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.

placing any orders for controlled substances. Id. at 4. The Show Cause Order alleged that during the interview, Respondent stated that she did not know how what drugs and quantities Ogele had ordered from R & S and also had none of the records that she was required to maintain under federal law. Id. According to the Show Cause Order, Respondent also told the investigators that she did not have a key to the ISMP office, notwithstanding that it was her new registered location. Id.

The Show Cause Order alleged that DEA investigators then contacted Ogele, who stated that he did not keep the records at ISMP's office but rather at his home. Id. According to the allegations, the investigators subsequently interviewed Ogele, who told them that controlled substances were ordered based on requests he received from Nigeria, and that he either personally carried the drugs to Nigeria or arranged for unidentified Nigerian "diplomats" to pick up the drugs in San Francisco and take them to Nigeria. Id.

The Show Cause Order further alleged that the investigators inventoried the controlled substances at the ISMP office. Id. The Show Cause Order alleged that the office had neither a substantially constructed cabinet nor an alarm system. Id. at 4-5.

The Show Cause Order next alleged that on January 22, 2004, an employee of the physician who had purchased Respondent's former office informed the investigators that several months earlier, a shipment of controlled substances had been received by a workman who was renovating the office and had been stored there. See id. at 5. The shipment was turned over to the investigators, who determined based on a packing slip, that five boxes were shipped by R & S on August 14, 2003, that each box held 36 bottles (each containing 500 tables of hydrocodone/apap), and that the order had been placed by Ogele. See id. The Show Cause Order further alleged that the other four boxes have not been accounted for. See id.

The Show Court Order also alleged that on January 26, 2004, DEA investigators went to ISMP's office to serve an administrative inspection warrant. Id. According to the Order, the investigators seized thirty thousand dosage units of hydrocodone/apap (in sixty 500-count bottles) and 211,000 dosage units of codeine/apap (in 500 and 1,000 count bottles). Id. at 6.

Finally, the Show Cause Order alleged that Respondent did not maintain any of the records documenting the receipt and disposition of the controlled substances that were ordered under her registration. Id. at 6-7. The Order further alleged that

the disposition of "the bulk of the controlled substances ordered under [Respondent's] name and registration from March 2003" through the issuance of the Order of Immediate Suspension were unknown. Id. at 7.

On April 5, 2004, DEA Investigators personally served Respondent with the Order to Show Cause and Immediate Suspension. ALJ Ex. 2, at 1. Thereafter, on May 3, 2004, Respondent through her counsel, timely requested a hearing. See id. Respondent also responded to the Show Cause Order's allegations.

The matter was assigned to Administrative Law Judge (ALJ) Gail Randall, who conducted a hearing in San Francisco, CA, on August 2 and 3, 2005. At the hearing, both parties called witnesses and introduced documentary evidence. Following the hearing, both parties submitted proposed findings of fact and conclusions of law.

On September 26, 2006, the ALJ issued her decision. ALJ at 1. The ALJ concluded that the Government had proved by a preponderance of the evidence that the continuation of Respondent's registration would be inconsistent with the public interest. The ALI also concluded that "Respondent's lack of responsible handling of the authority granted to her through her DEA registration poses a threat to the public health and safety," and recommended that I revoke her Certificate of Registration. Id. at 38. Neither party filed exceptions.

Having carefully reviewed the record as a whole, I hereby issue this decision and final order. I adopt the ALJ's findings of fact and conclusions of law except as expressly noted herein. I further affirm the immediate suspension of Respondent's registration and make the following findings.

Findings Of Fact

Respondent has held a California Physician and Surgeon's license since July 1, 1975, which remains in active status. Respondent practiced medicine as a plastic surgeon from 1980 until March 2003. During March 2003, Respondent closed her practice and sold her office condominium to Dr. Randy Weil. Her state license has never been subjected to disciplinary action. ALJ at 3-4.

Respondent held DEA Certificate of Registration, AL8962993, which was issued on December 1, 2003, and expired on March 31, 2006. Gov. Ex. 1. According to DEA records, Respondent has not submitted a renewal application.2 I thus find that

Respondent is not currently registered. Respondent testified, however, that "[j]ust because [she] closed [her] practice didn't mean [she] was never going to work again." Tr. 353.

With respect to the events which are the subject of this proceeding, Respondent's registered location was initially 203 Willow St., Suite 303, San Francisco, CA. On December 1, 2003, Respondent's registered location was changed to 120 Broadway St. Suite 3, Richmond, CA. Gov. Ex. 2.

On November 5, 1996, Chuka Ogele founded International Surplus Medical Products, Inc. (ISMP), which was organized for charitable purposes under section 501(c)(3), of the Internal Revenue Code. Resp. Ex. 10, at 2. According to its articles of incorporation, ISMP's purpose was "to distribute medical supplies in developing nations." Id. Ogele appointed himself Chairman and Managing Director. Resp. Ex. 12.

Sometime in either 2001 or 2002, Respondent was introduced to Ogele by Sherrone Smith, an ISMP board member who had taught Ogele at the College of Alameda. Tr. at 66-67, 262. Respondent met with Ogele, who told her that ISMP had been in existence for six or seven years and that the entity provided vitamins to developing countries. Id. at 262-63. Ogele told Respondent that he wanted to provide medications to treat HIV/AIDS. Id. at 263. Ogele offered Respondent a position on ISMP's board gave her the title of Associate Medical Director. Id. 263.

