DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Robert Wayne Mosier, D.O.; Denial of Application

On September 30, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Robert Wayne Mosier, D.O. (Respondent), of Talihina, Oklahoma. The Show Cause Order proposed the denial of Respondent's application for a DEA Certificate of Registration, as a practitioner, on the ground that he is "currently without authority to handle controlled substances or practice medicine in the State of Oklahoma, the state in which [he is] registered with DEA." Show Cause Order at 1.

More specifically, the Show Cause Order alleged that Respondent had possessed a DEA Certificate of Registration, BM5225289, which expired by its terms on January 31, 2009, and that because he did not file an application for renewal of his DEA registration until April 23, 2009, his renewal application "is treated as a new application for DEA registration." *Id.* The Order further alleged that "[a]s a result of actions by the Oklahoma State Board of Osteopathic Examiners and the Oklahoma Bureau of Narcotics and Dangerous Drugs," Respondent lacked the authority to handle controlled substances or to practice medicine in Oklahoma *Id.* The Order further explained that Respondent had the right to request a hearing on the allegations or to submit a statement in lieu of a hearing, the procedures for doing so, and the consequences if he failed to do so. *Id.*

On October 6, 2009, the Order to Show Cause was served on Respondent by certified mail as evidenced by the signed return receipt card. Since that time, neither Respondent, nor any one purporting to represent him, has requested a hearing. Because more than thirty days have passed since Respondent was served with the Show Cause Order, and Respondent has not requested a hearing (or submitted a written statement), I conclude that Respondent has waived his rights to do either. 21 CFR 1301.43(d). I therefore enter this Decision and Final Order based on relevant material contained in the record and make the following findings.

Findings

Respondent was previously registered with DEA to dispense controlled substances in schedules II through V as a practitioner, and was assigned Certificate of Registration, BM5225289, which expired by its terms on January 31, 2009. Ex. H. Although the DEA mailed Respondent a renewal notice on December 10, 2008 and a delinquency notice on April 7, 2009, the Agency did not receive a renewal application from Respondent until April 23, 2009. *Id.*

Respondent holds a license to practice osteopathic medicine in the State of Oklahoma. However, on June 18, 2009, the Oklahoma State Board of Osteopathic Examiners found Respondent to be in violation of various provisions of the Oklahoma Osteopathic Medicine Act and that "in the interest of public safety," Respondent's license "shall be suspended immediately" and "remain suspended until further order of the Board." Order of Suspension with Conditions 2–3, *State Board of Osteopathic Examiners* v. *R. Wayne Mosier, D.O.,* No. 0712–0001 (June 18, 2009).

Respondent also held an Oklahoma Controlled Substance Registration. However, on February 10, 2009, the Oklahoma State Bureau of Narcotics and Dangerous Drugs (BNDD) issued an Order to Show Cause to Respondent as to why it should not revoke Respondent's state controlled substance registration. Order to Show Cause at 1 & 9, *Oklahoma ex rel. Oklahoma State Bureau of Narcotics and Dangerous Drugs Control* v. *Robert Wayne Mosier, D.O.,* (No. SCH–2009–02). The Order alleged that, between 2007 and 2008, four of Respondent's patients had died from lethal overdoses of controlled substances and that "each of these patients had, not long before their death, received prescriptions for various controlled dangerous substances from Respondent." *Id.* at 4.

The BNDD also alleged that Respondent had "failed to guard against the diversion of controlled dangerous substances," that he "dispensed controlled dangerous substances to patients without a legitimate medical need," that he treated individuals addicted to controlled substances for addiction without being licensed to provide a narcotic treatment program, that he self-prescribed controlled substances, that he failed to maintain accurate dispensing records, and that his office lacked the proper security controls to store controlled substances. *Id.* at 4–8.

On April 7, 2009, following a proceeding before a state Administrative Law Judge, BNDD immediately revoked Respondent's state controlled substance registration. Final Order at 2, *Oklahoma ex rel. Oklahoma State Bureau of Narcotics and Dangerous Drugs Control* v. *Robert Wayne Mosier, D.O.* The BNDD Order provided that Respondent was further "prohibited from making application for a[] [state] registration for a period of at least one (1) year." *Id.* A printout from the BNDD Web site dated January 13, 2010, indicates that Respondent had undergone disciplinary action and that the status of his registration is "inactive." Ex. E.

Discussion

DEA does not have statutory authority to grant or maintain a DEA registration if the applicant or registrant lacks authority to handle controlled substances under the laws of the State in which he is engaged in professional practice. *See* 21 U.S.C. 802(21) (defining the term "practitioner" as a person "licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to distribute, dispense * * * [or] administer * * * a controlled substance"); *id.* § 823(f) ("The 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."); *id.* § 824(a)(3) (authorizing revocation "upon a finding that the registrant has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the distribution[] or dispensing of controlled substances"). DEA has consistently held that holding authority under state law is a prerequisite for obtaining a registration under the CSA. *See Worth S. Wilkinson,* 71 FR 30173 (2006); *Stephen J. Graham,* 69 FR 11661 (2004); *Dominick A. Ricci,* 58 FR 51104 (1993); *Bobby Watts,* 53 FR 11919 (1988).

Moreover, the Agency has held that revocation is warranted (and denied applications) even in those instances where a practitioner's state license has only been suspended, and there is the possibility of reinstatement. *See Bourne Pharmacy,* 72 FR 18273, 18274 (2007); *Alton E. Ingram, Jr.,* 69 FR 22562 (2004); *Anne Lazar Thorn,* 62 FR 12847 (1997) ("the controlling question is not whether a practitioner's license to practice medicine in the state is suspended or revoked; rather, it is whether the Respondent is currently authorized to handle controlled substances"). As Respondent clearly lacks authority to handle controlled substances under Oklahoma law, the State in which he has applied for registration, his application will be denied.

