emotional consternation, 63 but that is not the same as accepting responsibility, which is something he clearly is unwilling to do. On this point there is little room for logical, dispassionate dissent. Thus, in the face of a *prima facie* case, without the Respondent meeting the evidence with a convincing, unequivocal acceptance of responsibility and proposing thoughtful, concrete remedial measures geared toward avoiding future transgressions, the record supports the imposition of a sanction. That a sanction is supported does not end the inquiry, however.

In determining whether and to what extent imposing a sanction is appropriate, consideration must also be given to the Agency's interest in both specific and general deterrence and the egregiousness of the offenses established by the Government's evidence. Ruben. 78 FR at 38,364, 38,385. Considerations of specific and general deterrence in this case militate in favor of revocation. As discussed, supra, the Respondent has made it clear that he feels that he was not so much wrong as misunderstood and, in a way, nitpicked. As discussed, supra, he feels his prescriptions were legitimate, if lenient. Tr. 424-425. Although he uttered words in support of regret, where a person does not accept as true the errors shown to him by hard evidence, the hopes of true future deterrence are diminished, and mortally so. The interests of specific deterrence, therefore, compel the imposition of a sanction.

Likewise, as the regulator in this field, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. Ruben, 78 FR at 38,385. To continue the Respondent's registration privileges on the present record would send a message to the regulated community that it is acceptable to spend less than ten minutes, and sometimes less than two minutes with a patient, conduct no exams, document exams not conducted, procure neither prior records nor objective testing, prescribe dangerous controlled substances, increase the dosages without basis or regret, and continue to do so even in the face of information that the purported patient is not even filling the prescriptions. The interests of general deterrence militate powerfully in favor of a sanction on this record.

Regarding the egregiousness of the Respondent's conduct, as discussed, *supra*, the Respondent did virtually nothing to satisfy (or even further) his responsibilities as a DEA registrant on four occasions. He had no basis for a

valid diagnosis, he had no prior medical records, called no prior treating physician, had no imaging, conducted no examination to speak of, doctored up phony examination results, ignored evidence that the prescriptions were not being filled by his purported patient, disregarded the gaps where the patient would have been without the medicine he was prescribing (even if it had been dispensed and taken as directed), and actually increased the dosage for no articulated reason beyond the fuzzy concept that he had an increased level of "comfort[]" 64 (based apparently on little more than the TFO's decision to keep coming back for more drugs). Even disregarding the very real likelihood that these four UC Visits presented a vivid snapshot of the Respondent's practice in general, the blithe manner in which he doled out controlled medicine to this undercover officer was nothing short of astonishing. The egregiousness of the established transgressions in this case, and the reckless abandon with which the Respondent ignored his obligations provides a unique window into the systemic gravity of the current opioid crisis.

A balancing of the statutory public interest factors, coupled with consideration of the Respondent's failure to meaningfully accept responsibility, the absence of record evidence of thoughtful and continuing remedial measures to guard against recurrence, and the Agency's interest in deterrence, supports the conclusion that this Respondent should not continue to be entrusted with a registration.

Accordingly, it is respectfully recommended that the Respondent's DEA COR should be REVOKED, and any pending applications for renewal should be DENIED.

Dated: August 20, 2020.

John J. Mulrooney, II,

U.S. Chief Administrative Law Judge. [FR Doc. 2021–20247 Filed 9–17–21; 8:45 am] BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. 19–31]

Lisa M. Jones, N.P.; Dismissal of Proceedings

I. Introduction

On June 28, 2019, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Lisa Mae Jones, N.P. (hereinafter, Applicant), of Mount Airy, North Carolina. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause (hereinafter, OSC)), at 1. The OSC proposed the denial of Applicant's application (Application No. W19018692M) for a DEA certificate of registration (hereinafter, North Carolina-based registration application) and "any other applications for any other DEA registrations" on the ground that she "materially falsified" her application "in violation of 21 U.S.C. 824(a)(1) and 823(f)." Id.

The substantive ground for the proceeding, as more specifically alleged in the OSC, is that Applicant's "failure to disclose the disciplinary actions taken against . . . [her] nursing licenses (viz., the denial of . . . [her] application in Illinois and the fact that . . . [her] Tennessee and Iowa nursing licenses were placed on probation) constitutes material falsification of . . . [her] application for a DEA Certificate of Registration." *Id.* at 4.

The OSC notified Applicant of her right to request a hearing on the allegations or to submit a written statement while waiving her right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. Id. at 4 (citing 21 CFR 1301.43). The OSC also notified Applicant of the opportunity to file a corrective action plan. OSC, at 5 (citing 21 U.S.C. 824(c)(2)(C)). Applicant requested a hearing. ALJX 2 (Request for Hearing dated July 22, 2019), ALJX 4 (Order for Prehearing Statements dated July 23, 2019), at 1 (stating that counsel for Applicant filed a hearing request on July 22, 2019).1

The matter was placed on the docket of the Office of Administrative Law Judges and assigned to the Chief Administrative Law Judge (hereinafter, ALJ), John J. Mulrooney, II. The Chief ALJ noted thirteen stipulations agreed upon by the parties and "conclusively accepted as fact in these proceedings. Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge dated November 21, 2019 (hereinafter, RD), at 4-5. The second and third stipulations state that Applicant "is currently licensed in the State of North Carolina as a Nurse Practitioner under Approval No. 5011528" and that her "North Carolina Approval (license) expires by its own terms on May 31, 2020." Id. at

¹The Request for Hearing is stamped received on July 30, 2019

The hearing in this matter took place at the DEA Hearing Facility on September 17, 2019. The RD is dated November 21, 2019. The Government filed exceptions to the RD. The Government's Exceptions to the Chief Administrative Law Judge's Recommended Decision, dated December 11, 2019 (hereinafter, Govt Exceptions).

