

by accessing its internet server at <https://www.usitc.gov>.

FOR FURTHER INFORMATION CONTACT:

Pathenia M. Proctor, the Office of Unfair Import Investigations U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2023).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on August 14, 2023, *Ordered that—*

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–4, 6, and 7 of the '577 patent; claim 1 of the '268 patent; and claims 1, 4–7, 9, 10, 14, and 15 of the '328 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is "LED fixtures, luminaires, downlights, bulbs, lamps, LED drivers, LED power supplies and components thereof".

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:
Signify North America Corporation, 400 Crossing Boulevard, Suite 600, Bridgewater, NJ 08807.
Signify Holding B.V., High Tech Campus 48, 5656 AE Eindhoven, The Netherlands.

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served:
Current Lighting Solutions, LLC, 25825 Science Park, Beachwood, OH 44122.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainants of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: August 15, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–17821 Filed 8–17–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Ndubuisi J. Okafor, M.D.; Decision and Order

On April, 10, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Ndubuisi J. Okafor, M.D. (Registrant) of Washington, DC. Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1.¹ The OSC/ISO informed Registrant of the immediate suspension of his DEA

¹ Registrant's registered address is 7603 Georgia Avenue NW, Suite 100, Washington, DC 20012. *Id.* 2.

Certificate of Registration No.

FO4353188 (registration) 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.* at 1. The OSC/ISO also proposed the revocation of Registrant's registration, alleging that Registrant's continued registration is inconsistent with the public interest. *Id.* (citing 21 U.S.C. 824(a)(4), 823(g)(1)).

The OSC/ISO notified Registrant of his right to file a written request for a hearing, and that if he failed to file such a request he would be deemed to be in default. *Id.* at 4 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing, RFAA, at 1.² "A default, unless excused, shall be deemed to constitute a waiver of the [registrant's] right to a hearing and an admission of the factual allegations of the [OSC/ISO]." 21 CFR 1301.43(e); *see also* RFAAX 1, at 4.

Further, "[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67." 21 CFR 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f) because Registrant has not timely requested a hearing nor filed an Answer to the April 10, 2023, OSC/ISO. *See also id.* § 1316.67.

I. Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC/ISO are admitted. Accordingly, between November 15, 2022, and February 1, 2023, Registrant unlawfully issued at least eleven prescriptions for promethazine with codeine 6.25–10mg/5ml (a schedule V opioid) to eleven fictitious individuals. RFAAX 1, at 3.³ Registrant sent all eleven prescriptions to be filled by out-of-state pharmacies. *Id.* Pursuant to Registrant's default, Registrant admits that this conduct reflects negative experience in prescribing controlled substances and was in violation of federal and state laws. RFAAX 1, at 2–3. Registrant further admits that his

² Based on the Government's submissions in its RFAA dated May 30, 2023, the Agency finds that service of the OSC/ISO on Registrant was adequate. The April 11, 2023 Receipt for Cash or Other Items appears to be signed by Registrant and asserts that a DEA Special Agent personally served Registrant with the OSC/ISO. RFAAX 2.

³ The eleven individuals had no associated public records, indicating that they were fictitious. *Id.*

conduct was outside the usual course of professional practice. RFAAX 1, at 3.

II. Discussion

A. 21 U.S.C. 823(g)(1): The Five Public Interest Factors

Under the Controlled Substances Act (CSA), “[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:

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

(B) The applicant’s experience in dispensing, or conducting research with respect to controlled substances.

(C) The applicant’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.

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

When making this determination, DEA considers the public interest factors in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (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 37507, 37508 (1993).

While the Agency has considered all of the public interest factors of 21 U.S.C. 823(g)(1),⁴ the Government’s evidence

in support of its *prima facie* case for revocation of Registrant’s registration is confined to Factors B and D. *See* RFAA, at 2. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44.

Here, the Agency finds that the Government satisfies its *prima facie* burden showing that Registrant’s continued registration would be “inconsistent with the public interest.” 21 U.S.C. 824(a).

1. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. *See Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022). In the current matter, the Government has alleged that Registrant has violated both federal and D.C. law regulating controlled substances. RFAAX 1, at 2–3. 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). 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.’”⁵ *X Dewey C. Mackaw*, 75 FR 49956, 49973 (2010).

D.C.’s regulations require that “a prescription for a controlled substance shall be issued or dispensed only for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.”⁶ D.C. Mun. Regs. tit. 22–B, section 1305.2 (2023); *see also* D.C. Code section 48–903.08(d) (2023) (“A controlled substance included in Schedule V shall not be distributed or

the public interest inquiry” and is therefore not dispositive. *Id.* 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 Registrant.

⁵ D.C. Mun. Regs. tit. 22–B, section 1399.1 provides that establishing a patient-practitioner relationship requires “that at a minimum the practitioner has met face to face with the patient, has obtained a patient history, and conducted a physical examination or evaluation adequate to establish a diagnosis, identify underlying conditions and contraindications to the treatment recommended.”

⁶ The OSC/ISO quotes the language contained in D.C. Mun. Regs. tit. 22–B, section 1305.2, but incorrectly attributes that language to section 1305.1.

dispensed other than for a medical purpose.”).

Registrant admits that his prescribing was outside the usual course of professional practice and that his conduct reflects negative experience in prescribing controlled substances and was in violation of federal and state laws. Indeed, the record demonstrates that Registrant issued at least eleven controlled substance prescriptions to eleven fictitious individuals. Based on registrant’s admissions, the Agency finds that Registrant’s prescribing was outside the usual course of professional practice, and sustains the Government’s uncontroverted allegations that Registrant violated 21 CFR 1306.04(a); D.C. Mun. Regs. tit. 22–B, section 1305.2; and D.C. Code section 48–903.08(d).

In sum, the Agency finds that Factors B and D 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(g)(1). The Agency further finds that Registrant failed to provide sufficient evidence to rebut the Government’s *prima facie* case.

III. Sanction

Where, as here, the Government has established sufficient grounds to revoke Registrant’s registration, the burden shifts to the registrant to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18882, 18910 (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 62316, 62339 (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 33738, 33746 (2021).

Here, Registrant did not request a hearing, 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 nor demonstrated that he can be entrusted with registration.

⁴ As to Factor A, there is no record evidence of disciplinary action against Registrant’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 at 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 [Registrant’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 Registrant 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, 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. *Dewey C. MacKay, M.D.*, 75 FR 49956, 49973 (2010). Agency cases have therefore found that “the absence of such a conviction is of considerably less consequence in

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. FO4353188 issued to Ndubuisi J. Okafor, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Ndubuisi J. Okafor, M.D., to renew or modify this registration, as well as any other pending application of Ndubuisi J. Okafor, M.D., for additional registration in Washington, DC. This Order is effective September 18, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on August 14, 2023, 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.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 21-27]

William Tuong, M.D.; Decision and Order

On July 2, 2021, the Drug Enforcement Administration (DEA) issued an Order to Show Cause (OSC) to William Tuong, M.D. (Respondent), of Wilmington, Delaware. Request for Final Agency Action (RFAA), Exhibit (RFAAX) 9, at 1, 7. The OSC proposed the revocation of Respondent's DEA Certificate of Registration, Control No. BT1102653, alleging that Respondent has "committed such acts as would render [his] registration inconsistent with the public interest." *Id.* at 1-2

(citing 21 U.S.C. 824(a)(4) and 823(g)(1) ¹).²

The Agency makes the following findings of fact based on the uncontroverted evidence submitted by the Government in its RFAA, which was received by the Agency on January 30, 2023.