Respondent subsequently gave Ogele a copy of her state medical license and her DEA registration. Id. 327. Respondent maintained that she did so to enable Ogele to order supplies, that "[a]ll the suppliers require that you give them both licenses," and that she had "never had one, even if [she was not] ordering * * * controlled substances, [that] didn't request both licenses." Id. Respondent further testified that she provided her DEA registration to Ogele without checking out his background. Id. at 329.

The DEA Investigation

Respondent first came to the attention of DEA in September 2003, when R &

stage in a proceeding-even in the final decision." U.S. Dept. of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA regulations, Respondent is "entitled on timely request, to an opportunity to show to the contrary." 5 U.S.C. 556(e); see also 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the fact of which I am taking official notice, publication of this final order shall be withheld for fifteen days, which shall begin on the date of service by placing this order in the mail.

² Under the Administrative Procedure Act (APA), an agency "may take official notice of facts at any

S Sales notified the DEA Louisville office of Respondent's excessive purchases of controlled substances including hydrocodone, acetaminophen with codeine, and promethazine with codeine. ALJ at 4 (citing Tr. 12–13). The information was forwarded to a Diversion Investigator (DI) with the San Francisco Diversion Group.

The DI went to Respondent's registered location at 203 Willow Street, San Francisco only to find that her office was vacant. Tr. 14–15. The DI inquired with the building's management company as to Respondent's whereabouts; the DI was told that, in March 2003, she had retired and vacated her office. *Id.* 15.

The DI subsequently contacted R & S Sales. R & S advised the DI that, on September 10, 2003, an additional purchase of a controlled substance had been made with Respondent's registration. Tr. 15–16. The purchase was for 300 bottles, each containing 500 tablets of hydrocodone/apap. Gov. Ex. 17. The invoice lists the name "CHUKA" under the Purchase Order Number. *Id.* It also indicates that ISMP was to be billed for the order and that the drugs were to be shipped to Respondent at the Willow St. office which she had since vacated. *Id.*

The DI contacted UPS to ascertain whether the shipment had been delivered. Tr. at 16. UPS informed the DI that it had attempted two deliveries at Respondent's former office and that someone had changed the address of the delivery to ISMP's office at 120 Broadway in Richmond. *Id.* UPS subsequently delivered the drugs to Chuka Ogele at this address. *Id.*

On November 26, 2003, the DI received a voicemail message from Respondent. In this message, Respondent stated that Chuka Ogele, ISMP's chairman, had been attempting to call the DI regarding the ordering of supplies. *Id.* at 17. In the message, Respondent also stated that she was ISMP's medical director and that ISMP "was using her medical license to order medical supplies." *Id.* Respondent requested that the DI call her. *Id.* at 18.

The DI phoned Respondent.
Respondent told the DI that R & S would not deliver medical products to ISMP's office because it was not registered under her name and address. *Id.* The DI told Respondent that she needed to change the address of her registration. *Id.* According to the DI, Respondent said during the call that "she was not ordering controlled substances, but was ordering * * * AIDS drugs such as AZT." *Id.*

Subsequently, Respondent submitted a letter requesting a change of the

address of her registered location. *Id.* On December 1, 2003, DEA changed the address of her registered location to ISMP's office. *Id.* at 19.

Shortly thereafter, the DI received another phone call from R & S. *Id.*During this call, the DI was informed that on November 26, 2003, another order for controlled substances had been placed using Respondent's registration and her former office as the address that the drugs were to be shipped to. *Id.*; see also Gov. Ex. 16, at 2. This order was for 504 bottles each containing 500 count of hydrocodone/apap 7.5/750mg.³

Following the receipt of this information, the DI obtained an administrative inspection warrant for the ISMP's office. Tr. 19. On December 10, 2003, the DI, along with other DEA investigators, attempted to serve the warrant. *Id.* Upon their arrival at ISMP's office, the DIs could not serve the warrant because no one was present. *Id.* at 20.

On January 15, 2004, the DI, accompanied by another DI and a Special Agent, went to Respondent's residence to interview her regarding the large quantities of controlled substances that were being ordered using her registration. *Id.* at 20–21. During the interview, Respondent told the investigators that she was the medical director of ISMP, that the organization assisted AIDS patients in Nigeria, and that Chuka Ogele was the chairman. *Id.* at 21.

Respondent further told the DIs that Ogele was using her DEA number to order medical supplies from R & S Sales and that she had not personally placed any of the orders. Id. at 23. Respondent told the DI that "she did not know what types of controlled substances [were] being ordered by Ogele," id., but indicated that the drugs were being ordered for AIDS patients. Id. at 24. Respondent did not have any records documenting the purchases of the controlled substances but thought that the records might be at ISMP's office. Id. Respondent did not, however, have access to the office as Ogele "had the only key." Id.

During the interview, the other DI told Respondent that she was liable for giving her registration to another person and not knowing what drugs were being ordered. *Id.* at 25. Respondent stated that she understood. *Id.* The investigators also told Respondent that they needed to see the records. *Id.* Respondent contacted Ogele, who agreed to meet with the investigators

later that day at ISMP's office. *Id.* at 25–26.

