

Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on March 2, 2020, Novitium Pharma LLC, 70 Lake Drive, East Windsor, New Jersey 08520, applied to be registered as an importer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Lisdexamfetamine	1205	II

The company plans to import the listed controlled substance as a raw material for drug product development and research.

The company may import Active Pharmaceutical Ingredients (API) for research purposes only but not for the manufacturing of Food and Drug Administration-approved products. Approval of permit applications will occur only when the registrant's activity is consistent with what is authorized under 21 U.S.C. 952(a)(2).

William T. McDermott,

Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Michael Thomas Watkins, M.D.; **Decision and Order**

On November 4, 2019, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Michael Thomas Watkins, M.D. (hereinafter, Registrant) of Boston, Massachusetts. OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. BW0913132 and the denial of "any applications for renewal or modification of such registration and any applications for any other DEA registrations." *Id.* It alleged that Registrant is "without authority to handle controlled substances in the Commonwealth of Massachusetts, the state in which . . . [he is] registered with the DEA." *Id.* at 2 (citing 21 U.S.C. 824(a)(3); 21 CFR 1301.37(b)).

Specifically, the OSC alleged that, "[o]n or about May 30, 2019, the Massachusetts Board of Registration in Medicine . . . ratified a 'Voluntary Agreement Not to Practice Medicine'

that . . . [Registrant] signed on May 22, 2019, in which . . . [he] agreed to 'cease . . . [his] practice of medicine in the Commonwealth of Massachusetts effective immediately.'" OSC, at 1. The OSC further alleged that Registrant's "Massachusetts Controlled Substances License was terminated due to the Board action" and, "[t]hus, . . . [he is] currently without authority to handle controlled substances in . . . the state in which . . . [he is] registered with the DEA." *Id.* at 2. The OSC concluded that "DEA must revoke . . . [Registrant's] DEA registration based on . . . [his] lack of authority to handle controlled substances in the Commonwealth of Massachusetts." *Id.*

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

Adequacy of Service

In a Declaration dated February 24, 2020, a Diversion Investigator (hereinafter, DI) assigned to the New England Division, stated that she and another DI traveled to the address her investigation identified to be Registrant's home on November 12, 2019. Request for Final Agency Action dated February 26, 2020 (hereinafter, RFAA), Exhibit (hereinafter, EX) 4 (Declaration of Service of Order to Show Cause dated February 24, 2020), at 1. The DI stated that she and the other DI showed their credentials to the "woman who answered the door" and asked if Registrant was "available." *Id.* The woman, according to the DI's Declaration, responded that Registrant "was not home." *Id.* After verifying the woman's identity as Registrant's spouse, DI "explained . . . that Registrant was being served with the . . . [OSC] and handed the . . . [OSC] to . . . [the woman] to give to Registrant." *Id.* The woman signed a receipt for the OSC. *Id.*; see also *id.* at EX 4B (signed DEA-12 receipt dated November 12, 2019), at 1. According to the DI's Declaration, the woman "stated that she would give the documents to Registrant." *Id.* at EX 4, at 1.

The Government forwarded its RFAA, along with the evidentiary record, to this office on February 26, 2020. In its RFAA, the Government represented that "[a]t least 30 days have passed since the time the Order was served on Registrant. Registrant has not requested a hearing

and has not otherwise corresponded or communicated with DEA regarding the Order . . . including the filing of any written statement in lieu of a hearing." RFAA, at 2. The Government requested that Registrant's registration be revoked, based on his having "no valid medical license in Massachusetts" and his being "without state authority to handle controlled substances in Massachusetts, the state where he is registered with DEA." *Id.* at 3.

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of the OSC on Registrant on November 12, 2019. *Dale L. Taylor, M.D.*, 72 FR 30,855, 30,855 (2007) (concluding that service was sufficient when OSC and Immediate Suspension Order were left at registrant's residence with his wife); *Sajjan Gangappa Chikkannaiah, M.D.*, 54 FR 8608, 8608 (1989) (noticing OSC and Immediate Suspension Order to registrant through the **Federal Register** when family, wife, and staff were unable to provide any information on registrant's whereabouts); *Fredric J. Sloan, M.D.*, 52 FR 10,957, 10,957 (1987) (serving registrant's wife with OSC at their residence was sufficient notice to registrant).