I. Findings of Fact

A. Investigation of Respondent

DEA's investigation of Respondent found that between August 30, 2017, and August 28, 2019, Respondent issued seven prescriptions for 56-84 tablets of methadone 10 mg, eight prescriptions for 168 tablets of oxycodone ³ 30 mg, and four prescriptions for 56 tablets of oxymorphone 30 mg to a patient identified as Patient C.D. Declaration, at 1-2; RFAAX 2. Further, DEA's investigation found that between March 30, 2017, and July 18, 2019, Respondent issued thirteen prescriptions for 54-56 tablets of morphine sulfate ⁴ 100 mg and fourteen prescriptions for 135-168 tablets of oxycodone 30 mg to a patient identified as Patient K.G. Declaration, at 1-2; RFAAX 3. Finally, DEA's investigation found that between May 31, 2017, and August 22, 2018, Respondent issued eighteen prescriptions for 168-174 tablets of methadone 10 mg and eighteen prescriptions for 112-168 tablets of oxycodone 30 mg to a patient identified as Patient J.W. Declaration, at 1-2; RFAAX 4.⁵

B. The Government Expert's Review of Respondent's Prescriptions

The DEA hired Dr. Aviva Fohrer, M.D., to opine on Respondent's controlled substance prescribing based on, among other things, the patient files

described above (RFAAX 2-4) and medical records for the patients in question that predated Respondent's treatment of the patients. Declaration, at 1. The Agency finds that Dr. Fohrer is an expert in the standard of care for prescribing controlled substances in Delaware and gives her Declaration full credit in this Decision. *See* RFAAX 5.

Prior to opining on each patient individually, Dr. Fohrer reviewed the relevant prescriptions and described the standard of care for prescribing controlled substances in Delaware. Declaration, at 2-4; *see also* RFAAX 2-4; RFAAX 8. Regarding the standard of care, Dr. Fohrer explained that "[i]n addition to carefully justifying high-dose opioid prescriptions, practitioners must also ensure that their patients give valid informed consent prior to receiving these dangerous prescriptions." Declaration, at 3. Dr. Fohrer noted that "[o]f special concern is methadone . . . [and] practitioners who prescribe methadone should generally not combine it with other opioids, outside of limited circumstances." *Id.* at 3-4. Dr. Fohrer also explained that practitioners must monitor patients who receive high-dose opioids "to ensure they are not abusing or diverting controlled substances" and that such monitoring "should involve checking the prescription drug monitoring program (PDMP) reports and conducting urine drug screens." *Id.* at 3. Dr. Fohrer added that "[w]here there are aberrant urine screen results, practitioners must adequately address the results." *Id.* Finally, Dr. Fohrer explained that practitioners should "periodically attempt to wean patients off high-dose opioid prescriptions and discuss nonpharmacological and nonopioid pharmacological alternatives." *Id.*

1. Patient C.D.

On August 30, 2017, Respondent began treatment of Patient C.D., who was a pre-existing patient of Respondent's medical practice, and continued Patient C.D.'s prescriptions, issuing prescriptions to Patient C.D. for 56 tablets of methadone 10 mg and 168 tablets of oxycodone 30 mg. Declaration, at 4; *see also* RFAAX 2, at 156. According to Dr. Fohrer, "[t]here was no justification in the medical record for this high-dose opioid prescription" nor was there "any justification for combining methadone with oxycodone." *Id.* Dr. Fohrer also noted that Respondent "did not obtain Patient C.D.'s informed consent prior to issuing these dangerous prescriptions." *Id.*

Through at least August 28, 2019, Respondent continued to treat Patient

¹ Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117-215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and other statutes. Relevant to this matter, the MRA redesignated 21 U.S.C. 823(f), cited in the OSC, as 21 U.S.C. 823(g)(1). Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1), and to the MRA-amended CSA throughout.

² The Government represents that Respondent made a timely hearing request. RFAA, at 1. Subsequently on October 28, 2021, Respondent withdrew his hearing request and the proceedings were terminated. RFAAX 10, at 1.

³ The patient files for Patients C.D., K.G., and J.W. indicate that Registrant prescribed Roxicodone, which is a brand name for oxycodone. RFAA, Attachment 2 (hereinafter, Declaration), at 2 n.1; *see also* RFAAX 2-4.

⁴ Specifically, Respondent prescribed MS Contin, a brand name of morphine sulfate. Declaration, at 2 n.2.

⁵ Oxycodone, methadone, oxymorphone, and morphine are all Schedule II controlled substances. 21 CFR 1308.12(b)(1)(ix), (b)(1)(xiv), (b)(1)(xv), (c)(15).