respondent's attempts to minimize misconduct undermined acceptance of responsibility); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (noting that the respondent did not acknowledge recordkeeping problems, let alone more serious violations of federal law, and concluding that revocation was warranted).

The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations. *Jeffrey Stein, M.D.,* 84 FR 46,968, 46,972 (2019). A registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction, *Garret Howard Smith, M.D.,* 83 FR at 18,910 (collecting cases); as is whether the registrant's acceptance of responsibility is unequivocal, *Lon F. Alexander, M.D.,* 82 FR 49,704, 49,728 (2017) (collecting cases). In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offense established by the Government's evidence and the Agency's interest in both specific and general deterrence. *Wesley Pope,* 82 FR 14,944, 14,985 (2017) (citing *Joseph Gaudio,* 74 FR 10,083, 10,095 (2009)); *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoption of ''deterrence, both specific and general as a component in analyzing the remedial efficacy of sanctions.'').

Here, Respondent Pharmacy has presented no evidence on the record that I could consider as accepting responsibility. I have considered the written response, which denies any misconduct, stating multiple times that it ''would be impossible'' for ''the medications [to be] short of the original count[s],'' and asserting that ''we were far from deceit when we talked to [DEA].'' RFAAX 3, at 2–3. The written response further seems to pass blame for the findings of violations against Respondent Pharmacy onto the DEA—claiming that DEA ''raided the pharmacy,'' on a ''witch hunt waged against [Respondent] Pharmacy'' arising from ''hatred toward the owner.'' *Id.* at 2. It is clear from the written response that Respondent Pharmacy has not accepted responsibility for its actions.

I have also considered the proposed Corrective Action Plan that the Government submitted into the record. RFAAX 4. The proposed Corrective Action Plan does not include any acceptance of responsibility; rather it proposes policies that essentially mirror the requirements already existing in law. *Id.* Even if I were to consider remedial measures, in spite of Respondent Pharmacy's complete lack of acceptance of responsibility, these proposed remedial measures are insufficient to convince me to entrust Respondent Pharmacy with a registration. 21 U.S.C. 824(c)(3); *see also Melanie Baker, N.P.,* 86 FR 23,998, 24,011 (2021) (*citing Jones Total Health Care Pharmacy, L.L.C.,* 81 FR 79,188, 79,202–03 2016).

Moreover, Respondent Pharmacy's found lack of candor during the investigation demonstrates an unwillingness to cooperate with this agency in future compliance inspections. Truthful cooperation with agency requests for information ensures that agency officials can easily monitor and ensure compliance with the CSA and help to correct violations. *See Jeffrey Stein, M.D.,* 84 FR 46,968, 46,973 (2019) (finding that a registrant's honesty during law enforcement regulations is ''crucial to the Agency's ability to complete its mission of preventing diversion within such a large regulated population''). In order to entrust Respondent Pharmacy with a registration, I need to know that its personnel will not repeat their dishonest behavior, and in this case, Respondent Pharmacy has given me no reason to believe that I can trust it with a registration.

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.,* 74 FR 10,083, 10,095 (2009); *Singh,* 81 FR at 8248. I find that considerations of both specific and general deterrence weigh in favor of revocation in this case. There is simply no evidence that Respondent Pharmacy's egregious behavior is not likely to recur in the future such that I can entrust it with a CSA registration; in other words, the factors weigh in favor of revocation as a sanction. Accordingly, I shall order the sanctions the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration FL4375730 issued to Creekbend Community Pharmacy. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Creekbend Community Pharmacy to renew or modify this registration. This order is effective August 27, 2021.

Anne Milgram,

Administrator.

[FR Doc. 2021–16000 Filed 7–27–21; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

William Ralph Kinkaid, M.D.; Decision and Order

On November 7, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to William Ralph Kinkaid, M.D. (hereinafter, Respondent), of Johnson City, Tennessee. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposed the denial of Respondent's application for DEA Certificate of Registration, Control No. W18085586C, because Respondent was ''mandatorily excluded . . . from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. 1320a–7(a)'' and that such exclusion ''warrants denial of [Respondent's] application pursuant to 21 U.S.C. 824(a)(5).'' *Id.* at 1–2 (citing *Richard Hauser, M.D.,* 83 FR 26,308 (2018)).

