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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Victor Augusto Silva, M.D.; Order

On February 22, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Victor Augusto Silva, M.D., of Tampa, Florida (Respondent). Request for Final Agency Action (RFAA), at 1; RFAA Exhibit (RFAAX) 1, at 1. The OSC/ISO informed Respondent of the immediate suspension of his DEA Certificate of Registration, No. FS3590266, pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes "an imminent danger to the public health or safety." RFAAX 1, at 1 (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Respondent's registration, No. FS3590266, alleging that Respondent's registration is inconsistent with the public interest. *Id.*

More specifically, the OSC/ISO alleged that Respondent allowed an unauthorized person to use his registration to prescribe controlled substances in violation of federal regulations and Florida law. RFAAX 1, at 1-3. On April 18, 2024, the Government submitted an RFAA to the Administrator requesting that the Agency issue a default final order revoking Respondent's registration. RFAA, at 1.

As a preliminary matter, this decision addresses whether or not Respondent is in default and finds that he is. Thereafter, the decision makes specific factual findings on the alleged violations as set forth in the OSC. Next, the decision considers whether Respondent's continued registration is inconsistent with the public interest by evaluating the found violations in the context of the public interest factors. Where, as here, the Agency determines that Respondent's continued registration is inconsistent with the public interest, the Respondent is then given an opportunity to argue for mitigation of the sanction by establishing that he can be trusted with a registration. After carefully reviewing the entire record and conducting the analysis as set forth

in more detail below, the Agency grants the Government's request for final agency action and revokes Respondent's registration.

I. Default Determination

Under 21 CFR 1301.43, a registrant entitled to a hearing who fails to file a timely hearing request "within 30 days after the date of receipt of the [OSC] . . . shall be deemed to have waived their right to a hearing and to be in default" unless "good cause" is established for the failure. 21 CFR 1301.43(a) & (c)(1). In the absence of a demonstration of good cause, a registrant who fails to timely file an answer also is "deemed to have waived their right to a hearing and to be in default." 21 CFR 1301.43(c)(2). Unless excused, a default constitutes "an admission of the factual allegations of the [OSC]." 21 CFR 1301.43(e).

Here, the OSC/ISO notified Respondent of his right to file with DEA a written request for a hearing and informed him that if he failed to file a hearing request or an answer, he would be deemed to have waived his right to a hearing and be in default. RFAAX 1, at 4. Respondent requested a hearing on April 2, 2024.[1] RFAAX 3, at 3. On April 3, 2024, the Government filed proof that it had served the OSC/ISO on Respondent on February 23, 2024. Government's Notice of Service, Exhibit A, at 1. Administrative Law Judge (ALJ) Teresa A. Wallbaum provided a briefing schedule for any Government motions related to the timeliness of Respondent's hearing request with an opportunity for Respondent to file a response addressing his reasons for failing to file the request for a hearing within the time provided by the OSC/ISO. Briefing Order Regarding Timeliness of Request for Hearing, at 1-2. Respondent's response to any Government motion was due on April 17, 2024. *Id.*, at 3. On April 4, 2024, the ALJ reminded Respondent of the filing deadline for his response. Order Regarding Status Conference, at 2. On April 10, 2024, the Government filed a motion to terminate proceedings.[2]

[1] Respondent submitted the hearing request electronically after 5:00 p.m. on April 1, 2024. Briefing Order Regarding Timeliness of Request for Hearing, at 1 & n.1 (citing 21 CFR 1316.45).
[2] The Government submitted the motion after 5:00 p.m. on April 9, 2024; the ALJ deemed it filed the following business day. RFAAX 3, at 2 n.3.

RFAAX 3, at 1-2; Government's Motion to Terminate Proceedings, at 1. When Respondent failed to file a response by the deadline, the ALJ issued an order on April 18, 2024, granting the Government's motion and terminating the administrative proceedings. RFAAX 3, at 2, 4.