Having considered the record in its entirety, I find that the Government has failed to establish by clear, unequivocal, and convincing evidence that Applicant violated 21 U.S.C. 824(a)(1) as to the North Carolina-based registration application. Due to the current "inactive" status of Applicant's North Carolina nurse practitioner license, however, I am precluded by statute from ordering that the North Carolina-based registration application be granted. 21 U.S.C. 823(f) ("The Attorney General shall register practitioners . . . if the applicant is authorized to dispense. . controlled substances under the laws of the State in which [s]he practices."). Infra section II.B.

I make the following findings.

II. Findings of Fact

A. The Material Falsification Allegations

According to the OSC's allegations, Applicant submitted an application for a DEA Certificate of Registration as a mid-level practitioner in Schedules II through V with a registered address in North Carolina on or about March 1, 2019. OSC, at 2. The North Carolinabased registration application, the OSC further alleges, was assigned control number W19018692M. Id. Applicant allegedly answered "yes" to Liability Question 2. Id. ("Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?"). Also according to the OSC, for "nature of incident," Applicant submitted the following material: "Failed to read directions/instructions correctly, I misread the part of state licensure being restricted." Id. Regarding "incident result," Applicant allegedly wrote: "Surrendered to DEA Agent on/about date stated above," meaning January 31, 2019. Id.

According to the OSC, Applicant also answered "yes" to Liability Question 3. Id. ("Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation or is any such action pending?"). Regarding the "nature of the incident," Applicant

allegedly stated: "I misread the application, I failed to read the part about state licensure being placed on probation." Id. For "incident result," according to the OSC, Applicant again submitted: "Surrendered to DEA Agent on/about date stated above," meaning January 31, 2019. Id.

There is factual agreement among the witnesses on a number of matters. When there is factual disagreement, I apply my credibility determinations and the credibility recommendations of the Chief ALJ. Infra sections II.D. and II.E.

B. Applicant's Current Licensure

In the course of adjudicating this matter, it came to my predecessor's attention that the North Carolina Board of Nursing (hereinafter, NCBON) website listed the status of Applicant's North Carolina nurse practitioner license as "inactive." https:// www.ncbon.com/licensure-listing-verifya-license. Further, Applicant was not listed on the North Carolina Board of Pharmacy website as being registered to dispense controlled substances in North Carolina. https://portal.ncbop.org/ verification/search.aspx.

My predecessor issued Applicant an (unpublished) Interim Order on May 21, 2021 (hereinafter, Interim Order).2 In the Interim Order, the then-Acting Administrator explained that the "inactive" status of Applicant's nurse practitioner license impacts the status of Applicant's North Carolina authority to dispense controlled substances.³ Interim Order, at 1. He explicitly stated that the status of Applicant's North Carolina nurse practitioner license "is essential to . . . [his] decision about the OSC because Applicant must have North Carolina authority to dispense controlled substances to be eligible for a DEA registration in North Carolina. *Id.* My predecessor ordered Applicant to address the status of her North Carolina authority to dispense controlled substances. Id. at 2. Applicant's response was due over a month ago, yet the Agency has not received any response, let alone the information ordered, from Applicant to date. As of the date of this Decision/Order, I find that the NCBON website continues to show Applicant's nurse practitioner license as "inactive." https:// www.ncbon.com/licensure-listing-verifya-license. Accordingly, as my

predecessor advised Applicant in the Interim Order, I am crediting and using the current "inactive" information on the NCBON website and denying the North Carolina-based registration application. 21 U.S.C. 823(f); 21 U.S.C. 802(21). I shall also adjudicate the OSC's allegations in the event Applicant submits a registration application in the future.

C. The Investigation of Applicant

I find that Applicant submitted an online application for a DEA registration with a registered address in North Carolina on or about March 1, 2019. GX 1 (Certification of Non-Registration), at 1. I find that her application was assigned DEA control number W19018692M. *Id.* I find that Applicant answered "yes" to two of the "Background Information," or Liability, questions. Id. at 1–2; infra II.F. I find that, when an application contains a "yes" response to a Liability question, it is referred for investigation. Transcript (hereinafter, Tr.) 38.

D. The Government's Case

The Government called one witness, the DEA Diversion Investigator assigned to investigate Applicant's North Carolina-based registration application (hereinafter, DI), and offered eight exhibits. The eight Government exhibits are either DEA documents showing Applicant's DEA registration status and history, or documents from states showing Applicant's license status and history. At the beginning of the hearing, Applicant's attorney stipulated to the admission of all of the Government's eight noticed exhibits. Id. at 25-26.

DI testified about her DEA employment, training, and duties as a DI at DEA's office in Greensboro, North Carolina. Id. at 24, 26-28. She testified that her first meeting with Applicant stemmed from a telephone call she received from the DEA Roanoke office in January 2019. Id. at 28-35. From that telephone call, she stated, she learned that a Special Agent (hereinafter, SA) and a Task Force Officer (hereinafter, TFO) from the Roanoke office were traveling to North Carolina to interview Applicant and that DI's presence was requested at the meeting. Id. at 28, 31.

DI explained that the Roanoke office found that Applicant had answered Liability questions inaccurately on the application she had submitted for the controlled substance registration under which Applicant was practicing in Virginia at the time. Id. at 28. DI described "liability questions" as questions about matters that "we consider liabilities for that registrant" or "things that we would consider as to

² Applicant's attorney during the Hearing, on whom the Interim Order was served, orally confirmed that she received the Interim Order and forwarded it to Applicant.