Specifically, the OSC alleged that, on June 24, 2013, the United States District Court for the Eastern District of Tennessee (hereinafter, E.D. Tenn.) issued a judgment against Respondent ''after [Respondent] pled guilty to one count of 'Receiving in Interstate Commerce a Misbranded Drug with Intent to Defraud or Mislead,' in violation of 21 U.S.C. 331(c).'' *Id.* at 2 (citing *U.S.* v. *William Ralph Kinkaid,* No. 2:12–CR–116 (E.D. Tenn. June 24, 2013)). The OSC further alleged that ''based on [Respondent's] conviction, the U.S. Department of Health and Human Services, Office of Inspector General (''HHS/OIG''), mandatorily excluded [Respondent] from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. 1320a–7(a)'' effective June 28, 2013, for a period of ten years. *Id.*

The OSC notified Respondent 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 Respondent of the opportunity to submit a corrective action plan. *Id.* at 2–3 (citing 21 U.S.C. 824(c)(2)(C)).

Respondent submitted a Waiver of Hearing, Statement/Response to Order to Show Cause, and Corrective Action Plan dated December 5, 2018 (hereinafter, Response to the OSC). Request for Final Agency Action Exhibit (hereinafter, RFAAX) 7. On January 10, 2019, DEA issued a letter to Respondent denying his proposed Corrective Action Plan. RFAAX 8.

The Government submitted a Request for Final Agency Action (hereinafter, RFAA), along with Respondent's Response to the OSC and the evidentiary record, for adjudication on May 30, 2019. I issue this Decision and Order based on the record submitted by the Government, which includes Respondent's Response to the OSC, and constitutes the entire record before me. 21 CFR 1301.43(e).

I. Findings of Fact

a. Respondent's Application for DEA Registration

On August 6, 2018, Respondent submitted an application (Application Control No. W18085586C) for a DEA Certificate of Registration, at the proposed registered location of 193 Keefauver Road, Johnson City, TN 37615 for a practitioner with drug schedules II–V. RFAAX 1 (Certification of Registration Status). The application is in pending status. *Id.* Respondent previously held DEA Certificates of Registration Nos. BK2452819 and FK2770320, which are in retired status. *Id.*

b. Respondent's Criminal Conviction

The evidence in the record demonstrates that, on June 24, 2013, judgment was entered against Respondent following a guilty plea in E.D. Tenn. based on one count of ''Receiving in Interstate Commerce a Misbranded Drug With Intent to Defraud or Mislead'' in violation of 21 U.S.C. 331(c). RFAAX 4 (Judgment, *U.S.* v. *William Ralph Kinkaid,* No. 2:12–CR–116 (E.D. Tenn. June 24, 2013)). In Respondent's guilty plea, he stipulated to a number of facts, which satisfied the offense elements. RFAAX 3 (Plea Agreement, *U.S.* v. *William Ralph Kinkaid,* No. 2:12–CR–116 (E.D. Tenn. June 24, 2013)). In summary, Respondent admitted that he was majority owner and managing partner of McLeod Cancer and Blood Center in Johnson City, Tennessee (hereinafter, McLeod Cancer). *Id.* at 2. McLeod Cancer bought misbranded, unapproved prescription drugs, which were prescribed by Respondent and other doctors and administered to patients at McLeod Cancer from approximately September 2007 to early 2008 and from August 2009 to February 2012. *Id.* at 2, 5. The drugs were from foreign sources that were not inspected and approved by the U.S. Food and Drug Administration for distribution or use in the United States. *Id.* at 2–5. McLeod Cancer sought reimbursement for the drugs and their administration from Medicare, Medicaid, and other health benefit programs. *Id.* at 2. After nurses at McLeod Cancer raised concerns that the drugs were not approved for use in the United States, McLeod Cancer briefly stopped purchasing the drugs. *Id.* at 5–6. When McLeod Cancer resumed purchasing the unapproved drugs, they had the drugs shipped to a storage business that Respondent owned to prevent the nurses from learning McLeod Cancer was again purchasing unapproved foreign drugs. *Id.* at 6.