Order

Pursuant to the authority invested in me by 21 U.S.C. 823(f), as well as by 28 CFR 0.100(b) and 0.104, I hereby order that the application of Robert Wayne Mosier, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This order is effective immediately.

Dated: July 30, 2010.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08–15]

Hilmes Distributing, Inc.; Dismissal of Proceeding

On October 31, 2007, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Hilmes Distributing, Inc. (Respondent), of Trenton, Illinois. The Order proposed the revocation of Respondent's DEA Certificate of Registration, which authorizes it to distribute List I chemicals, and the denial of any pending applications for renewal or modification of the registration, on the ground that its "continued registration * * * is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(h)." ALJ Ex. 1, at 1.

The Show Cause Order specifically alleged that "[c]onvenience stores and gas stations continue to be the primary source for precursors that are diverted to illicit methamphetamine laboratory operators in many states" and that Respondent "distributes large amounts of ephedrine-based products almost exclusively to convenience stores and gas stations." *Id.* at 1–2. The Order alleged that "the normal expected sales range to meet legitimate demand for combination ephedrine products is between $0 and $25 per month, with an average of $12.58 per month," and that Respondent's "sales of combination ephedrine products greatly surpass the expected sales range to meet any legitimate demand for combination ephedrine products." *Id.* at 2. The Order further alleged that Respondent's sales to four stores during the months of June through August 2006 "greatly surpass[ed] the expected sales range to meet any legitimate demand for combination ephedrine products," and that while not "exhaustive," these sales are "nonetheless representative of [Respondent's] sales pattern of [sic] combination ephedrine products" in amounts which "are inconsistent with the known legitimate market." *Id.* The Order thus concluded by alleging that "these types of businesses do not sell such inordinately large volumes of List I chemicals for legitimate uses," that Respondent's "continued registration will result in the continued diversion of List I chemicals," and that it "is inconsistent with the public interest." *Id.*

On November 21, 2007, Respondent, through its counsel, requested a hearing on the allegations. ALJ Ex. 2. The matter was placed on the docket of the Agency's Administrative Law Judges (ALJs), and a hearing was held on April 15, 2008, in St. Louis, Missouri. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, only Respondent filed a brief.

On October 7, 2009, the ALJ issued her recommended decision (also ALJ) in the matter. Therein, the ALJ examined the five public interest factors (*see* 21 U.S.C. 823(h)) and concluded that the Government had not met its burden of proving that Respondent's continued registration is inconsistent with the public interest. ALJ at 25.

With respect to the first factor—the maintenance of effective controls against diversion—the ALJ noted that during a November 2006 inspection of Respondent, there were no deficiencies in its physical security and that DEA has never advised Respondent that its "physical security for its listed chemical products was inadequate." ALJ at 17. The ALJ also found that Respondent had implemented various procedures to ensure its customers followed both Federal and state laws applicable to the retail distribution of listed chemicals. *Id.* The ALJ thus concluded that this factor weighed "in favor of renewing the Respondent's DEA registration." ALJ at 17.

Examining the second and fourth factors together—the registrant's compliance with applicable State, Federal and local law, as well as its past experience in the distribution of List I chemicals—the ALJ noted that while Respondent has held a registration since 1997, it has never been cited by DEA for any regulatory violations. *Id.* at 18. Moreover, the ALJ noted that the Diversion Investigator (DI) who performed the inspection had testified that Respondent "is probably one of the better distributors, as far as recordkeeping goes." *Id.*

With respect to the Government's principal allegation, the ALJ found that the Government had not established a baseline figure necessary to show that Respondent's sales were so excessive as to support a finding that the products were being diverted. *Id.* at 21. While the ALJ noted that the Government had submitted the declarations of an expert witness as to the expected sales range of combination ephedrine products at convenience stores to meet legitimate demand and had previously relied on this evidence in several cases to prove that diversion had occurred, the ALJ noted that in a subsequent case, the expert's methodology was found to be unreliable. *Id.* (citing *Novelty Distributors, Inc.,* 73 FR 52689, 52693–95 (2008)). Accordingly, the ALJ concluded that "the Government has not established by a preponderance of the evidence that these figures accurately represent the average dollar amount of expected sales of listed chemical products." *Id.*

Citing my decision in *Novelty,* 73 FR at 52703–04, the ALJ calculated the customers' average monthly sales (which she found to be $ 453.86) and then used this as the baseline for determining whether its sales to individual stores were in excess of legitimate demand. *Id.* The ALJ concluded, however, that while its sales to one gas station during a three-month period "seem excessive," these sales created only a "suspicion of diversion," which under agency precedent was not sufficient to prove that its products were being diverted. *Id.* at 21–22 (citing *John J. Fotinopoulos,* 72 FR 24602, 24604 (2005)). The ALJ thus found that "th[es]e factor[s] weigh[] in favor of Respondent being allowed to continue handling listed chemical products." *Id.* at 24.

As for the third factor—Respondent's conviction record under Federal or State laws relating to controlled substances or listed chemicals—the ALJ found that neither Respondent nor any of its employees have been convicted of an offense "related to their handling of listed chemical products under either Federal or State law." *Id.* at 23. As for the fifth factor—other factors relevant to and consistent with public health and safety—the ALJ concluded that "absent evidence of such excessive sales that diversion is a reliable conclusion * * * Respondent's continued sale of listed chemical products to its customers, in the manner in which [it] conducts its business, does not create a risk of diversion of these products to the illicit market." *Id.* at 24. The ALJ thus concluded that the Government had not proved that Respondent's continued registration would be inconsistent with the public interest. *Id.* at 25.