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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Michel P. Toret, M.D.; Decision and Order

On July 13, 2017, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Michel P. Toret, M.D. (hereinafter, Applicant) of Jeannette, Pennsylvania. GX 5. The Show Cause Order proposed the denial of Applicant's application for a DEA Certificate of Registration on the ground that Applicant's "registration is inconsistent with the public interest." GX 5, at 1 (citing 21 U.S.C. 823(f)).

As to the Agency's jurisdiction, the Show Cause Order alleged that, on February 14, 2017, Applicant applied for DEA Certificate of Registration. GX 5, at 2. *See also* GX 4 (DEA Form 224 submitted by Applicant).

As the substantive grounds for the proceeding, the Show Cause Order alleged that Applicant was registered with the DEA as a practitioner in schedules II through V pursuant to Certificate of Registration No. AT9432460, and that Applicant surrendered that registration for cause on November 29, 2016. GX 5, at 1. The Show Cause Order further alleged that Applicant "continued to issue prescriptions for controlled substances" after he surrendered that DEA registration. GX 5, at 2. According to the Show Cause Order, "DEA's investigation of ... [Applicant's] medical practice reveals that ... [Applicant] issued approximately 17 prescriptions for controlled substances after November 29, 2016 in violation of Federal law." *Id.* (citing 21 U.S.C. 841(a) and 843(a)(2)).

The Show Cause Order further alleged that Applicant materially falsified his application for a Certificate of Registration. GX 5, at 2. Specifically, the Show Cause Order alleged that Applicant's material falsification was his having "answered 'no' when asked, '[h]as the applicant ever surrendered (for cause) or had a federal controlled substance(s) registration revoked, suspended, restricted, or denied, or is any such answer pending.'" GX 5, at 2. According to the Show Cause Order, "this answer represents a material falsification on an application for a DEA Registration and, as such, is sufficient for denial of the pending application." GX 5, at 2 (citing 21 U.S.C. 843(a)(4) and 824(a)(1)).

The Show Cause Order notified Applicant 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. GX 5, at 2 (citing 21 CFR 1301.43). The Show Cause Order also notified Applicant of the opportunity to submit a corrective action plan. GX 5, at 3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

By Declaration dated August 23, 2017, a Diversion Investigator (hereinafter, DI), who described herself as the lead DI assigned to the regulatory matter involving Applicant, stated that, on July 21, 2017, she "personally served Registrant with a copy of the Order to Show Cause why Registrant's application for a new DEA COR should not be denied." GX 6, at 2 (hereinafter, DI Declaration). Based on the Government's sworn statement, I find that the Government's service of the Show Cause Order on Applicant was legally sufficient.

In its Request for Final Agency Action dated August 25, 2017, the Government represented that "more than thirty days have passed since the Order to Show Cause was served on ... [Applicant] and no request for hearing or other correspondence has been received by

DEA.” Request for Final Agency Action (hereinafter, RFAA), at 1. The Government requested that Applicant’s application for a DEA Certificate of Registration be denied based on Applicant’s “issuing prescriptions without a DEA COR and then committing a material falsification on his subsequent application for a new DEA COR.” RFAA, at 5.

Based on the Government’s sworn statement and written representations, and based on my review of the record, I find that more than 30 days have now passed since the date on which Applicant was served with the Show Cause Order. Further, based on the Government’s written representations, I find that neither Applicant, nor anyone purporting to represent him, has requested a hearing, submitted a written statement while waiving Applicant’s right to a hearing, or submitted a corrective action plan. Accordingly, I find that Applicant has waived his right to a hearing and his 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. 21 CFR 1301.43(e).

FINDINGS OF FACT

Jurisdictional Facts

On or about February 13, 2017, Applicant submitted an application for a DEA registration under the Controlled Substances Act. GX 4. On that application, Applicant certified to the truth and correctness of the information he furnished on the application, including that he never “surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied.” *Id.* at 1. Based on the evidence in the record, I find that this certification was false.