As a result of his conviction, Respondent was sentenced to 24 months in federal detention, followed by a year of supervised release. RFAAX 4, at 2–3. He was also fined $10,000 and assessed $100 in costs. *Id.* at 4.

c. Respondent's Exclusion

In June 2013, Respondent entered into a Settlement Agreement with the United States of America, in which he agreed ''to be excluded under [42 U.S.C. 1320a–7(a)(1) and 42 U.S.C. 1320a–7(b)(7)] from Medicare, Medicaid, and all Federal health care programs, as defined in 42 U.S.C. 1320a–7b(f), for a period of ten (10) years.'' RFAAX 5 (Settlement Agreement), at 7. Respondent also agreed to pay $2,550,000 to the United States and to the State of Tennessee in damages and penalties. *Id.* at 3.

d. Respondent's State Medical License

On July 22, 2015, the Tennessee Department of Health held a hearing regarding Respondent's state medical license. Response to the OSC, Ex. 10 (Deliberations and Decision of the Panel, *State of Tennessee Board of Medical Examiners* v. *William Kincaid, M.D.*). At the hearing, the panel voted to revoke Respondent's license. *Id.* In the transcript from the hearing, the two panelists who voted to revoke Respondent's license explained that they were voting for revocation because Respondent had knowingly violated the law, *id.* at 4, 8, 13; had placed business interests ahead of his responsibilities to his patients, *id.* at 5–6; and the discipline ''should reflect the severity of what he did,'' *id.* at 14. The panel, however, did not vote for a permanent revocation. One of the panelists explained her vote for non-permanent revocation this way, ''I believe that the doctor is a good doctor who should be rehabilitated, but it's up to him to rehabilitate himself for at least a year and come back.'' *Id.* at 13.

Respondent reapplied for a state medical license, and the State of Tennessee decided to grant him a limited medical license under a preceptorship on October 4, 2017. Response to the OSC, Ex. 12 (Oct. 4, 2017 Letter from Tennessee Board of Medical Examiners). The State of Tennessee subsequently granted Respondent a medical license on July 24, 2018. Response to the OSC, Ex. 13 (Respondent's Medical License).

II. Discussion

a. The Parties' Positions

i. Government's Position

The OSC's sole allegation is that Respondent's exclusion from all federal health care programs pursuant to 42 U.S.C. 1320a–7(a) warrants denying his application under 21 U.S.C. 824(a)(5). OSC, at 2. The Government alleges that Respondent's exclusion was based on his guilty plea to one count of ''Receiving in Interstate Commerce a Misbranded Drug With Intent to Defraud or Mislead'' in violation of 21 U.S.C. 331(c). RFAA, at 1. The Government further alleges that Respondent's exclusion from Medicare, Medicaid, and all Federal health care programs warrants denial of his application notwithstanding the fact that the underlying conduct that led to his exclusion did not have a nexus to controlled substances. OSC, at 2.

The Government argues that 21 U.S.C. 824(a)(5) should be read ''as requiring revocation (or denial) of a respondent's DEA certificate of registration (or application), upon an adequate showing of the factual predicate, at least for the duration of the mandatory exclusion.'' RFAA, at 4. Accordingly, the Government has presented evidence that Respondent is excluded from participation in Federal health care programs pursuant to 42 U.S.C. 1320a–7(a) but has not presented any additional evidence or arguments regarding why Respondent's application for registration should be denied.

ii. Respondent's Position

Respondent filed a written statement in response to the Government's OSC. Respondent's Response to the OSC included a number of exhibits with

documentary evidence to support his arguments, a first-person statement written from Respondent to the Tennessee Board of Medical Examiners, and dozens of letters that members of Respondent's community wrote on Respondent's behalf to the judge in Respondent's criminal case prior to sentencing. Respondent does not contest the Government's allegation that he is excluded from Federal health care programs pursuant to 42 U.S.C. 1320a–7(a). Respondent acknowledges that on June 24, 2013, he was convicted of receiving in interstate commerce a misbranded drug in violation of 21 U.S.C. 331(c) and that as a result of that conviction, he was ''mandatorily excluded from all Federal healthcare programs by HHS/OIG for ten years from the date of conviction.'' Response to the OSC, at 1. Respondent argues, however, that DEA should grant his application for a controlled substances registration in spite of his exclusion.

