

Issued: August 6, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019-17134 Filed 8-6-19; 4:15 pm]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[USITC SE-19-031]

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: August 22, 2019 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205-2000..

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: 1. *Agendas for future meetings:* None.

2. Minutes.

3. Ratification List.

4. Vote on Inv. Nos. 701-TA-627-629 and 731-TA-1458-1461 (Preliminary)(Utility Scale Wind Towers from Canada, Indonesia, Korea, and Vietnam). The Commission is currently scheduled to complete and file its determinations on August 23, 2019; views of the Commission are currently scheduled to be completed and filed on August 30, 2019.

5. *Outstanding action jackets:* None.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: August 6, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019-17133 Filed 8-6-19; 4:15 pm]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19-19]

Parth S. Bharill; Decision and Order

On March 13, 2019, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause to Parth S. Bharill, M.D.

(hereinafter, Respondent) of Pittsburgh, Pennsylvania. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposed the revocation of Respondent's Certificate of Registration No. BB3258034 on the ground that Respondent does "not have authority to handle controlled substances in Pennsylvania, the state in which [Respondent is] registered with the DEA." *Id.* (citing 21 U.S.C. 823(f) and 824(a)(3)).

Specifically, the OSC alleged that the Commonwealth of Pennsylvania State Board of Medicine (hereinafter, Board) issued an Order of Temporary Suspension And Notice (hereinafter, Temporary Suspension Order 1) on June 18, 2018. *Id.* This Temporary Suspension Order, according to the OSC, immediately restricted Respondent's license to practice Medicine and Surgery because Respondent's "continued practice of medicine and surgery in Pennsylvania constitutes 'an immediate and clear danger to the public health and safety.'" *Id.* at 1-2. Further, the OSC alleged that on July 13, 2018, the Board "issued an 'Order Granting Continuance with Immediate Temporary Suspension Remaining In Effect' (hereinafter, Temporary Suspension Order 2), whereby the Board maintained the suspension of [Respondent's] medical license." *Id.* at 2.

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

By letter dated April 12, 2019, Respondent timely requested a hearing. Hearing Request, at 1. According to the Hearing Request, Respondent's interest in the proceedings is to defend his "constitutionally protected right to pursue a gainful occupation" and he objects to the issuance of the OSC because he applied to transfer his certificate of registration (hereinafter, COR) from his Pennsylvania address to a West Virginia address on December 31, 2018, and he "has a current and active Medical License . . . in the State of West Virginia." *Id.* at 1.

Respondent argues that "the use of the phrase 'may be suspended or revoked' [in 21 U.S.C. 824(a)] demonstrates that this is a discretionary authority of the DEA and does not take effect by operation of law based upon the loss of a license." *Id.* at 2 (citations

omitted). He further contends that due to Respondent's request for a change of address to West Virginia, "where an application for modification is received, it must be handled in the same manner as an application for registration." *Id.* (citing 21 U.S.C. 823(f)). He argues that DEA was required to grant the modification because DEA has not found "that Respondent's requested modification was inconsistent with the public interest," and he "has not [sic] disciplinary action taken against his West Virginia Medical License and, therefore, the DEA has not [sic] authority to revoke or suspend his license." *Id.*

The Office of Administrative Law Judges put the matter on the docket and assigned it to Administrative Law Judge Mark M. Dowd (hereinafter, ALJ). The ALJ issued an Order for Prehearing Statements (hereinafter, PH Order) dated April 22, 2019, setting a date by which the Government should file either a Prehearing Statement or a Motion for Summary Disposition, and affording Respondent one additional week to file either its Prehearing Statement or its Reply. PH Order, at 1-2.

The Government filed its Motion for Summary Disposition and Argument in Support of Finding that Respondent Lacks State Authorization to Handle Controlled Substances (hereinafter, Government's Motion) on April 29, 2019. In its motion, the Government stated that Respondent lacks authority to handle controlled substances in Pennsylvania, the state in which he is registered with the DEA, and argued that therefore, DEA must revoke his registration. Government's Motion, at 1.

On May 2, 2019, Respondent filed both a Prehearing Statement and a separate Response in Opposition to the Government's Motion for Summary Disposition (hereinafter, Respondent's Response). In his Prehearing Statement, Respondent requested that the "revocation of his registration be stayed pending a determination on his application for modification, or, in the alternative, that the application for modification be unaffected if revocation is approved." Respondent's Prehearing Statement, at 1. He also requested that "this case be determined on the documents submitted by the parties." *Id.*, at 2, 3. In Respondent's Response, he contends that "prior to seeking to revoke Respondent's registration, the DEA is required to decide the matter of the application of modification," or, in the alternative, if his current registration is revoked, his "application for modification should continue and be granted, unless the Government enters

an order to show cause and demonstrates before an ALJ that granting the application is not in the public interest.” Respondent’s Response, at 4.