The investigators subsequently met with Ogele at ISMP's office. Id. at 26. During the meeting, Ogele told the investigators that he was ISMP's chairman and that the controlled substances he was ordering from R & S were for Nigerian AIDS patients. *Id.* at 27–28. Ogele provided the investigators with several documents from officials of the Government of Benue State, Nigeria. Id. at 30; see also Gov. Ex. 6 & 7. While these documents show that Benue State Ministry of Health requested that ISMP supply it with various drugs for treating HIV and other opportunistic infections, Benue State officials did not request that ISMP supply any controlled substances. See Gov. Exs. 6 & 7.

As for the controlled substance records, Ogele provided the investigators with four invoices for the purchase of controlled substances. Tr. 30. Subsequently, a DI determined that about thirteen orders for controlled substances had, in fact, been placed with R & S using Respondent's registration. *Id.* at 29.

Moreover, Ogele did not provide any records documenting the distribution of the controlled substances. Id. at 27. During the interview, Ogele stated that he would sometimes take controlled substances to Nigeria in his luggage. Id. at 31. Ogele also stated that sometimes Nigerian diplomats would come to San Francisco to obtain the controlled substances and take them back to Nigeria. Id. Ogele did not hold any DEA registration and Respondent was not registered as an exporter. Id. at 31-32. The investigators told Ogele that he did not have the registration required under federal law to export controlled substances. Id. at 31. The investigators also determined that there were controlled substances on the premises and took an inventory. Id. at 32.

On January 22, 2004, an employee of Dr. Randall Weil (who had purchased Respondent's former office) contacted DEA. Id. at 32–33. Dr. Weil's employee informed DEA that the office had received a shipment of controlled substances that had been shipped to Respondent. Id. at 33. The next day, the DI and her supervisor went to Dr. Weil's office and retrieved one box holding 36 bottles, each containing 500 tablets, of hydrocodone/apap 7.5/750. Id. at 34. The shipment's packing slip, which was dated August 14, 2003, indicated that a total of 180 bottles (five boxes) of the drug had been ordered. Resp. Ex 3, at 2. The investigators have not been able to determine the disposition of the other 144 bottles. Tr. 34.

 $^{^3\,\}rm The$ order also included one bottle of 100 ativan (2 mg.) tablets. Gov. Ex. 16, at 2.

On January 26, 2004, the DI obtained and served another administrative inspection warrant at ISMP's office. Id. at 34-35. DEA personnel went to ISMP's office but found no one present. Id. at 37. The investigators then contacted Ogele by phone. Id. Following Ogele's arrival, the investigators informed Ogele that he was improperly using Respondent's registration. Id. at 39. The investigators then seized approximately 300 bottles of hydrocodone/apap and codeine/apap, which were taken to the DEA office. Id. at 39-40; Gov. Ex. 8. The investigators subsequently contacted Respondent and offered to arrange for the drugs to be returned to R & S with a credit to her account. Id. at 40.

Respondent agreed and, on January 30, 2004, went to the DEA office to assist in the inventory. *Id.* at 40–41. The inventory differed, however, from the inventory that was taken during the January 26 administrative inspection by one bottle of hydrocodone/apap. *Id.* at 171.

During this meeting, the DI told Respondent that DEA was concerned about the large orders of controlled substances that were placed with her registration. *Id.* at 41. The DI also told Respondent that it was improper to allow Ogele to use her DEA registration to order controlled substances for export to Nigeria. *Id.* The DI also discussed with Respondent the shipment that DEA had retrieved from her former office. *Id.* at 42. Respondent told the DIs that she had not ordered those drugs. *Id.*

The DI advised Respondent that DEA was seeking to suspend her registration. *Id.* at 45–46. The DI asked Respondent whether she would voluntarily surrender her registration. *Id.* Respondent refused. *Id.* at 46.

The investigators subsequently obtained from R & S Sales, copies of the invoices documenting the controlled substance purchases made using Respondent's registration between August 15, 2002, and December 29, 2003. Tr. 52, Gov. Exs. 12 & 17. The Government also introduced into evidence a compilation of the purchases. See Gov. Ex.13.

The compilation shows that Ogele used Respondent's registration to obtain from R & S, 1,537,500 tablets of hydrocodone/apap in various strengths and 450,000 dosage units of codeine/ apap in various strengths; these drugs are schedule III controlled substances. See 21 CFR 1308.13(e). The compilation further shows that Respondent's registration was used to purchase from R & S, 97,340 dosage units of lorazepam (in various strengths), 19,900 dosage units of phenobarbital (in various strengths), 9700 dosage units of ativan (2mg.), 400 tablets of diazepam, and 3100 tablets of flurazepam. All of these drugs are schedule IV controlled substances. *Id.* 1308.14(c). Finally, the compilation shows that Respondent's registration was used to order 13,800 tablets of diphenoxylate/atropine sulfate, and 455,040 milliliters of promethazine/codeine cough syrup; both drugs are schedule V controlled substances. Id. 1308.15

The investigation also determined that Ogele used Respondent's registration to order controlled substances from an additional supplier, Priority Healthcare, between July 16, 2003, and September 15, 2004.5 See Gov. Ex. 10. The compilation of these purchases shows that Ogele obtained 285,900 dosage units of codeine (30mg.)/apap and 135,900 dosage units of codeine (60 mg.)/apap. See Gov. Ex. 11, ALJ at 3. The compilation also shows that Ogele obtained 77,100 dosage units of hydrocodone/apap (of various strengths). *Id.* Finally, the compilation shows that Ogele obtained 46,694 sixteen oz. bottles of promethazine w/codeine, the wholesale price of this medication was approximately \$664,900.