³ The Interim Order attached a copy of the website of the North Carolina Board of Nursing showing the status of Applicant's nurse practitioner license as "inactive."

whether or not there's a public interest reason why that individual should be perhaps their registration [sic] rejected for some reason." ⁴ *Id.* at 29. Specifically, regarding Applicant, DI testified that Applicant "had answered negative to all of those questions, but later investigation found that she did in fact have some past issues with her state licensing." ⁵ *Id.* at 30.

DI testified that, at the meeting on January 31, 2019, Applicant acknowledged that she completed and digitally signed an application for a DEA registration in September 2018, the registration under which she practiced in Virginia. Id. at 32-33. DI stated that SA "then presented her with a copy of it and pointed to the liability questions and asked her to read those." *İd.* at 33. DI explained that, after Applicant read them once, responded affirmatively to SA's question about whether "she had had any past state issues regarding her license," and re-read them, Applicant "acknowledged that she had incorrectly answered those questions" in September 2018. Id. According to DI, Applicant stated that she "misunderstood" the question. Id. at 67. DI also testified that, "[t]o be honest, I recall . . . [Applicant] reviewing the paperwork, there actually kind of seemed to be a sense of, like, she was realizing what had happened as she read it. And then, she did admit at that point." Id. Indeed, according to DI, the probationary actions on Applicant's licenses by Tennessee and Iowa came up during the meeting. Id. at 79.

According to DI, after Applicant acknowledged her incorrect responses, SA "basically presented her with the option to sign a voluntary surrender form" or go to a hearing. *Id.* at 35, 65. DI testified that Applicant "read over it, . . . [SA] explained it to her, and she

signed that voluntary surrender" of her Virginia registration with TFO and DI as witnesses. *Id.* at 35, 68. DI identified GX 7 as a copy of the voluntary surrender that Applicant executed on January 31, 2019. *Id.* at 36.

DI described the conversation that ensued after Applicant surrendered her Virginia registration. According to DI, Applicant "acknowledged that she did not plan to work in Virginia any longer and would be working in North Carolina." Id. at 68-69, 72. DI testified that someone from the DEA investigative team explained that, "under the circumstances of her surrendering that prior registration," Applicant "would need to reapply for a registration in the state of North Carolina." Id. at 73. DI recalled that SA told Applicant that "she would need to answer in the affirmative to the liability questions." Id. at 74; see also id. at 97-98 (DI testifying that "I don't necessarily recall exactly if . . . [SA] said for 2 and 3, you need to be in the affirmative. I believe that his instruction was, assuming you provide the DEA with a complete and correct application, there won't be any issues regarding getting a new registration. I do recall him essentially explaining that, for Question 2, because he was taking a voluntary surrender, there would need to be an affirmative to that particular question regarding the details of that date. I don't necessarily remember there being any more on Question 3 . . .—other than a general, you will need to explain the situation."). DI also testified that SA told Applicant that the voluntary surrender "would not affect her state licensing." *Id.* at 74–75.

DI testified that DEA received Applicant's North Carolina-based registration application. Id. at 37; see also RX 12 (showing the North Carolinabased registration application's submission date as February 28, 2019). Initially, the North Carolina-based registration application was assigned to "one of the brand new investigators in the office who was still in our training program," DI stated. Tr. 37. DI explained that the new investigator's field training officer saw Applicant's name, the name "sounded familiar to him," so "he kind of yelled over the cubicle" to DI asking if she was familiar with the name. Id. DI testified that she responded in the affirmative, stating that Applicant "was the one . . . [she] recently had a meeting with [in] Roanoke." *Id.* at 37–38. DI explained how the matter was then assigned to her. *Id.* at 38.

DI testified about Applicant's specific answers to two of the Liability questions on the North Carolina-based registration

application. Id. at 83-89. First, regarding the second Liability question, DI confirmed that Applicant responded "yes" to that question: "Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?" Id. at 83; see also GX 1, at 1. DI stated her "understanding" that Applicant's "yes" answer would have caused the electronic application to drop down a blank box. Tr. 83. Concerning Applicant's submission for "incident nature" regarding the second Liability question, "failed to read directions/instructions correctly, I misread the part of state licensure being restricted," DI testified about what that response meant to her. GX 1, at 1. DI stated that "[i]n this situation, it tells me that she has surrendered for-cause a federal controlled substance registration and that the explanation that she has given is that essentially, she misunderstood the instructions on how she was supposed to respond to that . . . particular question." Tr. 84; see also id. at 86. DI further testified that Applicant's submission told her that "there is a state licensure being restricted" and "that is why she surrendered her DEA registration." Id. at 84. DI confirmed that Applicant's submission put DI on notice and gave DI "some information regarding the potential'' that Applicant has a state licensure restriction. *Id.* at 85–86; see also id. at 103.

Second, regarding the third Liability question, DI confirmed that Applicant responded "yes" to that question: "Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?" Id. at 87; see also GX 1, at 2. DI consistently testified that she is "not aware that there's any instruction" about how to fill out the drop-down box that would appear when there is a "yes" answer to the third Liability question. Tr. 87, see also id. at 93-94. Concerning Applicant's submission for "incident nature" regarding the third Liability question, "I misread application. I failed to read the part about state licensure being placed on probation," DI testified about what that response meant to her. 6 GX 1, at 2. DI agreed that Applicant's response indicated that Applicant's state licensure was placed on probation and that she previously surrendered her

⁴When asked for details about completing the DEA registration application form, DI responded that she is "not an expert when it comes to the actual application process" and that she has "not actually completed one as a registrant." Tr. 80, 83. Regarding instructions for completing the form and resources to help someone who is unsure about how to answer a question on the form, DI testified that she is "not aware that there's any [instruction] form, it's just a ask a question, answer the question, ask a question, answer the question" and that "[t]here is a telephone number . . . to basically the Registration Program Specialist within the DEA . . .—there's kind of a help 800 number that they can contact." *Id.* at 81–82; *see also id.* at 83.

