Agency v. *U.S. Oil & Refining Co.,* D.J. Ref. 90–5–2–1–09514.

During the public comment period, the Decree may be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $19.25 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 06–63]

R & M Sales Company, Inc.; Revocation of Registration

On June 1, 2006, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA, or "the Government"), issued an Order to Show Cause to R & M Sales Company, Inc. (Respondent), of Blountville, Tennessee. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, 004413RAY, which authorizes it to distribute List I chemicals, as well as the denial of any pending application to renew its registration, on the ground that Respondent's continued registration is "inconsistent with the public interest." OTSC at 1 (citing 21 U.S.C. 823(h) & 824(a)(4)).

More specifically, the Show Cause Order alleged that during an inspection for its initial registration, Respondent received copies of DEA notices and cites to the Code of Federal Regulations pertinent to listed chemical distributors. *Id.* Relatedly, the Order alleged that "Mr. Mitchell was further advised by DEA personnel on proper record-keeping procedures for a DEA registrant, including, but not limited to, the requirement of maintaining records of the destruction of out of date listed chemical products." *Id.*

Next, the Show Cause Order alleged that many of Respondent's customers are convenience stores, gas stations and small independent grocers located in the Cumberland Plateau area of Tennessee, which is known for its problem with illicit methamphetamine production, and that Respondent distributes pseudoephedrine and ephedrine products in both tablet and gel-capsule form, which are precursor chemicals used in the illicit manufacture of methamphetamine. *Id.* at 2–3.

The Show Cause Order further alleged that on June 8 and 9, 2005, DEA Investigators (DIs) conducted an inspection of Respondent, during which they performed an accountability audit of its handling of two ephedrine products, MaxBrand 25 mg. ephedrine tablets (48-count bottles) and Ephedrine Multi-Action 25 mg. (also 48-count bottles), which revealed a shortage of each product. *Id.* at 3–4. The Order thus alleged that Respondent "failed to maintain complete and accurate records of a regulated transaction as required by 21 CFR 1310.06(a)." *Id.* at 4. The Order also alleged that Respondent "stores List I chemical products in its delivery trucks and/or trailers * * * creat[ing] the potential for the diversion of List I chemicals." *Id.* (citing 21 U.S.C. 823(h)(1) and 21 CFR 1309.71).

Next, the Show Cause Order alleged that based on its June 2005 inspection, DEA "developed additional information regarding [Respondent's] sale of large quantities of ephedrine to various convenience stores and related establishments," and that these "sales were vastly in excess of the amounts of this over-the-counter product needed to meet the medical and scientific needs of the community." *Id.* The Order also alleged that Respondent engaged in 35 regulated transactions with seven different customers in which it distributed 24-count, 36-count, and 48-count bottles of ephedrine products, "knowing or having reason to believe that its product would be used in the illicit manufacture of controlled substances in violation of 21 U.S.C. 841(d)(2)." [1] *Id.*, at 4–6. In addition, the Order alleged that Respondent failed "to provide notification of 'suspicious' activity pursuant to 21 U.S.C. 830(b)(1)(A) and 21 CFR 1310.05(a)(1) with respect to" these 35 transactions. *Id.* Finally, the Order alleged that DEA "conducted [a] customer verification" at the Fast Stop Covington, a convenience store located in Covington, Virginia, during which the owner informed a DI "that he purchased one case (144 bottles) of ephedrine products from [Respondent] every two to four weeks"; the Order then alleged that these purchases were "far in excess of legitimate demand for these products." *Id.* at 6.

On June 26, 2006, Respondent requested a hearing in the matter. ALJ Ex. 2. The matter was assigned to a DEA Administrative Law Judge (ALJ), who conducted a hearing in Arlington, Virginia on May 15 and 16, 2007. During the hearing, both parties called witnesses to testify and introduced documentary evidence. Following the hearing, both parties submitted briefs containing proposed findings of fact, conclusions of law, and argument.

On February 13, 2009, the ALJ issued her recommended decision (ALJ), which concluded that Respondent's continued registration would be inconsistent with the public interest. With respect to factor one—the maintenance of effective controls against diversion—the ALJ found that Respondent violated 21 CFR 1309.71(b) by storing listed chemicals in trucks away from its premises, that it sold "excessive quantities of listed chemicals to some customers and failed to report suspicious order[s] for these chemicals to DEA," and that it "failed to ascertain whether [its] customers purchased listed chemicals from other distributors." *Id.* at 36. She therefore concluded that "Respondent does not maintain adequate controls against the diversion of the listed chemicals it sells," and that "this factor weighs in favor of a finding that Respondent's continued registration would be inconsistent with the public interest." *Id.*

With respect to factor two—Respondent's compliance with applicable Federal, State and local law—the ALJ concluded that Respondent's storage of chemicals away from its premises and its failure to report suspicious transactions constituted violations of Federal law and DEA regulations. *Id.* She also found that Respondent had failed to provide prior notification to DEA of mail shipments of listed chemical products, in violation of 21 CFR 1310.03(c), and that, having "sold excessive quantities of listed chemicals," Respondent further violated 21 U.S.C. 841(c)(2) in that it "should have known that some of those chemicals were likely to be diverted to the illicit manufacture of the controlled substance methamphetamine." *Id.* at 36–37. The ALJ thus concluded that this factor supported a finding that

[1] The correct statutory citation is actually 21 U.S.C. 841(c)(2).

Respondent's continued registration was inconsistent with the public interest. *Id.* at 37.

Finding that neither Mr. Mitchell (Respondent's owner), nor any of its employees had ever been convicted of a crime related to controlled substances or listed chemicals (factor three), the ALJ concluded that this factor "weigh[ed] in favor of a finding that Respondent's continued registration would not be inconsistent with the public interest." *Id.* As to factor four—Respondent's past experience in the distribution of listed chemicals—the ALJ referenced Respondent's inadequate controls against diversion and its violations of applicable Federal law and found that "this factor weigh[ed] in favor of a finding that Respondent's continued registration would not be consistent with the public interest." *Id.*

As to the fifth factor—such other factors as are relevant to and consistent with public health and safety—the ALJ found that "it is likely that chemicals purchased in Virginia are used to make methamphetamine in Tennessee" and that "methamphetamine can be produced from liquid-filled dosage form products as well as the sol[i]d form products." *Id.* at 37–38. The ALJ thus reasoned that this factor also supported the conclusion that Respondent's continued registration would be inconsistent with the public interest. *Id.* at 38.

Based on her consideration of all the factors, the ALJ found "that a preponderance of the evidence * * * demonstrates that Respondent's continued registration would not be consistent with the public interest." *Id.* The ALJ thus recommended that Respondent's registration be revoked and that all pending applications for renewal or modification be denied. *Id.*

Neither party filed exceptions to the ALJ's decision. Thereafter, the record was forwarded to me for final agency action.