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

Findings of Fact

Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. BW0913132 at the registered address of Dept. of Surgery-Vascular-MGH, 15 Parkman Street, ACC 440, Boston, MA 02114. RFAA, EX 1 (Certification of Registration Status for DEA No. BW0913132 dated December 4, 2019), at 1. Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II

through V as a practitioner. *Id.* Registrant's registration expires on May 31, 2020 and is in an "active pending status." *Id.*

The Status of Registrant's State License

The Government submitted evidence that Registrant signed a "Voluntary Agreement Not to Practice Medicine" (hereinafter, Voluntary Agreement) on May 22, 2019. RFAA, EX 3, at 3. The Massachusetts Board of Registration in Medicine (hereinafter, MBRM) accepted the Voluntary Agreement on May 23, 2019, and ratified it on May 30, 2019. *Id.* According to the Voluntary Agreement, Registrant ceased his practice of medicine in Massachusetts "effective immediately." *Id.* at 1. By signing the Voluntary Agreement, Registrant also agreed that "[a]ny violation of this [Voluntary] Agreement shall be prima facie evidence for immediate summary suspension of my license to practice medicine." *Id.* According to the records of the MBRM, of which I take official notice, the Voluntary Agreement remains in effect.¹ MBRM Physician Search, <https://www.mass.gov/orgs/board-of-registration-in-medicine> (last visited April 28, 2020).²

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the 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, 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 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 FR 27,616, 27,617 (1978).

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, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever she is no longer authorized to dispense controlled substances under the laws of the state in which she practices. *See, e.g., James L. Hooper, M.D.*, 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, M.D.*, 43 FR at 27,617.

According to the Massachusetts Controlled Substances Act, "every person who . . . dispenses . . . any controlled substance within the commonwealth shall . . . register with the commissioner of public health, in accordance with his regulations." Mass. Gen. Laws ch. 94C, § 7(a) (Westlaw, current through Chapter 44 of the 2020 2nd Annual Session). Further, the automatic issuance of a controlled substances registration to a physician is only required when the physician is "duly authorized to practice his profession in the commonwealth." Mass. Gen. Laws ch. 94C § 7(f) (Westlaw, current through Chapter 44 of the 2020 2nd Annual Session).

Here, the undisputed evidence in the record is that Registrant voluntarily agreed to cease practicing medicine in Massachusetts.³ According to *Julian A. Abbey, M.D.*, 72 FR 10,788, 10,788 (2007), the MBRM announced by press release dated November 9, 2005, that a "consequence" of a Voluntary Agreement is that the "physician may not prescribe controlled substances." This result of a Voluntary Agreement is consistent with the provision of Massachusetts statute that the automatic issuance of a controlled substances registration to a physician is only required when the physician is "duly authorized to practice his profession in the commonwealth." Mass. Gen. Laws ch. 94C § 7(f) (Westlaw, current through Chapter 44 of the 2020 2nd Annual Session). This result of a Voluntary Agreement is also consistent with a regulation implementing the Massachusetts Controlled Substances Act stating that a "registration is void if the registrant's underlying professional licensure on which the registration is based is suspended or revoked." 105 Mass. Code Regs. § 700.120 (Westlaw, current through Register No. 1413, dated March 20, 2020).⁴

In sum, Registrant voluntarily agreed to cease practicing medicine in Massachusetts and, as a result, lacks authority in Massachusetts to handle controlled substances. He is, therefore, not eligible to maintain a DEA registration. Accordingly, I will order that Registrant's DEA registration be revoked.

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. BW0913132 issued to Michael Thomas Watkins, M.D. This Order is effective June 8, 2020.

Uttam Dhillon,

Acting Administrator.

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¹ 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 my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response may be filed and served by email (dea.addo.attorneys@dea.usdoj.gov) or by mail to Office of the Administrator, Attn: ADDO, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152.

² The same record from the MBRM Physician Search shows that Registrant's Massachusetts medical license expired on November 17, 2019. The RFAA does not address the expiration of Registrant's Massachusetts medical license, although evidence submitted with the RFAA about the Voluntary Agreement shows that Registrant's medical license expired. RFAA, EX 5, at 1.

³ In addition, as already noted, MBRM's online records show that Registrant allowed his medical license to expire.

⁴ Regarding 105 Mass. Code Regs. § 700.120, I note that the Massachusetts Controlled Substances Act explicitly authorizes the Public Health Commissioner to "promulgate rules and regulations relative to registration and control of the manufacture, distribution, dispensing and possession of controlled substances within the commonwealth." Mass. Gen. Laws ch. 94C, § 6 (Westlaw, current through Chapter 44 of the 2020 2nd Annual Session).