⁵ Neither the Government nor Applicant offered for admission documentary evidence supporting or refuting the findings of the investigation DI referenced concerning Applicant's Virginia registration under which she was practicing in January 2019 and that she voluntarily surrendered at the January 31, 2019 meeting. This is consistent with the sole charge in the OSC—denial of Applicant's North Carolina-based registration application due to material falsification.

⁶ DI also testified that ''[i]n my reading of that, I'm not sure exactly what she's telling me there." Tr.

DEA registration because she failed to report the probation. Tr. 88-89.

DI testified that, after she received Applicant's North Carolina-based registration application, she "started searching under licensing" for Applicant and contacted SA and TFO. Id. at 85–86. Due to those contacts, DI testified that SA provided her "with some documentation regarding the original surrender" on January 31, 2019.7 Id. at 86.

DI testified about the extent of her knowledge of Applicant's state licensing history at the time Applicant's North Carolina-based registration application was assigned to her. *Id.* at 89–92. From her attendance at the meeting on January 31, 2019, DI stated she was aware that Applicant's licenses in Tennessee and Iowa were put on probation. Id. at 90-92. She also testified about her investigative work after being assigned Applicant's North Carolina-based registration application. DI stated that she "went online and . . . actually just started searching the nursing boards for the states for which . . [she] knew . . . [Applicant] had licensing." Id. at 39. From this online research, DI testified that she learned about Applicant's Illinois license status "based on information given in consent orders that were public information on their websites." Id. at 39-40; see also id. at 41 (DI testimony that the Iowa documentation mentioned that "there was a refusal to renew in Illinois . . [a]nd so that led me to check Illinois as

well.").
DI testified that her investigative work moved beyond conducting online research and included contacting Tennessee to "find out the underlying facts, because all of them kind of pointed to Tennessee as sister state disciplinary action." *Id.* at 40. DI described three individuals and the assistance they gave her investigation. The first was an attorney involved in the Tennessee action against Applicant, the second was an individual in the Air Force Surgeon General's office whose name DI obtained from the Tennessee attorney, and the third was an individual from the Illinois Department of Professional Regulation who explained the meaning of "refuse to renew" status in Illinois. Id. at 47-63. From Tennessee, Iowa, and Illinois, DI obtained consent decrees, settlement agreements, and other records. Id. at 104. From the Air Force, DI obtained a "59-page report" and "a packet that

included the review of . . . [Applicant's] patient encounters." 8 Id. DI testified that she found nothing in the states' and Air Force's records that "went after her licensing." Id. at 106. Instead, she testified, "it was actually kind of a chain reaction." Id. DI explained that "after the Air Force took action and Tennessee took action, because of the action in Tennessee, then Illinois and Iowa took action." Id. DI specifically addressed the Air Force report, GX 2, and the Air Force's action concerning Applicant, testifying that there is "not anything [in GX 2] that specifically says [that Applicant committed] a controlled substance violation." *Id.* at 105; *compare id.* at 111-128, RD, at 24-32, and Govt Exceptions, at 4-18.

When asked what made her decide that Applicant made false statements in the North Carolina-based registration application, DI initially responded that her reading of Applicant's answer to the third Liability question "did not actually answer the question being asked" in her opinion. Tr. 94. "The information that . . . [Applicant] provided seems to be an answer to Question 2 and not the answer to Question 3," she elaborated. Id. at 95. When asked whether her testimony was that "the words state licensure being placed on probation" are false, DI responded that "I'm not saying that that is false, I'm saying that the information provided does not answer the question being asked." Id.; see also id. at 104 ("No, I wouldn't say that it was false."). DI's testimony was that Applicant's words were "inadequate." Id. at 95. She also stated that "the details . . . seem in conflict with one another" because Applicant never had "any state licensure that's been placed on probation in the state of North Carolina," yet Applicant listed "Winston-Salem, North Carolina" as the "incident location." Id. at 95-96; see also id. at 109-111 (DI testifying that, to her knowledge, no action was taken against Applicant's state professional license on January 31, 2019, no action was taken against Applicant's professional license in North Carolina, Applicant's professional license in

North Carolina was never disciplined for misreading or falsifying an application, and Applicant never surrendered a state professional license to any DEA agent).9 DI acknowledged that, if she had been in the place of the "initial Diversion Investigator" to whom the matter was assigned, she would have looked for every state in which Applicant was licensed. Id. at 102. She characterized such an effort as "due diligence." Id. at 104.

I agree with the RD that DI presented as "an objective, dispassionate regulator whose testimony was sufficiently detailed, internally consistent, and plausible to be afforded full credibility." RD, at 11.

E. Applicant's Case

At the hearing, Applicant testified and succeeded in having seven of her exhibits admitted into evidence. Tr. 131-261.

