DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Tel-Pharmacy; Decision and Order

On August 3, 2017, the then Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Tel-Pharmacy (hereinafter, Applicant) of Coconut Creek, Florida. OSC, at 1. The OSC proposed the denial of Applicant's application for DEA Certificate of Registration No. W16006664A. It alleged that Applicant ''does not have authority to operate a pharmacy in Florida, the state for which it seeks a [DEA registration].'' *Id.* (citing 21 U.S.C. 823(f)). Specifically, the OSC alleged that Applicant's Florida pharmacy permit expired on February 28, 2017, and was not renewed. *Id.* at 2.

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

Adequacy of Service

In a Declaration dated December 6, 2021, a Diversion Investigator (hereinafter, the DI) assigned to the DEA's Miami Field Division stated that on August 4, 2017, a Special Agent and Task Force Officer from DEA's Miami Field Division hand-delivered a copy of the OSC to Applicant's agent at the agent's residence. Request for Final Agency Action (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 1, at 1–2; *see also* RFAAX 1, Appendix (hereinafter, App.) B.

The Government forwarded its RFAA, along with the evidentiary record, to this office on December 8, 2021. In its RFAA, the Government represents that ''neither [Applicant] nor any attorney representing [Applicant] has requested a hearing'' nor ''has [Applicant] nor any attorney for [Applicant] submitted a written statement.'' RFAA, at 2. The Government ''seeks to deny [Applicant's] application for a [DEA registration] because [Applicant] lacks authority to handle controlled substances in [Florida], the state in which it seeks registration with DEA.'' *Id.* at 1. Accordingly, the Government requests that the Administrator deny Applicant's application. *Id.* at 5.

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 Applicant on August 4, 2017. 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, I find that neither Applicant, nor anyone purporting to represent the Applicant, 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 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

Applicant's Application for DEA Registration

On or about January 27, 2016, Applicant submitted an application for a DEA Certificate of Registration as a retail pharmacy in Schedules II through V with a proposed registered address at 5489 Wiles Rd. 302, Coconut Creek, FL 33073. RFAAX 1, App. A, at 1. Applicant's application was assigned Control No. W16006664A.[1] *Id.*

The Status of Applicant's State License

In her Declaration, the DI stated that as of December 6, 2021, Applicant's state license was listed as ''null and void'' on the Florida Department of Health website. RFAAX 1, at 2; *see also* RFAAX 1, App. C. According to the Florida Department of Health's online records, of which I take official notice, Applicant's state pharmacy registration PH29813 is ''null and void.'' [2] Florida Department of Health's License Verification, *https://mqa-internet.doh.state.fl.us/MQASearchServices/Home* (last visited date of signature of this Order).

Accordingly, I find that Applicant is not currently licensed to engage in the practice of pharmacy in Florida, the state in which Applicant applied for registration with the DEA.

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 [its] 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, 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 F. App'x 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 pharmacy . . . 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.,*

[1] In spite of Applicant's discontinuance of business, its application remains pending and I will continue to assess the application under 21 U.S.C. 823. *See Lawrence E. Stewart, M.D.,* 86 FR 15,257 (2021).

[2] 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, Applicant 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 and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

James L. Hooper, 76 FR 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,* 43 FR 27,617.

According to Florida statute, ''It is unlawful for any person to own, operate, maintain, open, establish, conduct, or have charge of, either alone or with another person or persons, a pharmacy: (a) Which is not registered under the provisions of this chapter.'' Fla. Stat. Ann. 465.015(1). Further, ''the practice of the profession of pharmacy'' definition ''includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug[3] . . . .'' Fla. Stat. Ann. 465.003(13) (West, 2021).

Here, the undisputed evidence in the record is that Applicant currently lacks authority to operate a pharmacy in Florida. As already discussed, a pharmacy must be a licensed to dispense a medicinal drug, including a controlled substance, in Florida. Thus, because Applicant lacks authority to practice pharmacy in Florida and, therefore, is not authorized to dispense controlled substances in Florida, Applicant is not eligible to receive a DEA registration. Accordingly, I will order that Applicant's application for a DEA registration be denied.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby order that the pending application for a Certificate of Registration, Control Number W16006664A, submitted by Tel-Pharmacy, is denied, as well as any other pending application of Tel-Pharmacy for additional registration in Florida. This Order is effective February 18, 2022.

Anne Milgram,

Administrator.

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[3] ''Medicinal Drugs'' or ''Drugs'' means ''those substances or preparations commonly known as 'prescription' or 'legend' drugs which are required by federal or state law to be dispensed only on a prescription . . . .'' Fla. Stat. Ann. 465.003(8).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–08]

AARRIC, Inc. d/b/a at Cost RX; Decision and Order

On January 3, 2020, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC) to AARRIC, Inc. d/b/a AT COST RX (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC/ISO informed Respondent of the immediate suspension of its DEA Certificate of Registration Number FA2125640 (hereinafter, registration or COR) and proposed its revocation, the denial of any pending applications for renewal or modification of such registration, and the denial of any pending applications for additional DEA registrations pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Respondent's ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4) and 823(f)).