Having 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 explained herein. I further find that Respondent violated Federal law by knowingly selling drug paraphernalia. I further concur with the ALJ's ultimate conclusion that Respondent's continued registration would be inconsistent with the public interest and adopt her recommendation that its registration be revoked and that any pending applications be denied. I make the following findings.

Findings

Methamphetamine and List I Chemicals

Both pseudoephedrine and ephedrine have therapeutic uses and are lawfully marketed as non-prescription (OTC) drug products under the Federal Food, Drug and Cosmetic Act. GX 4, at 3. Pseudoephedrine is approved for marketing as a decongestant; ephedrine (in combination with guaifenesin) is approved for marketing as a bronchodilator.[2] *Id.* at 3–4. Both pseudoephedrine and ephedrine are, however, regulated as list I chemicals under the Controlled Substances Act because they are precursor chemicals that are easily extracted from OTC products and used in the illicit manufacture of methamphetamine, a schedule II controlled substance.[3] *Id.; see* GX 4, at 7 (noting that pseudoephedrine and ephedrine can be converted into methamphetamine in a simple one-step reaction which can be accomplished with little or no chemistry expertise).

Methamphetamine "is a powerful and addictive central nervous system stimulant."[4] *T. Young Associates, Inc.,* 71 FR 60567 (2006). Methamphetamine abuse has destroyed numerous lives and families and ravaged communities. *See Rick's Picks, L.L.C.,* 72 FR 18275, 18276 (2007). Moreover, because of the nature of the chemicals used to make methamphetamine, its illicit manufacture poses a significant environmental hazard, as it generates toxic chemical by-products. Tr. 17–18. Not only do the by-products cause damage when discarded into waterways and public lands, the presence of chemical fumes during methamphetamine production creates a potential for fires and explosions. *Id.* at 18–19. Such illicit methamphetamine laboratories may be of the "mom and pop type," and be found in motels, homes, or trunks of automobiles; the toxic fumes they emit also create a health hazard for children who are exposed to them. *Id.*

As evidenced by the number of law enforcement seizures of illicit meth. labs, the State of Tennessee, which is where Respondent is located, has had a particularly high incidence of illicit methamphetamine manufacturing. More specifically, in 2003, Tennessee ranked seventh out of 47 reporting states, with 983 seizures. GX 3, at 4. In 2004, Tennessee ranked second of 48 reporting states, with 1,432 seizures. *Id.*

While following the passage of the Meth-Free Tennessee Act of 2005[5] (which became effective May 1, 2005), the number of illicit lab seizures declined, *Id.* at 4–5; between January 1 and July 31, 2006, Tennessee still had 249 illicit methamphetamine laboratory seizures according to the statistics maintained by DEA's El Paso Intelligence Center (EPIC).[6] Tr. 32–33; GX 23. Moreover, according to data compiled by the National Clandestine Laboratory Database of which I take official notice, during 2008, law enforcement authorities reported 553 clandestine meth. lab incidents in Tennessee. U.S. Drug Enforcement Administration, Maps of Methamphetamine Lab Incidents, available at *http://www.usdoj.gov/dea/concern/map_lab_seizures.html/*

[2] In July 2005, the FDA proposed to remove combination ephedrine-guaifenesin products from its over-the-counter (OTC) drug monograph and to declare them not safe and effective for OTC use. *See* 70 FR 40232 (2005). This rulemaking remains pending.

[3] In 1988, Congress amended the Controlled Substances Act (CSA) by enacting the Chemical Diversion and Trafficking Act (CDTA), which subjected bulk ephedrine to regulation. GX 5, at 7. Shortly thereafter, law enforcement authorities encountered ephedrine tablets instead of bulk ephedrine at illicit methamphetamine laboratories. *Id.* In 1993, the CSA was again amended by the Domestic Chemical Diversion Control Act of 1993 (DCDCA), which regulated single-entity ephedrine products and required distributors of these products to register. *Id.* Illicit methamphetamine manufacturers then switched from single-entity ephedrine products to OTC combination products containing ephedrine. *Id.* at 8. The DCDCA also led to the large-scale diversion of pseudoephedrine tablets to the illicit manufacture of methamphetamine. *Id.* In response, Congress enacted the Comprehensive Methamphetamine Control Act of 1996 (CMCA), which expanded regulatory control of lawfully marketed drug products containing ephedrine, pseudoephedrine and phenylpropanolamine. *Id.* at 8–9.

More recently, in 2006, Congress passed the Combat Methamphetamine Epidemic Act of 2005 (CMEA). GX 3, at 5. Under the CMEA, effective April 8, 2006, all tablet-form drug products containing pseudoephedrine, ephedrine, and/or phenylpropanolamine were required to be sold at retail in blister packs. *Id.* Also effective April 8, 2006, the law imposed a daily transaction limit of 3.6 grams of base product per person, per day, and a sales limit of 9 grams of base product in a 30-day period. *Id.* As of September 30, 2006, these products must be placed behind the counter, and purchasers must show identification and sign a logbook. *Id.*

[4] According to data compiled by the Drug Abuse Warning Network (DAWN), between 1993 and 1999, medical examiners throughout the country reported 4,593 methamphetamine related deaths. GX 4, at 9.

[5] The law limits the sale of tablet-form products containing pseudoephedrine or ephedrine to pharmacists and licensed pharmacy technicians. *Id.* at 5. In addition, all purchasers must be over 18 years of age, present photo identification, and sign a logbook. *Id.* While the law limits the sale of the tablet forms of list I chemicals, Tr. 90, it exempts gel capsules and liquid preparations. Tenn. Code Ann. § 39–17–431(b)(3).

[6] By contrast, a Government witness acknowledged that the number of seizures in Virginia is considerably lower than the number in Tennessee. Tr. 33.

(visited October 6, 2009).[7] The data also show that in 2008, Kentucky, another State where Respondent distributes List I chemicals, had 416 lab incidents, an increase from 294 the year before. *Id.* While the majority of seized methamphetamine laboratories utilized tablet-form pseudoephedrine and ephedrine products, DEA scientific studies indicate that liquid and gel-cap formulations of these precursors can easily produce methamphetamine when the appropriate reagents or solvents are used. GX 23, at 8.

Respondent's Business

Respondent is a wholesale distributor of various products including list I chemicals to convenience stores and gas stations located in rural Appalachia in the States of Tennessee, Kentucky, Virginia, North Carolina, and South Carolina. Tr. 353–54. Respondent was founded in 1972 by Mr. Joe Allen Mitchell, and was incorporated in 1990. Id. at 352–53. Mr. Mitchell is Respondent's President; the firm also employs two route salesmen and an office manager.[8] *Id.* at 306 & 358.