Applicant testified about her experience using the online registration application submission process for her North Carolina-based registration application. Id. at 132-40, 141-45; RX 12, at 1. She stated that, when she responded "yes" to a Liability question, "a blank box pops up" and "[t]here is no instructions [sic] as to what information to put in there." 10 Tr. 133. During her testimony, she surmised that "it would have solved the problem if

⁷ DI also indicated that SA provided her the documentation regarding Applicant's January 2019 surrender "because there were some concerns regarding if . . . [Applicant's] answer was complete." Tr. 86.

⁸ DI authenticated the six non-DEA Government exhibits, all of which she obtained through her investigative work: GX 2 (United States Department of the Air Force Professional Staffing Record), GX 3 (Tennessee Board of Nursing Consent Order), GX 4 (Illinois Department of Financial and Professional Regulation, License Lookup Information), GX 5 (Iowa Board of Nursing Notice of Hearing and Statement of Charges), GX 6 (Iowa Board of Nursing Settlement Agreement and Final Order), and GX 8 (State of Illinois Department of Financial and Professional Regulation Consent Order dated June 8, 2015). Tr. 41-63.

 $^{^9\,}See$ also Tr. 98–99 (DI testifying that "My understanding of what she has written, her answer to Question 3 does not answer the question. The facts may be true that are listed there, but it's not answering the question that has been asked. Question 3 is specifically asking about state licensure and she is telling me about a surrender of her DEA registration, which would be a federal registration. And as I said, so she's listing the date she surrendered her federal registration, she lists the incident result as the surrender of her DEA registration, and the location is when she did that. When it comes to-she does mention her misreading the-basically, she gives an explanation of why she surrendered her DEA registration. The information that she has provided there . . . I have some background knowledge on this only because I was at that meeting. The initial Diversion Investigator who received this information would not have had that information at his fingertips and reading that, I don't believe he would have been able to come to the information quite as easily or have already had some background knowledge of what had happened regarding her state registration.").

¹⁰ Applicant testified consistently that only a blank box appeared when she responded "yes" to Liability questions two and three. Tr. 239; see also id. at 239-42, 249 (Applicant testifying that she consulted Google for instructions and, when responding to questions about RX 12, at 67 showing three categories of information (location, nature, and disposition) under the heading of "Answers to Liability Questions," testified that, as she recalls, she "independently determined that the relevant categories of information were location, nature, and disposition"); cf. id. at 241-42 (Applicant testifying that "it's possible" there were prompts asking for date, nature of incident, location, and disposition).

. . . [the online registration application submission process] would have said what State licensure, what State, what license, was it revoked, suspended, denied, restricted." *Id.* at 144–45. Applicant's testimony continued with her stating that she "think[s] that would have solved the problem because . . . [she] could have answered Tennessee, probation, Iowa, probation." *Id.* at 145.

In the context of her testimony about her suboptimal experience attempting to complete the online DEA registration application, Applicant testified that she "took it upon . . . [herself] to answer the questions based on what . . . [she] was instructed to from the January 31st meeting as far as the yesses that needed to be in there." Id. She similarly testified in response to questioning by the Chief ALI about the "confusion . . because it asks you if you had a State professional license action, essentially, against you, and the answer was yes and you start talking about Winston-Salem, North Carolina, and that really had nothing to do with the State. . . . That's what a lot of this comes down to." Id. at 136. Applicant responded that she "put that down there because when . . [she] was in the meeting on January 31st with the three DEA agents . . . [she] was informed that . . . [DI] would be the investigating officer and it was already disclosed that . . . [she] already had . . . [her] license placed on probation, the two States." Id. at 137. After the Chief ALJ restated the question as "why would you answer a question dealing with State licenses with that date and that place," Applicant responded that, "I guess that's how I read it, sir." Id. at 138-39. She elaborated that "the DEA agents already knew that . . . [her] license had been placed on probation in the State of Tennessee and Iowa for nurse practitioner, so they already knew the information from . . . [the] meeting." Id. at 139; see also id. at 140 (Applicant responding "no" to whether she thought it was necessary to explain each state because DEA "already knew about . . [her] two nurse practitioner licenses already being placed on probation"); id. at 142 (Applicant testifying that she "read over the State licensure . . . [and] immediately went to controlled substance registration revocation. . . . [she] just didn't grab that State licensure wording in there."); id. at 142-43 (Applicant responding to why she thought the second and third Liability questions asked about the same thing, stating she "blew past the State professional license words. . . . just blew through them.").

Applicant also testified about the meeting with the DEA investigative

team on January 31, 2019. *Id.* at 140–41, 152–56. She stated that the meeting took place in the evening from about 6:00 to 8:00. *Id.* at 152. Applicant testified that SA told her that her boss, a provider at the Woodlawn Pain Care Clinic where she was working at the time, "was under investigation and they wanted to speak to . . . [her] about . . . [him]." ¹¹ *Id.* at 152–55. She stated that "[i]t was a lot of questions." *Id.* at 156.

Applicant testified that, at the conclusion of the meeting, SA "showed . . [her] the questionnaire [application that she had submitted for her Virginiabased DEA registration], . . . [she] read it once, and then he had . . . [her] reread it again and then . . . [she] realized . . . [she] had made a mistake, that . . . [she] had put a no when it should have been a yes that . . . [her] license was placed on probation." Id. at 140; see also id. at 156-57. She testified that SA "didn't say anything about . . . [her] licensure being placed on probation.' Id. at 141. She added that SA "didn't disclose that information to . . . [her, she] disclosed it to him." Id. She testified that she "told him [SA], yes, that . . . [she] read it wrong, that . . [her] license in Tennessee and Iowa had been placed on probation." Id. Applicant added that she then "noticed under his [SA's] left arm he had a copy of . . . [her] Tennessee licensure probation information because . . . [she] saw . . . [her] signature on there and . . . [she] had already known what the information was." Id.

