DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–26]

Keith Ly, M.D.; Decision and Order

I. Introduction

On April 28, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Keith Ly, M.D. (Applicant), of Houston, Texas.[1] OSC, at 1, 4. The OSC proposes the denial of Applicant's application for a DEA Registration (Control No. W21134341C), pursuant to 21 U.S.C. 824(a)(2 and 4) and 823(g)(1). *Id.* at 1. The OSC more specifically alleges that Applicant is a convicted felon, due to his violations of federal controlled substance laws, and committed other acts rendering his registration inconsistent with the public interest.[2] *Id.*

The hearing Applicant requested was held on September 8, 2022. Transcript of Video-Teleconference. Referencing Applicant's prior seven felony convictions and his failure to accept unequivocal responsibility for his actions, the RD recommends that Applicant's application be denied. RD, at 19–21, 23. Given the seriousness and extent of Applicant's founded violations, *infra* sections II.C., II.D., III.B., III.C., and IV., the Agency agrees.

Having thoroughly analyzed the record and applicable law, the Agency summarizes its findings and conclusions: (1) the Government presented a *prima facie* case that Applicant is a felon convicted of seven violations of federal law relating to a controlled substance and that Applicant wrote prescriptions for controlled substances when he was not legally authorized to do so, (2) Applicant attempted, but failed, to rebut the Government's *prima facie* case, and (3) substantial record evidence shows that the extent of Applicant's legal violations calls for the denial of his application for a DEA registration. Accordingly, the Agency will deny Applicant's registration application. *Infra* Order.

II. Findings of Fact

A. The Government's Case

The Agency finds that the parties stipulated to Applicant's seven felony convictions.[3] Joint Stipulation No. 2 (set out in Prehearing Ruling, at 2); *see also* GX 3 (Amended Judgment in a Criminal Case: *United States* v. *Keith Ly*, 2:13CR00157MJP–002), at 1–2. The Agency finds that Applicant did not object to the introduction of GX 3, and does not dispute that he was sentenced to prison for sixty months. Tr. 28–29; GX 3, at 3; see also, e.g., Tr. 150–51; Applicant's Closing Argument, at 1. Accordingly, the Agency finds uncontroverted, substantial record evidence that Applicant has seven prior felony convictions under federal law.

Regarding the allegation of unlawful controlled substance prescribing, the Government successfully moved into evidence the Agency's prior Decision/Order concerning Applicant. GX 6 (*Keith Ky Ly, D.O.,* 80 FR 29025 (May 20, 2015)). Accordingly, there is substantial record evidence that the Agency immediately suspended Applicant's prior DEA registration and affirmed that suspension in a published final Decision/Order dated May 20, 2015. Further, there is substantial record evidence that Applicant had reason to be aware of that immediate suspension on January 28, 2013. GX 6, at 3; *see also* Tr. 54–55, 61.

The Government successfully moved into evidence four controlled substance prescriptions. GX 5a–d (lorazepam, OxyContin, clonazepam, and phenobarbital).[4] The Diversion Investigator (DI) who testified that he obtained these prescriptions also testified that he confirmed with pharmacies that they dispensed, and with Applicant's patients that they received, the controlled substances issued in GX 5a–d.[5] Tr. 56–70. Accordingly, the Agency finds substantial record evidence that Applicant issued controlled substance prescriptions between February 1, 2013 and March 12, 2014, when his DEA registration was suspended.

B. Applicant's Case

As already discussed, Applicant admits that he is a felon. *Supra* section II.A. He argues, though, that the convictions are ''totally unrelated to any conduct in his medical practice. It was for marijuana and not a prescribed drug, nor one that is presently illegal in most states.'' Applicant Exceptions, at 1. Applicant also argues that the convictions stem ''from actions that took place almost a decade ago,'' and that nobody has ever alleged that his controlled substance prescribing reflected an ''inappropriate medical diagnosis, practice or procedure.'' [6] *Id.* at 2. He posits that the RD reflects a prejudging of his case ''due to a conviction . . . totally unrelated'' to his registration application. *Id.* at 2. Applicant similarly argues that the RD shows a ''misinterpret[ation]'' of his approach to acceptance of responsibility, as it fails to ''distinguish between a person who explains what took place,'' as he claims to have done, ''as opposed to someone who seeks to offer an excuse for what took place.'' *Id.*

Regarding the allegation that he prescribed controlled substances when he did not have legal authority to do so, Applicant argues that GX 5a–d includes prescriptions that are not for controlled substances, that some of the alleged prescriptions are not ''prescriptions'' because they do not include all of the elements required by regulation, and that the signature on the alleged controlled substance prescriptions is not his. Tr. 172–176; 186–192; 198–206; *see also, e.g.,* Applicant's Closing Argument at 5. He also argues that the ''prescriptions'' do not evidence or ''constitute any substandard medical procedures or diagnosis.'' Applicant Exceptions, at 2; Applicant's Closing Argument, at 4, 5. Instead, Applicant states that, throughout his practice, he has ''provide[d] medical[ly] necessary assistance with prescribed, controlled substances when the patient's condition(s) suggest that such a

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[1] Also referred to as ''Keith Ly, D.O.'' *Compare* Order Rejecting Applicant's Subpoena Request, at 1, *with* Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (RD), at 1.

Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022) (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] During the hearing, without Applicant's objection, the Government corrected two, legally irrelevant errors in the OSC. Tr. 65, 69. Applicant did not file Exceptions about and, therefore, the Agency does not address, any of the Administrative Law Judge's pre-hearing, hearing, or post-hearing rulings.

[3] ''On December 19, 2014, Applicant was convicted of seven felonies under Title 21 in the United States District Court for the Western District of Washington, in Case No. 13–CR–157. Specifically, Applicant was convicted of the following: a. Count One, Conspiracy to Distribute and Dispense a Schedule I Controlled Substance, in violation of 21 U.S.C. 841 and 846; b. Counts Two-Four, Manufacturing Marijuana a Schedule 1 Controlled Substance, in violation of 21 U.S.C. 841; and c. Counts Five-Seven, Maintaining a Drug Involved Premises, in violation of 21 U.S.C. 856.'' Joint Stipulation No. 2 (set out in Prehearing Ruling, at 2).

[4] In addition to containing controlled substance prescriptions, GX 5a–d also includes prescriptions for items that are not controlled.

[5] The Agency agrees with the RD's decision to afford DI's testimony ''full credibility.'' RD, at 6.

[6] Applicant also asserts that the notion that past performance is the best indicator of future results is ''archaic reasoning'' that ''flies in the face of countless examples of rehabilitation, restitution and recovery.'' Applicant Exceptions, at 1.

treatment would be in the patient's best interest.'' *Id.*

Applicant's case highlights the continuing medical education (CME) classes he took while incarcerated and the Texas Medical Board's re-issuance of his medical license. *Id.* at 2.

The Agency agrees with the RD's analysis of, and conclusions about, the credibility of Applicant's testimony. RD, at 8–9. Accordingly, in this adjudication, the Agency gives DI's testimony controlling weight when there is a conflict between it and Applicant's testimony, and gives Applicant's testimony little to no weight in all other circumstances. *Id.* at 9.

C. Allegation That Applicant Is a Convicted Felon

Based on a review of all of the record evidence, the Agency notes Applicant's admission that he has been convicted of seven felonies. *Supra* section II.A.; n.3. Accordingly, the Agency finds substantial, uncontroverted record evidence that Applicant is a seven-time convicted felon.

D. Allegation That Applicant Issued Controlled Substance Prescriptions When His DEA Registration Was Suspended

Based on a review of all of the record evidence, and application of its credibility assessments, the Agency rejects the arguments of Applicant about the content of GX 5a–d that conflict with DI's testimony.[7] Applicant's argument that GX 5a–d's controlled substance prescriptions are not valid, because they do not include the elements required by federal regulation, lacks merit against DI's credible testimony that a pharmacy filled them and dispensed controlled substances to Applicant's patients.[8] *See* RD, at 14–15. Accordingly, the Agency finds substantial record evidence that Applicant issued controlled substance prescriptions when his DEA registration was suspended.

III. Discussion

A. The Controlled Substances Act (CSA) and Implementing Regulations

According to the CSA, a practitioner's application for a DEA registration may be denied upon a determination that ''the issuance of such registration . . . would be inconsistent with the public interest.'' 21 U.S.C. 823(g)(1). In making the public interest determination, the CSA requires consideration of five factors. 21 U.S.C. 823(g)(1)(A–E). The five factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003).

According to Agency decisions, the Agency ''may rely on any one or a combination of factors and may give each factor the weight [it] deems appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016)); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *U.S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while the Agency is required to consider each of the factors, it ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. ''In short, . . . 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, M.D.,* 74 FR 459, 462 (2009).

Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821. In this matter, while all of the 21 U.S.C. 823(g)(1) factors have been considered, the Government's evidence is confined to Factors B, C, and D.[9] OSC, at 1–2.

B. Factor ''C''—Applicant's Conviction Record Under Federal Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

As already discussed, the record, including Applicant's admissions, contains substantial evidence that Applicant has been convicted of seven felonies. *Supra* sections II.A. and II.C.; n.3. It is self-evident that each of these seven felonies involves a controlled substance and relates to the ''manufacture, distribution, or dispensing'' of a controlled substance. n.3; 21 U.S.C. 823(g)(1)(C). Accordingly, the Agency finds substantial record evidence that Applicant was convicted of seven felonies ''relating to the manufacture, distribution, or dispensing of controlled substances,'' that the Government presented a *prima facie* case under Factor C, that Applicant failed to rebut the Government's *prima facie* case, and that Applicant's continued registration is inconsistent with the public interest, supporting denial of his registration application. *Id.*

C. Factors B and D—Applicant's Experience Dispensing Controlled Substances and Compliance With Applicable Laws Relating to Controlled Substances

As already discussed, the Agency finds substantial record evidence that Applicant issued controlled substance prescriptions when his DEA registration was suspended. *Supra* section II.D; *see also* section II.A. Under the CSA, a practitioner must possess a DEA registration to dispense a controlled substance lawfully. *See, e.g.,* 21 U.S.C. 823(g)(1). Accordingly, the Agency finds substantial record evidence of Applicant's unlawful controlled substance dispensing and failure to comply with federal law relating to controlled substances, that the Government presented a *prima facie* case under Factors B and D, that Applicant failed to rebut the Government's *prima facie* case, and that Applicant's continued registration is inconsistent with the public interest, supporting denial of his registration application. *Id.; see also* RD, at 14 (first full paragraph) through 17 (the penultimate sentence of the first full paragraph).

IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Applicant's continued registration is inconsistent with the public interest, the burden shifts to Applicant to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18882 (2018). Moreover, as past performance is the best predictor of future performance, the Agency has required that an applicant who has committed acts inconsistent with the public interest must unequivocally accept responsibility for those acts and demonstrate that he will not engage in future misconduct. *Id.* In addition, an applicant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* In addition, the Agency has found that the egregiousness and extent of the misconduct are

[7] Applicant's argument that the contents of GX 5a–d include prescriptions for non-controlled substances is not germane because GX 5a–d also contain prescriptions for controlled substances. *See* n.4, *supra.* The latter are material to the evaluation of Respondent's application, the former are not.

[8] Applicant's argument that the signatures on those controlled substance prescriptions do not belong to him is not credible for the same reasons.

[9] Neither Applicant nor the Government purports to offer evidence relevant to Factors A or E. The Agency considered Factors A and E, and finds that neither of them is relevant to this adjudication.

significant factors in determining the appropriate sanction. *Id.* The Agency has also considered the need to deter similar acts by an applicant and by the community of registrants. *Id.*

Applicant posits that the RD ''prejudge[s]'' him and ''misinterprets'' his approach by not ''distinguish[ing] between a person who explains what took place,'' as he argues he did, ''as opposed to someone who seeks to offer an excuse for what took place.'' Applicant Exceptions, at 2; *supra* section II.B. Applicant also argues that he stated, ''truthfully,'' ''how the grow houses became used for marijuana'' and ''admit[ted] his responsibility in same.'' Applicant Exceptions, at 2. Citing his ''remarkable'' CME compliance and re-issued Texas medical license, Applicant also claims that he ''has demonstrated, through his actions since, that he is worthy of any discretion the Court could provide.'' *Id.; but see* RD, at 19.

Even if the Agency were to credit Applicant's arguments, they do not change the fact that he did not unequivocally accept responsibility for the founded violations. *Supra* sections III.B. and III.C. For example, regarding the allegation that he prescribed controlled substances after the 2013 suspension of his registration, Applicant even refused to admit that the signatures on the controlled substance orders were his. *Supra* section II.B. The RD credits the DI's testimony over Applicant's steadfast refusal to acknowledge his signatures, and the Agency agrees. RD, at 14–15; *see also supra* sections II.A., II.B., and II.D.

This record evidence also shows that Applicant, despite his ''remarkable'' CME compliance, does not understand the responsibilities the CSA places on practitioners. Applicant posits that, ''throughout his practice, he has provide[d] medical[ly] necessary assistance with prescribed, controlled substances when the patient's condition(s) suggest that such a treatment would be in the patient's best interest.'' Applicant's Closing Argument, at 2; *see also* Applicant Exceptions, at 2–4. Such statements attempt to minimize, or divert attention from, his unlawful activity, and show Applicant's lack of understanding of the CSA's requirements. Accordingly, the Agency finds that Applicant did not unequivocally accept responsibility for the unlawful acts he committed and has not convinced the Agency that he can be entrusted with a registration.[10]

The interests of specific and general deterrence weigh in favor of denying Applicant's registration application. *See, e.g., Garrett Howard Smith, M.D.,* 83 FR at 18910 (collecting cases) (''The egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction.''). Given the seriousness and extent of Applicant's founded violations, a sanction less than application denial would tell prospective registrants that compliance with the law is not a condition precedent to the issuance of a registration.

Accordingly, the Agency shall order the sanction the Government requested.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny the DEA registration application of Keith Ly, M.D. (Control No. W21134341C). 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 application of Keith Ly, M.D., for a DEA Registration in Texas. This Order is effective June 26, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on May 16, 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. DEA–1181]

Bulk Manufacturer of Controlled Substances Application: Benuvia Operations LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Benuvia Operations LLC. has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 24, 2023. Such persons may also file a written request for a hearing on the application on or before July 24, 2023.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 9, 2023, Benuvia Operations, LLC., 3950 North Mays Street, Round Rock, Texas 78665, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Ibogaine	7260	I
Lysergic Acid Diethylamide	7315	I
Tetrahydrocannabinols	7370	I
Mescaline	7381	I

[10] Remedial measures are insufficient without an unequivocal acceptance of responsibility. *Brenton D. Wynn, M.D.,* 87 FR 24228, 24261 (2022); *see also Michael T. Harris, M.D.,* 87 FR 30276, 30278 (2022) (collecting Agency decisions).