Controlled Substances Privileges) that he signed. Tr. 112-13. She also testified that Applicant was aware that he surrendered his DEA registration because, on a DEA registration application that Applicant had previously submitted and then withdrawn, he "mentions in there that he surrendered his DEA." Tr. 110; GX 1b, at 3. This shows, MT DI testified, that Applicant was aware that he surrendered his DEA registration. Tr. 110. According to GX 1b, however, Applicant's narrative statement for the second liability question does not state that he "surrendered" his DEA "registration." Instead, it states that he "voluntarily suspended" his "DEA license." GX 1b, at 1. According to MT DI's testimony, she understands Applicant's narrative statement to be referencing the "surrender" of his DEA "registration." Tr. 111-12. She also testified that his having disclosed his surrender of his DEA registration on a previous, subsequently withdrawn application is not sufficient to make his pending DEA registration application accurate because Applicant had withdrawn that application and because "every time you apply you have to give the details in every application." Id. at 116.

¹⁵ Similarly, MT DI testified that Applicant falsified his narrative response to the affirmatively answered third liability question of a previously submitted, then withdrawn, DEA registration application, and also exhibited a lack of candor, because he failed to mention the suspension of his New Jersey CDS registration. Tr. 120–21; GX 1b.

a New Jersey CDS nor a DEA registration. Id. at 122-30; GX 7. MT DI testified that she "cross-checked" the dates on these controlled substance prescriptions with the date Applicant surrendered his DEA registration and determined that Applicant had handwritten and signed the eleven controlled substance prescriptions after he had surrendered his DEA registration. Tr. 130. MT DI testified that she obtained copies of the eleven controlled substance prescriptions by issuing administrative subpoenas to the pharmacies that filled them. 16 Id. at 130-32; GX 8. After Applicant looked at the eleven controlled substance prescriptions, MT DI testified, he checked his records and concluded that he had, indeed, issued them. Tr. 199. According to MT DI's testimony Applicant would not withdraw his pending application in the face of this evidence, and stated that they were not "that big of a deal because they were lower level drugs." *Id.* at 151, 199. MT DI testified that Applicant's

interactions with her, in telephone conversations and in-person meetings, included statements that evidence Applicant's lack of candor. *Id.* at 118. MT DI testified that candor involves full, honest disclosure of everything that happened. *Id.* at 118–19. She testified that Applicant's denials of having written controlled substance prescriptions after he surrendered his DEA registration demonstrate a lack of candor. Id. at 141-46, 149-51. MT DI testified that there are discrepancies between NJMB documents and Applicant's representations. Id. at 153– 54. She testified that Applicant did not answer her questions about why he did not enter into controlled substance agreements with five individuals for whom he prescribed opiates on a longterm basis, thus exhibiting a lack of candor. Id. at 157-59.

MT DI also testified that Applicant did not answer her questions related to his urine drug screen practices. *Id.* at 160. More specifically, MT DI testified that she asked Applicant why he continued to prescribe opiates to those whose urinalyses tested positive for heroin and cocaine, or for those whose urinalyses did not test positive for opiates he had prescribed for them, but that he did not give her an answer. *Id.* 160–62. In addition, MT DI testified that she asked Applicant about a specific individual, L.K., and why Applicant

prescribed oxycodone for her without recording any basis for the prescription, why he continued to prescribe controlled substances for her even though she "consistently failed to provide requested urine drug screens," and why his first oxycodone prescription for her did not document why it was for double the dosage that her previous physician prescribed for her. Id. at 162-70. MT DI testified that she did not always tell Applicant that his answers to her questions were not sufficient. Id. at 201-05. She also acknowledged on cross-examination that, had she given Applicant this feedback, he would have been able to amend his DEA registration application. Id. at 208.

Regarding MT DI's credibility, I agree with the RD, and I find that MT DI's testimony is credible. RD, at 110. I shall afford it considerable weight. Tr. 78–209.

Accordingly, I find uncontroverted, substantial, clear, unequivocal, and convincing record evidence that Applicant truthfully answered Liability questions 2 and 3 in the affirmative on DEA registration application No. W18015986C, the application about which the OSC was issued. *Id.* at 107; GX 1c, at 1, 3; *see also infra*, section II.D. Further, I find substantial record evidence that Applicant handwrote and signed the eleven controlled substance prescriptions in GX 8 after he had surrendered his DEA registration. Tr. 130, 199; *see also infra*, section II.D.

The Government's third witness testified that, during the times relevant to this adjudication, she was assigned to DEA's office in Salt Lake City, Utah and was a diversion Group Supervisor (hereinafter, GS). Tr. 240. She assigned MT DI to investigate Applicant's DEA registration application because that application responded affirmatively to a Liability question and "[a]ll DEA applications that have yes to a liability question must be looked at more thoroughly before approving, or disapproving, or going forward with the order to show cause process." Id. at 247-48.