According to Applicant's testimony, SA told her that she "could either go in front of a judge, or . . . [she] could sign the surrender for cause certificate that they had already made up for . . [her]." Id. at 157-58. She testified that she signed the surrender certificate "[b]ecause . . . [she] realized . . . [she] had made an error." Id. at 159. Applicant stated that she asked about reapplying for "another DEA number" and that SA said she could "but . . . [she] needed to make sure that . . . [she] answered yes to . . . the ones . . . [she] had previously answered wrong." Id. at 157–58. She testified that SA said nothing more about how to answer the second and third Liability questions and that SA told her it would take two to three weeks for her to get a new registration. Id. at 158-59. She testified that SA told her DI "would be handling . . . [her] application when . . . [she] reapplied" and that, at the time, DI said

nothing pertaining to reapplication. *Id.* at 157, 159.

I agree with the Chief ALJ that, "where . . . [Applicant's] testimony conflicts with other objective evidence and testimony received during the proceedings, it must be scrutinized with great caution." RD, at 17.

F. Allegation That Applicant Submitted a Materially False Registration Application

Having read and analyzed all of the record evidence, I find from clear, unequivocal, convincing, and unrebutted record evidence that Applicant answered "yes" to Liability questions two and three. GX 1, at 1–2. I further find from clear, unequivocal, convincing, and unrebutted record evidence that Applicant's "yes" answers to Liability questions two and three are true. See, e.g., GX 3, GX 6, and GX 7.

Concerning Applicant's responses to the follow-up required due to her affirmative answer to the second Liability question, having read and analyzed all of the record evidence, I find from clear, unequivocal, convincing, and unrebutted record evidence that those responses told DI that Applicant "surrendered for-cause a federal controlled substance registration," that Applicant's explanation was, "essentially, she misunderstood the instructions on how she was supposed to respond to that . . . particular question," and that "there is a state licensure being restricted" and "that is why she surrendered her DEA registration." Tr. 84, 86. I further find from clear, unequivocal, convincing, and unrebutted record evidence that Applicant's submission put DI on notice and gave DI "some information regarding the potential" that Applicant had a state licensure restriction. *Id.* at 85-86, 103. Having read and analyzed all of the record evidence. I also find from clear, unequivocal, convincing, and unrebutted record evidence that DI was one of the witnesses to Applicant's voluntary surrender of her Virginiabased registration on January 31, 2019. Id. at 35-36, 68.

Concerning Applicant's responses to the follow-up required due to her affirmative answer to the third Liability question, having read and analyzed all of the record evidence, I find from clear, unequivocal, convincing, and unrebutted record evidence that DI did not consider those responses false; DI considered that the information Applicant provided "does not answer the question being asked." *Id.* at 94. I further find from clear, unequivocal, convincing, and unrebutted record

¹¹ Applicant testified that she was working as a nurse practitioner for this same provider at the North Carolina practice he opened after DEA investigated him in Virginia. Tr. 252–53.

evidence that DI "started searching under licensing" for Applicant after receiving Applicant's North Carolinabased registration application. *Id.* at 85–86. Having read and analyzed all of the record evidence, I also find from clear, unequivocal, convincing, and unrebutted record evidence that DI learned about the Tennessee and Iowa probationary actions on Applicant's licenses from her attendance at the meeting on January 31, 2019. *Id.* at 79, 90–92.

Having read and analyzed all of the record evidence, I find from clear, unequivocal, and convincing record evidence that Applicant met with a DEA investigative team on January 31, 2019. See, e.g., id. at 32-37 (DI's corrected testimony), GX 7. I also find from clear, unequivocal, convincing, and unrebutted record evidence that the DEA investigative team's meeting with Applicant took place in Winston-Salem, North Carolina in a hotel lobby in the evening from about 6:00 until 8:00. Tr. 71 (DI's testimony); id. at 151–52, 155 (Applicant's testimony). I further find from clear, unequivocal, convincing, and unrebutted record evidence that the outcomes of the Winston-Salem meeting included Applicant's voluntary surrender of her Virginia-based registration and the DEA investigative team's provision of input and instructions to Applicant about the next DEA registration application she might submit. See, e.g., id. at 35-36, 65-75 (DI's testimony); *id.* at 156–159 (Applicant's testimony); GX 7. I also find from unrebutted record evidence that the DEA investigative team advised Applicant at the Winston-Salem meeting that she may apply for a DEA registration at a registered location in North Carolina, cautioned Applicant, in the event she reapplies, to answer "yes" to the Liability questions she previously incorrectly answered in the negative, told Applicant that DI would handle any application she submitted for registration in North Carolina, and predicted that it would take two to three weeks for Applicant to get a new registration if she were to submit a complete and correct application. Tr. 71–75 (DI's testimony); id. at 157–59 (Applicant's testimony).

I already found that Applicant submitted an online application for a DEA registration with a registered address in North Carolina on or about March 1, 2019. Supra section II.C. Having read and analyzed all of the record evidence, I find that the unrebutted record evidence is that Applicant's North Carolina-based registration application was initially assigned to "one of the brand new

investigators in the office who was still in . . . [the] training program," that the new investigator's field training officer recognized Applicant's name and confirmed DI's familiarity with Applicant, and that Applicant's North Carolina-based registration application was reassigned to DI. Tr. 37–38 (DI's testimony). I find that the unrebutted record evidence is that the investigation into Applicant's North Carolina-based registration application remained DI's responsibility and that Applicant's North Carolina-based registration application was not assigned away from DI. See, e.g., id. at 28. I find that the Government did not submit clear, unequivocal, and convincing evidence about the online registration application process, including what information the online application elicits after an applicant responds "yes" to a Liability question. See, e.g., id. at 87, 93 (DI's testimony).

