

Act on September 4, 2018 (83 FR 44903).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Patheon API Manufacturing, Inc.

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 January 22, 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: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on September 26, 2018, Patheon API Manufacturing, Inc., 309 Delaware St., Greenville, South Carolina 29605 applied to be registered as a bulk manufacturer for the basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Thebaine	9333	II
Noroxymorphone	9668	II

The company plans to manufacture the above-listed controlled substances

as an Active Pharmaceutical Ingredient (API) for supply to its customers.

Dated: November 2, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–25228 Filed 11–19–18; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 18–36]

Eldor Brish, M.D.; Decision and Order

On June 25, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Eldor Brish, M.D. (Respondent), of Houston, Texas. The Show Cause Order proposed the revocation of Respondent’s DEA Certificate of Registration No. FB2033049 on the ground that he has “no state authority to handle controlled substances.” Order to Show Cause, at 1 (citing 21 U.S.C. 824(a)(3)). For the same reason, the Order also proposed the denial of any of Respondent’s “applications for renewal or modification of such registration and any applications for any other DEA registrations.” *Id.*

With respect to the Agency’s jurisdiction, the Show Cause Order alleged that Respondent is the holder of Certificate of Registration No. FB2033049, pursuant to which he is authorized to dispense controlled substances as a practitioner in schedules II through V, at the registered address of 5400 Pinemont Drive, #108, Houston, Texas. *Id.* The Order also alleged that this registration does not expire until July 31, 2019. *Id.*

Regarding the substantive grounds for the proceeding, the Show Cause Order alleged that on May 18, 2018, the Texas Medical Board (TMB) “issued an Order of Temporary Suspension suspending” Respondent’s Texas medical license, and Respondent is therefore “without authority to practice medicine or handle controlled substances in Texas, the [S]tate in which [he is] registered with DEA.” *Id.* at 2. Based on his “lack of authority to [dispense] controlled substances in . . . Texas,” the Order asserted that “DEA must revoke” Respondent’s registration. *Id.* (citing 21 U.S.C. 824(a)(3); 21 CFR 1301.37(b)).

The Show Cause Order notified Respondent of (1) his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, (2) the procedure for electing either

option, and (3) the consequence for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The Order also notified Respondent of his right to submit a corrective action plan. *Id.* at 2–3 (citing 21 U.S.C. 824(c)(2)(C)).

On July 23, 2018, Respondent, through counsel, filed a letter requesting a hearing on the allegations. July 23, 2018 Letter from Respondent’s Counsel to Hearing Clerk (hereinafter, Hearing Request). In his Hearing Request, Respondent “requests a hearing be conducted to contest all of the legal issues and factual allegations raised in the DEA’s Order in support of its proposed revocation.” *Id.* at 1. Respondent specifically requested a hearing “to determine whether the DEA is authorized to revoke” Respondent’s registration and, “even if the DEA has authority to revoke, whether a revocation in the instant case represents an abuse of power and/or a failure to exercise appropriate discretion.” *Id.* at 1–2.

The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge Mark M. Dowd (hereinafter, ALJ). On July 31, 2018, the ALJ ordered the Government to “file evidence to support the allegation that the Respondent lacks state authority to handle controlled substances” and file “any motion for summary disposition” no later than August 3, 2018. Order Directing the Filing of Government Evidence of Lack of State Authority Allegation and Briefing Schedule, at 1. The ALJ also directed Respondent to file his response to any summary disposition motion no later than August 8, 2018. *Id.* at 2.

