

of Registration No. BS6061345 issued to Nicky Shah, M.D. 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 applications of Nicky Shah, M.D., to renew or modify this registration, as well as any other pending application of Nicky Shah, M.D., for additional registration in California. This Order is effective December 8, 2022.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 1, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–24299 Filed 11–7–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

George M. Douglass, M.D.; Decision and Order

On June 28, 2022, the Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC/ISO) to George M. Douglass, Jr., M.D., (hereinafter, Registrant) of Lake Oswego, Oregon. Request for Final Agency Action (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 2 (OSC/ISO), at 1. The OSC/ISO informed Registrant of the immediate suspension of his DEA Certificate of Registration, Control No. BD5898575, pursuant to 21 U.S.C. 824(d), alleging that Registrant's continued registration constitutes “an imminent danger to the public health or safety.” *Id.* The OSC/ISO also proposed the revocation of Registrant's registration, alleging that Registrant has “committed such acts as would render [his] registration inconsistent with the public interest” and that Registrant is “without authority to handle controlled

substances in Oregon, the state in which [he is] registered with DEA.”¹ *Id.* at 1, 3 (citing 21 U.S.C. 824(a)(4), 823(f), 824(a)(3)).

The Agency makes the following findings of fact based on the uncontroverted evidence submitted by the Government in its RFAA dated September 20, 2022.²

I. Findings of Fact

On June 2, 2022, the Oregon Medical Board issued a Final Order Upon Default revoking Registrant's Oregon medical license. RFAAX 3, at 4, 7. According to Oregon's online records, of which the Agency takes official notice, Registrant's license is still revoked.³ Oregon Medical Board License Search, <https://omb.oregon.gov/search> (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not currently licensed to engage in the practice of medicine in Oregon, the state in which he is registered with the DEA.

The Agency further finds that the Government's evidence shows that Registrant continued to prescribe controlled substances after his Oregon medical license was revoked; he issued at least six controlled substance prescriptions from June 9–21, 2022. RFAAX 4.

II. Discussion

A. 21 U.S.C. 824(a)(3): Loss of State Authority

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to

¹ The registered address of Registrant's DEA Certificate of Registration, Control No. BD5898575, is 17355 Boones Ferry Road, Suite C, Lake Oswego, Oregon 97035. *Id.* at 2.

² Based on a Declaration from a DEA Diversion Investigator, the Agency finds that the Government's service of the OSC/ISO on Registrant was adequate. RFAAX 3, at 2. Further, based on the Government's assertions in its RFAA, the Agency finds that more than thirty days have passed since Registrant was served with the OSC/ISO and Registrant has neither requested a hearing nor submitted a written statement or corrective action plan and therefore has waived any such rights. RFAA, at 2; *see also* 21 CFR 1301.43 and 21 U.S.C. 824(c)(2).

³ Under the Administrative Procedure Act, an agency “may take official notice of facts at any stage in a proceeding—even in the final decision.” United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), “[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.” Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at dea.addo.attorneys@dea.usdoj.gov.

suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) “upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.” With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.*, 76 FR 71,371 (2011), *pet. for rev. denied*, 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 FR 27,616, 27,617 (1978).⁴

According to Oregon statute, “dispense” means “to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, and includes the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.” Or. Rev. Stat. § 475.005(10) (2022). Further, a “practitioner” means a person “licensed, registered or otherwise permitted by law to dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in [the] state.” *Id.* at § 475.005(17).

Here, the undisputed evidence in the record is that Registrant has had his Oregon medical license revoked and thus lacks authority to practice medicine in Oregon. As discussed above, an individual must be a licensed practitioner to dispense a controlled

⁴ This rule derives from the text of two provisions of the CSA. First, Congress defined the term “practitioner” to mean “a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.” 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that “[t]he Attorney General shall register practitioners . . . 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). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper*, 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.*, 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.*, 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton*, 43 FR at 27,617.

substance in Oregon. Accordingly, the Agency finds that Registrant is unauthorized to handle controlled substances in Oregon, the state in which he is registered with the DEA.

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

Section 304(a) of the CSA provides that “[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.” 21 U.S.C. 824(a). In making the public interest determination, the CSA requires consideration of the following factors:

(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).

The DEA considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15,227, 15,230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. Drug Enf’t Admin.*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 FR 37,507, 37,508 (1993). While the Agency has considered all of the public interest factors⁵ in 21 U.S.C. 823(f), the Government’s evidence in support of its *prima facie* case for revocation of Registrant’s registration is confined to Factors One, Two, and Four.