The testimony of GS corroborated the testimony of MT DI concerning their interactions with Applicant and their assessments of his candor during those interactions. ¹⁷ Supra. GS also corroborated the testimony of MT DI that Applicant initially denied issuing controlled substance prescriptions after

he surrendered his DEA registration, pointing out that "he was pretty firm or adamant that he had not done that" and "[u]nlike the other questions, he answered this one pretty quickly." Tr. 266. She also testified about the April 9, 2019 meeting in Salt Lake City with Applicant during which she obtained a handwriting exemplar from Applicant and at which she showed Applicant the eleven prescriptions MT DI obtained by administrative subpoena. 18 Id. at 267-77. GS testified that Applicant "really didn't say much" when she showed him the prescriptions. Id. at 272. She testified that Applicant "did not acknowledge if they were his writing or not, or if they were his patients or not," and, "once he was flipping through them, there was one prescription in there where it was an . . . exclamation of, 'That's why we're here, because of Lomotil?'" Id. She testified that his statement "told" her that "these were true and accurate prescriptions that he wrote because he did not denv at the time it was his writing, but Lomotil is a very low schedule controlled substance." Id. She also testified that, from "that kind of exclamation," it seemed to her "he was frustrated that all of this time trying to get a DEA registration boiled down to writing a prescription after his DEA was surrendered . . . [for] such a low-level drug." Id.; see, e.g., GX 8, at 7, 8. GS testified that Applicant took notes on the prescriptions and said that "he would like to check his records and his calendar to see what may have been going on that day." Tr. 275. According to the testimony of GS, Applicant did not "show any remorse" or "apologize" for issuing the prescriptions after he surrendered his DEA registration. Id. at 276. She testified that, "because of the inconsistencies still after all of this time and the new revelation of prescribing controlled substances after the surrender," the decision was made to go forward with "show cause proceedings to deny the application." *Id.* She also testified that, given the substance of the New Jersey proceedings and his having written controlled substance prescriptions after he surrendered his DEA registration, an OSC would have been issued about his DEA registration application. Id. at 278-79.

Regarding the credibility of GS, I agree with the RD and I find that the testimony of GS is credible. RD, at 111. I shall afford it considerable weight. Tr. 238–314, 690–705.

The Government called Applicant to the stand and, through direct

¹⁶ The controlled substances that Applicant prescribed in the eleven prescriptions are Sonata (Schedule IV), Qsymia (Schedule IV), Lomotil (Schedule V), Belviq (Schedule IV), phenobarbital (schedule IV), and Restoril (Schedule IV). GX 8; Stipulations 13–29.

¹⁷ The testimony of GS specifically addressed Applicant's candor during the investigators' questioning of him about his inconsistent use of written controlled substance agreements, the role of urinalysis in his controlled substance prescribing, and his treatment of L.K. Tr. 251–65.

¹⁸ Applicant's handwriting exemplar is GX 9. GX 9 was admitted without objection. Tr. 271.

questioning and cross-examination, solicited his testimony about his medical licenses, his New Jersey and DEA controlled substance registrations and registration applications, his employment as a physician, his prescribing of controlled substances, and his interactions with DEA investigators, among other things. See, e.g., id. at 328-417, 554-601, 618-23. Some of Applicant's testimony confirmed evidence offered by the Government and some of it conflicted with evidence offered by the Government. Infra, section II.D., section II.G.

D. Applicant's Case

As already discussed, Applicant testified. Supra, section II.C. He also offered the testimonies of three individuals, family and friends, and successfully moved twelve exhibits into evidence, including affidavits or certifications of eight other individuals, including family members and friends. 19

In addition to the subjects already listed about which Applicant testified when called by the Government, Applicant testified about his career before medical school, his decision to study medicine and become a physician, his efforts to ensure his appropriate prescribing of controlled substances, his acceptance of responsibility, and his remedial measures, among other things. Tr. 418–59, 490–529, 608–15.

Applicant testified that he did not submit false material in registration applications he submitted to DEA. *Id.* at 356–59, 364–67.

Applicant admitted multiple times when testifying that he issued eleven controlled substance prescriptions when he did not have federal and state authority to do so. See, e.g., id. at 359-62, 369-74, 379, 728; see also Stipulations 12–23. Applicant's testimony admits that he did not realize that the medications he was prescribing were controlled when he wrote them. Tr. 374. He testified that he relied on drug representative representations that the drugs were not controlled. Id. at 377. He testified "[t]hat [it] was . . . [his] mistake that . . . [he] didn't do due diligence to . . . look them up on the internet . . . [him]self." Id . Applicant testified that he knows of no software package that identifies a drug as scheduled when a prescriber is writing it, or a database he could have used to

learn if a drug was scheduled. *Id.* at 377–78.

Applicant denied submitting false documents to DEA, lying to DEA investigators, and intending to mislead DEA and DEA investigators. See, e.g., id. at 358–59, 381–84, 402–03, 415. He also admitted managing incorrectly and inappropriately those for whom he prescribed controlled substances. See, e.g., id. at 400–01, 404–05, 413–14. The record does not, however, include any statement by Applicant unequivocally accepting responsibility for this incorrect and inappropriate management of those for whom he prescribed controlled substances.

As already discussed, in the final Consent Order with the NJMB, Applicant denied "any and all wrongdoing." Supra, section II.B. That written denial was echoed in Applicant's hearing testimony, more than two years later. After Government counsel argued that Applicant had not accepted responsibility, Applicant's counsel asked him, instead, "with respect to the New Jersey consent order of temporary suspension, do you accept that you are bound by that suspension?" Tr. 528. Applicant answered, "[y]es, absolutely," adding that he "was concerned by . . . [Government counsel's] comments." Id. Applicant then added that he "accept[s] responsibility," he is "an adult," he "want[s] to do better," he is "embarrassed by some of . . . [his] errors, and . . . [he] take[s] full responsibility. I regret these." Id.; see also id. at 612-13 (Applicant's testimony that he is not seeking to relitigate the decision of the NJMB). I find that Applicant specified neither what he was accepting responsibility for nor the errors of his for which he took "full responsibility."