Respondent first obtained a DEA registration in July 1999, and currently holds Certificate of Registration, 004413RAY, which authorizes it to distribute list I chemicals. GX 1. While the certificate indicates that the registration expired on April 30, 2006, on March 16, 2006, Respondent submitted a renewal application. GX 2. Therefore, in accordance with the Administrative Procedure Act and DEA regulations, I find that Respondent's registration has remained in effect pending the issuance of this Final Order. *See* 5 U.S.C. 558(c); 21 CFR 1309.45.

The DEA Inspections

On June 29, 1999, a DEA Diversion Investigator (DI) visited Respondent to conduct a pre-registration investigation.[9] GX 25. During the inspection, the DI provided Respondent with several informational notices issued by DEA including a red notice; this notice explains, *inter alia,* that combination ephedrine and pseudoephedrine products are being used in the illicit manufacture of methamphetamine and directs registrants to report "suspicious orders" to their local DEA office.[10] GX 16, at 1; Tr. 78–81; GX 25, at 1–2.[11]

In an affidavit, the DI who conducted the 1999 inspection testified that he also provided Mr. Mitchell with "copies of the Code of Federal Regulation (CFR) cites relative to chemical distributors." GX 25, at 1. The DI further stated that he "informed Mr. Mitchell that any suspicious orders and thefts or losses must be reported to the DEA in accordance with 21 CFR 1310.05" and advised him as to "the threshold requirements and * * * the recordkeeping requirements pursuant to 21 CFR 1310.05 including reports of theft and loss, suspicious orders, and destruction of damaged or out of date merchandise." *Id.* at 2.

In his testimony, Mr. Mitchell stated that he could not recall ever having been "apprised or informed of [the] requirement to report suspicious orders" and that he had thought that any amount "over the threshold limit would be suspicious." Tr. 385–86. Mr. Mitchell also testified that he was "not really" aware that list I chemicals were used in the manufacture of methamphetamine or that cigarette lighter fluid was also used in the process. *Id.* at 376.[12] In any event, because the requirement to report suspicious orders is set forth in both Federal law and DEA regulations, *see* 21 U.S.C. 830(b)(1); 21 CFR 1310.05(a); whether Mr. Mitchell was specifically notified of the requirement (either in conversation with the DI or by being provided with the red notice) is immaterial.[13] *See Fed. Crop Ins. Corp.* v. *Merrill,* 332 U.S. 380, 385 (1947) ("Just as everyone is charged with knowledge of the United States Statutes at Large, Congress has provided that the appearance of rules and regulations in the **Federal Register** gives legal notice of their contents.") (citation omitted); *United States* v. *International Min. & Chem. Corp.,* 402 U.S. 558, 562 (1971) ("The principle that ignorance of the law is no defense applies whether the law be a statute or a duly promulgated and published regulation.").

Some time after the 1999 inspection, Respondent received a facsimile of a DEA memo, "Guidelines Regarding the Submission of Reports," which contained a table of "Threshold Quantities" for various formulations of ephedrine, pseudoephedrine, and phenylpropanolamine products. RX 30, at 1, 5; Tr. 369. Mr. Mitchell testified that "[t]o me it was the Bible. It showed what the threshold limits are. This is the information that I went by." Tr. 369. According to Mr. Mitchell, he "calculated the number of products that [he] could sell, and [he] instructed [his] salespeople these are [the] limits." *Id.*

DEA did not visit Respondent again until June 8–9, 2005, when two DIs went to Respondent, met Mr. Mitchell and presented him with a Notice of Inspection, which he signed indicating his consent to the inspection. Tr. 84; GX 6, at 2. The DIs inspected Respondent's security arrangements, reviewed its procedures for handling list I products, examined its recordkeeping, and audited two list I products it distributed.

According to one of the DIs, Respondent is located within a "good-sized building," which is surrounded by a chain-link fence with a gate. Tr. 178. The building includes an area in the front where novelty items are displayed, a warehouse in the rear, and offices. *Id.* at 86–87. The building is protected by an alarm system, which the DIs tested and found to be in working order. *Id.* at 123; GX 17. Moreover, Respondent's enclosed yard area is lit with spotlights at night. Tr. 360, 363; RX 29.

Inside the warehouse, the DIs found that Respondent stored list I chemical products in a caged area; the cage was, however, constructed of chicken wire and could be easily compromised. Tr. 176. The DIs also found that Respondent stored list I chemicals overnight in its delivery trucks, which are parked within the chain-link perimeter. *Id.* at

[7] Under the Administrative Procedure Act (APA), an agency "may take official notice of facts at any 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's 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). Respondent can dispute the facts of which I take official notice by filing a properly supported motion for reconsideration within twenty days of service of this Order, which shall begin on the date it is mailed.

[8] Neither Mr. Mitchell, nor any of Respondent's employees, has been convicted of a criminal offense. Tr. 357–59. Mr. Mitchell further testified that he has never had reason to believe that any current or former employees have diverted list I chemical products. *Id.*

[9] Respondent did not undergo another inspection until June 2005. Tr. 82–84.

[10] The other notices included a green notice which informed Mr. Mitchell that chemicals such as red and white phosphorus are being used in the illicit manufacture of methamphetamine, and a yellow notice, which informed him about the increasing theft of pseudoephedrine and ephedrine products. *See* GX 16, at 2–3.

[11] According to the DI who testified at the hearing, when he conducted his close-out interview for the June 2005 inspection, Mr. Mitchell indicated that he had never received the colored notices. Tr. 130.

[12] Mr. Mitchell further testified that he took "the attitude that I have no control on what the retail public does with the product." Tr. 404. This testimony suggests that he was aware of the illicit uses of ephedrine products. Moreover, short of burying one's head in the sand, it is hard to imagine how anyone engaged in the distribution of these products (especially in Tennessee, given the scope of the State's meth. problem) could be unaware that they are subject to diversion into the illicit manufacture of methamphetamine.

[13] There is no dispute that DEA inspected Respondent on June 29, 1999. *See* GX 25; RX 33.

124. The DI testified that he cited Respondent for a violation of DEA regulations, because the trailer and delivery vehicles are "mobile, and they could easily be broken into." *Id.* Mr. Mitchell testified, however, that he was willing to change Respondent's practice and have the trucks parked inside the warehouse at night upon their return. *Id.* at 364.

At the hearing, Mr. Mitchell acknowledged that it is Respondent's practice to store list I chemical products overnight on the delivery trucks on nights when the driver-salesmen are staying in hotels along their routes. *Id.* at 397. In Respondent's twenty-day business cycle, one driver-salesman stays overnight on his route approximately two nights; the other driver-salesman stays overnight on his route approximately three nights. *Id.* Mr. Mitchell did not express any willingness to change this practice.

