suspended but asserted that the state superior court had ruled that his alleged offenses were misdemeanors and not felonies and that he was currently in negotiations with the Board for the reinstatement of his license. Respondent's Response at 1. Respondent further contended that notwithstanding the suspension of his medical license, ''Georgia law allows unlicensed individuals to work as subordinates and laborers in the manufacturing, distributing, and dispensing of controlled substances.'' *Id.* at 3. Respondent further asserted that he was ''still eligible to apply for employment in the state as a physician's assistant, pharmacy technician, drug manufacturing employee or drug representative, among other occupations involving the handling of controlled substances.'' *Id.* Respondent maintained that ''[t]he fact that [21 U.S.C. 824(a)(3)] requires both action on the Respondent's license and an inability to engage in the manufacture, distribution, and dispensing of drugs would seem to indicate that suspension of one's license does not necessarily render the individual unable to handle controlled substances.'' *Id.* Respondent thus contended that there was an issue of fact presented and an evidentiary hearing was required. *Id.*

On April 17, 2006, the ALJ issued her opinion and recommended decision. The ALJ rejected Respondent's argument explaining that ''[i]mplicit in'' DEA's long-standing interpretation of the Controlled Substances Act ''is the assumption that the authority at issue is that inuring to the registrant as a practitioner, not whatever authority the state grants to individuals who do not hold a license to practice medicine.'' ALJ Dec. at 3. The ALJ further explained that ''[t]o hold otherwise would permit unlicensed physicians to maintain DEA registrations, contrary to the plain purpose of the CSA.'' *Id.*

The ALJ also found that it was undisputed that Respondent's state license was suspended and that he was without authority to handle controlled substances as a practitioner. *Id.* Because there was no factual issue in dispute, the ALJ granted the Government's motion for summary disposition and recommended that Respondent's DEA registration be revoked. *Id.* at 4.

Having considered the record as a whole, I hereby issue this decision and final order. I adopt the ALJ's opinion and recommended decision.

Respondent's contention that he is entitled to maintain his DEA registration notwithstanding that he lacks authority under Georgia law to practice medicine is easily dismissed. Even assuming that Georgia law allows Respondent to engage in some activities involving controlled substances, the CSA makes plain that one must be currently authorized by the State to engage in the specific activities for which he holds a DEA registration.[1]

The CSA's definition of the ''[t]he term 'practitioner' means a physician * * * 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) (emphasis added). Relatedly, the CSA directs 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.'' *Id.* section 823(f). See also *id.* section 802(10) (''the term 'dispense' means to deliver a controlled substance to an ultimate user * * * pursuant *to the lawful order of a practitioner*'') (emphasis added).

As the CSA's definition of the term ''practitioner'' makes plain, a physician must be currently authorized to dispense a controlled substance ''in the course of professional practice.'' *Id.* section 802(21). A physician whose state license has been suspended or revoked does not have authority under state law to engage in the ''professional practice'' of medicine and cannot lawfully issue an order to dispense a controlled substance. Accordingly, section 304 of the CSA authorizes the revocation of a registration ''upon a finding that the registrant * * * has had his State license or registration suspended or revoked * * * and is no longer authorized by State law to engage in the * * * dispensing of controlled substances.'' *Id.* § section824(a)(3).[2]

DEA has consistently held that the CSA requires the revocation of a registration issued to a practitioner whose state license has been suspended or revoked. See Sheran Arden Yeates, 71 FR 39130, 39131 (2006); Dominick A. Ricci, 58 FR 51104, 51105 (1993); Bobby Watts, 53 FR 11919, 11920 (1988).

I therefore conclude that Respondent's argument is without merit. Because Respondent has produced no evidence that the Georgia's Board's summary suspension order has been set aside or stayed, I conclude that Respondent lacks authority under Georgia law to handle controlled substances as a practitioner and is not entitled to maintain his DEA registration.

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, BD4754683, issued to Gerald E. Dariah, M.D., be, and it hereby is, revoked. I further order that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This order is effective February 28, 2007.

Dated: January 19, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–1320 Filed 1–26–07; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Stephen J. Heldman, Denial Of Application

On November 18, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Stephen J. Heldman of Cincinnati, Ohio (Respondent). The Show Cause Order proposed to deny Respondent's pending application for a DEA Certificate of Registration as a distributor of the List I chemicals ephedrine and pseudoephedrine on the ground that his registration would be inconsistent with the public interest. See 21 U.S.C. 823(h) & 824(a).

The Show Cause Order specifically alleged that Respondent was proposing to distribute products containing pseudoephedrine and ephedrine, which are precursor chemicals used to manufacture methamphetamine, to non-traditional retailers of these products such as convenience stores and gas stations. See Show Cause Order at 1–2.