On August 3, 2018, the Government filed its Motion for Summary Disposition. In its Motion, the Government argued that Respondent lacks authority to handle controlled substances in Texas because the TMB “suspended Respondent’s Texas Medical License” on May 18, 2018. Government’s Motion for Summary Disposition (hereinafter Government’s Motion or Govt. Mot.) at 3; Government Exhibit (GX) 2 to Govt. Mot. The Government also noted that the TMB conducted a hearing on June 25, 2018 and then “issued a second suspension order” on June 27, 2018. Govt. Mot. at 3 (citing GX 3 to Govt. Mot.). The Government further argued that, “[a]bsent authority by the State of Texas to dispense controlled substances, Respondent is not authorized to possess a DEA registration in that state.” *Id.* Lastly, the Government argued that under Agency precedent, revocation is warranted even where a State has

temporarily suspended a practitioner's state authority with the possibility of future reinstatement. *Id.* at 4 (citations omitted). As support for its summary disposition request, the Government attached, *inter alia*, a copy of the TMB's June 27, 2018 Order directing that Respondent's license "is hereby temporarily suspended . . . effective on the date rendered [June 27, 2018, and] shall remain in effect until it is superseded by an Order of the Board." GX 3 to Govt. Mot., at 5.

In his responsive pleading, Respondent did not dispute that "the TMB's temporary suspension order issued on June 27, 2018 is currently in effect." Respondent's Aug. 13, 2018¹ Response to Government's Motion for Summary Disposition and Respondent's Request in the Alternative to Stay Proceedings Until November 1, 2018 (hereinafter, *Resp. Br.*), at 3. Instead, Respondent argued that "DEA failed to observe any level of discretion when it resolved to issue revocation (rather than suspension)" because 21 U.S.C. 824(a) "do[es] not represent grounds for *mandatory* revocation." *Id.* at 2 (emphasis in original). Respondent also argued that DEA issued its Show Cause Order "in the absence of crucial facts" because DEA did not "wait[] to learn whether the underlying temporary suspension order would be overturned or upheld" by the TMB *Id.* at 2–3. Respondent further argued that DEA's proposed revocation of Respondent's DEA registration "would functionally eradicate Respondent's due process rights" and "would fundamentally undermine his ability to avail himself of the procedural safeguards guaranteed by [Texas] law as part of the process leading up to and including the" TMB's Informal Show Compliance and Settlement Conference (ISC) scheduled for October 1, 2018. *Id.* at 3–4. Finally, Respondent argued that "granting the Government's Motion before Respondent has had an opportunity to fully participate in the upcoming ISC would preclude Respondent from fully participating in that . . . process and would stifle the parties' ability to reach an agreement without trial." *Id.* at 4. In the alternative, Respondent requested that "the ALJ stay proceedings and delay issuing a ruling on the

Government's Motion until November 1, 2018." *Id.* at 4.

After considering these pleadings, the ALJ issued an Order on August 27, 2018 denying Respondent's stay request because "Respondent fail[ed] to cite adequate and sufficient grounds for these proceedings to be stayed pending completion of the state medical board's proceedings" and "fail[ed] to provide sufficient reasons why his ability to fully participate in these proceedings would be hindered by the subsequent state proceedings." Order Denying Respondent's Request to Stay Proceedings, at 2. The ALJ concluded that "Agency precedent dictates that a stay of proceedings should not be granted based on the possible outcome of state proceedings." *Id.*

On September 12, 2018, the ALJ issued an order recommending that I find that there was no dispute "over the fact that Respondent currently lacks state authority to handle controlled substances in the State of Texas because the Texas Medical Board has suspended his medical license." Order Granting the Government's Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter "Recommended Decision" or "R.D."), at 6. As a result, the ALJ granted the Government's motion for summary disposition and recommended that I revoke Respondent's DEA registration. *Id.* at 7.

Neither party filed exceptions to the ALJ's Recommended Decision. Thereafter, the record was forwarded to my Office for Final Agency Action. Having reviewed the record, I find that Respondent is currently without authority to handle controlled substances in Texas, the State in which he holds his registration with the Agency, and thus is not entitled to maintain his DEA registration. I adopt the ALJ's recommendation that I revoke Respondent's registration. I make the following factual findings.