As noted above, during the inspection, the DIs reviewed Respondent's recordkeeping and conducted an audit of two products: Max Brand 25 mg. ephedrine 48-count bottles [14] and Ephedrine Multi-Action 25 mg. ephedrine 48-count bottles. Tr. 105; GX 9. The audit found shortages of 109 bottles of Max Brand and 275 bottles of Ephedrine Multi-Action; these figures amounted to 1.44% and 2.19% of the total quantity of each product handled during the audit period. GX 9; Tr. 108. According to one of the DIs, the shortage could have resulted from recordkeeping errors such as unrecorded sales, from diversion, or from loss. *Id.* at 108–09. The DI testified, however, that he did not consider the shortages significant in terms of Respondent's total sales. *Id.* at 201.

During an interview, Mr. Mitchell stated that his list I chemical products were "fast movers" and that Respondent's customer base for the products consisted primarily of convenience stores and gas stations located in eastern Tennessee, Virginia, Kentucky, West Virginia, and both North and South Carolina.[15] *Id.* at 90. Mr. Mitchell further stated that seventy-five percent (75%) of Respondent's customers sell list I products, and that thirty-five percent (35%) of Respondent's "overall business" is attributable to list I products. *Id.* at 89–90. Mr. Mitchell estimated that at the time of the hearing, Respondent had approximately 200 customers for all of its products and that its gross profit [16] from ephedrine sales was $200,000 annually.[17] *Id.* at 426, 428.

During the inspection, the DIs also found that Respondent used either the U.S. Postal Service or some other common carrier to make deliveries of list I products. *Id.* at 90–91. According to a spreadsheet which Mr. Mitchell gave the DIs, between July 20, 2004, and May 25, 2005, there were thirty-four instances in which Respondent shipped list I products containing pseudoephedrine in this manner; the shipments were sent to three stores and involved such products as Tylenol Sinus, Advil Cold and Sinus, NyQuil, Dayquil, and Benadryl. GX 22; 21 U.S.C. 802(34)(K).

According to the DI, under Federal law and DEA regulations, Respondent was required to file monthly reports with the Agency for each of these transactions. Tr. 194; *see* 21 U.S.C. 830(b)(3); 21 CFR 1310.03(c). However, DEA never received any such reports from Respondent. *Id.* at 194.

Also during the inspection, a DI received a handwritten document from Respondent's office manager detailing the destruction of list I chemical products by Respondent. Tr. 121; GX 14. According to this document, Respondent burned twelve bottles of Multi-Action (60-count) in March 2005 and 12 bottles of Mini-Thin (60-count) in January 2005. GX 14. The document, which was dated and signed by Respondent's Office Manager, states that while Respondent had "destroyed [out-of-date] merchandise in the past," "the count would not be any greater than what is listed above" for the March and January 2005 destructions of merchandise.[18] *Id.*

According to the DI, Respondent was required to give notification "prior to the destruction," but did not do so. Tr. 121. Mr. Mitchell testified that he had been unaware of the requirement that DEA be notified of the destruction of list I chemical products. *Id.* at 365. He also testified that he never contacted DEA with questions about the destruction of list I chemical products. *Id.* at 392.

The DI further testified that during the inspections, he found various instances of sales that he considered suspicious. Tr. 154. His office subsequently compiled a record of these suspicious sales, which was based on the quantity of product sold. *Id.* at 155; GX 24.

As found above, the DI who performed Respondent's pre-registration inspection had discussed the necessity of reporting suspicious transactions with Mr. Mitchell. Tr. 162. This DI did not, however, testify at the hearing, and the DI who performed the 2005 inspection did not know how, or if, that DI had defined "suspicious orders." *Id.*

On cross-examination, the DI further testified that, while "[t]here is no document" specifying the criteria for determining whether an order is suspicious,[19] during the pre-registration investigation, the DI "explain[ed] the criteria." *Id.* at 161; *see also id.* at 169. According to the DI, such criteria would include the location of a customer, a sudden increase in a store's purchasing patterns, and a store's sales in comparison to "other stores in the geographic area." [20] *Id.* at 157–58. The DI further explained that even if Respondent did not know the population in an area where one of its customers is located, "if you look at their sales in general" and "most of the sales are" for twelve bottles, "and then you got some that are 100, 300, 300, 900, that sticks out to me." *Id.* at 160–61; *see also* GX 21 (Respondent's DEA Log of distributions).

I agree with the DI that a store's location, its sales in comparison to other stores, and an increase in its purchasing patterns are relevant (but not the exclusive) criteria which a distributor

[14] Max Brand product has been found at seized methamphetamine laboratories. Tr. 105, 380.

[15] Approximately sixty-five percent (65%) of Respondent's list I chemical business is conducted in Virginia, and about thirty percent (30%) occurs in Tennessee, often along the border with Virginia. Tr. 350–51, 354.

[16] Gross profit is the mark-up minus distribution expenses such as commissions, warehouse electricity, and the water bill, etc. Tr. 429–30.

[17] At the time of the hearing, Respondent did not carry pseudoephedrine products. Tr. 428.

[18] The Office Manager testified that she had made the notation regarding the additional amounts that were destroyed apparently because there had been additional destructions but there were no records documenting them. Tr. 439–40; 446–48 The Office Manager further maintained that this statement was not accurate and that she made the statement because the DIs had told her that "they needed something." *Id.* at 445. In its brief, the Government does not cite to any provision of the CSA or DEA regulations which specifically require that the destruction of products be reported to the Agency.

[19] DEA has, however, published criteria in the *Chemical Handlers Manual,* as well as the Report of the Attorney General's Suspicious Order Task Force. Although the *Chemical Handlers Manual* was withdrawn because it is currently undergoing revisions to reflect changes in Federal law, the Manual was in effect at the time of the events at issue here. In addition, DEA has published its "'Know Your Customer' Policy," and the identification criteria developed by the Suspicious Orders Task Force on its website. *See http://www.deadiversion.usdoj.gov/chem_prog/susp.htm.*

[20] The DI testified that "any businessman is going to know their competition and who they're selling to. They're going to know what people want. For instance, Mr. Mitchell even told me himself that these were fast movers and that he needed to carry these products because if he didn't carry these products that other people would sell those products for him if he didn't sell them." Tr. 158. The DI also testified that "the firm if they're selling in that area, they're going to be there every few weeks. They're going to know the area a lot more than I would as an investigator." *Id.* at 160. The Government did not, however, introduce any evidence about comparable sales by Respondent's competitors.

must consider in evaluating whether an order is suspicious. However, I reject the DI's testimony that a distributor can be charged with knowledge of the sales levels of list I products at those stores which are not its customers. Moreover, I reject the DIs testimony that most of Respondent's sales were for twelve bottles, noting that the exhibit which he referred to in giving this testimony is obviously incomplete.[21]

The ALJ further noted that "Respondent did not controvert [the DI's] testimony that most if its customers purchased twelve or twenty-four bottles per month." ALJ at 35. The ALJ ignored, however, that Respondent introduce several exhibits showing its sales of various products to its customers. Moreover, my review of this data suggests that Respondent's sales were considerably greater than twelve to twenty- four bottles per month.