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[1] Contrary to the understanding of Respondent's counsel, the word ''handle'' as used in DEA cases interpreting the CSA is a term of art. It refers to a registrant's authority to perform the specific activities for which registration is required.

[2] Even if it is true, Respondent's ''contention that he is still authorized by state law to engage in the manufacturing [and] distribution * * * of controlled substances,'' Respondent Resp. at 3, is irrelevant. Respondent was registered under the CSA as a practitioner and not as a manufacturer or distributor. The Act specifically defines ''the term 'distribute''' to exclude ''dispensing.'' 21 U.S.C. § 802(11). The only activity which is relevant in assessing whether Respondent can maintain his practitioner's registration is dispensing. *See id.* § 823(f); see also 21 CFR 1301.13(e) (table) (distributing and dispensing are independent activities and require separate registrations).

Finally, even if ''Georgia law allows unlicensed individuals to work as subordinates * * * in the * * * dispensing of controlled substances,'' Resp. Resp. at 3, Respondent does not maintain that he can lawfully issue a prescription for a controlled substance under state law, which is what matters for purposes of the CSA.

The Show Cause Order alleged that these retailers are sources for the diversion of these products into the illicit manufacture of methamphetamine. See id.

The Show Cause Order next alleged that during a pre-registration investigation, Respondent indicated that he had no prior experience in handling List I chemical products, that he was unaware of the problem of diversion of these products into the illicit manufacture of methamphetamine, and that he was proposing to store listed chemical products in a commercial self-storage locker which had inadequate security. See id. The Show Cause Order also alleged that while Respondent told investigators that he intended to distribute only traditional products containing pseudoephedrine, the primary business of one of his two proposed suppliers is the distribution of combination ephedrine products which are sold by gray market retailers. See id.

The Show Cause Order further alleged that during customer verifications, DEA investigators determined that several of Respondent's proposed customers obtained List I chemical products from other suppliers and had no intention of purchasing these products from him. See id. at 3. Finally, the Show Cause Order alleged that during an August 2005 investigation of another DEA registrant, DEA investigators determined that Respondent had obtained List I chemicals without being registered to do so. See id.

On November 25, 2005, the Government initially attempted to serve the Show Cause Order by Certified Mail, Return Receipt Requested, by sending it to the address Respondent gave on the application for his proposed registered location. The mailing, however, was returned unclaimed. Thereafter, on January 17, 2006, the Government served the Show Cause Order by First Class Mail. Since that date, neither Respondent, nor anyone purporting to represent him, has responded. Because (1) more than thirty days have passed since the service of the Show Cause Order, and (2) no request for a hearing has been received, I conclude that Respondent has waived his right to a hearing. See 21 CFR 1309.53(c). I therefore enter this final order without a hearing based on relevant material found in the investigative file and make the following findings.

Findings

Pseudoephedrine and ephedrine are List I chemicals that, while having therapeutic uses, are easily extracted from lawful products and used in the illicit manufacture of methamphetamine, a schedule II controlled substance. See 21 U.S.C. 802(34); 21 CFR 1308.12(d). As noted in numerous DEA orders, ''methamphetamine is an extremely potent central nervous system stimulant.'' Sujak Distributors, 71 FR 50102, 50103 (2006); A–1 Distribution Wholesale, 70 FR 28573 (2005). Methamphetamine is highly addictive; its abuse has destroyed lives and families and ravaged communities. Moreover, because of the toxic nature of the chemicals used to make the drug, its manufacture creates serious environmental harms. David M. Starr, 71 FR 39367 (2006).

On October 27, 2003, Respondent, a sole proprietor, applied for a registration as a distributor of List I chemicals at the address of his residence in Cincinnati, Ohio. According to the investigative file, on January 15, 2004, a DEA Diversion Investigator (DI) contacted Respondent requesting additional information. The DI also contacted Respondent on additional occasions to request information. On October 11, 2004, Respondent sent a letter to the DI providing the requested information. In this letter, Respondent informed the DIs that the List I chemical products would actually be kept in a storage unit at a commercial storage facility.

On December 16, 2004, the DIs conducted an on-site inspection of the facility. Respondent's proposed use of the facility raised substantial concerns. According to the investigative file, the entrance gate to the facility remained open long enough to allow unauthorized persons to obtain access to the facility. Moreover, while Respondent's storage unit had an alarm system, the alarm sounded only at the facility's office and not at the local police station. Furthermore, during the visit, the facility's office was unoccupied. Finally, the DIs noted that it was unclear who would be responsible for handling the products that were delivered to the storage facility.