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ Ex. 2. The hearing in this matter was conducted from November 16–20, 2020, at the DEA Hearing Facility in Arlington, Virginia, with the parties and their witnesses participating through video-teleconference.*[A] On April 7, 2021, Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, Chief ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD). On

*[A] [This footnote has been relocated from RD n.5.] At all times prior to and during the hearing, the Respondent was represented by multiple, able counsel. The Respondent's (then) counsels raised no issue during the proceedings or in the Respondent's closing brief regarding the fairness of the proceedings. The day after its closing brief was filed, the Respondent sought to discharge its lawyers and opted to have itself represented by its (non-lawyer) owner. ALJ Ex. 56. Acting as a non-attorney representative (*see* 21 CFR 1316.50), the Respondent's owner moved to disqualify the Government's expert and to recuse me [the Chief ALJ]. ALJ Exs. 57, 58, 61. These motions have been disposed of in separate orders issued contemporaneously with this recommended decision. ALJ Exs. 67, 68. A joint motion to be excused from further representation of the Respondent (ALJ Ex. 60) filed by his lawyers (at the request of the tribunal) was granted for the reasons stated therein. ALJ Ex. 62.

[I agree with the Chief ALJ's procedural rulings in this case, including his dismissal of Respondent's two recusal motions. In these motions, Respondent argued that the Chief ALJ ''den[ied] Respondent [the] right to a fair trial'' by ''creat[ing] an atmosphere of prejudice and lack of impartiality.'' ALJ Ex. 57, at 3. Respondent further argued that the Chief ALJ ''morphed [the Government's case] into a plausible case'' by ''w[earing] the hat of the Government's lawyer during most of the witness examination.'' *Id.* at 2. Respondent's motions reference portions of the record where the Chief ALJ assisted the Government in authenticating documents and questioning its witnesses. Although Respondent acknowledged that ALJs are permitted to question witnesses, Respondent argues that the Chief ALJ used his questioning authority to buttress the Government's case and ''patch[ ] up areas where there were obvious gaps in the Government's case,'' while not ''provid[ing] the same helping hand to Respondent when Respondent was attempting to authenticate documents that Respondent believes were critical to its defense. *Id.* at 5, 10. Additionally, Respondent alleged that it was inappropriate for the Chief ALJ to ask Respondent's representative, Dr. Howard, whether he agreed with certain testimony by Respondent's expert, because it ''placed . . . Dr. Howard in an awkward position to have to incriminate his own expert just to appease the ALJ.'' *Id.* at 26, 30.

I find that Respondent's recusal motions are without merit. As the Chief ALJ stated in his neutral and carefully-reasoned dismissal order, Respondent—the proponent of the recusal motion—has the burden of demonstrating that the Chief ALJ exhibited a ''deep-seated favoritism or antagonism that would make fair judgment impossible.'' Order Denying the Respondent's Recusal Motions, at 6. Respondent did not identify any evidence of favoritism or antagonism, much less the type of deep-seated favoritism or antagonism that would make fair judgment impossible. Rather, Respondent identified instances where the Chief ALJ was exercising his discretionary authority to regulate the hearing, by asking clarifying questions of counsel and witnesses and issuing evidentiary rulings. *See* Order, at 7 (citing 5 U.S.C. 556(c)(5); 21 CFR 1316.52(e)). Courts have uniformly held that judicial rulings issued during the course of litigation rarely constitute evidence of cognizable bias. *Id.* (citing *Liteky* v. *United States,* 510 U.S. 540, 555 (1994), *Hamm* v. *Members of Bd. of Regents,* 708 F.2d 647, 651 (11th Cir. 1983), *Dewey C. Mackay, M.D.,* 75 FR 49,956, 49,958–59 (2010)). Additionally, as the Chief ALJ highlighted in his dismissal order, the Chief ALJ frequently clarified the record for Respondent's benefit and overwhelmingly issued evidentiary rulings in Respondent's favor. *Id.* at 8–9. Furthermore, Respondent's recusal motions were untimely, which is an independent basis for their dismissal. *Id.* at 7, 15–16.

Beyond the substantive and procedural defects of Respondent's recusal motions, the motions convey a contemptuous tone towards the Chief ALJ, which supports my decision that Respondent's registration is inconsistent with the public interest. Respondent was particularly outraged that the Chief ALJ questioned Respondent's representative about whether he agreed with the Respondent's expert's expressions of hostility towards DEA as a regulator. Based on Respondent's attitude towards DEA and the Chief ALJ, I find it unlikely that Respondent would modify its behavior and become a law-abiding, cooperative registrant. Certainly, Respondent's focus on repudiating the Chief ALJ rather than acknowledging its own misconduct shows that it falls far short of the ''true remorse'' that is required when a registrant has committed acts that are inconsistent with the public interest. *Michael S. Moore, M.D.,* 76 FR 45,867, 45,877 (2011).

For the same reasons stated above, I find that Respondent's Exceptions to ALJ's Denial of Respondent's Motions for Recusal and Request for Expedited Ruling on the Order Denying Recusal are without merit. ALJ Ex. 69 (dated April 27, 2021).]