Also regarding acceptance of responsibility, Applicant testified about the second to last paragraph of his email to DEA investigators on August 3, 2018, stating "if a misstep has occurred" he has "tremendous desire to correct the previous action, most scrupulously!" RX 13, at 2. Applicant testified that he "typically . . . would have closed the meeting" by stating "tell me what you'd like me to do" or "[t]ell me how we can get through this so I can receive a DEA registration." Tr. 504-05. By way of further example, Applicant testified that he was "trying as a doctor to do . . . [his] best," he "recognize[d] that . . . he could be liable for these mistakes," he "was accepting and taking ownership," and "he wanted to figure this out and improve so . . . [he] could go forward more fully as a doctor, not only with . . . [his] license, but the DEA

registration." *Id.* at 502. Applicant did not specify the "mistakes" he was accepting and taking ownership of and has not convinced me that he understands how his past actions did not comply with legal requirements.

In sum, I find that Applicant's acceptance of responsibility ranged from his accepting responsibility for unspecified errors and mistakes and his wanting to correct any misstep that may have occurred, to being willing to do whatever it would take to avoid liability and to practice medicine with a DEA registration. *Infra*, section IV.

Applicant testified that he "learned greatly" and "tremendously" from his experience with the NJMB. Tr. 524. Specifically, Applicant testified that he would be "way more cognizant and tight with . . . [his] documentation and record keeping." Id. at 525; see also id. at 613–14. He also testified that he does not "believe in using narcotics at all for pain medications in any way" and that he "actually specialize[s] in nonnarcotic pain relief." Id. at 525. He testified that he would accept "monitoring and recording" in return for a DEA registration, and that he is "willing to do what they think they need so that . . . [he] can continue working as a doctor with the proper registration." Id.; see also id. at 528.

Also regarding his future practice of medicine, Applicant testified, and introduced documentary evidence, about four continuing medical education courses he took. ²⁰ See RX 12a (Certificate of participation in "Proper Prescribing of Controlled Prescription Drugs—June 2016" at Vanderbilt

¹⁹ The ALJ denied Applicant's request that an affidavit and a certification of two of the three individuals who offered oral testimony also be admitted into the record. Tr. 548.

 $^{^{20}}$ Applicant moved RX 11, his proposed CAP, into evidence. Tr. 545–48. The Government objected and the ALJ denied Applicant's motion, stating that "it would just confuse the matter, because it's really a pre-hearing proceeding . . and I have no jurisdiction to consider it, to rule on it." $\emph{Id}.$ at 547. The ALJ also stated that the content of the proposed CAP "is not inadmissible" and that "as format it would just be too confusing for the record for us to introduce this into the evidence of the hearing." $\emph{Id}.$

A CAP is to be submitted "on or before the date of appearance." 21 U.S.C. 824(c)(2)(C). There is no date on RX 11. Applicant's Supplemental Prehearing Statement, dated May 18, 2020 (hereinafter, Appl Supp Prehearing), addresses the proposed CAP, stating that Applicant "also submits a Corrective Action Plan (CAP), which is attached hereto . . . [and] outlines the previous issues with . . . [Applicant's] registration and practice in New Jersey." Appl Supp Prehearing, at 3. The fact that Applicant's proposed CAP was attached to Applicant's Supplemental Prehearing Statement necessarily appears to mean that Applicant's proposed CAP was not timely filed.

Further, the option of submitting a CAP offers a respondent the opportunity to avoid a hearing. That opportunity had long passed for Applicant when he moved his proposed CAP into evidence.

For all of the above reasons, I agree with the ALJ's ruling not to admit RX 11 into evidence.

University School of Medicine), 12b (Certificate of Completion of "Office-Based Treatment of Opioid Use Disorders," an online course offered by the American Academy of Addiction Psychiatry), 12c (Certificate of Credit for "Center for Personalized Education for Physicians Medical Record Keeping Seminar—June 3, 2016" at Memorial Hospital University of Colorado Health).²¹ Applicant testified that the NJMB "had recommended these courses in the past," that he "took them on . . . [his] own volition so that . . . [he] could demonstrate that . . . [he] . . . wanted the additional information," and that they were "the path . . . [he] took to try to have any correction occur in . . . [his] protocol as a physician." Tr. 446; see also id. at 442–46. The RD acknowledges the course work Applicant undertook, stating that Applicant "worked admirably to improve his medical skill and range of abilities, and to further educate himself as to his professional responsibilities." RD, at 140. I agree.

Regarding Applicant's credibility, I find that Applicant is the witness with the most at stake in these proceedings. For that reason, I shall consider Applicant's testimony with caution when his testimony conflicts with credible record evidence.²² Tr. 327–460, 489–623, 644–45, 706–13.

Applicant successfully offered, over the Government's objections, testimonial and documentary record evidence by eleven individuals. See, e.g., id. at 528-45, 625-89. The eleven individuals include two brothers, two brothers-in-law, and friends. Id. This record evidence includes the individuals' positive opinions about Applicant's integrity, honesty, and trustworthiness. See, e.g., id. at 629–30, 650–53, 685–86. There is no record evidence that Applicant serves as the physician for any of these eleven individuals or for any family member of these individuals, let alone that Applicant has prescribed a controlled substance for any of them. The closest this evidence comes to addressing

Applicant's general practice of medicine includes the affidavit of a mother of seven referencing her "always" having a "need of a doctor's opinion" and whose "first thought is always to call" Applicant who "would drop everything and make time to come to . . . [her] home and examine a sick child, day or night," the affidavit of a friend stating that Applicant "provided first aid to both workers and homeowners with a wide variety of cuts, scratches, puncture wounds, and sprained ankles" in the aftermath of Superstorm Sandy, and the testimony of a friend that Applicant provided him medical treatment only for "very minor thing[s]" such as an eye infection, a cold, or something "very mild like that." RX 5, at 1; RX 10, at 2; Tr. 688.