During the course of the investigation, the DIs determined that Respondent engages in the business of distributing assorted products to convenience stores, gas stations, truck stops and liquor stores. Respondent told the DIs that he had no experience in the distribution of List I chemical products and that he had no knowledge of the diversion of these products into the illicit manufacture of methamphetamine.

Respondent provided the DIs with a list of proposed customers for List I products. A substantial number of the proposed customers were Ameristop Food Marts, a chain of company-owned and franchise-owned convenience stores in Ohio and adjacent states. One of the DIs contacted the buyer for Ameristop Corporation, who informed him that all company-owned stores and most of the franchise-owned stores were supplied by Liberty Distribution, a subsidiary of Ameristop Corp. The buyer acknowledged that Respondent had supplied some items to ten Ameristop stores but stated that Ameristop would discourage its stores from buying List I chemical products from Respondent or any other independent vendor.

Subsequently, on August 23, 2005, DEA DIs executed an Administrative Inspection Warrant at R J General Corporation, a Cincinnati-based firm which was soon to become—as in that day—an ex-DEA registered distributor of List I chemical products. During the inspection, the DIs interviewed Mr. John Meinerding, who admitted that R J General had sold List I chemical products to Respondent on various dates between January 7, 2004, and December 8, 2004. Of note, on October 11, 2004, Respondent had faxed a letter to DEA in which he stated that his firm was a ''wholesale distributor.'' Moreover, in response to a question regarding whether he would engage in retail sales of List I chemical products, Respondent answered: ''No.''

Discussion

Under 21 U.S.C. 823(h), an applicant to distribute List I chemicals is entitled to be registered unless the registration would be ''inconsistent with the public interest.'' In making this determination, Congress directed that I consider the following factors:

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

Id.

''These factors are considered in the disjunctive.'' Joy's Ideas, 70 FR 33195, 33197 (2005). 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. See, *e.g.*, Starr, 71 FR at 39367; Energy Outlet, 64 FR 14269 (1999). Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie*

v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). In this case I conclude that Factors One, Two, Four, and Five establish that granting Respondent's application would be inconsistent with the public interest.

Factor One—Maintenance of Effective Controls Against Diversion

The investigative file establishes that Respondent does not have effective controls against diversion. In this case, it is unclear who would have access to List I chemical products upon their delivery to the storage facility and whether they would be handled in a manner which would prevent theft. See 21 CFR 1309.71(b). Furthermore, Respondent's proposed use of a commercial storage facility raises substantial questions about the adequacy of his security controls. Among other things, it appears that unauthorized persons can easily gain access to the facility. Moreover, Respondent has no control over the selection of the facility's other tenants or the persons they bring onto the property. See Sujak Distributors, 71 FR 50102, 50104 (2006). As I have previously explained, the use of commercial storage facilities presents an unacceptable risk that a criminal may gain access to the property and steal List I chemical products.

Finally, while the facility has an alarm system, the alarm sounds only at the facility's office. This raises the further question of whether the facility provides effective monitoring twenty-four hours a day. I thus conclude that Respondent does not maintain effective controls against diversion and that this factor alone is dispositive in concluding that granting him a registration would be inconsistent with the public interest.

Factor Two—The Applicant's Compliance With Applicable Laws

The investigative file contains disturbing evidence that Respondent repeatedly purchased List I chemicals products from R J General Corp., between January 7, 2004, and December 8, 2004. Moreover, in a letter which Respondent faxed to the DIs, he expressly stated that he did not engage in the retail sale of List I chemical products.

Federal regulations clearly state that ''[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is approved and a Certificate of Registration is issued by the Administrator to such person.'' 21 CFR 1309.31(a). Respondent did not have a registration, and the regulations no longer exempt an applicant from the requirement of obtaining a registration prior to distributing List I chemical products. *Id.* 1309.25.

Based on the evidence in the file, I conclude that Respondent violated federal law by distributing List I chemicals without the required registration. See 21 U.S.C. 822(a)(1). As I have previously noted, ''[r]egistration in one of the essential features of the Controlled Substances Act.'' Sato Pharmaceutical, Inc., 71 FR 52165, 52166 (2006). Respondent's engaging in the distribution of List I chemicals without first obtaining a registration is a serious violation of the Act. I therefore conclude that this factor also provides sufficient reason by itself to deny Respondent's application.[1]

Factor Three—The Applicant's Experience in Distributing List I Chemicals

Beyond the misconduct discussed above, Respondent stated in his letter to the DIs that he had no experience in the sale of List I chemical products. Were there no evidence of Respondent having engaged in illicit activity, I would nonetheless conclude that his lack of experience bars his registration.