Respondent's Response to the OSC outlines his education and employment history, provides ''background'' information on his criminal offense, and discusses the loss of his state medical license and his re-licensure.[1] In his first-person statement, Respondent briefly described how he came to be the senior partner and business manager for his clinic, McLeod Cancer. Respondent stated that he was ''ill-equipped as the business manager'' and that when the clinic hired a business manager, he thought ''[his] management problems were over.'' Response to the OSC, Ex. 1. Respondent then stated, however, ''[l]ittle did I know I was sowing the seeds of my own destruction. I let [the business manager] do as he pleased, not realizing the full extent of the consequences and the depth of his treachery.'' *Id.*

Respondent states that after hiring the business manager, McLeod Cancer decided to purchase drugs from a particular supplier because they were ''cost-effective,'' but stopped because ''of concerns about applicable FDA regulations and laws.'' Response to the OSC, at 3. The McLeod Cancer physicians and business manager then sought a legal opinion from a private attorney ''on whether purchasing drugs from Canada for use in the United States was illegal.'' *Id.* Respondent submitted the attorney's response to the record as an exhibit to his Response to the OSC. *Id.* at Ex. 3. After receiving the attorney's opinion, Respondent decided to resume purchasing drugs from the supplier. *Id.* at Ex. 4, at 3. Respondent states that he ''interpreted the opinion paper as approving the practice,'' but now admits ''he was wrong and did not understand the possible significance of a 'technical violation' and resulting consequences.'' *Id.*

b. Analysis of Respondent's Application for Registration

In this matter, the OSC calls for my adjudication of the application for registration based on the charge that Respondent was excluded from participation in a program pursuant to section 1320a–7(a) of Title 42, which is a basis for revocation or suspension under 21 U.S.C. 824(a)(2). OSC, at 1–2. The OSC does not allege that granting Respondent's application would be inconsistent with the public interest based on consideration of the factors in 21 U.S.C. 823(f)(1) through (5) (hereinafter, the public interest factors).

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, Agency decisions have concluded that it is. *Robert Wayne Locklear, M.D.,* 86 FR 33,738, 33,744–45 (2021) (collecting cases). In the recent decision *Robert Wayne Locklear, M.D.,* the former Acting Administrator stated his agreement with the results of these past decisions and reaffirmed that a provision of section 824 may be the basis for the denial of a practitioner registration application. 86 FR at 33,745. He also clarified that allegations related to section 823 remain relevant to the adjudication of a practitioner registration application when a provision of section 824 is involved. *Id.*

Accordingly, when considering an application for a registration, I will consider any allegations related to the grounds for denial of an application under 823 and will also consider any allegations that the applicant meets one of the five grounds for revocation or suspension of a registration under section 824. *Id. See also Dinorah Drug Store, Inc.,* 61 FR 15,972, 15,973–74 (1996).

i. 21 U.S.C. 823(f): The Five Public Interest Factors

Pursuant to section 303(f) of the 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). Section 303(f) 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, or conducting research with respect to 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.

21 U.S.C. 823(f).

In this case, it is undisputed that Respondent holds a valid state medical license and is authorized to dispense controlled substances in the State of Tennessee where he practices. Response to the OSC, Ex. 12, 13. The Government did not allege that Respondent's registration would be inconsistent with the public interest pursuant to section 823 in the OSC and did not advance any arguments or present any evidence under the public interest factors in its RFAA. *See* RFAA; RFAAX 2. Instead, the Government based its case in section 824 alleging that Respondent's conviction of receiving a misbranded drug with intent to defraud or mislead and his subsequent exclusion from federal health care programs by the U.S. Department of Health and Human Services merit the denial of his registration under 21 U.S.C. 824(a)(5). RFAA, at 1–4. Because the Government has not alleged that Respondent's registration is inconsistent with the public interest under section 823, I will not deny Respondent's application based on section 823, and although I have considered 823, I will not analyze Respondent's application under the

[1] Respondent also included descriptions of the Department of Justice's conduct during its investigation and prosecution of his criminal case and dedicated a full page of his seven-page Response to the OSC (and attached dozens of pages of exhibits) to a criminal case that is unrelated, but Respondent states is factually similar, to Respondent's criminal case. Respondent presented documentation that, in this unrelated case, the Department of Justice moved to dismiss the case with prejudice when the defendants appealed their conviction. *See* Response to the OSC, at 3–5; Ex. 9 (Motion to Vacate Judgments of Conviction and Remand for Dismissal of Indictment with Prejudice, *United States of America* v. *Patricia Posey Sen and Anindya Kumar Sen,* Nos. 14–5786 (6th Cir. December 15, 2014). I am not addressing these portions of Respondent's Response to the OSC because this is not the proper forum to appeal Respondent's criminal conviction or to address any grievances Respondent may have regarding actions taken by the Department of Justice in relation to Respondent's criminal case.

public interest factors. Therefore, in accordance with prior agency decisions, I will move to assess whether the Government has proven by substantial evidence that a ground for revocation exists under 21 U.S.C. 824(a). *Supra* II.b.