Applicant’s Voluntary Surrender of His Registration

Applicant, a medical doctor, previously held DEA Certificate of Registration AT9432460, pursuant to which he was authorized to dispense controlled substances in schedules II-V, at the address of Colony Building, 8962 Hill Drive, North Huntingdon, PA 15642. GX 1. On November 29, 2016, Applicant signed a “Voluntary Surrender of Controlled Substances Privileges,” Form DEA-104 (hereinafter, Voluntary Surrender Form). GX 2. According to the Voluntary Surrender Form he signed, Applicant “freely and under no duress, implied or express, execute[d] ... [the] document and ... [chose] to take the actions ... [i]n view of ... [his] alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of ... [his] good faith in desiring to remedy any incorrect or unlawful practices.” *Id.* Applicant’s signed Voluntary Surrender Form stated that Applicant voluntarily surrendered his DEA registration certificate, unused order forms, and all controlled substances. *Id.* It also stated that, “I understand that, beginning on the date that I sign below, I am not authorized to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other controlled substance activities whatsoever.” *Id.*

The only evidence the Government submitted with its RFAA concerning Applicant’s voluntary surrender of his registration was the Voluntary Surrender Form. In other words, the Government did not submit any evidence concerning the events leading up to Applicant’s voluntary surrender of his registration, the facts constituting Applicant’s “alleged failure to comply with the Federal requirements pertaining to controlled substances,” the specific Federal requirements that Applicant was alleged to have violated, or the resolution, if any, of the allegations against Applicant referenced in the Voluntary Surrender Form.

Applicant’s Issuance of Controlled Substance Prescriptions After He Voluntarily Surrendered His Registration

According to the Government, after Applicant voluntarily surrendered his DEA registration, Applicant issued 17 prescriptions for controlled substances. GX 5, at 2; GX 3. *See also* GX 6, at 2 (DI Declaration). According to the DI Declaration, GX 3 consisted of copies of the prescriptions Applicant issued after November 29, 2016. GX 6, at 2.

I reviewed each page of GX 3. Based on my review of GX 3, 15 of the pages reflect prescriptions clearly written after November 29, 2016, the date Applicant voluntarily surrendered his DEA registration. GX 3, at 1-8, 10-12, 14-17. Of those 15, 14 clearly concerned at least one controlled substance. *Id.* at 1-3, 5-8, 10-12, 14-17. Based on my review of GX 3, the prescriptions Applicant issued after November 29, 2016 included Suboxone and Subutex, controlled substances in schedule III; Ambien, Tramadol, Lunesta, and Xanax, controlled substances in schedule IV; and Lyrica, a controlled substance in schedule V. *Id.* at 1, 5, 7-8; *id.* at 2, 3, 6, 10, 11, 14-17; and *id.* at 12, respectively.

Thirteen of the pages in GX 3 were written on Applicant's prescription pad and included the number of the registration that Applicant voluntarily surrendered on November 29, 2016. GX 3, at 1, 3-11, 13, 14, 17. Two of the pages in GX 3 were written on Applicant's prescription pad but did not show a DEA registration number on the line after "DEA #." GX 3, at 2, 12. *See* 21 CFR 1306.05(a) ("All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the ... registration number of the practitioner."). Two of the pages in GX 3 consisted of "365 Hospice LLC" "Medication Profile" for patient PS and indicated, in their top right corner, that Applicant issued two "new" schedule IV prescriptions for patient PS on December 2nd and 19th, 2016. GX 3, at 15-16.

Based on my review of the Government's evidence, I find that Applicant issued at least 14 controlled substance prescriptions after he voluntarily surrendered his registration on November 29, 2016.

DISCUSSION

Pursuant to section 303(f) of the Controlled Substances Act, hereinafter CSA, “[t]he Attorney General shall register practitioners ... to dispense ... controlled substances ... 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). Section 303(f) further provides that an application for a practitioner's registration may be denied upon a determination that “the issuance of such registration ... would be inconsistent with the public interest.” *Id.* In making the public interest determination, the CSA requires consideration of the following factors:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing ... controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

Id.