Ögele purchased the majority of the drugs from Priority after the service of the Notice of Immediate Suspension.

See Gov. Exs. 10 & 11. Respondent did not become aware of the purchases from Priority until a few months before the hearing when Ogele's wife apparently found an invoice or some other document from Priority and told Respondent. Tr. 347. Respondent did not provide DEA with any records related to the receipt and distribution of these drugs. *Id.* 54–55.

DEA has been unable to determine the disposition of the great majority of the drugs Ogele ordered using Respondent's registration. See ALJ at 15; Tr. at 53, 55, 64. The only drugs which can be accounted for are those which DEA

retrieved from Respondent's former office and those seized during the execution of the warrant at ISMP's office. Tr. 53.

On September 2, 2004, Ogele was arrested by local authorities at the George Bush Intercontinental Airport in Houston, Texas. Id. at 55. At the time, Ogele was carrying \$975,481 in cash and 395 Vicodin tablets for which he lacked a prescription. *Id.*; see also Gov. Ex. 22. During an interview with Houston police, Ogele claimed that the cash had been donated to ISMP. Tr. 56. Ogele further stated that a person named Mike, who lived in Houston, would sometimes hold fundraisers at churches for ISMP. Id. at 56-57. Ogele did not, however, know Mike's last name or his address. Id. Initially, Ogele told the police that he did not know how to contact Mike. *Id.* at 57. Ogele later changed his story and stated that Mike had called him upon his arrival at his hotel and brought the cash to him. Id. Subsequently, Ogele waived his interest in the cash and forfeited it. Gov. Ex. 22. He was also charged with unlawful possession of controlled substances. Tr.

On September 22, 2004, Ogele was arrested at another Houston airport (William P. Hobby). Gov. Ex. 19. On this occasion, Ogele was carrying \$7774 in cash and various controlled substances including 24 Vicodin tablets, 135 Ativan tablets, and two Lortab tablets. *Id.* at 2. He did not have a valid prescription for any of these drugs. Tr. 58. He also had in his possession thirteen invoices from Priority Healthcare. *Id.* at 58–59. The cash was again seized and forfeited. Id. at 58. Ogele was subsequently convicted of delivery of a controlled substance, a felony offense under Texas law, and sentenced to eight years of community supervision. Gov. Ex. 20.

Respondent's Knowledge of Ogele's Use of Her DEA Registration

One of the central issues in this case is whether Respondent knew that Ogele was using her DEA registration to order controlled substances. Both in her testimony and her post-hearing brief, Respondent has maintained that prior to the January 15, 2004 interview with DEA, she "did not know about the ordering of [the] controlled substances and is not responsible for record keeping involved with such orders." Resp. Br. at 20. See also id. at 6 (Respondent "did no[t] anticipate that there would be any controlled substances ordered to be used in the project.").

In reference to Respondent's giving her DEA registration to Ogele, the ALJ found that "Respondent credibly

⁴ On some date which the record does not clearly establish, Ogele played for the ISMP board a tape recording of a phone message from a Mr. Dan Neeson, an employee of the Department of Commerce's Bureau of Export Administration. The message stated that "[m]ost medical products do not require an export license. And if you do require a license it would be for a particular country for a particular transaction. If you want more information, give me a call." Resp. Ex. 36. Respondent asserted that Ogele told the board that he had contacted DEA and that Mr. Neeson had left the above message. Tr. 293. The Bureau of Export Administration is not part of DEA and does not enforce the Controlled Substances Act.

⁵ DEA did not become aware that Ogele had also made purchases from Priority Healthcare until after his arrest on September 22, 2004, at Hobby Airport in Houston, Texas.

testified that she told Mr. Ogele that she understood that ISMP would order 'medications, primarily AIDS and AIDS-related medications, but no IV injectables and no narcotics.'" ALJ at 5–6 (FOF 17) (quoting Tr. at 351). The ALJ also found that "Respondent did not anticipate that there would be any controlled substances ordered by ISMP." *Id.* at 6 (quoting Tr. at 351).

In her testimony, Respondent further maintained that she did not become aware that Ogele was using her registration to order controlled substances until January 15, 2004, when she was told this while being interviewed by DEA investigators. During cross examination, Respondent was asked whether she knew "there were any controlled substances being ordered?" Tr. 326. Respondent answered "No." Id. The Government then asked Respondent: "[Y]ou didn't know there were any controlled substances being ordered until DEA informed you in January of 2004, correct?" Id. Respondent answered: "Yes." Id.

The ALJ found, however, that a preponderance of the evidence 'supports the conclusion that * * * Respondent knew that controlled substances were being ordered using her DEA registration." ALJ at 16 (FOF 61). Among other evidence, the ALJ noted the testimony of Dr. Green, another ISMP board member. Dr. Green testified that she had knowledge that Respondent allowed her registration to be used to obtain AIDS and pain medications, and that she and Ogele had also visited a company in the Midwest after which ISMP began receiving from it AIDS and "pain medications." Tr. 236.

The ALJ's finding does not, however, specify at what point in time Respondent knew that Ogele was using her registration to order controlled substances. Another finding appears to credit Respondent's testimony that she did not learn of this until the January 2004 DEA meeting and "was surprised" to find that Ogele was ordering controlled substances. ALJ at 10 (FOF 42).

42).