⁵ As to Factor Three, there is no evidence in the record that Registrant has been convicted of an offense under either federal or state law “relating to the manufacture, distribution, or dispensing of controlled substances.” 21 U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.*, 75 FR 49,956, 49,973 (2010). Agency cases have therefore found that “the absence of such a conviction is of considerably less consequence in the public interest inquiry” and is therefore not dispositive. *Id.* As to Factor Five, the Government’s evidence fits squarely within the parameters of Factors One, Two, and Four and does not raise “other conduct which may threaten the public health and safety.” 21 U.S.C. 823(f)(5). Accordingly, Factor Five does not weigh for or against Registrant.

See RFAA, at 6–8. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44.

Here, the Agency finds that the Government’s evidence satisfies its *prima facie* burden of showing that Registrant’s continued registration would be “inconsistent with the public interest.” 21 U.S.C. 824(f). The Agency further finds that Registrant failed to provide sufficient evidence to rebut the Government’s *prima facie* case.

1. Factor One

In determining the public interest under Factor One, the Agency considers the recommendation of the appropriate State licensing board or professional disciplinary authority. Although the record evidence demonstrates that the Oregon Medical Board has not made a recommendation in the current matter, “DEA has interpreted [F]actor [O]ne more broadly and thus considers disciplinary actions taken by a state board as relevant in the public interest determination when they result in a loss of state authority.” *Kenneth Harold Bull, M.D.*, 78 FR 62,666, 62,672 (2013); see also *John O. Dimowo*, 85 FR 15,800, 15,809 (2020).

Here, the record shows that the Oregon Medical Board revoked Registrant’s Oregon medical license and that Registrant’s Oregon medical license has not since been restored. As such, the Agency finds that Factor One weighs against Registrant’s continued registration.

2. Factors Two and Four

Evidence is considered under Public Interest Factors Two and Four when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. Established violations of the CSA, DEA regulations, or other laws regulating controlled substances at the state or local level are cognizable when considering whether continuing a registration is consistent with the public interest. *Kareem Hubbard, M.D.*, 87 FR 21,156, 21,162 (2022).

The Government has alleged that Registrant has violated both federal and Oregon state law regulating controlled substances. RFAAX 2 (OSC/ISO), at 3–4. According to the CSA’s implementing regulations, a lawful controlled substance order or prescription is one that is “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a). Oregon law prohibits the practice of medicine in Oregon without a license. Or. Rev. Stat. § 677.080(4)

(2022). Here, the record demonstrates that Registrant issued at least six controlled substance prescriptions after his Oregon medical license was revoked. This conduct clearly violated Oregon law and rendered Registrant’s prescribing outside the usual course of professional practice. As such, the Agency sustains the Government’s allegations that Registrant violated 21 CFR 1306.04(a) and Or. Rev. Stat. § 677.080(4).

In sum, the Agency finds that Factors One, Two, and Four weigh in favor of revocation of Registrant’s registration and thus finds Registrant’s continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(f).

III. Sanction

Where, as here, the Government has established grounds to revoke Respondent’s registration, the burden shifts to the respondent to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18,882, 18,910 (2018). When a registrant has committed acts inconsistent with the public interest, he must both accept responsibility and demonstrate that he has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195*, 77 FR 62,316, 62,339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency’s interest in deterring similar acts. See, e.g., *Robert Wayne Locklear, M.D.*, 86 FR 33,738, 33,746 (2021).

Here, Registrant did not request a hearing, submit a written statement, submit a corrective action plan, respond to the OSC/ISO, or otherwise avail himself of the opportunity to refute the Government’s case. As such, Registrant has made no representations as to his future compliance with the CSA or made any demonstration that he can be trusted with a registration. The evidence presented by the Government clearly shows that Registrant violated the CSA and indicates that he cannot be entrusted.

Accordingly, the Agency will order the revocation of Registrant’s registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C.

824(a), I hereby revoke DEA Certificate of Registration No. BD5898575 issued to George M. Douglass, Jr., M.D. 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 applications of George M. Douglass, Jr., M.D., to renew or modify this registration, as well as any other pending application of George M. Douglass, Jr., M.D., for additional registration in Oregon. This Order is effective December 8, 2022.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 1, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022-24301 Filed 11-7-22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1083]

Bulk Manufacturer of Controlled Substances Application: Chattem Chemicals, Inc.; Correction

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application; correction.