At the hearing, Mr. Mitchell also claimed that he was unaware of these criteria and that no one had told him that he required to monitor his sales and report suspicious orders. *Id.* at 372. While Mr. Mitchell testified that he was obliged to know how to identify a suspicious order, he nonetheless insisted that DEA was responsible for giving him information on suspicious orders. *Id.* at 394. Mr. Mitchell admitted, however, that he had never requested this information from DEA.[22] *Id.* at 392, 394.

Mr. Mitchell testified that he thought that only those transactions which exceeded the threshold amounts as indicated on the fax he received (RX 30, at 3) were suspicious orders. Tr. 386. The DI testified, however, that while the threshold amounts for sales to retail establishments trigger reporting requirements, they are not related to the determination of whether a given sale should be considered suspicious. *Id.* at 168. In answer to the question, "[i]s there a relationship between these threshold amounts and what you term suspicious sales?," the DI testified:

> No, because of the extreme number of variables. You couldn't put a number on suspicious sales in black and white because each geographical area would be different. If DEA said if you sell over 1,000 that's suspicious, well, 1,000 in northern Virginia is quite different from 1,000 being sold in Eastern Tennessee because there's a larger customer base.

Id. at 168–69.

The DI concluded that in thirty-five instances, Respondent's monthly sales constituted suspicious orders based solely on the quantities; he also testified that these sales should have been reported to DEA but were not. *Id.* at 154–55. The Government submitted into evidence its compilation of the sales (GX 24), which shows the following sales by store and number of bottles:

	Number of bottles
Chevron Food Mart, Hazard, Kentucky	
January 2004	324
February 2004	144
March 2004	252
April 2004	432
May 2004	288
June 2004	156
August 2004	228
September 2004	216
October 2004	288
November 2004	240
December 2004	240
January 2005	216
February 2005	216
March 2005	396
April 2005	216
May 2005	180
Fast Stop, Covington, Virginia	
September 2004	168
October 2004	60
February 2005	156
March 2005	144
April 2005	156
May 2005	144
Fast Mart Appomattox, Appomattox, Virginia	
September 2004	84
October 2004	144
December 2004	144
Holiday Chevron, Marion, Virginia	
January 2005	468
February 2005	708
March 2005	948
April 2005	900
May 2005	984
Garner Mountain Food Market, Isom, Kentucky	
May 2005	108
Glade Spring Chevron, Glade Spring, Virginia	
April 2005	168
May 2005	60
Hillbilly Market, Bristol, Virginia	
April 2005	324
May 2005	144

GX 24.

Notably, this compilation provides no information as to the number of tablets in each bottle, the strength of the ephedrine in each tablet, and the chemical composition of the ephedrine (hcl or sulfate). Mr. Mitchell admitted, however, that Respondent's sales in March, April and May of 2005 to the Holiday Chevron in Marion, Virginia, exceeded the threshold amount of 1000 grams, which was then in effect, and which made the distributions a regulated transaction under Federal law.[23] Tr. 372–73; *see* 21 CFR 1310.04(f) (2004 & 2005). Mr. Mitchell further testified that the salesman who handled the Holiday Chevron's account had told him that the store's owner "had two locations, and he sometimes moved product from one place to the other." Tr. 380–81.

In addition, according to Respondent's compilation of its sales to the Holiday Chevron, it sold even greater quantities of ephedrine products to the store in the months of August (1272 bottles totaling 54,864 tablets), October (1284 totaling 55,440 tablets), and November 2005 (1248 totaling 55,872 tablets). *See* RX 39, at 4–6. Each of these transactions exceeded the 1,000 gram threshold and yet none of them were reported to the Agency.

The Government also relied on Respondent's DEA Log (GX 21), as support for its contention that it had engaged in excessive sales. *See* Tr. 143. Beyond the fact that the log is incomplete, the Government did not use this data to calculate an average monthly sale of ephedrine products per store or the statistical probability that any sale was excessive.[24]

[21] To further explain, both Mr. Mitchell's testimony and Respondent's records establish that the company had far more list 1 customers than GX 21 indicates. Moreover, at the bottom of each page of the exhibit, there is a notation indicating the page number. *See* GX 21. For example, the first page of the exhibit indicates that it covers January 2004, and the bottom of the page includes the notation: "Page 4 of 5." *Id.* at 1. Yet the next page of the exhibit indicates that it covers February 2004, and includes the notation: "Page 1 of 5." *Id.* at 2. The next two pages are for March 2004; the pages include the notations: "Page 1 of 5" and "Page 2 of 5," respectively. *Id.* at 3–4. This pattern is repeated throughout the exhibit, which includes no more than two pages for any one month. *See generally* GX 21.

[22] Mr. Mitchell maintained that he had on several occasions refused to sell to people who had come to his warehouse seeking to "buy ephedrine and ephedrine only." Tr. 433.

[23] Following the enactment of the Combat Methamphetamine Epidemic Act of 2005, the thresholds for combination ephedrine products were eliminated. Accordingly, all transactions involving ephedrine, "regardless of size, are subject to recordkeeping and reporting requirement as set forth in 21 CFR part 1310." 21 CFR 1310.04(g).

[24] Apparently based on these transactions, the Government also alleged that Respondent's "sales were vastly in excess of the amounts of this * * * product needed to meet" legitimate medical needs. Show Cause Order at 4. The Government did not, however, introduce any studies to support this contention. Instead, the Government apparently

As to the Holiday Chevron in Marion, Virginia, Mr. Mitchell testified that he still sold listed chemical product to it and that the store was visited twice a month. Tr. 413. He also testified that he knew the store had purchased listed chemicals from another distributor in the past, but maintained that he did not know if the store was still doing so. *Id.*

Mr. Mitchell also admitted that he had not inquired as to whether several of the stores identified in GX 24 were obtaining listed chemicals from other distributors. Tr. 422 (Hillbilly Market); *id.* at 424 (Holiday Chevron). He then admitted that he knew that the Hillbilly Market, the Fast Mart, and again the Holiday Chevron, had had accounts with other distributors, and yet Respondent had continued to sell to them. *Id.* at 422–25. He also admitted that his route salesmen had "been told of other stores that receive this product by mail in large quantities." *Id.* at 409.

More generally, Mr. Mitchell stated that he did not think that his salesmen would, in soliciting a new customer, ask the customer whether they were purchasing listed chemical products from another distributor. *Id.* at 430–31. He also acknowledged that a customer's purchasing of list I chemicals from another distributor had never affected Respondent's decision to sell to that customer and that Respondent would continue to sell to it. *Id.* at 408. According to the DI, a retailer's having multiple distributors for list I chemical products was typical for sales in the illicit market. *Id.* at 139.