ii. 21 U.S.C. 824(a)(5): Mandatory Exclusion From Federal Health Care Programs Pursuant to 42 U.S.C. 1320a–7(a)

Under Section 824(a) of the Controlled Substances Act (hereinafter, CSA), a registration ''may be suspended or revoked'' upon a finding of one or more of five grounds. 21 U.S.C. 824. The ground in 21 U.S.C. 824(a)(5) requires that the registrant ''has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of Title 42.'' *Id.* Here, there is no dispute in the record that Registrant is mandatorily excluded from federal health care programs under 42 U.S.C. 1320a–7(a). The Government has presented substantial evidence of Respondent's exclusion and the underlying criminal conviction that led to that exclusion, and Respondent has admitted to the same. RFAAX 4, 5; Response to the OSC, at 1. I will, therefore, sustain the Government's allegation that Respondent has been excluded from participation in a program pursuant to section 1320a–7(a) of Title 42 and find that the Government has established that a ground exists upon which a registration could be revoked pursuant to 21 U.S.C. 824(a)(5).[2]

Although the language of 21 U.S.C. 824(a)(5) discusses suspension and revocation of a registration, for the reasons discussed above, it may also serve as the basis for the denial of a DEA registration application. *Robert Wayne Locklear, M.D.,* 86 FR at 33,745–46; *Dinorah Drug Store, Inc.,* 61 FR at 15,973 (interpreting 21 U.S.C. 824(a)(5) to serve as a basis for the denial of a registration because it ''makes little sense . . . to grant the application for registration, only to possibly turn around and propose to revoke or suspend that registration based on the registrant's exclusion from a Medicare program''). Accordingly, Respondent's exclusion from participation in a program under 42 U.S.C. 1320a–7(a) serves as an independent basis for denying his application for DEA registration. 21 U.S.C. 824(a)(5).

III. Sanction

The Government can meet its burden in a case involving a registrant who has been excluded from federal health care programs simply by showing evidence of the exclusion and the underlying conviction. Further, DEA has long held that the underlying conviction forming the basis of a registrant's mandatory exclusion from participation in Federal health care programs need not involve controlled substances for DEA to issue a sanction pursuant to 21 U.S.C. 824(a)(5). *Jeffrey Stein, M.D.,* 84 FR 46,968, 46,971–71 (2019); *Richard Hauser, M.D.,* 83 FR at 26,310.

The Government argues that in cases brought pursuant to 21 U.S.C. 824(a)(5), the statutory language *requires* DEA to revoke a respondent's registration (or deny a respondent's application) once the Government has proven that a respondent is mandatorily excluded from participation in Federal health care programs and that DEA should not permit a respondent to have a DEA registration for as long as the respondent is excluded. RFAA, at 4. Since the Government filed the RFAA, however, the Agency issued a Decision and Order in another exclusion case, in which the Government made the same argument, *Jeffrey Stein, M.D.,* that directly addressed and rejected the Government's argument. 84 FR 46,968 (2019); *see also Kansky J. Delisma, M.D.,* 85 FR 23,845 (2020).

The clear language of 21 U.S.C. 824(a)—''[a] registration . . . may be suspended or revoked by the Attorney General''—gives the Administrator the *discretion* to revoke the registration of a registrant who has been excluded from participation in Federal health programs. *Jeffrey Stein, M.D.,* 84 FR at 46,970–71 (providing detailed analysis of the language and legislative history of 21 U.S.C. 824(a)(5)). It does not require automatic revocation or denial on that ground. *Id.* Accordingly, although section 824(a) provides DEA with the authority to revoke a respondent's registration (or deny an application) upon a finding of one or more of the five listed grounds, if a respondent presents evidence, either in a written statement or in the context of a hearing, I will review the evidence provided by the respondent to determine whether revocation or suspension (or denial) is appropriate given the particular facts. *See* 5 U.S.C. 556(d) (''A party is entitled to present his case or defense by oral or documentary evidence.''); 21 CFR 1301.43(c) (permitting a Respondent to file ''a waiver of an opportunity for a hearing . . . together with a written statement regarding such person's position on the matters of fact and law involved in such hearing.''); *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 829 (11th Cir. 2018) (''[W]e may set aside a decision as 'arbitrary and capricious when, among other flaws, the agency has . . . entirely failed to consider an important aspect of the problem.' ''); *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 177 (D.C. Cir. 2005) (''To uphold DEA's decision, . . . we must satisfy ourselves 'that the agency ''examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.' '').