Having read and analyzed all of the record evidence, I do not find clear, unequivocal, and convincing record evidence that Applicant's North Carolina-based registration application was false. Having read and analyzed all of the record evidence, I do not find any record evidence rebutting Applicant's testimony that her responses to the second and third Liability questions' follow-up reflected the input and instructions she received from the DEA investigative team on January 31, 2019.¹²

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).

In this matter, as already discussed, the OSC calls for my adjudication of the North Carolina-based registration application based on the charge that Applicant submitted materially false responses to its second and third Liability questions. OSC, at 1-4; supra sections II.A and II.D. Material falsification, of course, is a basis for revocation or suspension. 21 U.S.C. 824(a)(1). While the OSC references 21 U.S.C. 823(f), it does not specifically allege that granting Applicant's North Carolina-based registration application would be inconsistent with the public interest based on consideration of the factors in 21 U.S.C. 823(f)(1) through (5). Supra section III.A. In addition, while the Government presented some evidence and argument that the North Carolina-based registration application should be denied due to concerns about

¹² The Government neither cross-examined Applicant concerning her testimony about the input and instructions she stated the DEA investigative team gave her during the Winston-Salem meeting, nor put on a rebuttal case after Applicant's testimony.

Applicant's controlled substance prescribing, Government counsel confirmed that material falsification is the exclusive basis for the application denial sought by the Government. Tr. 214–16. Given the allegations noticed in this matter, no other conclusion is legally supportable. Accordingly, the sole, specific substantive basis for proposing the denial of Applicant's North Carolina-based registration application is material falsification under 21 U.S.C. 824(a)(1). OSC, at 1–4; see also Tr. 211–218.

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. For over forty-five years, and as recently as a few months ago, Agency decisions have concluded that it is. See, 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 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 factors remain relevant to the adjudication of a practitioner registration application when a provision of 21 U.S.C. 824 is involved.

B. The Material Falsification Allegations

Regarding 21 U.S.C. 824(a)(1), the Agency recently addressed the elements of a material falsification concluding, among other things, that *Kungys* v. *United States*, 485 U.S. 759 (1988), and its recent progeny remain consistent with the CSA. *Frank Joseph Stirlacci*, *M.D.*, 85 FR 45229, 45238 (2020). According to the Supreme Court, material means having 'a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed." *Id.* (citing *Kungys*, 485 U.S. at 771).

The Government argues that, although Applicant correctly responded "yes" to the third Liability question, "when called upon to provide a 'complete' explanation for her answer, she provided substantive information that was false . . . and concealed information that was true.' Government's Proposed Findings of Fact, Conclusions of Law, and Argument, dated November 1, 2019, at 1. According to the Government, the "substantive information that was false" was that "her state license had been subject to action in North Carolina in 2019," and the "concealed information

that was true" was that "her state licenses had been subject to various disciplinary actions in Tennessee, Iowa, and Illinois in 2015." *Id.* In other words, the Government argues that Applicant's responses to the follow up engendered due to her "yes" response were false, on the one hand, and did not disclose responsive information that was true, on the other hand. *Id.* Consequently, I now address whether the North Carolinabased registration application was materially false according to the *Kungys* definition of "material."

As already discussed, I find from clear, unequivocal, convincing, and unrebutted record evidence that Applicant answered "yes" to Liability questions two and three. Supra section II.F. In addition, as already discussed, I find from clear, unequivocal, convincing, and unrebutted record evidence that Applicant's "yes" answers to Liability questions two and three are true. Id. According to the record evidence that the Government submitted regarding Applicant's responses to the follow-up required due to her "yes" answers, I also find clear, unequivocal, convincing, and unrebutted record evidence that DI did not consider those responses false, but that DI considered that the information Applicant provided "does not answer the question being asked." Id. I further find the Government did not submit clear, unequivocal, and convincing evidence about the online registration application process, including what information the online application elicits after an applicant responds "yes" to a Liability question. Id.

As already discussed, I find from clear, unequivocal, convincing, and unrebutted record evidence that the DEA investigative team provided input and instructions to Applicant about the next DEA registration application she might submit during their meeting on January 31, 2019. Supra section II.F. In addition, as already discussed, I find from unrebutted record evidence that the DEA investigative team advised Applicant at that time that she may apply for a DEA registration at a registered location in North Carolina, cautioned Applicant, in the event she reapplies, to answer "yes" to the Liability questions she previously incorrectly answered in the negative, told Applicant that DI would handle any application she submitted for registration in North Carolina, and predicted that it would take two to three weeks for Applicant to get a new registration if she were to submit a

complete and correct application.¹³ Id. Also, as already discussed, I do not find any record evidence rebutting Applicant's testimony that her responses to the second and third Liability questions' follow-up reflected the input and instructions she received from the DEA investigative team on January 31, 2019. Id. According to the arguments made by Applicant's counsel during the hearing, Applicant admits that her responses to the follow-up were incomplete and inadequate. Tr. 199. Applicant's counsel argued that Applicant did her best and what she thought she was supposed to do based on what she had been told in January.