These factors are ... considered in the disjunctive.” *Robert A. Leslie, M.D.*, 68 FR 15,227, 15,230 (2003). I “may rely on any one or a combination of factors and may give each factor the weight [I] deem[] appropriate in determining whether ... an application for registration [should be] denied.” *Id.* Moreover, while I am required to consider each of the factors, I “need not make explicit findings as to each one,” and I “can ‘give each factor the

weight ... [I] determine[] is appropriate.” *MacKay v. Drug Enforcement Admin.*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman v. Drug Enforcement Admin.*, 567 F.3d 215, 222 (6th Cir. 2009) quoting *Hoxie v. Drug Enforcement Admin.*, 419 F.3d 477, 482 (6th Cir. 2005)). In other words, the public interest determination “is not a contest in which score is kept; 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*, 74 FR 459, 462 (2009).

Pursuant to section 304(a)(1), the Attorney General is also authorized to suspend or revoke a registration “upon a finding that the registrant ... has materially falsified any application filed pursuant to or required by this subchapter.” 21 U.S.C. 824(a)(1). It is well established that the various grounds for revocation or suspension of an existing registration that Congress enumerated in this section are also properly considered in deciding whether to grant or deny an application under section 303. *See Richard J. Settles, D.O.*, 81 FR 64,940, 64,945 (2016); *Arthur H. Bell, D.O.*, 80 FR 50,035, 50,037 (2015); *The Lawsons, Inc.*, 72 FR 74,334, 74,338 (2007); *Samuel S. Jackson, D.D.S.*, 72 FR 23,848, 23,852 (2007); *Alan R. Schankman, M.D.*, 63 FR 45,260, 45,260 (1998); *Kuen H. Chen, M.D.*, 58 FR 65,401, 65,402 (1993). Thus, the allegation that Applicant materially falsified his application is properly considered in this proceeding. *Richard J. Settles, supra*, 81 FR at 64,945; *Arthur H. Bell, supra*, 80 FR at 50,037; *Samuel S. Jackson, supra*, 72 FR at 23,852. Moreover, just as materially falsifying an application provides a basis for revoking an existing registration without proof of any other misconduct, *see* 21 U.S.C. 824(a)(1), it also provides an independent and adequate ground for denying an application. *Richard J. Settles, supra*, 81 FR at 64,945; *Arthur H. Bell, supra*, 80 FR

at 50,037; *The Lawsons, Inc., supra*, 72 FR at 74,338; *Bobby Watts, M.D.*, 58 FR 46,995, 46,995 (1993); *Shannon L. Gallentine, D.P.M.*, 76 FR 45,864, 45,865 (2011).

The Government has the burden of proving that the requirements for a registration are not satisfied. 21 CFR 1301.44(d).

Having considered all of the public interest factors, as well as the separate allegation that Applicant materially falsified his application for a DEA registration, I conclude that the Government has established that the granting of Applicant's application would not be in the public interest because Applicant issued controlled substance prescriptions after he voluntarily surrendered his DEA registration. Accordingly, even though the Government did not submit sufficient evidence to prove that Applicant's false application was "materially false," I will order that Applicant's application be denied.

Acts Inconsistent With the Public Interest Factors

In its Show Cause Order, the Government alleged that Applicant's registration would be inconsistent with the public interest as that term is defined in 21 U.S.C. 823(f). As to this allegation, I reviewed the evidence the Government submitted and determined that Applicant issued at least 14 controlled substance prescriptions after he voluntarily surrendered his registration on November 29, 2016. This evidence is properly considered in the public interest determination. 21 U.S.C. 823(f)(2) and (4).