To the extent this finding was intended to credit Respondent's testimony that she did not learn of the controlled substance purchases until January 2004, I reject it. Instead, I find that Respondent knew at least as early as May 2003, that Ogele was using her registration to order controlled substances.

In her letter requesting a hearing, Respondent filed a lengthy point by point response to the allegations of the Show Cause Order. See ALJ Ex. 2. In this filing, Respondent "admit[ted] that between May 2003 and August 2003 she authorized the ordering of hydrocodone or vicodin from R & S Sales." ALJ 2 at Respondent further stated that "[t]he purpose of these orders was to ship the vicodin to Nigeria to aid in the treatment of women with AIDS and HIV." Id. More specifically, Respondent "admit[ted] to authorizing the ordering of three hundred bottles of hydrocodone (vicodin) from R & S * * * between May 2003 and August 2003," that the "drugs were ordered on behalf of" ISMP, and that they "were purchased under [Respondent's] license for the purposes of export to Nigeria to fulfill existing commitments that [ISMP] has with the Nigerian military and other Nigerian government entities." *Id.*

In this same document, Respondent further stated that in her November 24, 2003 telephone conversation with a DEA investigator, she "never said she was 'not ordering controlled substances' because vicodin and [T]ylenol #3 is an integral part of the treatment of AIDS/ HIV in Nigeria." Id. at 3-4. Moreover, with respect to the order that was placed with R & S on November 26, 2003, Respondent "denie[d] ever having told the DEA agent that she was not ordering [V]icodin and Tylenol # 4 for the Nigeria project." *Id.* at 4. Respondent further "admit[ted] authorizing the order and that the drugs were shipped to the Broadway Street address." Id. Finally, Respondent stated that she "may not always have known the quantities of the substances ordered but she always knew what the drugs were that were being ordered and shipped. The orders are for standard quantities of particular drugs and do not vary very much, order to order." Id. at 4-5.

The ALJ did not acknowledge these admissions and thus did not discuss the fundamental inconsistencies between them and Respondent's statements under oath at the hearing. While I am mindful that the ALJ observed Respondent's testimony, deference to the ALI's findings is clearly not appropriate where, as here, a witness tells two materially different tales and the ALJ gives no explanation as to why one is more credible than the other. Based on her written admissions, I thus find disingenuous Respondent's testimony on cross-examination that she did not become aware that Ogele was ordering controlled substances until the January 2004 interview with DEA investigators. And consistent with her admissions, I further find that Respondent knew at least as early as May 2003 that Ogele was ordering controlled substances.

Respondent's Response to Ogele's Misuse of Her Registration

On January 15, 2004, DEA investigators informed Respondent that an excessive amount of controlled substances had been ordered under her registration. Tr. 302. Furthermore, on January 26, 2004, DEA executed an administrative search warrant at ISMP's office and seized a substantial quantity of controlled substances.

Notwithstanding these two events, Respondent did not demand that Ogele produce the invoices. Furthermore, she did not even talk to Ogele about the matter until "probably April." *Id.* at 313.

In her testimony, Respondent asserted that the reason she did not talk to Ogele about the matter was because he "left the country * * * early the next morning." Id. Respondent testified, however, that Ogele had called her on January 26, 2004, the day that DEA investigators served the administrative warrant and told her that the investigators had already shown up at ISMP's office. Id. at 304. Respondent further testified that Ogele called her and asked her to go to the DEA office to conduct an inventory of the controlled substances because he "was getting ready to leave the country." Id. at 305. The inventory occurred on January 30. While Respondent did not testify as to the date this phone call occurred, it is clear that Ogele was in the country for a substantial period of time following Respondent's receipt of information that her registration was being misused (during the January 15, 2004 interview) and that she made no effort to investigate the matter for at least three months.

Respondent had long known that R & S Sales was one of ISMP's primary suppliers. Respondent testified that R & S was sending orders to her medical practice and that she contacted R & S in an attempt to have the orders shipped to the ISMP office. Id. at 267. Respondent did not, however, contact R & S during the period between the January 15 interview and service of the Show Cause Order to obtain copies of the invoices for the orders that had been placed under her registration. Furthermore, even following the service of the Show Cause Order, Respondent did not promptly contact R & S to obtain the invoices. Id. at 347; ALJ Ex. 2, at 5. While the record does not specify when Respondent finally contacted R & S, in her response to the Show Cause Order, Respondent stated that ISMP "has records of each drug shipment," ALJ Ex. 2, at 5, and made no mention that she had obtained or was then attempting to

obtain the records from R & S. Furthermore, when asked whether after service of the Show Cause Order she had "ask[ed] any of the suppliers for records?," Respondent answered: "[n]ot at that time." Tr. 347. Respondent further testified that she did not contact R & S until "later." *Id.*

Respondent did not obtain copies of the invoices from Priority Healthcare until "a few months" before the hearing, when Ogele's wife found some invoices from Priority and contacted it to obtain copies of them for her. *Id.* Finally, Respondent did not testify that she ever attempted to exercise her right as a director of ISMP to examine its books, records, and documents. See, *e.g.*, Cal. Corp. Code section 6334 (West 2006).

Discussion

Section 304(a) of the Controlled Substances Act provides that a registration to "dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render [her] registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). In making the public interest determination, the Act requires the 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.* section 823(f).

"[T]hese factors are * * * considered in the disjunctive." Robert A. Leslie, M.D., 68 FR 15227, 15230 (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 a registration should be revoked." *Id.* Moreover, case law establishes that I am "not required to make findings as to all of the factors." *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall* v. *DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005).