Because the regulatory scheme imposed by federal law is complex and the risk of diversion is substantial, this is not a line of business that is suitable for a new entrant to learn through on-the-job training. Accordingly, numerous DEA final orders have made clear that an applicant's lack of experience in distributing List I chemicals is a factor which weighs heavily against granting an application for a registration. Tri-County Bait Distributors, 71 FR 52160, 52163 (2006); Jay Enterprises, 70 FR 24620, 24621 (2005); ANM Wholesale, 69 FR 11652, 11653 (2004). I therefore conclude that this factor further supports the denial of Respondent's application.

Factor Four—Other Factors That Are Relevant to and Consistent With Public Health and Safety

Numerous DEA orders recognize that convenience stores and gas-stations constitute the non-traditional retail market for legitimate consumers of products containing pseudoephedrine and ephedrine. See, *e.g.*, Tri-County Bait Distributors, 71 FR at 52161; D & S Sales, 71 FR 37607, 37609 (2006); Branex, Inc., 69 FR 8682, 8690–92 (2004). DEA orders also establish that the sale of certain List I chemical products by non-traditional retailers is an area of particular concern in preventing diversion of these products into the illicit manufacture of methamphetamine. See, *e.g.*, Joey Enterprises, 70 FR 76866, 76867 (2005). As Joey Enterprises explains, ''[w]hile there are no specific prohibitions under the Controlled Substances Act regarding the sale of listed chemical products to [gas stations and convenience stores], DEA has nevertheless found that [these entities] constitute sources for the diversion of listed chemical products.'' Id. See also TNT Distributors, 70 FR 12729, 12730 (2005) (special agent testified that ''80 to 90 percent of ephedrine and pseudoephedrine being used [in Tennessee] to manufacture methamphetamine was being obtained from convenience stores''); OTC Distribution Co., 68 FR 70538, 70541 (2003) (noting ''over 20 different seizures of [gray market distributor's] pseudoephedrine product at clandestine sites,'' and that in eight month period distributor's product ''was seized at clandestine laboratories in eight states, with over 2 million dosage units seized in Oklahoma alone.''); MDI Pharmaceuticals, 68 FR 4233, 4236 (2003) (finding that ''pseudoephedrine products distributed by [gray market distributor] have been uncovered at numerous clandestine methamphetamine settings throughout the United States and/or discovered in the possession of individuals apparently involved in the illicit manufacture of methamphetamine'').

Significantly, all of Respondent's proposed customers participate in the non-traditional market for ephedrine and pseudoephedrine products. Moreover, many of Respondent's proposed customers have other suppliers. Finally, Respondent's lack of knowledge regarding the diversion of List I chemicals into the illicit manufacture of methamphetamine is also disconcerting.

DEA orders recognize that there is a substantial risk of diversion of List I chemicals into the illicit manufacture of methamphetamine when these products are sold by non-traditional retailers. See, *e.g.*, Joy's Ideas, 70 FR at 33199 (finding that the risk of diversion was ''real, substantial and compelling''); Jay Enterprises, 70 FR at 24621 (noting ''heightened risk of diversion'' should application be granted). Under DEA precedents, an applicant's proposal to sell into the non-traditional market weighs heavily against the granting of a registration under factor five. So too here.

[1] Because of the seriousness of this misconduct, I conclude that even though there is no evidence that Respondent has ever been convicted of an offense related to listed chemicals, this factor is entitled to no weight.

Because of the methamphetamine epidemic's devastating impact on communities and families throughout the country, DEA has repeatedly denied an application when an applicant proposed to sell into the non-traditional market and analysis of one of the other statutory factors supports the conclusion that granting the application would create an unacceptable risk of diversion. Thus, in Xtreme Enterprises, 67 FR 76195, 76197 (2002), my predecessor denied an application observing that the respondent's ''lack of a criminal record, compliance with the law and willingness to upgrade her security system are far outweighed by her lack of experience with selling List I chemicals and the fact that she intends to sell ephedrine almost exclusively in the gray market.'' More recently, I denied an application observing that the respondent's ''lack of a criminal record and any intent to comply with the law and regulations are far outweighed by his lack of experience and the company's intent to sell ephedrine and pseudoephedrine exclusively to the gray market.'' Jay Enterprises, 70 FR at 24621. Accord Prachi Enterprises, 69 FR 69407, 69409 (2004).