Where, as in the instant case, the Government has established a ground to deny a registration, I will review any evidence and argument the respondent submitted to determine whether or not respondent has presented ''sufficient mitigating evidence to assure the Administrator that [he] can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988)). '' 'Moreover, because ''past performance is the best predictor of future performance,'' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Samuel S. Jackson, D.D.S.,* 72 FR at 23,853; *John H. Kennnedy, M.D.,* 71 FR 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62,884, 62,887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

In evaluating the degree required of a respondent's acceptance of responsibility to entrust him with a

[2] The Government correctly argues, and Respondent did not rebut, that the underlying conviction forming the basis for a registrant's mandatory exclusion from participation in federal health care programs need not involve controlled substances to provide the grounds for revocation or denial pursuant to section 824(a)(5). *Jeffrey Stein, M.D.,* 84 FR 46,968, 46,971–72 (2019); *see also Narciso Reyes, M.D.,* 83 FR 61,678, 61,681 (2018); *KK Pharmacy,* 64 FR 49,507, 49,510 (1999) (collecting cases); *Melvin N. Seglin, M.D.,* 63 FR 70,431, 70,433 (1998); *Stanley Dubin, D.D.S.,* 61 FR 60,727, 60,728 (1996).

registration, in *Mohammed Asgar, M.D.,* the Agency looked for ''unequivocal acceptance of responsibility when a respondent has committed knowing or intentional misconduct.'' 83 FR 29,569, 29,572 (2018) (citing *Lon F. Alexander, M.D.,* 82 FR 49,704, 49,728). Here, Respondent pled guilty to a criminal charge involving intentional misconduct—''Receiving in Interstate Commerce a Misbranded Drug with Intent to Defraud or Mislead.'' I will, therefore, look for a clear acceptance of responsibility from Respondent.

Respondent took concrete actions to accept responsibility for his misconduct while his criminal case was ongoing. He did so by pleading guilty to the charge in Federal Court and entering into a settlement agreement with the United States of America and the State of Tennessee. Respondent's Response to the OSC also states, ''[Respondent] has admitted his mistakes and taken responsibility for his actions with his freedom and money.'' Response to the OSC, at 6.

During the pendency of this matter, however, Respondent has not made any statements accepting responsibility or expressed remorse for his actions. *See id.* To the contrary, Respondent made arguments in his Response to the OSC that deflect or minimize responsibility for his actions. In a first-person statement, which he attached as an exhibit to his Response to the OSC, Respondent appeared to place the blame for the actions leading to his criminal conviction on his clinic's business manager. *See id.* at Ex. 1. In reference to hiring the business manager for the clinic, Respondent stated, ''[l]ittle did I know I was sowing the seeds of my own destruction. I let [the business manager] do as he pleased, not realizing the full extent of the consequences and the depth of his treachery.'' *Id.* I am troubled by this statement and its implications for Respondent's acceptance of responsibility.

Respondent's guilty plea and evidence entered into the record by Respondent himself demonstrate that Respondent was not an unknowing and naive participant in the scheme that led to his conviction. Respondent admitted as part of his plea that clinic nurses raised concerns about the misbranded drugs, which led to the clinic doctors deciding to stop ordering the drugs. Later, Respondent ''decided McLeod Cancer would resume purchasing misbranded unapproved drugs . . . [and that] [t]o prevent the nurses from learning that McLeod Cancer was again purchasing unapproved foreign drugs, [Respondent] directed [the clinic's business manager] to have the drugs shipped to a storage business in Johnson City which [Respondent] owned in part.'' RFAAX 3 (Plea Agreement, *U.S.* v. *William Ralph Kinkaid,* No. 2:12–CR–116 (E.D. Tenn. June 24, 2013)). Respondent also submitted to the record a letter written by an attorney addressing whether Respondent's clinic was ''breaking federal law by importing foreign prescription drugs for use in the United States.'' Response to the OSC, Ex. 3. While the attorney greatly downplayed the significance of the legal violation, particularly focusing on the lack of enforcement by the Food and Drug Administration (hereinafter, FDA) and referencing the importation of the drugs as ''a technical violation,'' he did state the FDA could enforce if it chose to do so. *Id.* Respondent decided to resume purchasing the misbranded unapproved drugs after receiving this opinion.