As past Agency decisions show, my predecessors evaluate such oral testimonial and written affidavit and certification evidence based on the relevance of their contents to the matters being adjudicated. See, e.g., George Pursley, M.D., 85 FR 80162, 80180 (2020). There is no record evidence that Applicant ever provided any of these family members and friends formal medical treatment, let alone issued any of them a controlled substance prescription. I find that the three individuals who testified and the eight individuals who submitted a written affidavit or certification provided limited evidence relevant to Applicant's controlled substance prescribing and to whether I should grant DEA registration application No. W18015986C. 21 U.S.C. 823(f).

Accordingly, I find that the content of RX 3 through RX 10 and the oral testimony of Applicant's family member and friends provide limited evidence about Applicant's prescribing of controlled substances, an issue central to my legal responsibilities in this adjudication. Further, regarding RX 3 through RX 10, prior Agency decisions show that my predecessors afforded such written evidence limited weight because of the limited ability to assess the credibility of evidence in written form. See, e.g., Michael S. Moore, M.D., 76 FR 45867, 45873 (2011) (evaluating the weight to be attached to letters provided by the respondent's hospital administrators and peers in light of the fact that the authors were not subjected to the rigors of cross examination). For all of these reasons, I afford minimal weight to RX 3 through RX 10 and to the oral testimonies of Applicant's family member and friends. Tr. 624-89.

E. Allegation That Applicant Materially Falsified DEA Registration Application No. W18015986C

Having read and analyzed all of the record evidence, I find uncontroverted, substantial, clear, unequivocal, and convincing record evidence that affirmative responses to a Liability question prompt a DEA investigation. Id. at 82, 103. I further find uncontroverted, substantial, clear, unequivocal, and convincing record evidence that Applicant accurately responded "yes" to the second and third Liability questions on DEA registration application No. W18015986C. See, e.g., Stipulation 10; GX 1c, at 1, 3; Tr. 107. I find uncontroverted, substantial, clear, unequivocal, and convincing record evidence that NJ DI completed a Form DEA-104 and presented it to Applicant on May 20, 2015. See, e.g., Tr. 44. I find uncontroverted, substantial, clear, unequivocal, and convincing record evidence that Applicant signed the DEA-completed Form DEA-104 on May 20, 2015, thus surrendering his DEA registration. See, e.g., Stipulation 6; GX 5; Tr. 44-45.

I find uncontroverted, substantial, clear, unequivocal, and convincing record evidence that Applicant signed a Consent Order that temporarily suspended his New Jersey CDS registration on May 20, 2015. See, e.g., Stipulation 4; GX 2, at 4; Tr. 42.

I find uncontroverted, substantial, clear, unequivocal, and convincing record evidence accurately setting out Applicant's responses to, and the narrative content of, the second and third Liability questions on DEA registration application No. W18015986C.²³ See, e.g., Stipulation 10, GX 1c, at 1–2.

F. Allegation That Applicant Issued Controlled Substance Prescriptions Without Federal and State Authority

I find uncontroverted, substantial record evidence that Applicant admitted to issuing, and did issue, eleven controlled substance prescriptions when he had neither federal nor state authority to do so. *See*, *e.g.*, Stipulations 12–23; GX 8, GX 9; Tr. 359–62, 369–74, 379, 728.

²¹ The fourth course was about Ethics. Tr. 618. Applicant testified that he participated in the course actively, that he completed it, but that he did not receive continuing medical education credits for it because he did not submit the required final essay. *Id.* at 618–21. He testified that, because his New Jersey case was not resolved and his essay would have been sent to the NJMB, "it was difficult for . . [him] to . . include information in the essay that would be compromising in . . . [his] issues with the . . . [NJMB]. *Id.* at 621.

²²I note that the RD questions the credibility of some of Applicant's testimony, such as his testimony relating to his issuance of eleven controlled substance prescriptions after he surrendered his DEA registration. *See, e.g.,* RD, at 126, 134.

²³ While the Government's case includes mention of the insufficiency of Applicant's narrative responses to both the second and third liability questions on DEA registration application No. W18015986C, the OSC and other Government submissions specifically allege only that Applicant's narrative response to the second liability question is materially false. See, e.g., OSC, at 4–5.

G. Allegation That Applicant Did Not Exhibit Candor in His Interactions With the Agency and Agency Investigators

The record evidence about whether Applicant exhibited candor in his interactions with the Agency and Agency investigators is not conclusive. Portions of Applicant's testimony and portions of the Government witnesses' testimonies are consistent and other portions conflict. For example, Applicant testified that he did not provide false information in Application No. W18015986C. See, e.g., Tr. 359. The testimony of a DEA investigator, however, disagrees. See, e.g., id. at 109, 118 (testimony of MT DI). By way of further example, Applicant testified that his statements to DEA investigators were accurate to the best of his knowledge when he made them. *Id.* at 382 (testimony about whether he prescribed controlled substances after he no longer had state and federal controlled substance prescribing authority). The testimony of a DEA investigator, however, challenges that portion of Applicant's testimony. Id. at 266-67 (testimony of GS).