The Government's RFAA to the Administrator requested that the Agency issue a final order revoking Respondent's registration on the basis that his continued registration is inconsistent with the public interest. RFAA, at 1 (citing 21 U.S.C. 824(a)(4)). The Government requested final agency action "pursuant to 21 CFR 1301.43(c) and (f) . . . , because Respondent has neither timely requested a hearing, nor provided answers for the [OSC/ISO]." *Id.*

Under these facts, the Agency finds that the ALJ's termination of the proceedings—where Respondent failed to timely file a request for a hearing and an answer and did not demonstrate good cause for the failures—was appropriate.[3] *See* RFAAX 3, at 3-4 (citing 21 CFR 1301.43(a) & (c)(2)-(f)(1), 1316.47). Thus, the Agency finds that that Respondent is in default and has admitted to the factual allegations in the OSC/ISO.[4] 21 CFR 1301.43(e).

II. State and Federal Law Regarding Permitting Unauthorized Use of a DEA Registration

As the Supreme Court stated in *Gonzales v. Raich*, 545 U.S. 1 (2005), "the main objectives of the [Controlled Substances Act (CSA)] were to conquer drug abuse and control the legitimate and illegitimate traffic in controlled substances." 545 U.S. at 12.

> Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense,

[3] Subsequent filings by Respondent, even if viewed as motions to excuse the default, also fail to establish good cause for the default. 21 CFR 1301.43(f)(2). Both the OSC/ISO and the Order for Prehearing Statements provided notice of the requirement to timely file an answer. Order for Prehearing Statements, at 2; RFAAX 1, at 4.

[4] The Government's RFAA notes that certain facts alleged in the OSC/ISO are incorrect and seeks to correct them. RFAA, at 3 n.2. According to the Government, the timeframe alleged in the OSC of "June 2023 to December 2023" should be corrected to "June 2022, to December 2023." *Id.* Thus, the Government seeks to expand the timeframe of one of the two OSC/ISO paragraphs (paragraph five) containing the details of the allegations of Respondent's unlawful prescribing of controlled substances. RFAAX 1, at 3. Although the Government may propose corrections to an OSC during a hearing process, *Judson J. Somerville, M.D.*, 82 FR 21408, 21408 n.1 (2017) (correcting registration number), a registrant's deemed "admission of the factual allegations" based on a default applies to the facts in the OSC only. 21 CFR 1301.43(e) ("A default, unless excused, shall be deemed to constitute . . . an admission of the factual allegations of the [OSC]."). Accordingly, the Agency is unable to deem the modified facts of paragraph five (as proposed by the Government in the RFAA) to be admitted. Nor will the Agency deem the original facts in that paragraph to be admitted where, as here, the Government has asserted that they are incorrect. 21 CFR 1301.43(e).

> or possess any controlled substance except in a manner authorized by the CSA . . . . The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.

Id. at 12-14.

According to the CSA's implementing regulations, prescriptions may only be issued by an individual practitioner who is "[a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession" and has either been issued a DEA registration or is exempted from registration under DEA regulations. 21 CFR 1306.03. Furthermore, 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). A "practitioner must establish and maintain a *bona fide* doctor-patient relationship in order to act 'in the usual course of . . . professional practice' and to issue a prescription for a 'legitimate medical purpose.'" *Dewey C. Mackay, M.D.*, 75 FR 49956, 49973 (2010). When a registrant entrusts his registration to another person, "this Agency has long held that a registrant is strictly liable for [its] misuse." *Kevin Dennis, M.D.*, 78 FR 52787, 52799 (2013).

Similarly, under Florida law, "[p]rescribing . . . a legend drug, including any controlled substance, other than in the course of the physician's professional practice" is grounds for disciplinary action. Fla. Stat. section 458.331(1)(q). Moreover, Florida law states that the act of "[a]iding, assisting, procuring, or advising any unlicensed person to practice medicine contrary to [Chapter 458 of Florida Statutes Title XXXII] or to a rule of the [Department of Health] or the [Board of Medicine]" is a basis for disciplinary action of a physician. Fla. Stat. sections 458.305(a)-(b), 458.331(1)(f). The practice of medicine includes "the prescription for any human disease, pain, injury, deformity, or other physical or mental condition." Fla. Stat. section 458.305(4).

Based on the above, the Agency finds that it is a violation of both Florida and federal law for a registrant to allow a person who is not licensed to practice medicine in Florida (and

therefore who is not authorized to prescribe controlled substances in Florida) to issue prescriptions for controlled substances using their DEA registration.