Respondent's decision to resume purchasing the misbranded unapproved drugs after receiving an opinion that doing so was a ''technical violation'' that the FDA was unlikely to enforce creates concern about whether Respondent can be entrusted with the responsibilities of a controlled substances registration. If Respondent were to violate part of the CSA that he considered to be a ''technical violation,'' based on a perception of limited Agency enforcement, it could impact the Agency's mission in preventing the diversion and misuse of controlled substances. DEA budgets for approximately 1,625 Diversion positions involved in regulating more than 1.8 million registrants overall.[3] Ensuring that a registrant is trustworthy to comply with all relevant aspects of the CSA without constant oversight is crucial to the Agency's ability to complete its mission of preventing diversion within such a large regulated population. *Jeffrey Stein, M.D.,* 84 FR at 46,974.

Had there been a hearing on the OSC, it is possible that Respondent could have clarified his statements regarding his business manager and his reasoning for presenting the private attorney's opinion regarding purchasing the misbranded drugs. But with such limited information from Respondent, his statements and presentation of the attorney's opinion that purchasing the misbranded drugs was a ''technical violation'' appear to be aimed at minimizing the egregiousness of his conduct, which the Agency has previously weighed against a finding of acceptance of full responsibility. *See Ronald Lynch, M.D.,* 75 FR 78,745, 78,754 (2010) (Respondent did not accept responsibility noting that he ''repeatedly attempted to minimize his [egregious] misconduct''; *see also Michael White, M.D.,* 79 FR 62,957, 62,967 (2014) (finding that Respondent's ''acceptance of responsibility was tenuous at best'' and that he ''minimized the severity of his misconduct by suggesting that he thinks the requirements for prescribing Phentermine are too strict.''). In light of Respondent's minimization of his crime and his role in the crime, and the lack of a hearing to determine if Respondent's previous guilty plea and settlement agreement does, in fact, translate to sincere remorse and acceptance of responsibility, I cannot characterize Respondent's acceptance of responsibility as unequivocal.

In addition to acceptance of responsibility, the Agency also gives consideration to both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,810 (2015). Specific deterrence is the DEA's interest in ensuring that a registrant complies with the laws and regulations governing controlled substances in the future. *Id.* General deterrence concerns the DEA's responsibility to deter conduct similar to the proven allegations against the respondent for the protection of the public at large. *Id.* Where a respondent has committed a crime with no nexus to controlled substances, it is sometimes difficult to demonstrate that a sanction will have a useful deterrent effect. In this case, I believe a sanction would deter Respondent and the general registrant community from committing ''technical violations'' of the CSA or its implementing regulations and thinking that they could do so without serious consequence.

In Respondent's favor, Respondent has been held accountable for receiving misbranded drugs with intent to defraud or mislead, having been sentenced to prison, paying substantial financial penalties, and temporarily losing his medical license. I find that such significant consequences are likely to have some deterrent effect on Respondent repeating similar misconduct in the future. Additionally, according to Respondent's unrebutted claims, he has fully satisfied all requirements imposed upon him by the Federal courts and all terms of his settlement agreement with the United States of America and the State of Tennessee. Response to the OSC, at 3–4. He also satisfied all requirements imposed upon him by the state licensing

[3] *See* DEA FY2020 Budget Request *available at https://www.justice.gov/jmd/page/file/1142431/download.*

authorities to regain his medical license, including at least three months of practice under a preceptorship and the completion of forty hours of continuing medical education. *See* Response to the OSC, Ex. 12, 13. However, it is difficult to determine the amount of deterrence these consequences will have on Respondent due to the fact that he deflected responsibility for the underlying conduct.

Finally, Respondent submitted dozens of letters from former patients, colleagues, and community members regarding his aptitude as a physician and compassionate nature. Response to the OSC, Ex. 14. While these character references do not diminish Respondent's bad acts, I find the letters to be personal and sincere in their written form. They can be of limited weight in this proceeding, however, because I have limited ability to assess the actual credibility of the references given their written form. *See Michael S. Moore, M.D.,* 76 FR 45,867, 45,873 (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). They also were not written for the purposes of recommending that Respondent be granted a controlled substances registration, and, therefore, they offer little value in assessing the Respondent's suitability to discharge the duties of a DEA registrant. Further, absent Respondent's unequivocal acceptance of responsibility, what little value the letters might have offered me in evaluating my ability to trust Respondent is nullified by the fact that he himself has not shown me that he can be so entrusted.