Testimony the Government solicited from Applicant about his statements to DEA investigators challenged the substance of testimony provided by MT DI and GS about some of those statements. For example, MT DI testified that Applicant told her that he issued the eleven controlled substance prescriptions in GX 8 but that "it wasn't that big of a deal because they were lower level drugs," and GS testified that Applicant "exclaimed," as he was flipping through those eleven prescriptions, "That's why we're here, because of Lomotil?" *Id.* at 199 (testimony of MT DI), 272 (testimony of GS). Government counsel and the ALJ asked Applicant about the testimony of MT DI and GS concerning these matters. Id. at 389–94. Applicant testified that he did not recall making a comment to GS about Lomotil being the reason for the DEA investigation. Id. at 394. Regarding whether he told MT DI that, "because these were lower level prescriptions, it wasn't that big of a deal," Applicant testified that "[t]hat might have been her interpretation, but any scheduled medication is important. There are different degrees of oxycodone's schedule 2 versus something that's schedule 5. But without a DEA or CDS I cannot write it." *Id.* at 389; *see also id.* at 391-92 (Applicant's testimony that he did not specifically recall saying lowlevel prescriptions are not "that big of a deal''' and that ''[i]n fact, when . [he] lost . . . [his] DEA CDS, . . . [he] was calling pharmacies telling them

please don't fill any schedule medications, . . . [he doesn't] have . . . [his] DEA or . . . [his] CDS, so that they were aware. So, . . . [he doesn't] want to trivialize the fact that . . . [he] wrote a prescription that was a Schedule V and not a Schedule II."), id. at 393 (He ''can't recall that. . . . [He doesn't] think it's logical for someone to hear, for . . . [MT DI] to interpret that in the conversation if . . . [he] did that."). He further testified that "it doesn't seem unreasonable that when . . . [he] was asked if . . . [he] wrote—and . . . [he] was thinking about narcotics that . . [he] was surprised that it was something not narcotic related, that it was a [B]elviq or lower." *Id.* at 390. He testified that he did not recall specifically saying that prescribing "low-level prescriptions" is not "that big of a deal," yet he was "giving her [MT DI] the benefit of the doubt" that he wears his emotions on his face, and that he does not "think it's not out of the realm of possibilities . . . [a]nd so . . . [he] won't deny it." 24 Id. at 390-92.

By way of further example, DEA investigators and Applicant testified about his not having all the patients for whom he prescribed controlled substances sign controlled substance agreements. According to MT DI, Applicant "didn't really have an explanation to it . . . he didn't explain why he had some do it and not all." Id. at 158. According to GS, Applicant "[s]ometimes . . . diverted away from the question and didn't really answer it" and she concluded that he did not provide a "full and complete explanation." Id. at 252. Applicant testified that he did not have the "same recollection" as the DEA investigators on the matter. Id. at 397. He testified that his desire for the three-hour meeting with DEA investigators was to 'get . . . [his] DEA back.'' Id. He testified that he questioned why the investigators were asking him to justify what he did when he had already done that, unsuccessfully, before the NJMB and, successfully, in Montana. Id. Applicant testified that he was not trying to justify his controlled substance agreement actions "because . . . [he] made mistakes" and he "recognize d that . . . [he] made mistakes and there's things . . . [he] need[s] to learn, but that was what . . . [he] was trying to explain to . . . [the DEA investigators]." Id. at

397-98; see also id. at 400-01 (Applicant's response when the ALJ asked him for the explanation he gave the DEA investigators for giving the "pain contract to some patients but not all," including that he "did speak to each of . . . [his] patients verbally about things and talked with them and documented, but not full documentation. And that is the problem that I take full ownership in."). When Government counsel asked him to "explain why . . . in . . . [his] opinion . . . [the DEA investigators'] testimony on . . . [Applicant's response about controlled substance agreements] is incorrect as to the response you provided," Applicant testified that he "can't explain why they came away with that opinion unless the answer to the things . . . [he] was talking about didn't resonate with what they wanted to hear." Id. at 399-400.

The testimonies of the DEA investigators and Applicant also addressed whether Applicant's responses were "truthful and candid." MT DI testified that Applicant did not give her a "full and complete explanation" of why he did "nothing," and kept doing nothing, with the results of the urinalysis tests he employed, such as positive urine drug screens for illegal drugs and negative urine drug screens for controlled substances he had previously prescribed. Id. at 160-61; see also id. at 162. GS testified that she and MT DI asked Applicant "repeatedly why didn't he take more proactive steps to talk to his patients and find out where those drugs were going" and "he really didn't answer us." *Id.* at 256; *see also* id. at 257 (GS testimony that "[w]e were trying to get why would you continue to practice with all of these red flags right in front of you . . . but we just didn't understand why a physician would prescribe these drugs the way he did"). Applicant, on the other hand, testified that his responses to the DEA investigators' questions were "truthful and candid." Id. at 403.

Given that the facts pertaining to Applicant's prescribing of controlled substances with neither federal nor state authority are uncontroverted, it is not necessary that I find any facts pertaining to, nor adjudicate, the OSC's candor allegation, and I decline to do so.

Based on the uncontroverted, substantial record evidence that Applicant admitted to issuing, and did issue, eleven controlled substance prescriptions when he had neither federal nor state authority to do so, I find that the Government presented a prima facie case on that OSC allegation.

²⁴ In the Government's later questioning, counsel clarified that he was asking Applicant about a conversation with MT DI, not a face-to-face meeting with her. Tr. 392. It is possible that Applicant was testifying about the broad "no big deal"/Schedule II versus Schedule V allegation both DEA investigators raised in their testimonies.