I have reviewed and considered Respondent’s Prehearing Statement and Respondent’s Response as part of, and along with, the entire record before me.

On May 3, 2019, the ALJ granted the Government’s Motion, finding that “the subject of the instant litigation is not whether the Respondent has requested to modify his COR to reflect an address in West Virginia, but whether he has state authority to dispense controlled substances in the state in which his COR is currently registered, Pennsylvania, which he concedes, he does not.” Order Granting Summary Disposition and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, R.D.), at 7–8. “Therefore, summary disposition of an administrative case is warranted where, as here, ‘there is no factual dispute of substance.’” *Id.* at 11 (citing *Veg-Mix, Inc. v. U.S. Dep’t of Agric.*, 832 F.2d 601, 607 (D.C. Cir. 1987)). The ALJ recommended that Respondent’s registration be revoked because Respondent has conceded to his lack of medical license in Pennsylvania and the only “subject COR before this Tribunal . . . has been fatally undermined by the Respondent’s suspension of medical licensure in Pennsylvania.” *Id.* at 10.

By letter dated June 5, 2019, the ALJ certified and transmitted the record to me for final Agency action. In that letter, the ALJ advised that neither party filed exceptions and that the time period to do so had expired.

I issue this Decision and Order based on the entire record before me. 21 CFR 1301.43(e). I make the following findings of fact.

Findings of Fact

Respondent’s DEA Registration

Respondent is the holder of DEA Certificate of Registration No. BB3258034 at the registered address of 1350 Locust Street, Suite G102, Pittsburgh, Pennsylvania 15219. Government’s Motion, Attachment 1. Pursuant to this registration, Respondent is authorized to dispense controlled substances in schedules II through V as a practitioner and is also authorized as a DATA-waived practitioner to treat a maximum of 275 patients for narcotic treatment. *Id.*; see 21 CFR 1301.28(a) & (b)(iii). Respondent’s registration expires on July 31, 2019.

Government’s Motion, Attachment 1.

The Status of Respondent’s State License

On June 18, 2018, the Board issued an Order of Temporary Suspension and Notice of Hearing (hereinafter, Temporary Suspension Order) suspending Respondent’s license effective immediately upon service of the Order. Government’s Motion, Attachment 2, at 1–2. According to the Temporary Suspension Order, the Board determined that if the alleged facts were taken as true, “[r]espondent’s continued practice of medicine and surgery within the Commonwealth of Pennsylvania, along with the exercise of any other . . . ‘authorizations to practice the profession’ . . . make[] Respondent an immediate and clear danger to the public health and safety.” Government’s Motion, Attachment 2, at 1. The Board issued a second Order on July 12, 2018, granting Respondent’s request for a continuance on his preliminary hearing and ordering that the suspension of Respondent’s license to practice as a physician and surgeon remain in effect unless otherwise ordered by the SBM. Government’s Motion, Attachment 3 (Order Granting Continuance with Immediate Temporary Suspension Remaining in Effect), at 1.

A Diversion Investigator assigned to the Pittsburgh District Office, Philadelphia Field Division of this Agency stated that she accessed the public website for the Pennsylvania Bureau of Professional and Occupational Affairs on April 24, 2019, and obtained information from that website showing Respondent’s medical license was listed as under suspension on that date. Declaration of Diversion Investigator, Government’s Motion, Attachment 6, at 2.

According to the Commonwealth of Pennsylvania’s online records, of which I take official notice, Respondent’s license remains suspended. Pennsylvania Licensing System, State Board of Medicine License Verification, <https://www.pals.pa.gov/#/page/searchresult> (last visited July 23, 2019).¹

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, Respondent may dispute my finding by filing a properly supported motion for reconsideration within 15 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 Respondent files a

The Commonwealth of Pennsylvania’s online records show that Respondent’s medical license remains suspended and that Respondent is not authorized in the Commonwealth of Pennsylvania to prescribe controlled substances. *Id.*

Accordingly, I find that Respondent currently is neither licensed to engage in the practice of medicine nor registered to dispense controlled substances in the Commonwealth of Pennsylvania, the State in which he is registered with the DEA.