The investigative file in this case supports even more adverse findings than those which DEA has repeatedly held are sufficient to conclude that granting an application would be inconsistent with the public interest. Here, Respondent clearly lacks effective controls against diversion, has no experience in the elicit wholesale distribution of List I chemical products, and yet intends to distribute these products to non-traditional retailers, a market in which the risk of diversion is substantial. Furthermore, the file establishes that Respondent violated federal law by distributing List I chemicals without a registration. Given these findings, it is indisputable that granting Respondent's application would be ''inconsistent with the public interest.'' 21 U.S.C. 823(h).

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h), and 28 CFR 0.100(b) & 0.104, I order that the application of Respondent Stephen J. Heldman, for a DEA Certificate of Registration as a distributor of List I chemicals be, and it hereby is, denied. This order is effective February 28, 2007.

Dated: January 20, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–1326 Filed 1–26–07; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 04–36]

Rose Mary Jacinta Lewis, M.D.; Affirmance of Immediate Suspension

On March 22, 2004, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Notice of Immediate Suspension of the practitioner's Certificate of Registration, AL8962993, held by Rose Mary Jacinta Lewis, M.D. (Respondent), of Richmond, CA. The Notice of Immediate Suspension was based on my preliminary finding that substantial amounts of Schedule III controlled substances that had been ordered using Respondent's DEA registration could not be accounted for. Show Cause Order at 7. Based on the significant risk that these drugs had been diverted as well as evidence showing that Respondent had allowed unregistered entities and individuals to use her registration to obtain controlled substances, I concluded that Respondent's continued registration ''would constitute an imminent danger to the public health and safety.'' *Id.*

More specifically, the Show Cause Order alleged that in September 2003, R & S Sales, a registered distributor, had reported to DEA ''that excessive amounts of controlled substances were being ordered under'' Respondent's name and registration number. *Id.* at 2. The Show Cause Order further alleged that shortly thereafter, DEA investigators went to Respondent's registered location and determined that Respondent was no longer practicing medicine at the location and had retired from practice and vacated the premises six months earlier. *See id.* During the attempted visit, DEA investigators found several United Parcel Service (UPS) delivery notices including one from R & S. *See id.* According to the Show Cause Order, DEA investigators subsequently determined that on September 10, 2003, an order for 300 bottles, each containing 500 count hydrocodone/apap [1] (7.5/75), a Schedule III controlled substance, had been placed with R & S under Respondent's registration and that UPS had been unable to deliver the order to Respondent's former office. *See id.* The Show Cause Order further alleged that the order was subsequently delivered to an entity known as International Surplus Medical Products, Inc. (ISMP), at its Richmond, California office. *See id.* The address was not, however, a registered location. *See id.*

The Show Cause Order next alleged that on November 24, 2003, Respondent left a voicemail message with a DEA investigator in which she stated that she was ISMP's medical director and was using her medical license to order supplies. *See id.* According to the Show Cause Order, a DEA investigator then called Respondent and advised her that R & S could not ship supplies to ISMP's office because it was not a registered location. *Id.* at 3. The Show Cause Order alleged that during the conversation, Respondent stated that she was working for a non-profit project that provided medical supplies for AIDS patients in Nigeria, that the project ordered only AIDS-related drugs such as AZT, and that it was not ordering controlled substances. *See id.*

The Show Cause Order further alleged that following the conversation, Respondent submitted a written request to change the address of her registered location to ISMP's Richmond office. *Id.* The Show Cause Order alleged that in her letter requesting the change, Respondent stated that she worked with ISMP, a non-profit entity that ''sends AIDS drugs to Nigeria.'' *Id.* On December 1, 2003, DEA personnel changed the address of Respondent's registered location to ISMP's office. *Id.*

The Show Cause Order next alleged that during the week of December 3, 2003, R & S notified DEA that on November 26, 2003, an order for 504 bottles, each containing 500 tablets of hydrocodone/apap, had been placed using Respondent's registration. *See id.* The Show Cause Order alleged that R & S was told to ship the order to Respondent's former office, and that on December 1, 2003, 19 packages were received at that address and an additional package was sent to ISMP's office. *Id.*

The Show Cause Order alleged that on December 10, 2003, DEA investigators attempted to serve an Administrative Inspection Warrant at ISMP's office but no one was present. *See id.* The Show Cause Order next alleged that on January 15, 2004, DEA investigators interviewed Respondent at her home. *Id.* During the interview Respondent allegedly told investigators that she had retired from medical practice and was working as ISMP's medical director. *Id.*

The Show Cause Order further alleged that Respondent told the investigators that she had provided her DEA number to Mr. Chuka Ogele, ISMP's Chief Executive Officer, so that he could order medical supplies and controlled substances which were to be exported to Nigeria, and that she denied personally

[1] Apap is an abbreviation for acetaminophen.