Findings of Fact

Respondent is the holder of DEA Certificate of Registration No. FB2033049, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner. GX 1 (Certification of Registration History) to Govt. Mot. On May 18, 2018, the TMB issued an Order temporarily suspending Respondent's Texas Medical License No. N–5593 that "shall remain in effect until such time as a hearing on the Application for Temporary Suspension (With Notice of Hearing) is conducted and a

Disciplinary Panel enters an order, or until superseded by a subsequent order of the [TMB]." GX 2 (May 18, 2018 Order of Temporary Suspension) to Govt. Mot., at 6–7.² On June 27, 2018, after a hearing conducted on June 25, 2018, the TMB issued a second Order temporarily suspending Respondent's medical license and found that "Respondent's continuation in the practice of medicine would constitute a continuing threat to the public welfare." GX 3 (June 27, 2018 Order of Temporary Suspension) to Govt. Mot., at 5.³ In that Order, the TMB ordered that the suspension of Respondent's Texas medical license "shall remain in effect until it is superseded by an Order of the Board." *Id.* There is no evidence in the record establishing that the TMB ever issued a superseding order lifting this suspension.

Accordingly, I find that Respondent currently does not possess a license to practice medicine in the State of Texas, the State in which he is registered with the DEA. *See id.* at 5.

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 (CSA), "upon a finding that the registrant . . . has had his State license . . . suspended [or] revoked . . . by competent State authority and is

² In its May 18, 2018 Order, the TMB found that "Respondent suffers from an impairment that prohibits him from safely practicing medicine." GX 2 to Govt. Mot., at 1. Specifically, the TMB's Order included findings that "[c]ontemporaneous eyewitness accounts from co-workers noted that Respondent was injecting patients with needles with his eyes closed or almost closed" and "exhibited slurred speech and difficulty staying focused, and he aimlessly staggered around the unit." *Id.* at 2. The TMB also found that Respondent "pre-signed several triplicate prescriptions and gave them to a co-worker to refill" for patients. *Id.* The TMB concluded that "Respondent's continuation in the practice of medicine would constitute a continuing threat to the public welfare" and that Respondent "violated various sections of the Medical Practices Act," including "Texas Health and Safety Code § 481.129(c), related to prescribing controlled substances without a valid medical purpose." *Id.* at 5, 6.

³ The TMB reached this conclusion based, *inter alia*, on its findings that Respondent (1) "has a recent history of impairment due to the abuse of drugs and alcohol, including controlled substances;" (2) "was diverting the drugs for personal recreational use;" (3) "was impaired while treating patients . . . due to the use of controlled substances;" and (4) with respect to 15 patients, "failed to meet the standard of care and non-therapeutically prescribed opioids and Soma." GX 3 to Govt. Mot., at 1–3. As it did in its earlier Order, the TMB again concluded that Respondent "violated various sections of the Medical Practices Act," including "Texas Health and Safety Code § 481.129(c), related to prescribing controlled substances without a valid medical purpose." *Id.* at 3, 4.

¹ On August 8, 2018, Respondent filed an "Unopposed Motion for Continuance" requesting that the ALJ continue Respondent's deadline to file his response to the Government's Motion to August 13, 2018. Respondent's Unopposed Motion for Continuance. On the same day, the ALJ issued an Order granting Respondent's unopposed continuance motion. Order Granting the Respondent's Motion for Continuance for Response to Government's Motion for Summary Disposition, at 1.

no longer authorized by State law to engage in the . . . dispensing of controlled substances.” Also, DEA has 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*, 76 FR 71371 (2011), *pet. for rev. denied*, 481 Fed. Appx. 826 (4th Cir. 2012); *see also Frederick Marsh Blanton*, 43 FR 27616 (1978) (“State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.”).

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).