SUMMARY: The Drug Enforcement Administration (DEA) published a document in the **Federal Register** on October 11, 2022, concerning a notice of application that inadvertently did not include the controlled substance Cocaine (9041).

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** on October 11, 2022, in FR Doc No: 2022-21940 (87 FR 61368), on page 61368, in the second column, under **SUPPLEMENTARY INFORMATION**, controlled substance table,

correct the table to include the following basic class of scheduled controlled substance:

Controlled substance	Drug code	Schedule
Cocaine	9041	II

Kristi O'Malley,

Assistant Administrator.

[FR Doc. 2022-24105 Filed 11-7-22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22-34]

Gerald M. Baltz, N.P.; Decision and Order

On June 3, 2022, the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Gerald M. Baltz, N.P. (hereinafter, Respondent). OSC, at 1, 3. The OSC proposed the revocation of Respondent's Certificate of Registration No. MB2171128 at the registered address of 8060 Melrose Ave., Ste. 200, Los Angeles, CA 90046. *Id.* at 1. The OSC alleged that Respondent's registration should be revoked because Respondent is "without authority to handle controlled substances in the State of California, the state in which [he is] registered with DEA." *Id.* at 1-2 (citing 21 U.S.C. 824(a)(3)).¹

By letter dated July 11, 2022,² Respondent requested a hearing. On July 12, 2022, Administrative Law Judge Paul E. Soeffing (hereinafter, the ALJ) issued an Order for Evidence of Lack of State Authority and Directing the Government to File Evidence Regarding the Service of the Order to Show Cause (hereinafter, Briefing Order). On July 26, 2022, the Government filed its Submission of Evidence and Motion for Summary Disposition (hereinafter, Motion for Summary Disposition). On August 10, 2022,³ Respondent filed his

¹ According to Agency records, Respondent's Certificate of Registration No. MB2171128 expired on July 31, 2022. The fact that a registrant allows his registration to expire during the pendency of an OSC does not impact the Agency's jurisdiction or prerogative under the Controlled Substances Act (hereinafter, CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.*, 84 FR 68,474 (2019).

² The record demonstrates that service of the OSC on Respondent was accomplished on or before June 28, 2022, *see* Government Exhibit (hereinafter, GX) E, at 1-2, and the Government does not contest the timeliness of the request for a hearing.

³ The record demonstrates that Respondent's filing was untimely. *See* Briefing Order, at 2; Order Granting the Government's Motion for Summary

Opposition to Government's Motion for Summary Disposition (hereinafter, Opposition).⁴

On August 25, 2022, the ALJ granted the Government's Motion for Summary Disposition and recommended the revocation of Respondent's DEA registration, finding that because Respondent lacks authority to handle controlled substances in California, there is no genuine issue of material fact. Recommended Decision, at 6.⁵

The Agency issues this Decision and Order based on the entire record before it, 21 CFR 1301.43(e), and makes the following findings of fact.

Findings of Fact

On November 19, 2021, an Administrative Law Judge from the State of California, Office of Administrative Hearings, issued a Proposed Decision revoking Respondent's California nursing licenses. Government Exhibit (hereinafter, GX) C, at 45. On January 21, 2022, the State of California, Department of Consumer Affairs, Board of Registered Nursing (hereinafter, the Board), issued a Decision and Order adopting the Administrative Law Judge's Proposed Decision, effective February 18, 2022. *Id.* at 1. On February 24, 2022, the Board issued an Order Denying Reconsideration in which Respondent's request for reconsideration of the Proposed Decision was denied and the Board's January 21, 2022 Decision and Order was made effective February 28, 2022. GX B.

According to California's online records, of which the Agency takes official notice, Respondent's nursing licenses are revoked.⁶ California DCA

Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Recommended Decision), at 2 n.2. Nonetheless, the Agency will fully consider the Respondent's arguments made therein.

⁴ In his Opposition, Respondent argued that his DEA registration should not be revoked because he maintains active nursing licenses in Colorado and because he is still challenging the underlying action against his California nursing licenses. Opposition, at 3-6.

⁵ By letter dated September 21, 2022, the ALJ certified and transmitted the record to the Agency for final agency action and advised that neither party filed exceptions.

⁶ Under the Administrative Procedure Act, an agency "may take official notice of facts at any stage in a proceeding—even in the final decision." United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), "[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary." Accordingly,

Continued