After the on-site inspection, the DIs visited two of the stores to which Respondent distributed list I products (David's Market in Bristol, Tennessee, and the Fast Stop in Covington, Virginia) to verify that they were customers. Tr. 134. The manager at David's Market, Ms. A.O., provided copies of receipts which matched Respondent's sales records. *Id.* at 135. According to the DI, Ms. A.O. indicated that the list I chemical products sold quickly and, because she saw bad things happening in the market's parking lot, she believed people were buying the products for the "wrong reason." *Id.* at 135–36. As to the parking lot, Ms. A.O. stated that she had found what looked like a syringe and that she witnessed what she believed to be drug dealing taking place there. *Id.* at 136. According to Ms. A.O., David's Market also received list I chemical products from another distributor. *Id.* at 138–39.

At the Fast Stop, the owner indicated initially that he received list I chemical products every two to four weeks. Tr. 141. Subsequently, however, the owner told another DI that he only ordered such products every six to nine weeks. *Id.*

During the June 2005 investigation, the testifying DI asked Mr. Mitchell whether he had ever considered giving up the list I chemical products business, given its relationship to the illicit manufacture of methamphetamine. *Id.* at 131. Mr. Mitchell responded that "he was doing a pretty good business selling these products and was not interested in giving up the DEA registration at that time." [25] *Id.*

Moreover, during the June 2005 inspection, the DI observed that Respondent was selling "Love Roses," a product which is "a small glass cylinder that contains a plastic rose inside it," which is three to four inches in length and which has a removable cork at the ends. Tr. 118. The DI testified that this product is "commonly used" as a crack pipe, that it does not have a legitimate purpose, and that it is drug paraphernalia.[26] *Id.* at 191.

The DI further testified that he told Mr. Mitchell what the product was used for and that Mr. Mitchell found this information surprising. *Id.* at 192. While Mr. Mitchell testified that he was unaware that Love Roses were used as drug paraphernalia until the 2005 inspection, *id.* at 375; he admitted that Respondent was still selling the product as of the date of the hearing. *Id.* at 390.

On cross-examination, Mr. Mitchell testified that he did not know why the pill forms of ephedrine were "moving as fast as they were." *Id.* at 403. When asked whether he had "ever pause[d] to think that these products could be" resold "to the illicit market?"; Mr. Mitchell answered: "You know I guess I've taken the attitude that I have no control on what the retail public does with the [list I chemical] product." *Id.* at 404.

Discussion

Section 304(a) of the Controlled Substances Act provides that a registration to distribute a list I chemical "may be suspended or revoked * * * upon a finding that the registrant * * * has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). Moreover, under section 303(h), "[t]he Attorney General shall register any applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest." 21 U.S.C. 823(h). In making the public interest determination, Congress directed that the following factors be considered:

> (1) Maintenance by the [registrant] of effective controls against diversion of the listed chemicals into other than legitimate channels;
>
> (2) Compliance by the [registrant] with applicable Federal, State, or local law;
>
> (3) Any prior conviction record of the [registrant] under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
>
> (4) Any past experience of the [registrant] 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. § 823(h).

"These factors may be 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 to revoke an existing registration or to deny an application to renew a registration. *Robert A. Leslie,* 68 FR 15227, 15230 (2003). 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); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

In this matter I have considered all of the statutory factors. While I find that several of the allegations are not proved, I conclude that the record as a whole establishes that Respondent does not maintain effective controls against diversion (factor one) and that Respondent violated both the CSA's requirement to report suspicious orders and its prohibitions against the knowing sale of drug paraphernalia (factor two). While I have also considered Respondent's (and its employees') lack of criminal convictions, and its experience in distributing chemicals,[27] I

relies on findings made in other cases which were based on expert testimony. *See* Gov. Br. at 22–23. However, in *Novelty Distributors, Inc.,* 73 FR 52689, 52693–94 (2008), I noted that there were serious flaws in the methodology used by the Government's expert in determining the level of sales which is consistent with legitimate demand. I thus make no findings on the issue.

[25] Mr. Mitchell testified that, although the Meth-Free Tennessee Act reduced his sales of ephedrine, even soft-gel formulations of List I chemical products were "fast movers." Tr. 388–89, 418.

[26] The DI maintained that the product does not have a legitimate purpose. Tr. 191. When asked by Respondent's counsel if he had "ever give[n] a loved one a rose?," the DI answered: "Not a plastic rose that's three inches tall in a plastic vial for $ 1 from the convenience store." *Id.*

[27] I acknowledge that Respondent has been registered since 1999. However, as explained below, because the record establishes that Respondent has violated several provisions of Federal law and does

Continued

nonetheless conclude that factors one and two make out a *prima facie* case that Respondent's continued registration "is inconsistent with the public interest." 21 U.S.C. 823(h). I further conclude that Respondent has not adequately addressed the violations of law and the deficiencies identified in its diversion controls, and that therefore, it has not rebutted the Government's *prima facie* case. Accordingly, Respondent's registration will be revoked and its pending application to renew its registration will be denied.

Factor One—Maintenance of Effective Controls Against Diversion

Under DEA precedent and regulations, this factor encompasses a variety of considerations. *See Novelty Distributors, Inc.,* 73 FR 52689, 52698 (2008). These include, *inter alia,* the adequacy of the registrant's/applicant's security arrangements, the adequacy of its recordkeeping and reporting, and its distribution practices. *Id.* Moreover, a distributor must exercise a high degree of care in monitoring its customer's purchases. *See Sunny Wholesale, Inc.,* 73 FR 57655, 57663 (2008). In evaluating a registrant's security controls and procedures, DEA regulations direct that the Agency consider numerous factors including "[t]he adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of List I chemicals in its operations." 21 CFR 1309.71(b)(8).

In its brief, the Government does not contend that Respondent's physical security arrangements at its registered location are inadequate. *See* Gov. Br. at 22–24. While I note the DI's testimony that the cage in which the products are stored in its warehouse could be easily breached, I further note that Respondent's facility is protected by an alarm system and its perimeter is surrounded by a chain link fence. I thus agree with the ALJ that Respondent provides adequate physical security for those products which are kept inside the warehouse.

The record, however, also establishes that Respondent has a practice of storing list I products on its delivery trucks overnight (which do not appear to have alarms), both on the night before a salesman leaves on his route, as well as on those nights when a salesman stays in a hotel. DEA has previously held that this practice does not provide adequate security for list I products. As I have previously explained, when products are left overnight on trucks, a thief does not have to spend time offloading the products, but can steal the entire vehicle with its cargo, and do so in a manner of seconds. *See Novelty Distributors, Inc.,* 73 FR 52689, 52698 (2008), *pet. for review denied,* 571 F.3d 1176 (D.C. Cir. 2009); *McBride Marketing,* 71 FR 35710, 35711 (2006).