Finally, section 304(d) provides that "[t]he Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an

imminent danger to the public health or safety." 21 U.S.C. 824(d). In this case I conclude that Factors Four and Five conclusively establish that allowing Respondent to hold a registration would be inconsistent with the public interest. Analyzing these factors, I also conclude that Respondent's conduct created "an imminent danger to the public health or safety," id., and thus affirm the immediate suspension of her registration.

Factor Four—Respondent's Compliance With Applicable Laws

The evidence in this case establishes that Respondent acted with complete disregard for the obligations imposed on her as a registrant under federal law and regulations. These actions included entrusting her registration to someone she had no effective control over and knew little about, her total failure to comply with the CSA's recordkeeping requirements and to ensure the security of controlled substances, and her authorizing Ogele to use her registration to obtain controlled substances knowing that they would be exported to a foreign country without a registration. While the record shows that Respondent was motivated by humanitarian concerns and was likely duped by Ogele, Respondent's disregard for federal law cannot be excused.

As the evidence shows, Respondent entrusted her DEA number to Ogele shortly after meeting him and joining the ISMP board. She did so without investigating Ogele's background ⁸ and even though she had no effective control over him. Respondent's conduct violated the CSA because the Act does not authorize a registrant to allow an unregistered person to use her registration to handle controlled substances unless the latter is the employee or agent of the registrant. See 22 U.S.C. 822(c) (exempting from registration "an agent or employee" of a

registrant but only "if such agent or employee is acting in the usual course of his business or employment").

Respondent argues that authorizing Ogele to use her DEA number is "no different[t]" than "what goes on in the normal medical practice" where "[t]he doctor tells her nurse to order drugs under her number and the nurse does it on the doctor's behalf." ALJ Ex. 2 at 4. Contrary to Respondent's contention, there is a fundamental difference between what she did and what goes on in normal medical practices because Ogele was not her employee and thus was not subject to her control through the measures employers customarily use to discipline employees.

Moreover, Ogele was not Respondent's agent. The evidence clearly shows that Ogele did not act on Respondent's behalf but rather on behalf of ISMP and himself. The evidence further shows that Ogele was not Respondent's agent because while Respondent was a member of ISMP's board, she could not unilaterally remove him and had no effective means of controlling him. See, e.g., Restatement (Second) of Agency section 1 (1958) (comment a) ("The relation of agency is created as a result of conduct by two parties manifesting that one of them is willing for the other to act for him subject to his control * * *. [T]he agent must act or agree to act on the principal's behalf and subject to his control."); 9 Resp. Ex. 11. Respondent thus violated the CSA by entrusting her registration to Ogele, who was neither her employee nor her agent.

Respondent's conduct in authorizing Ogele to use her registration to order controlled substances violated the CSA for an additional reason. Respondent clearly contemplated that the drugs were being ordered to be shipped to Nigeria. A practitioner's registration, however, grants its holder authority to obtain controlled substances only for the limited purposes of conducting research or dispensing them to an ultimate user. See 21 U.S.C. 802(10) & (21); section 822(b). It does not provide its holder with authority to export a controlled substance. Id. section 822(b) ("Persons registered * * * under this subchapter to * * * dispense controlled substances * * * are authorized to possess * * * or dispense [controlled] substances * * * to the extent authorized by their registration."). See also id. section 957(a) ("No person may * export from the United States any

⁶ Having considered all of the factors, I deem it unnecessary to make findings on factors one, two,

⁷ While Respondent's registration has expired and she did not submit a renewal application, this case began with the immediate suspension of her registration and thus is not moot. See William R. Lockridge, 71 FR 77791, 77796–97 (2006). Furthermore, Respondent testified that while she had closed her office, she might return to the practice of medicine.

⁸DEA regulations provide that a "registrant shall not employ as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances." 21 CFR 1301.76(a). As explained in the text, Ogele was neither an employee nor an agent of Respondent. While by its terms the regulation does not apply to Respondent, it nonetheless demonstrates the recklessness of Respondent's authorizing Ogele to use her registration without conducting a background investigation.

¹ Cf. id. § 14 C (comment b) ("An individual director * * * has no power of [her] own to act on the corporation's behalf, but only as one of the body of directors acting as a board.") (emphasis added).

controlled substance * * * unless there is in effect with respect to such person a registration issued * * * under section 958 of this title.").

Consistent with the statutory scheme, DEA regulations provide that dispensing and exporting are activities which are "deemed to be independent of each other," 21 CFR 1301.13(e); exporting is not a "coincident activity" which is authorized under a practitioner's registration. *Id.* (Table). DEA regulations further require that "[a]ny person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities." *Id.* 1301.13(e).

While there is some question regarding the extent to which the controlled substances were actually exported to Nigeria (as opposed to being sold by Ogele in this country)—largely because of Respondent's failure to ensure that proper records were being maintained—Ogele told DEA investigators that he was personally carrying drugs to Nigeria. Moreover, Respondent made numerous admissions that show that she was aware that the controlled substances were being ordered for the purpose of export to Nigeria. Thus, it is clear that Respondent violated 21 U.S.C. § 957(a) by exporting controlled substances without a registration.