As discussed above, to receive a registration when grounds for denial exist, a respondent must convince the Administrator that his acceptance of responsibility and remorse are sufficiently credible to demonstrate that the misconduct will not recur and that he can be entrusted with a registration. Having reviewed the record in its entirety, I find that Respondent has not met this burden. Although Respondent did take some responsibility for his actions through his guilty plea and settlement agreement with the United States and the State of Tennessee, his acceptance of responsibility was not unequivocal. Respondent's minimization and deflection of responsibility for his criminal conduct raises concern that he would perhaps also be willing to circumvent CSA requirements that he deemed ''technical'' to the detriment of its effective implementation. I am also concerned that granting his registration absent a full acceptance of responsibility for his criminal actions would send the message to the registered community that they could violate so-called ''technical'' provisions of the CSA or its regulations without serious consequence. Unless and until Respondent is willing to credibly accept full responsibility for his unlawful conduct, I find that I cannot entrust him with a controlled substances registration. Accordingly, I will order the Agency to deny Respondent's application for a certificate of registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823, I hereby order that the pending application for a Certificate of Registration, Control Number W18085586C, submitted by William Ralph Kincaid, M.D., is denied. This Order is effective August 27, 2021.

Anne Milgram,

Administrator.

[FR Doc. 2021–16004 Filed 7–27–21; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Erica N. Grant, M.D.; Decision and Order

I. Introduction

On August 24, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Erica N. Grant, M.D. (hereinafter, Respondent) of Irving, Texas. OSC, at 1. The OSC proposed the revocation of Respondent's Certificate of Registration No. FG2374053 for three reasons. *Id.* First, it alleged that Respondent was ''convicted of a felony under State law relating to a controlled substance.'' *Id.* (citing 21 U.S.C. 824(a)(2)). Second, it alleged that it was ''inconsistent with the public interest'' for Respondent to maintain her registration. OSC, at 1 (citing 21 U.S.C. 824(a)(4) in conjunction with 21 U.S.C. 823(f)). Third, the OSC alleged that Respondent ''materially falsified the application'' for renewal of her registration. OSC, at 1 (citing 21 U.S.C. 824(a)(1)).

Specifically, the OSC alleged that Respondent's ''no contest'' plea to a second-degree felony in Texas, ''Attempting to Possess a Controlled Substance by Fraud in violation of Texas Health and Safety Code § 481.129,'' ''is a conviction providing a sufficient basis for the revocation'' of her registration. OSC, at 2, 3. Further, the OSC alleged that, ''[t]o determine what is in the 'public interest,' DEA considers, among other things, the registrant's 'conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.' '' *Id.* at 2. Finally, according to the OSC, ''DEA may revoke a registrant's DEA . . . [registration] upon a finding that the registrant materially falsified any application filed pursuant to, or required by, the Controlled Substances Act'' (hereinafter, CSA), such as by a ''failure to report . . . [an] arrest for a controlled substance felony.'' *Id.* at 2, 3.

The OSC notified Respondent 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.* at 3 (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. OSC, at 3–4 (citing 21 U.S.C. 824(c)(2)(C)).

By transmittal dated September 21, 2018, Respondent waived her right to a hearing and filed a written statement and a proposed Corrective Action Plan. Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, collectively, RFAAX) 10 (Respondent's Hearing Waiver and Written Statement in Response to the OSC (hereinafter, Written Statement)) and RFAAX 11 (Respondent's Request for Corrective Action Plan (hereinafter, CAP)).[1] Respondent's written statement explicitly references her receipt of the OSC.[2] RFAAX 10, at 1.

Based on all of the evidence in the record, I find that the Government's service of the OSC was legally sufficient. In addition, also based on all of the evidence in the record, I find that Respondent timely filed her Written Statement and proposed CAP.[3]

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[1] RFAAX 12 is the DEA Assistant Administrator's letter to Respondent, dated January 29, 2019, rejecting her proposed CAP.

[2] In addition, the RFAA represents that ''Respondent acknowledged service of a copy of the . . . [OSC] in a telephone conversation with [a] DEA Diversion Investigator.'' RFAA, at 3 (citing RFAAX 9 (Declaration of Diversion Investigator (hereinafter, DI), dated October 1, 2018), at 2).

[3] Respondent's Written Statement is dated September 21, 2018. It appears that Respondent transmitted her proposed CAP along with her Written Statement. The OSC is dated August 24, 2018; therefore, Respondent's submissions are

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