During the inspection, the DIs further found that Respondent had shortages of 109 bottles of Max Brand and 275 bottles of Ephedrine Multi-Action. While the DI testified that he did not consider the shortages to be significant in terms of Respondent's total sales of the products,[28] it is still a factor to be considered in assessing the adequacy of its controls against diversion.

Relatedly, the record establishes that Respondent destroyed products on at least two occasions. GX 14. While Respondent was not required to report the destructions to DEA under Federal law or Agency regulations, it did not make a contemporaneous record of either destruction. *Id.* Given the frailties of human memory, the creation of a contemporaneous record is essential to maintaining an accurate accounting of the products that were destroyed.

The ALJ further found that Respondent does not maintain effective controls against diversion because some of its customers purchase list I products from other distributors and Respondent's personnel do not ask its customers whether they are purchasing from other distributors. ALJ at 36. While a customer can seek out another supplier for a legitimate business reason (*i.e.,* because it offers a lower price), when the store is actively buying from multiple distributors, the distributor has an obligation to determine whether the quantities it is obtaining are excessive in relation to what the distributor knows about typical purchasing patterns of stores serving similar markets, and if so, not sell to the store. Mr. Mitchell's failure to instruct his salesmen to make these inquiries of his customers, as well as his admission that he continued to sell to several stores even though he knew that they were purchasing listed chemical products "by mail in large quantities" from other distributors, Tr. 409, provides further support for a finding that Respondent does not maintain effective controls against diversion. *See Holloway Distributing,* 72 FR 42118, 42124 (2007) ("[A] registrant has an affirmative duty to protect against diversion by knowing its customers and the nature of their list I chemical sales * * *. A registrant cannot avoid the requirements of Federal law by instructing its sales force to ask no questions of its customers and thereby be deliberately ignorant of diversion.").

I thus conclude that Respondent does not maintain effective controls against diversion. This finding provides reason alone to conclude that Respondent's continued registration is inconsistent with the public interest.[29]

Factor Two—Respondent's Compliance With Applicable Laws

At the hearing, the Government put on evidence suggesting four different ways in which Respondent violated Federal law.[30] More specifically, the Government alleged that: (1) It was required to report the transactions which it shipped by mail, (2) it failed to report suspicious transactions, (3) it sold drug paraphernalia, and (4) it knowingly or intentionally distributed ephedrine having reasonable cause to believe the product would be used in the illicit manufacture of methamphetamine.

In her decision, the ALJ concluded that Respondent violated Federal law by failing to report suspicious transactions,[31] by failing to file monthly

not maintain effective controls against diversion, I conclude that it is not necessary to make findings under this factor.

[28] It is also noted that the audit involved only two products and covered only a five-month period. *See* GX 9.

[29] In its post-hearing brief, the Government argued that I should apply the "market analysis performed by a DEA expert in the field regarding the 'normal expected sales range' of listed chemical products by 'non-traditional retailers.'" Gov't Br. at 22 (citing *Holloway Distributing,* 72 FR at 42123). Conceding that "the Government did not present a market study in these proceedings," the Government nonetheless argued that I apply the "findings of marketing expert Jonathan Robbin who found that '* * * the expected sales range for combination ephedrine products at a convenience store is 'between $0 and $25, with an average of $12.58 per month.'" *Id.* at 23 (citing *Planet Trading, Inc. d/b/a United Wholesale Distributors, Inc.,* 72 FR 11055, 11056 (2007)). However, in *Novelty Distributors,* I found that the methodology for determining the normal expected sales range for convenience stores' marketing of ephedrine products was unreliable. 73 FR at 52693–94. Accordingly, I reject the Government's argument.

[30] As discussed under factor one, the Government also elicited testimony from an Investigator to the effect that Respondent was required to report the destruction of List I products. In its brief, the Government does not cite this testimony as evidence relevant to any of the public interest factors. *See* Gov. Br. 22–29. More importantly, a destruction of a listed chemical does not fall within any of the circumstances which trigger the obligation to report to the Agency under Federal law or DEA regulations. *See* 21 U.S.C. 830(b); 21 CFR 1310.05(a). As explained above, a destruction should, however, be documented in the registrant's records.

[31] While the ALJ cited Respondent's failure to report suspicious transactions under both factors one and two, her reasoning was provided under factor one. *See* ALJ at 35–37. Because this requirement is directly imposed by statute, I discuss it under factor two. However, whether the requirement is discussed under factor one or two is not significant as what matters is the extent of the violations, if any.

reports of transactions which were shipped by mail, and by knowingly distributing listed chemicals when it had reasonable cause to believe the products would be diverted. ALJ at 36–37. The ALJ did not, however, address whether Respondent violated Federal law by selling drug paraphernalia.

Respondent's Failure To Report Mail-Order Transactions

As found above, on thirty-four occasions between July 20, 2004, and May 25, 2005, Respondent shipped list I products containing pseudoephedrine to three stores using either the mail or some other common carrier. GX 22. Moreover, it is undisputed that Respondent did not file reports for any of the shipments. Based on these findings, the ALJ concluded that Respondent violated DEA regulations, reasoning that "21 CFR 1310.03(c) at relevant times required handlers of listed chemicals to file monthly reports of transactions by mail." ALJ at 36–37.

The CSA specifically requires that:

> [e]ach regulated person who engages in a transaction with a nonregulated person * * * which—
>
> (i) involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals); and
>
> (ii) uses or attempts to use the Postal Service or any private or commercial carrier;
>
> shall, on a monthly basis, submit a report of each such transaction conducted during the previous month to the Attorney General in such form, containing such data, and at such times as the Attorney General shall establish by regulation.

21 U.S.C. 830(b)(3)(B); *see also* 21 CFR 1310.03(c) ("Each regulated person who engages in a transaction with a nonregulated person * * * that involves ephedrine [or] pseudoephedrine * * * including drug products containing these chemicals, and uses or attempts to use the Postal Service or any private or commercial carrier must file monthly reports of each such transaction * * * .").[32]

The CSA further defines "[t]he term 'regulated person'" to mean in relevant part, "a person who manufactures, distributes, imports, or exports a listed chemical." 21 U.S.C. 802(38). Moreover, the Act defines "[t]he term 'distribute'" to mean "to deliver (other than by administering or dispensing) * * * a listed chemical." 21 U.S.C. 802(11).