As already noted, the TMB temporarily suspended Respondent’s Texas license to practice medicine. Under the Texas Controlled Substances Act, a “practitioner” includes a “physician” who is licensed “to dispense . . . or administer a controlled substance in the course of professional practice.” Tex. Controlled Substances Act § 481.002(39)(A). Under the Texas Medical Practice Act, a “physician” is “a person licensed to practice medicine,” Tex. Occ. Code § 151.002(a)(12), and “practicing medicine” means the “diagnosis, treatment, or offer to treat a . . . disease . . . by any system or method.” *Id.* § 151.002(a)(13). Moreover, a “person may not practice medicine in th[e] state unless the person holds a license issued under” the Medical Practice Act, *id.* § 155.001, and “[a] person commits an offense if the person practices medicine in this state in violation of” the Act. *Id.* § 165.152(a). As the ALJ correctly noted, the TMB found in both of its Temporary Suspension Orders that Respondent had violated several provisions of Section 164 of the Texas Occupational Code. *See R.D.*, at 5. Thus, I find that Respondent is currently without

authority to dispense controlled substances under the laws of Texas, the State in which he is registered with the DEA. *Accord Gazelle A. Craig, D.O.*, 83 FR 27628, 27631 (2018).

Moreover, because “the controlling question” in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a DEA registration “is currently authorized to handle controlled substances in the [S]tate,” *Hooper*, 76 FR at 71371 (quoting *Anne Lazar Thorn*, 62 FR 12847, 12848 (1997)), the Agency has also long held that revocation is warranted even where a practitioner has lost his state authority by virtue of the State’s use of summary process and the State has yet to provide a hearing to challenge the suspension. *Bourne Pharmacy*, 72 FR 18273, 18274 (2007); *Wingfield Drugs*, 52 FR 27070, 27071 (1987). Thus, it is of no consequence that the TMB has suspended Respondent’s medical license and that Respondent may prevail in a future state hearing.⁴ What is consequential is the fact that Respondent is not currently authorized to dispense controlled substances in Texas, the State in which he is registered. *See GX3 to Govt. Mot.*, at 5.

Here, there is no dispute over the material fact that Respondent is no longer currently authorized to dispense controlled substances in Texas, the State in which he is registered. Accordingly, Respondent is not entitled to maintain his DEA registration. I will therefore adopt the ALJ’s recommendation that I revoke Respondent’s registration. R.D., at 7. I will also deny any pending application to renew or to modify his registration, or any pending application for any other DEA registration in Texas, as requested in the Show Cause Order. Order to Show Cause, at 1.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA

⁴ Similarly, and contrary to Respondent’s claim, Due Process does not require the ALJ to delay summary disposition of the case until after completion of his Texas State Informal Show Compliance and Settlement Conference. Resp. Br. at 3–4. Rather, Due Process required the ALJ to provide Respondent the opportunity to respond to the Order to Show Cause and the Government’s Request for Summary Disposition. The ALJ did provide Respondent such an opportunity, and the Respondent did so respond. Respondent provided no authority for the notion that the ALJ violated Respondent’s right to Due Process by, in fact, providing Respondent an opportunity to be heard instead of delaying such opportunity. Respondent’s claim that the ALJ should have delayed his recommended decision is particularly unavailing where, as here, there are no controlling facts in dispute. *Accord Emmanuel O. Nwaokocha, M.D.*, 82 FR 26516, 26518 n.3 (2017); *see also Kenneth N. Woliner, M.D.*, 83 FR 7223, 7225 n.6 (2018).

Certificate of Registration No. FB2033049, issued to Eldor Brish, M.D., be, and it hereby is, revoked. I further order that any pending application of Eldor Brish to renew or modify the above registration, or any pending application of Eldor Brish for any other DEA registration in the State of Texas, be, and it hereby is, denied. This Order is effective immediately.⁵

Dated: October 31, 2018.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2018–25223 Filed 11–19–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Janssen Pharmaceuticals Inc.

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 December 20, 2018. Such persons may also file a written request for a hearing on the application on or before December 20, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (January 25, 2007)

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of

⁵ For the same reasons which led the TMB to suspend Respondent’s Texas medical license, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.