I further find, consistent with the findings of the ALJ, that Respondent’s application for modification is not the subject of this proceeding, and agree that the Government did not challenge that application modification in its OSC. See R.D., at 9–10.²

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 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.” *Id.* 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 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

motion, the Government shall have 15 calendar days to file a response.

² Respondent’s COR expires July 31, 2019. See Government’s Motion, Attachment 1. Pursuant to 21 CFR § 1301.51(c), “[n]o fee shall be required for modification If the modification of registration is granted, the registrant . . . shall maintain it with the old certificate of registration until expiration.” Because the modification is tied to the expiration date of the original COR, the modification will expire on the same date as the COR, unless the applicant renews the COR. See *Craig S. Morris, D.D.S.*, 83 FR 36,966, 36,967 (2018) (“The fact that DEA handles a modification request ‘in the same manner as an application for registration’ pursuant to 21 CFR

[§] 1301.51(c) does not mean that a modification request is the same as an application for a new registration in every respect [U]nlike a timely renewal application, a request to modify the registration address of an existing registration . . . does not remain pending after that registration expires, nor does it operate to extend when that registration expires.” (citing 21 CFR 1301.51(c)).

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., Hooper, supra*, 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); *Blanton, supra*, 43 FR at 27,617.

Under the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, “no controlled substance . . . may be dispensed without the written prescription of a practitioner.” 35 Pa. Stat. and Const. Stat. Ann. § 780–111(a) (West April 7, 2014 to October 23, 2019). Further, the definition of “practitioner,” as used in the Act, includes a “physician . . . or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance . . . in the course of professional practice . . . in the Commonwealth of Pennsylvania.” *Id.* at 780–102(b).

Here, the undisputed evidence in the record is that Respondent currently lacks authority to practice medicine in the Commonwealth of Pennsylvania. As already discussed, a physician must be a licensed practitioner to dispense a controlled substance in Pennsylvania. Thus, because Respondent lacks authority to practice medicine in the Commonwealth of Pennsylvania and, therefore, is not authorized to handle controlled substances in the Commonwealth of Pennsylvania, Respondent is not eligible to maintain a DEA registration. Accordingly, I will order that Respondent’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. BB3258034 issued to Parth S. Bharill, M.D. This Order is effective September 9, 2019.

Dated: July 29, 2019.
Uttam Dhillon,
Acting Administrator.
 [FR Doc. 2019–17004 Filed 8–7–19; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Alcami Wisconsin Corporation

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before October 7, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 12 2019, Alcami Wisconsin Corporation, W130N10497 Washington Drive, Germantown, Wisconsin 53022 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
5-Methoxy-N-N-dimethyltryptamine.	7431	I
Thebaine	9333	II
Alfentanil	9737	II

The company plans to provide bulk active pharmaceutical ingredient to support clinical trials. In reference to drug codes 7350 marihuana extract, 7360 marihuana, and 7360 THC, the company plans to manufacturer these substances synthetically. No other activity for these drug codes is authorized for this registration.

Dated: July 30, 2019.
John J. Martin,
Assistant Administrator.
 [FR Doc. 2019–17002 Filed 8–7–19; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Anthony Schapera, M.D.; Decision and Order

On December 31, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Anthony Schapera, M.D. (hereinafter, Registrant), of Bishop, California. OSC, at 1. The OSC proposes the revocation of Registrant’s Certificate of Registration No. AS3008213, the denial of any applications for renewal or modification of his registration, and the denial of “any applications for any other DEA registrations” on the ground that he “has no state authority to handle controlled substances.” *Id.* (citing 21 U.S.C. 824(a)(3)).

The substantive ground for the proceeding, as alleged in the OSC, is that Registrant is “without authority to handle controlled substances in the State of California, the state in which . . . [he is] registered with DEA.” *Id.* Specifically, the OSC alleges that the Medical Board of California revoked Registrant’s medical license effective June 22, 2018. *Id.*

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

Adequacy of Service

In a Declaration dated March 19, 2019 (hereinafter, Declaration), a Diversion Investigator (hereinafter, DI) assigned to the Newark Field Division declared under penalty of perjury that he and another DI “personally served” the OSC on Registrant. Declaration, at 1. Attached to the DI’s Declaration is a DEA–12, Receipt for Cash or Other Items. According to the DI, Registrant acknowledged receipt of the OSC by signing this DEA–12 on January 17, 2019. *Id.*