Respondent also violated the Act by failing to adequately supervise Ogele's activities. Under DEA regulations, a registrant "shall provide effective controls and procedures to guard against theft and diversion of controlled substances," 21 CFR 1301.71(a), including adequate systems "for monitoring the receipt, * * * distribution, and disposition of controlled substances in its operations. Id. 1301.71(b)(14). Cf. id. 1301.71(b)(11) (require an assessment of "[t]he adequacy of supervision over employees having access" to controlled substances).

Respondent's supervision of Ogele's use of her registration was non-existent. As Respondent admitted, she "may not always have known the quantities of the substances ordered." ALJ Ex. 2, at 4. Indeed, Respondent was clueless as to the scope of Ogele's ordering of controlled substances. See Tr. 328–29 ("I didn't supervise him" (Ogele) to ensure that he was keeping records.); id. at 329 ("I wasn't following those records, no.").

As the ALJ found, this was because Respondent did not ensure that the required records documenting the purchase and distribution of controlled substances were maintained. ALJ at 34; see, e.g., 21 CFR 1304.21(a) ("Every registrant required to keep records

* * * shall maintain on a current basis
a complete and accurate record of each
such substance * * * received, sold,
delivered, exported, or otherwise
disposed of * * *."). See also 21 CFR
1304.22. Nor did she ensure that the
required inventories were conducted.
See id. 1304.11.

The direct consequence of Respondent's abdication of her obligations as a registrant is that the disposition of an extraordinary quantity of controlled substances cannot be accounted for and the drugs have likely been diverted. Of the drugs Ogele obtained from R & S, more than 2.1 million dosage units are unaccounted for. Moreover, none of the drugs Ogele obtained from Priority Healthcare (which included nearly 47,000 dosage units of promethazine with codeine cough syrup, with a wholesale price of nearly \$ 65,000) have been accounted for.

To be sure, Ogele ordered many of the drugs from Priority after DEA had told him to stop and Respondent was likely unaware of this. The fact remains, however, that Ogele would not have been able to do so if Respondent had never entrusted her registration to him in the first place. This Agency has previously held that a registrant who allows a non-registrant to use her registration is strictly liable for any misuse of the registration. See Anthony L. Cappelli, 59 FR 42,288 (1994).

Finally, the record establishes that Respondent authorized the ordering of controlled substances that were shipped to her former office in San Francisco which remained her registered location until December 1, 2003. Because Respondent had sold and vacated her office some eight months earlier, she had no effective means of securing the drugs that were delivered to this address. The record also establishes that with Respondent's authorization, controlled substances were being stored at ISMP's Richmond office even though this facility was not a registered location. Indeed, she did not even have a key for the office. Both the shipping of drugs to her former office and the shipping of drugs to the ISMP office when it was not her registered location violated the CSA.¹⁰

I thus conclude that Respondent's record of non-compliance with federal law is extensive and egregious. As the

ALJ explained, Respondent's conduct "evidences a reckless disregard for the legal obligations and responsibilities" of a registrant. ALJ at 34. The direct consequence of Respondent's indifference to her obligations under the CSA was to provide a drug dealer with the means to obtain his wares and to create an "imminent danger to the public health or safety." 21 U.S.C. 824(d).

I thus affirm the immediate suspension of Respondent's registration. I further conclude that this factor provides reason alone to conclude that allowing Respondent to hold a DEA registration would be "inconsistent with the public interest." 21 U.S.C. 823(f).

Factor Five: Such Other Conduct Which May Threaten Public Health and Safety

As explained above, because of Respondent's failure to comply with the CSA and DEA regulations, it is likely that over two million dosage units of controlled substances have been diverted. Respondent, however, engaged in additional conduct which threatened public health and safety by failing to take prompt and reasonable action to investigate the circumstances surrounding Ogele's misuse of her registration.

On January 15, 2004, DEA investigators told Respondent that an excessive amount of controlled substances had been ordered under her registration. Tr. 302. Moreover, on January 26, 2004, DEA seized controlled substances that Ogele had ordered under her registration. Notwithstanding the seriousness of each of these events, Respondent did not demand that Ogele produce the invoices. Indeed, she did not even talk to Ogele about the matter until "probably April." Id. at 313. Nor did she contact R & S Sales to independently obtain the invoices until some date after May 3, 2004.

Relatedly, the Show Cause Order, which was served on Respondent on April 5, 2004, alleged that "the bulk of the controlled substances ordered under [her] * * registration," which "include[d] over 750,000 dosage units of Schedule III controlled substances" could not be accounted for. Show Cause Order at 7. Furthermore, while there is conflicting evidence as to whether Respondent then attempted to obtain the invoices from Ogele, even giving her the benefit of the doubt on the issue, 11

¹⁰ Under the CSA, "[a] separate registration [is] required at each principal place of business or professional practice where the [registrant] * * * distributes, or dispenses controlled substances." 21 U.S.C. 822(e). The primary purpose of this requirement is to ensure that adequate security exists at each location. See 21 CFR 1301.71.

¹¹Compare Tr. 334 (Respondent answered "no" to Government's question regarding whether she had then attempted to obtain the invoices from Ogele) with ALJ Exh. 2 at 9 (listing in response to Show Cause Order seven different purchases of controlled substances).