III. Findings of Fact

In light of Respondent's default, the factual allegations in the OSC—other than paragraph 5, which the Government asserts was incorrect, *supra* n.4—are deemed admitted. 21 CFR 1301.43(e). Accordingly, the Agency deems as admitted that Respondent allowed B.L., the owner of a medical clinic, to prescribe controlled substances using Respondent's registration in 2023. RFAAX 1, at 3. B.L. was not a licensed medical professional and was not authorized to perform medical examinations, make diagnoses, or prescribe controlled substances. *Id.* The Respondent continued to allow an unauthorized person to access his registration outside the usual course of professional practice as recently as December 2023. *Id.*

Accordingly, the Agency finds substantial record evidence that in the year 2023 Respondent allowed a person who was not licensed to practice medicine, and therefore was not authorized to prescribe controlled substances, to access his DEA registration and use it to prescribe controlled substances.

IV. Public Interest Determination

A. Legal Background on Public Interest Determinations

When the CSA's strict requirements are not met, the Attorney General "may deny, suspend, or revoke [a] registration if . . . the [registrant's] registration would be 'inconsistent with the public interest.'" *Gonzales v. Oregon*, 546 U.S. 243, 251 (2006) (quoting 21 U.S.C. 824(a)(4)). In the case of a "practitioner," Congress directed the Attorney General to consider five factors in making the public interest determination. *Id.*; 21 U.S.C. 823(g)(1)(A-E).[5]

[5] The five factors are:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(C) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

The five factors are considered in the disjunctive. *Gonzales v. Oregon*, 546 U.S. at 292-93 (Scalia, J., dissenting) ("It is well established that these factors are to be considered in the disjunctive," quoting *In re Arora*, 60 FR 4447, 4448 (1995)); *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993); *see Morall v. Drug Enf't Admin.*, 412 F.3d 165, 181 (D.C. Cir. 2005) (describing the Agency's adjudicative process as "applying a multi-factor test through case-by-case adjudication," quoting *LeMoyne-Owen Coll. v. N.L.R.B.*, 357 F.3d 55, 61 (D.C. Cir. 2004)). Any one factor, or combination of factors, may be decisive, *David H. Gillis, M.D.,* 58 FR 37508, and the Agency "may give each factor the weight . . . deem[ed] appropriate in determining whether a registration should be revoked or an application for registration denied." *Morall*, 412 F.3d. at 185 n.2 (Henderson, J., concurring) (quoting *Robert A. Smith, M.D.*, 70 FR 33207, 33208 (2007)); *see also Penick Corp. v. Drug Enf't Admin.*, 491 F.3d 483, 490 (D.C. Cir. 2007).

Moreover, while the Agency is required to consider each of the factors, it "need not make explicit findings as to each one." *MacKay v. Drug Enf't Admin.*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman v. U. S. Drug Enf't Admin.*, 567 F.3d 215, 222 (6th Cir. 2009)); *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 830 (11th Cir. 2018); *Hoxie v. Drug Enf't Admin.*, 419 F.3d 477, 482 (6th Cir. 2005). "In short, . . . 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." *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, Agency decisions have explained that findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

B. Respondent's Continued Registration Is Inconsistent with the Public Interest

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(E) Such other conduct which may threaten the public health and safety.
21 U.S.C. 823(g)(1)(A-E).

While the Agency has considered all the public interest factors of 21 U.S.C. 823(g)(1),[6] the Government's evidence in support of its *prima facie* case for sanction is confined to Factors B and D. RFAAX 1, at 3. Evidence is considered under Factors B and D when it reflects compliance or non-compliance with laws related to controlled substances and experience dispensing controlled substances. *Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022).

Here, the Respondent's conduct reflects negative experience in prescribing with respect to controlled substances. *See supra* Section III. Moreover, the Agency found substantial record evidence that in the year 2023 Respondent allowed a person who was not licensed to practice medicine, and therefore was not authorized to prescribe controlled substances, to access his DEA registration and use it to prescribe controlled substances. Accordingly, there is substantial record evidence in support of the Agency's finding that in 2023 Respondent committed violations of both Florida state law and federal controlled substance regulations, namely 21 CFR 1306.04(a) and Fla. Stat. section 458.331(f).