III. Discussion

A. The Controlled Substances Act and the Public Interest Factors

Pursuant to the Controlled Substances Act (hereinafter, CSA), "[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(f). The CSA further provides that an application for a practitioner's registration may be denied upon a determination that "the issuance of such registration . . . would be inconsistent with the public interest." Id. In making the public interest determination, the CSA requires consideration of the following factors:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing . . . controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, 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. *Id.*

These factors are considered in the disjunctive. Robert A. Leslie, M.D., 68 FR 15227, 15230 (2003). I "may rely on any one or a combination of factors and may give each factor the weight [I] deem[] appropriate in determining whether . . . an application for registration [should be] denied." Id. Moreover, while I am required to consider each factor, I "'need not make explicit findings as to each one,' " and I "'can give each factor the weight . . . [I] determine[] is appropriate." Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin., 881 F.3d 823, 830 (11th Cir. 2018) (quoting Akhtar-Zaidi v. Drug Enf't Admin., 841 F.3d 707, 711 (6th Cir. 2016)); see also MacKay v. Drug Enf't Admin., 664 F.3d 808, 816 (10th Cir. 2011) (quoting Volkman v. Drug Enf't Admin., 567 F.3d 215, 222 (6th Cir. 2009) (quoting Hoxie v. Drug Enf't Admin., 419 F.3d 477, 482 (6th Cir. 2005))). In other words, the public interest determination "is not a contest in which score is kept; 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." Peter A.

Ahles, M.D., 71 FR 50097, 50098–99 (2006).

According to the regulations, "A prescription for a controlled substance may be issued only by an individual practitioner who is (1) Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and (2) Either registered or exempted from registration " 21 CFR 1306.03(a). I recently reiterated what the Agency has consistently stated: The CSA and its regulations are clear that a registrant must possess the requisite authority under both federal and state law to prescribe a controlled substance lawfully.25 Tamika Mayo, M.D., 86 FR 69681, 69684 (2021); see also, e.g., Richard J. Settles, D.O., 81 FR 64940, 64946 (2016); Hoi Y. Kam, M.D., 78 FR 62694, 62697-98 (2013): Anthony E. Wicks, M.D., 78 FR 62676, 62678 (2013); Belinda R. Mori, N.P., 78 FR 36582, 36588 (2013); Bob's Pharmacy and Diabetic Supplies, 74 FR 19599, 19601 (2009); Jerry Neil Rand, M.D., 61 FR 28895, 28897 (1996).

In this matter, as already discussed, the OSC calls for my adjudication of Applicant's DEA registration application No. W18015986C based on the charge that Applicant submitted a materially false narrative response to its second Liability question. OSC, at 4–5; supra, section II.C., section II.E. Material falsification, of course, is a basis for revocation or suspension of a DEA registration. 21 U.S.C. 824(a)(1).

Prior Agency decisions have addressed whether it is appropriate to consider a provision of 21 U.S.C. 824(a) when determining whether or not to grant a practitioner registration application. I recently agreed with the conclusions of Agency decisions over the last forty-five years that it is. *Lisa M. Iones, N.P.*, 86 FR 52196, 52202 (2021); see also, e.g., Robert Wayne Locklear, 86 FR 33738 (2021) (collecting Agency decisions). Those decisions have offered multiple bases and analyses for that conclusion. 86 FR at 33744-45. I again agree with my predecessors' conclusions that a provision of 21 U.S.C. 824 may be the basis for the denial of a practitioner registration application, and that the 21 U.S.C. 823 public interest factors remain relevant to the adjudication of a practitioner registration application when a

provision of 21 U.S.C. 824 is involved. *Id.*

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. In this matter, while I have considered all of the public interest factors, the Government's evidence in support of its *prima facie* case is confined to Factors Two and Four.²⁶ The Government's Proposed Findings of Fact, Conclusions of Law, and Argument dated July 22, 2020 (hereinafter, Govt Posthearing), at 31; 21 U.S.C. 823.

B. Allegation That Applicant Materially Falsified Registration Application No. W18015986C

Regarding 21 U.S.C. 824(a)(1), I recently decided that the elements of a material falsification according to the Supreme Court's decision in *Kungys* v. United States, 485 U.S. 759 (1988), and its recent progeny, are consistent with the CSA. Lisa M. Jones, N.P., 86 FR at 52202; see also, e.g., Frank Joseph Stirlacci, M.D., 85 FR 45229, 45238 (2020). According to that Supreme Court precedent, "material" means having "a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed." Frank Joseph Stirlacci, M.D., 85 FR at 45238 (citing Kungys, 485 U.S. at 770).

The Government argues that, although Applicant correctly responded "yes" to the second Liability question, his narrative response omitted specific reference to his DEA registration, focusing, instead, on why he thought the NJMB's conclusions about his medical practice were wrong. Govt Posthearing, at 27–31. In other words,

²⁵ Given the clear requirements of the CSA, 21 U.S.C. 802(10) and (21), and its regulations, 21 CFR 1306.03, that a practitioner must have the requisite authority under both federal and state law to prescribe a controlled substance, I need not, and I decline to, address the OSC's allegations that Applicant violated 21 U.S.C. 822(a)(2), 841(a)(1), and 843(a)(2).

²⁶ As to Factor One, neither party posits that the Montana state licensing board has recommended for or against the issuance of a DEA registration to Applicant. Further, I find that the final New Jersey Consent Order states that the "New Jersey State Board of Medical Examiners takes no position with respect to any application by . . . [Applicant] for DEA credentials/privileges in any other state." GX 4, at 2.

As to Factor Three, there is no evidence in the record that Applicant has a "conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances." 21 U.S.C. 823(f)(3). However, as prior Agency decisions have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor. let alone prosecuted for one. Dewey C. MacKay, M.D., 75 FR 49956, 49973 (2010), pet. for rev. denied, MacKay v. Drug Enf't Admin., 664 F.3d 808 (10th Cir. 2011). Those Agency decisions have therefore concluded that "the absence of such a conviction is of considerably less consequence in the public interest inquiry" and is therefore not dispositive. Id. I agree.