Factors Two and Four – The Registrant's Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

The Dispensing Allegations

With limited exceptions not applicable here, "[e]very person who dispenses ... any controlled substance ... shall obtain from the Attorney General a registration." 21 U.S.C. 822(a)(2). *See also* 21 U.S.C. 822(b) (authorizing registered persons to prescribe a controlled

substance). Further, according to the CSA, it is unlawful for any person knowingly or intentionally to dispense a controlled substance except as authorized by the CSA. 21 U.S.C. 841(a)(1). *See also* 21 U.S.C. 843(a)(2); 21 CFR 1306.03(a)(2).

Factor Two is Applicant's experience in dispensing controlled substances. According to my review of the Government's evidence, Applicant issued at least 14 controlled substance prescriptions after he voluntarily surrendered his registration on November 29, 2016. Applicant's issuance of these controlled substance prescriptions after he voluntarily surrendered his registration was contrary to legal requirements.

Factor Four is Applicant's compliance with applicable State, Federal, or local laws relating to controlled substances. The Government's evidence showed that Applicant issued at least 14 controlled substance prescriptions when Applicant was not registered with the Agency and, thus, in violation of Federal law relating to controlled substances. 21 U.S.C. 841(a)(1); 21 U.S.C. 822(a)(2).

I therefore find that the evidence with respect to Factors Two and Four supports the conclusion that issuing a registration to Applicant "would be inconsistent with the public interest." 21 U.S.C. 823(f).

The Material Falsification Allegation

When Applicant submitted his application for a registration on or about February 13, 2017, he answered "no" to whether he had "ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied." GX 4, at 1. As found above, this certification was false. The Government alleged that this false certification was "materially false," but the Government did not provide sufficient evidence for a finding of material falsification.

The Supreme Court has held that the “most common formulation” of the concept of materiality is that “a concealment or misrepresentation is material if it ‘has a natural tendency to influence, or was capable of influencing, the decision of’ the decisionmaking body to which it was addressed.” *Kungys v. United States*, 485 U.S. 759, 770 (1988) (quoting *Weinstock v. United States*, 231 F.2d 699, 701 (D.C. Cir. 1956) (other citation omitted)). The Court explicitly addressed what has “never been the test of materiality[,] that the misrepresentation or concealment would *more likely than not* have produced an erroneous decision, or even that it would *more likely than not* have triggered an investigation.” *Kungys, supra*, 485 U.S. at 771. Instead, the Court articulated the specific test as “whether the misrepresentation or concealment was predictably capable of affecting, *i.e.*, had a natural tendency to affect, the official decision.” *Id.*

The Government’s only evidence concerning the material falsification allegation was the Voluntary Surrender Form Applicant executed on November 29, 2016. On that Form, Applicant checked the box indicating that he “freely and under no duress, implied or express, execute[d] ... [the] document and ... [chose] to take the actions ... [i]n view of ... [his] alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of ... [his] good faith in desiring to remedy any incorrect or unlawful practices.” GX 2.

This evidence, alone, is an insufficient basis for a finding of “material falsification.” The Voluntary Surrender Form indicated nothing about Applicant’s failure to comply with any requirement concerning controlled substances. The Government did not submit any evidence explaining why Government investigators had sought the surrender of Applicant’s registration. Applicant’s admitting to an “alleged failure” to “comply with Federal requirements pertaining to controlled substances” indicated nothing about the nature of his “alleged failure,” let alone how

that “alleged failure” was relevant to any of the public interest factors or to any other ground which would support the denial of his application. Thus, Applicant’s admission, standing alone, is insufficient for a determination that a “misrepresentation or concealment was predictably capable of affecting, *i.e.*, had a natural tendency to affect, the official decision.” *Kungys, supra*, 485 U.S. at 771.

Accordingly, I find that the Government did not meet its burden of showing that Applicant’s false certification constituted a “material falsification.”

ORDER

Pursuant to the authority vested in me by 21 U.S.C. 824(a) and 823(f), as well as 28 CFR 0.100(b), I order that Applicant’s application for DEA Certificate of Registration be denied. This order is effective **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

Dated: December 1, 2017.

Robert W. Patterson,

Acting Administrator.

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