The Agency further finds that after balancing the factors of 21 U.S.C. 823(g)(1), Respondent's continued registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4). Accordingly, the Government satisfied its *prima facie* burden of showing that Respondent's continued registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4). The Agency also finds that there is insufficient mitigating evidence to rebut the Government's *prima facie* case. Thus, the only remaining issue is whether, in spite of the public interest determination, Respondent can be trusted with a registration.

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[6] As to Factor A, there is no record evidence of disciplinary action against Respondent's state medical license. 21 U.S.C. 823(g)(1)(A). State authority to practice medicine is "a necessary, but not a sufficient condition for registration." *Robert A. Leslie, M.D.*, 68 FR 15230. Therefore, "[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest." *Roni Dreszer, M.D.*, 76 FR 19434, 19444 (2011). As to Factor C, there is no evidence in the record that Respondent has been convicted of any federal or state law offense "relating to the manufacture, distribution, or dispensing of controlled substances." 21 U.S.C. 823(g)(1)(C). However, as Agency cases have noted, "the absence of such a conviction is of considerably less consequence in the public interest inquiry" and is therefore not dispositive. *Dewey C. MacKay, M.D.*, 75 FR 49973. As to Factor E, the Government's evidence fits squarely within the parameters of Factors B and D and does not raise "other conduct which may threaten the public health and safety." 21 U.S.C. 823(g)(1)(E). Accordingly, Factor E does not weigh for or against Respondent.

V. Sanction

Where, as here, the Government has met the burden of showing that Respondent's continued registration is inconsistent with the public interest, the burden shifts to Respondent to show why he can be entrusted with a registration. *Morall*, 412 F.3d. at 174; *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.*, 83 FR 18882, 18904 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent. *Jeffrey Stein, M.D.*, 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, the Agency requires that a registrant who has committed acts inconsistent with the public interest accept responsibility for those acts and demonstrate that it will not engage in future misconduct. *See Jones Total Health Care Pharmacy*, 881 F.3d at 833; *ALRA Labs, Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995). The Agency requires a registrant's unequivocal acceptance of responsibility. *Janet S. Pettyjohn, D.O.*, 89 FR 82639, 82641 (2024); *Mohammed Asgar, M.D.*, 83 FR 29569, 29573 (2018); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 830-31. In addition, a registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction. *See Jones Total Health Care Pharmacy*, 881 F.3d at 830-31; *Hoxie*, 419 F.3d at 483-84. Further, the Agency considers the egregiousness and extent of the misconduct as significant factors in determining the appropriate sanction. *See Jones Total Health Care Pharmacy*, 881 F.3d at 834 & n.4. The Agency also considers the need to deter similar acts by the respondent and by the community of registrants. *Jeffrey Stein, M.D.*, 84 FR 46972-73.

Here, Respondent filed an untimely hearing request, did not file an answer, and was found to be in default. RFAAX 3, at 3-4. Thus, there is no record evidence that Respondent takes responsibility, let alone unequivocal responsibility, for the misconduct. Accordingly, he

has not convinced the Agency that his future controlled-substance-related actions will comply with the CSA such that he can be entrusted with the responsibilities of a registration.

Further, the interests of specific and general deterrence weigh in favor of revocation. Respondent's conduct in this matter concerns the CSA's "strict requirements regarding registration" and, therefore, goes to the heart of the CSA's "closed regulatory system" specifically designed "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Raich*, 545 U.S. 1, 12-14 (2005). To permit Respondent to continue to maintain a registration under these circumstances would send a dangerous message that compliance with the law is not essential to maintaining a registration.

In sum, Respondent has not offered any credible evidence on the record that rebuts the Government's case for revocation of his registration, and Respondent has not demonstrated that he can be entrusted with the responsibility of registration. Accordingly, the Agency will order the revocation of Respondent's registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificate of Registration No. FS3590266 issued to Victor Augusto Silva, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby deny any other pending application of Victor Augusto Silva, M.D., for registration in Florida. This Order is effective **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

Signing Authority

This document of the Drug Enforcement Administration was signed on April 10, 2025, by Acting Administrator Derek Maltz. 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.

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