The Government does not argue that its case includes an allegation cognizable under Factor Five. Govt Posthearing, at 31.

the Government argues that Applicant's response to the follow-up engendered due to his "yes" response to the second Liability question is materially false because it does not disclose responsive information pertaining to his DEA registration. *E.g., id.* at 5–7. Consequently, I now address whether Applicant's DEA registration application No. W18015986C is materially false according to the *Kungys* definition of "material."

As already discussed, I find uncontroverted, substantial, clear, unequivocal, and convincing record evidence that Applicant answered "yes" to the second Liability question on DEA registration application No. W18015986C. Supra, section II.E. In addition, as already discussed, I find uncontroverted, substantial, clear, unequivocal, and convincing record evidence that Applicant's "yes" answers to Liability questions two and three were true. Id. As already discussed, I find uncontroverted, substantial, clear, unequivocal, and convincing record evidence that NJ DI completed and presented to Applicant the Form DEA-104 that Applicant signed on May 20, 2015. Id. From the record evidence that the Government submitted, I also find uncontroverted, substantial, clear, unequivocal, and convincing record evidence that both MT DI and GS knew, or had reason to know, that Applicant had surrendered his DEA registration based on Applicant's affirmative response to the second Liability question on DEA registration application No. W18015986C. Id.

The found facts of this adjudication are unique and not likely ever to recur. Based on those facts, there are many reasons why Applicant's narrative follow-up to his "yes" response to the second Liability question did not have a "natural tendency to influence" and was not "capable of influencing" the Agency's decision regarding Applicant's DEA registration application No. W18015986C. For example, Applicant accurately responded in the affirmative to the second Liability question on DEA registration application No. W18015986C and responded with the correct "incident date" and the correct "incident location" in the narrative. Further, DEA investigators filled in a Form DEA-104, presented it to Applicant, explained it to Applicant, told Applicant why they were offering him the opportunity to sign it and surrender his DEA registration, and obtained from Applicant his signature on it and the surrender of his DEA

registration No. FT2321797.²⁷ *Id.* All of this accurate information about Applicant's DEA registration surrender (for cause) was available to the assigned DEA investigator.

Accordingly, on the unique and unlikely ever to recur record evidence before me, I conclude that the narrative responses regarding "incident nature" and "incident result" Applicant provided for the second Liability question on his DEA registration application No. W18015986C were not "predictably capable of affecting, that is, had a natural tendency to affect, the official decision" of DEA.

C. Factors Two and/or Four—The Applicant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances; Allegation That Applicant Issued Controlled Substance Prescriptions Without Federal and State Authority

At the core of the CSA is the principle that having the requisite federal and state authority is essential to the lawful issuance of a controlled substance prescription. See Gonzales v. Raich, 545 U.S. 13–14, 27 (2005). The adjudication of the OSC allegation that Applicant issued controlled substance prescriptions without federal or state authority is factually and legally clear. As already discussed, Applicant admitted to issuing eleven controlled substance prescriptions when he did not have the requisite federal and state authority. Supra, section II.F. Further, it is clear that, for a practitioner to issue a controlled substance prescription lawfully, he must have both federal and state authority to do so. 21 CFR 1306.03; supra, section III.A. Accordingly, I conclude that there is uncontroverted, substantial record evidence that Applicant unlawfully issued eleven controlled substance prescriptions, as he admitted. Supra, section II.F, section III.A; see also Appl Exceptions, at 4-6. The founded violations of unlawfully prescribing controlled substances eleven times implicate Factors Two and Four. 21 U.S.C. 823(f)(2) and (4).

Applicant's eleven unlawful controlled substance prescriptions

violate a core principle of the CSA and constitute egregious misconduct. *Supra*. Accordingly, I conclude that it is appropriate to sanction Applicant for these violations.

Summary of Factors Two and Four

As already discussed, Applicant admitted to issuing eleven controlled substance prescriptions when had neither federal nor state authority to do so. *Supra*, section II.F, section III.A; *see also* Appl Exceptions, at 4–6. Accordingly, I conclude that Applicant engaged in egregious misconduct and that the denial of DEA registration application No. W18015986C is, thus, appropriate. 21 U.S.C. 823(f)(2) and (4); *see Wesley Pope*, 82 FR 14944, 14985 (2017).

IV. Sanction

Where, as here, the Government has met its prima facie burden of showing that my issuance of a DEA registration to Applicant would be inconsistent with the public interest due to his issuance of eleven controlled substance prescriptions when he had neither federal nor state authority to do so, the burden shifts to Applicant to show why he can be entrusted with a DEA registration. Garrett Howard Smith, M.D., 83 FR 18882, 18910 (2018) (collecting cases). Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that an applicant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that he will not commit violations in the future. Id. An applicant's acceptance of responsibility must be unequivocal. Id. In addition, an applicant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* (collecting cases). In addition, DEA Administrators have found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. Id. DEA Administrators have also considered the need to deter similar acts by the applicant and by the community of registrants and potential registrants. Id.