Respondent did not then contact R & S to independently verify whether Ogele had provided her with all of the invoices. See Tr. 347. Those invoices would have shown that Ogele had ordered large amounts of additional controlled substances such as promethazine cough syrup with codeine and various benzodiazepines that were unrelated to "the Nigeria project." Gov. Ex. 12 at 8, 13, 15, & 20. Nor did she exercise her right as a director of ISMP to inspect its books, records, and documents. See Cal. Corp. Code section 6334 (West 2006) ("Every director shall have the absolute right at any reasonable time to inspect and copy all books, records and documents of every kind * * * of the corporation of which such person is a director.").

By the date the Show Cause Order was served on her, Ogele had obtained other drugs from R & S and had also placed numerous orders with Priority Healthcare. See Gov. Ex. 11. Taking timely action such as obtaining the invoices from R & S would have uncovered the fact that Ogele was ordering additional controlled substances and engaged in diversion. Furthermore, exercising her right as a director to inspect all of ISMP's records including its accounts payable and checking account records would likely have shown that Ogele was ordering from an additional supplier.

To be sure, Ogele may have attempted to obstruct any such inquiry by withholding documents that showed that he was ordering controlled substances from Priority Healthcare. Respondent did not, however, take anything bordering on timely action to investigate the extent of Ogele's illegal use of her registration. Her failure to take even the most rudimentary steps to investigate the misuse of her registration was a breach of her duty as a registrant. Moreover, it likely allowed Ogele to continue his criminal activity well past the point at which it should have been stopped.

Consistent with a registrant's obligation to "provide effective controls and procedures to guard against theft and diversion of controlled substances," 21 CFR 1301.71(a), every registrant has a duty to conduct a reasonable investigation upon receiving credible information to suspect that a theft or diversion has occurred. Performing a reasonable investigation is essential to preventing the continuation of criminal activity. While the precise scope of this duty necessarily depends upon the facts and circumstances, doing nothing for months—as Respondent did hereclearly warrants a finding that a

registrant has committed acts which threaten public health and safety.

In her analysis of factor five, the ALJ further observed that Respondent "exhibited no remorse for her conduct at the hearing" and "downplayed her misconduct." Id. at 36-37. I agree. Beyond that, I am especially disturbed by Respondent's testimony under oath that she did not know that Ogele was ordering controlled substances until DEA investigators informed her of this during the January 15, 2004 meeting. As explained above, this testimony was fundamentally inconsistent with the letter Respondent submitted in response to the Show Cause Order in which she stated that she had authorized the ordering of 300 bottles of hydrocodone and vicodin between May 2003 and August 2003. See, e.g., ALJ Ex. 2, at 2. Of course, Respondent's written statement was submitted before Ogele was arrested and pled guilty to drug offenses. I thus conclude that Respondent lied under oath to downplay her responsibility for supplying Ogele with the means to obtain his wares. Such conduct buttresses the conclusion that Respondent cannot be entrusted with a registration.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824, as well as 28 CFR 0.100(b) & 0.104, the order of immediate suspension of DEA Certificate of Registration, AL8962993, issued to Rose Mary Jacinta Lewis, M.D., is hereby affirmed. The Office of Diversion Control is further directed to cancel Respondent's DEA number. This order is effective February 28, 2007.

Dated: January 19, 2007.

Michele M. Leonhart,

Deputy Administrator. [FR Doc. E7–1318 Filed 1–26–07; 8:45 am] BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Wild West Wholesale Revocation of Registration

On August 18, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Wild West Wholesale (Respondent) of Cedaredge, Co. The Show Cause Order proposed to revoke Respondent's DEA Certificate of Registration, 005516WWY, as a distributor of list I chemicals, and to deny any pending applications for renewal or modification of the registration, on the ground that Respondent's continued registration is inconsistent with the public interest. Show Cause Order at 1.

The Show Cause Order specifically alleged that Respondent distributed list I chemical products containing ephedrine, a precursor chemical used to manufacture methamphetamine, a Schedule II controlled substance. See id. at 1-2. The Show Cause Order alleged that Respondent distributed combination ephedrine products to gas stations and convenience stores, which are non-traditional retailers of these products. Id. at 2. The Show Cause Order further alleged that Respondent was distributing "approximately five or more case of various ephedrine products to its 45 customers each month," id., and that only a very small percentage of the licit retail market for these products is sold in convenience stores and gas stations. Id. 2-3. Finally, the Show Cause Order alleged that Colorado and adjacent states "have experienced a proliferation of small methamphetamine laboratories" and that "[l]aw enforcement officials have observed that a substantial proportion of precursors found at illicit methamphetamine sites have involved non-traditional brands sold through convenience stores." Id.

On September 26, 2005, the Show Cause Order was served on Respondent by first class mail.¹ On October 14, 2005, Respondent, through its counsel, requested a hearing. The case was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who ordered the parties to prepare pre-hearing statements. However, on February 22, 2006, Respondent withdrew its request for a hearing. The ALJ then ordered that the proceeding be terminated so that the investigative file could be forwarded to me for final agency action.

I find that Respondent has waived its right to a hearing. I therefore enter this final order without a hearing based on information contained in the investigative file.

Findings

Respondent is a supplier of sundry items to approximately forty-five convenience stores and gas stations in western Colorado. Among the items

¹The Show Cause Order was initially sent by certified mail to the street address of Respondent's registered location but was returned with a notation indicating that Respondent's owner had moved and that the time for forwarding mail had lapsed. This address was also used by Respondent's owner when she submitted a renewal application in April 2005. In May 2004, Respondent's owner had submitted a request for a change of its registered location to the address at which Respondent was eventually served.