As already mentioned, the found facts of this case are unique and not likely ever to recur. Based on those facts, Applicant's responses to the follow-up that ensued from her "yes" responses to two Liability questions did not have a "natural tendency to influence" and were not "capable of influencing" the Agency's decision regarding Applicant's North Carolina-based registration application because the responses stemmed from Applicant's meeting with the DEA investigative team on January 31, 2019. In addition, the Government did not submit evidence rebutting Applicant's evidence about what transpired during her meeting with the DEA investigative team on January 31, 2019. For these reasons, I credit Applicant's evidence about what the DEA investigative team told her during that meeting and what impact that had on the content of the North Carolinabased registration application. It would, therefore, be inappropriate for me to find a material falsification violation when the Government submitted no evidence rebutting Applicant's rendition of what the DEA investigative team told her that impacted the content of the North Carolina-based registration application.¹⁴ Supra section II.F.

Accordingly, on the unique and unlikely ever to recur record evidence before me, I find that the follow-up

 $^{^{13}}$ Applicant submitted the North Carolina-based registration application on or about March 1, 2019, about a month after she met with the DEA investigative team. GX 1, at 1.

¹⁴ 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 61,145, 61,147 (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).

responses Applicant provided in her North Carolina-based registration application were not "predictably capable of affecting, that is, had a natural tendency to affect, the official decision" of DEA given Applicant's unrebutted record evidence of the input and instructions she said she received during her meeting with the DEA investigative team on January 31, 2019.

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. For the above-stated reasons, I find that the Government has failed to meet its burden. The record evidence does not include clear, unequivocal, and convincing evidence that Applicant materially falsified her North Carolinabased registration application. 21 U.S.C. 824(a)(1); Frank Joseph Stirlacci, M.D., 85 FR 45,229 (2020). Accordingly, I am dismissing the OSC.

However, as explained *supra* section II.B., Applicant is not currently "authorized to dispense controlled substances under the laws of the State" of North Carolina, I have no statutory authority to grant Applicant's North Carolina-based registration application. 21 U.S.C. 823(f); 21 U.S.C. 802(21); *supra* section II.B.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f) and 824(a), I hereby dismiss the Order to Show Cause issued to Lisa Mae Jones, N.P. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), in conjunction with 21 U.S.C. 802(21), I deny Application No. W19018692M. This Order is effective October 20, 2021.

Anne Milgram,

Administrator.

[FR Doc. 2021–20241 Filed 9–17–21; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Humberto A. Florian, M.D.; Decision and Order

On March 24, 2021, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Humberto A. Florian, M.D. (hereinafter, Registrant) of Anaheim, California. OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. FF0235451. *Id.* It alleged that Registrant is "without authority to handle controlled substances in

California, the state in which [he is] registered with DEA." *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that the Medical Board of California, Department of Consumer Affairs (hereinafter, the Board) issued a Decision on November 21, 2018, to revoke Registrant's medical license. Id. at 2. On December 21, 2018, the Board issued an Order denying Registrant's Petition for Reconsideration of the Decision and Registrant's medical license was revoked. Id. The California Medical Board revoked Registrant's medical license following its findings, inter alia, that Registrant was grossly negligent, committed repeated negligent acts, failed to maintain accurate and adequate medical records, and violated the California Medical Practice Act. Id.

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

Adequacy of Service

In a Declaration, dated August 11, 2021, a Diversion Investigator (hereinafter, the DI) assigned to the Riverside District Office, Los Angeles Field Division, attempted to contact Registrant, including at his registered address in Anaheim, California, "to determine if he would voluntarily surrender his [DEA registration] in light of his lack of state authority to prescribe controlled substances." Request for Final Agency Action (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 3 (DI's Declaration), at 1-2. The DI stated that a receptionist at the registered address said that "[Registrant] had retired, but [the] office still forwarded mail to him." Id. at 2. Following the issuance of the OSC, the DI traveled with another DI on April 2, 2021, to "the last known residence" of Registrant to attempt to serve Registrant with the OSC, but service was unsuccessful as "no one appeared to be at the residence at that time." Id. On April 12, 2021, the Riverside District Office, Los Angeles Field Division mailed a copy of the OSC to Registrant's last know residence via first-class mail and the mailing was not returned as undeliverable. Id. On May 14, 2021, the Los Angeles Field Division mailed a copy of the OSC to Registrant's registered address via first-class mail with return receipt requested, to which the DEA received "an unsigned return receipt on May 24, 2021, indicating that

the [OSC] had been delivered." Id.; see also RFAAX 3, Appendix (hereinafter, App.) B. Finally, on May 20, 2021, the DI sent a copy of the [OSC] to Registrant via his registered email address and did not receive any error message that indicated that the email was not delivered. RFAAX 3, at 2.; see also RFAAX 3, App. C (copy of email). The DI also stated that a review of the email system showed that the email had been delivered. RFAAX 3, at 2. The DI concluded that, "[t]o date, neither [Registrant] nor any attorney representing [Registrant] has requested a hearing. Neither has [Registrant] nor any attorney for [Registrant] submitted a written statement." Id. at 3.

The Government forwarded its RFAA, along with the evidentiary record, to this office on August 12, 2021. In its RFAA, the Government represents that "[Registrant] has not submitted a timely request for a hearing in this matter." RFAA, at 1. The Government "seeks to revoke the [DEA registration] of [Registrant] because he lacks authority to handle controlled substances in the State of California, the state where he is registered with DEA." *Id*.

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of the OSC on Registrant on or before May 20, 2021. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the DI's Declaration and the Government's written representations, I find that neither Registrant, nor anyone purporting to represent the Registrant, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

Findings of Fact

Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. FF0235451 at the registered address of 2090 S Euclid St. Ste. 104, Anaheim, CA 92802. RFAAX 1 (DEA Certificate of Registration). Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules III through V as a practitioner.