Regarding his issuing eleven controlled substance prescriptions when he had neither federal nor state authority to do so, Applicant was asked "with respect to the prescriptions that you wrote, the alleged prescriptions, have you acknowledged writing after your DEA registration was surrendered? Do you accept responsibility for that?" Tr. 528. Applicant responded, "Yes. I'm

²⁷ Given the unique found facts in this matter, my findings and conclusions do not impact prior Agency decisions stating, for example, that misinterpretation of the application does not relieve an applicant of the responsibility to read the question carefully and answer all parts of it honestly, or that negligence and carelessness in completing an application could be a sufficient reason to revoke a registration. See, e.g., Martha Hernandez, M.D., 62 FR 61145, 61147 (1997) (finding that respondent submitted material falsifications that are grounds for revocation, but concluding that revocation is not an appropriate sanction in light of the facts and circumstances).

embarrassed by some of my errors, and I take full responsibility. I regret these.' Id. The meaning of this portion of Applicant's testimony is far from clear. First, it is impossible to determine to which question Applicant was responding "yes" given that the transcript shows that he was asked two different questions. Id. Second, Applicant stated that he is "embarrassed" by "some" of his "errors." Id. Again, it is impossible to determine which of Applicant's "errors" embarrass him because Applicant neither explained what he considers his "errors" to be nor stated which subset of his "errors" embarrass him. Id. Third, Applicant's testimony is not clear about what the subject of his taking "full responsibility" is.

Further, in the context of his issuing controlled substance prescriptions with neither federal nor state authority, Applicant's attempt to minimize his wrongdoing by distinguishing between "narcotics" and the Schedule IV and Schedule V prescriptions he issued is troubling because the distinction is legally irrelevant. Tr. 390 (Applicant's testimony that "it doesn't seem unreasonable" for him to have been surprised that he had written "a [B]elviq or lower" when he had been thinking about "narcotics"). The law does not distinguish among controlled substances' schedules. It is unlawful to issue a prescription for any controlled substance without the requisite federal and state authority. 21 CFR 1306.03. In sum, the record evidence does not support my concluding that Applicant unequivocally accepts responsibility for issuing eleven controlled substance prescriptions when he did not have federal and state authority to do so. See also supra, section II.D. None of Applicant's record evidence, including his testimony, convinces me that I can entrust him with a DEA registration by granting DEA registration application No. W18015986C.

Also during his testimony, Applicant's counsel asked him "with respect to the New Jersey consent order of temporary suspension" whether he ''accept[s] that . . . [he] is bound by that suspension." Tr. 528. Applicant's answer was "[y]es, absolutely. I was concerned by . . . comments [of Government counsel]. I accept responsibility; I'm an adult, and I want to do better." Id. Again, I am not able to conclude from this testimony that Applicant accepts unequivocal responsibility and, if he does, for what. I also note that Applicant "denie[d] any and all wrongdoing" in the final Consent Order, thus indicating that he did not accept unequivocal

responsibility for his NJMB-founded controlled substance-related violations. GX 4, at 2; see also supra, section II.D.

In sum, Applicant did not unequivocally accept responsibility and has not convinced me that he can be entrusted with the registration he applied for in DEA registration application No. W18015986C. See also infra.

The interests of specific and general deterrence weigh in favor of denial of Applicant's DEA registration application No. W18015986C. Applicant issued eleven controlled substance prescriptions when he had neither federal nor state authority to do so, a violation at the core of the CSA. While Applicant is to be recognized for taking controlled substance-related and documentation/recordkeeping-related courses, his testimony in this proceeding has not convinced me that his future controlled substance prescribing, documentation, and recordkeeping will comply with legal requirements.

Further, given the egregious nature of Applicant's violations, including that he unlawfully wrote eleven controlled substance prescriptions for six different Schedule IV and Schedule V controlled substances, a sanction less than denial of Applicant's DEA registration application No. W18015986C would send a message to the current and prospective registrant community that compliance with the law, including compliance with core controlled-substance legal principles, is not a condition precedent to receiving and maintaining a DEA registration.

Accordingly, I shall order the sanction 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. 823(f), I hereby deny DEA registration application No. W18015986C submitted by Eric David Thomas, M.D. I further hereby deny any other pending application(s) of Eric David Thomas, M.D., for registration in Montana. This Order is effective June 17, 2022.

Anne Milgram,

Administrator

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. 21–19]

Michael T. Harris, M.D.; Decision and Order

On May 20, 2021, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause (hereinafter, OSC), seeking to revoke the DEA Certificate of Registration, Control No. FH1510709, of Michael T. Harris, M.D. (hereinafter, Respondent) and deny any pending applications for renewal or modification of such registration, or for additional registrations, pursuant to 21 U.S.C. 824(a)(4). OSC, at 1. The Government alleges that Respondent's continued registration is inconsistent with the public interest, as defined in 21 U.S.C. 823(f). Id.

A hearing was held before an Administrative Law Judge (hereinafter, ALJ) on October 12, 2021. The ALJ issued Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Recommended Decision or RD), which recommended that I revoke Respondent's registration and deny his pending application for renewal. RD, at 39. Respondent filed Exceptions to the RD on January 7, 2021, and the Government filed its Response on January 28, 2022.

I. Findings of Fact

A. Witness Credibility

The Government presented its case through the testimony of two witnesses, a DEA Diversion Investigator (hereinafter, DI), Tr. 16–58, 200–01, and Dr. L, a former colleague of Respondent, Tr. 60–80. The ALJ gave the DI and Dr. L's testimonies full weight and credit. RD, at 7, 9. I adopt her summary of their testimonies and credibility determinations. *Id.* at 5–9.

Respondent presented his case through two witnesses, Dr. R., who medically monitored Respondent's drug rehabilitation, Tr. 80–144, and Respondent, Tr. 144–190. The ALJ gave little weight to Dr. R's testimony—finding that Dr. R was a "combative and, at times, condescending witness," who had a vested interest in Respondent retaining his DEA registration. RD, at 13–14. I agree with the ALJ's findings and adopt her credibility determination for Dr. R's testimony. *Id*.

I also agree with the ALJ's credibility findings regarding Respondent's