Respondent is thus clearly a "regulated person" under the Act and subject to the mail order reporting provision. However, as the text of the mail order reporting provision makes clear, the reporting requirement does not apply to all mail order transactions which a regulated person engages in, but rather, only those it engages in "with a nonregulated person," 21 U.S.C. 830(b)(3)(B), a term which neither Congress nor the Agency have defined. *See generally* 21 U.S.C. 802; 21 CFR 1300.02. The critical question therefore is whether a retail store is a "nonregulated person" under this provision.

Neither the Government in its brief, nor the ALJ in her decision, even acknowledge the statutory text, let alone address this issue. *See generally* Gov. Br. at 22–29; ALJ at 36–37. Moreover, there are numerous reasons that support the conclusion that retail stores were—even prior to the enactment of the CMEA—regulated persons under the Act.

The first reason is that a retail store which sells listed chemicals engages in distribution as that term is defined by the Act—it delivers (other than by administering or dispensing) a chemical to a customer. *See* 21 U.S.C. 802(11). Relatedly, Congress defined the term "retail distributor" to "mean a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to pseudoephedrine or phenylpropanolamine products are limited almost exclusively to sales for personal use * * * either directly to walk-in customers or in face-to-face transactions by direct sales."[33] *Id.* section 802(46)(A); *see also* 21 CFR 1300.02(b)(29). It is thus clear that under the Act, retail sales constitute distribution.

Second, while DEA has exempted from registration list I retail distributors "whose activities * * * are limited to the distribution of below-threshold quantities of a pseudoephedrine * * * or combination ephedrine product * * * in a single transaction to an individual for legitimate medical use," 21 CFR 1309.24(e), DEA regulations further provided that "[a]ny person exempted from the registration requirement under this section shall comply with the security requirements set forth in § 1309.71–1309.73 of this part and the record-keeping and reporting requirement set forth under parts 1310 and 1313 of this chapter." *Id.* § 1309.24(k). A retail distributor was thus (and remains) subject to Agency regulations and cannot be deemed to be a "nonregulated person" under 21 U.S.C. 830(b)(3)(B).

This conclusion finds further support in the exceptions which Congress created to the reporting requirement. *See id.* section 830(b)(3)(D). Among these is the exception for "[d]istributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in section 802(46)." *Id.* section 830(b)(3)(D)(ii). Because the reporting requirement only applies to regulated persons, there would be no need to exempt retail distributors if they were nonregulated persons. Accordingly, I am compelled to reject the ALJ's conclusion that Respondent violated Federal law when it failed to report the mail order transactions.

Respondent's Failure To Report Suspicious Transactions

The Government argued, and the ALJ concluded, that Respondent violated Federal law and DEA regulations by failing to report suspicious transactions. More specifically, the ALJ apparently found that Respondent violated Federal law by failing to report each of the thirty-five transactions identified in Government Exhibit 24. *See* ALJ at 35–36. She further rejected Respondent's contention that this requirement only applies to sales which exceed the threshold amount. *Id.* at 36; *see also* Gov. Br. at 23 (asserting that DEA has rejected the defense that a registrant is not required to report suspicious transactions which are below the threshold).

Adopting the Government's reasoning, the ALJ explained that:

> First, * * * a sale of an over-the-threshold amount of listed chemical is subject to recordkeeping and reporting requirements, and may or may not be a suspicious transaction. Likewise, a sale of a quantity less than the threshold amount may nonetheless be suspicious. Second, and more importantly, an order from a small retailer for hundreds of bottles of a product that is regulated precisely because it can be used for illicit purposes should immediately cause the distributor of that product concern as to why his customer is ordering such quantities.

ALJ at 35–36.

Here again, neither the ALJ in her decision, nor the Government in its brief, even acknowledge the text of the relevant statute, 21 U.S.C. 830(b)(1). *See id.* at 35–37. The statute provides in pertinent part:

> (1) Each regulated person shall report to the Attorney General, in such form and manner as the Attorney General shall prescribe by regulation—

[32] Unless otherwise noted in this discussion, all citations and quotations to the U.S. Code and DEA regulations are to the statute and regulations that were in effect at the time of the conduct at issue and as they were then numbered.

[33] While this version does not list ephedrine, the statute was subsequently amended to include this chemical. *See* 21 U.S.C. 802(49)(A).

(A) *any regulated transaction* involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this subchapter.

21 U.S.C. 830(b)(1)(A) (emphasis added). *See also* 21 CFR 1310.05(a)(1) ("Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows: * * * Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part.").

Notably, Congress did not require that *any* transaction "involving an extraordinary quantity of a listed chemical" (or involving the other two circumstances set forth in this paragraph) be reported by a regulated person. 21 U.S.C. 830(b)(1)(A). Rather, it required the reporting only of a "*regulated* transaction involving an extraordinary quantity of a listed chemical," or a regulated transaction involving the other two circumstances. *Id.* (emphasis added)

Moreover, Congress defined "[t]he term 'regulated transaction'" to mean "a distribution, receipt, [or] sale * * * of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions * * * of a listed chemical[.]" *Id.* § 802(39)(A). With respect to the combination ephedrine products at issue here, DEA regulations in effect at the time of the transactions set a threshold of 1000 grams "within a calendar month" for distributions between Respondent and a retail store customer.[34] 21 CFR 1310.04(f) & (f)(ii) (2004) & (2005). Accordingly, only those cumulative transactions which met the 1000 gram threshold within a given calendar month constituted regulated transactions for the purpose of the requirement to report a suspicious order under 21 U.S.C. 830(b)(1).

As noted above, the ALJ held that all of the transactions identified by the Government in its exhibit 24 were suspicious orders which Respondent was required to report. The ALJ's holding was based entirely on policy considerations and was not grounded in the relevant statutory texts. While these policy considerations are undoubtedly valid, they cannot trump the clear and unambiguous text of the statute. As the Supreme Court has explained: "When a court reviews an agency's construction of the statute it administers * * * [i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc.,* v. *NRDC, Inc.,* 467 U.S. 837, 842–43 (1984). In short, on this issue, Congress made the policy determination when it limited the reporting requirement to those transactions which met the definition of a "regulated transaction."

Mr. Mitchell admitted, however, that the sales his firm made in March, April and May 2005 to the Holiday Chevron in Marion, Virginia exceeded the threshold.[35] The record establishes that these sales were for 948, 900, and 984 bottles in the respective months. In addition, Respondent's evidence further showed that it sold even greater quantities, and which exceeded the threshold, in August (1272 bottles), October (1284 bottles), and November (1248 bottles) of 2005.

According to Respondent's brief, "[a]ny sales above the[] 'threshold' quantities * * * [Mr.] Mitchell considered 'suspicious' and any quantity less than the computed 'threshold' [Mr.] Mitchell did not consider suspicious." Resp. Br. at 4 (proposed findings of fact at ¶8). Notwithstanding Mr. Mitchell's acknowledgement that sales above threshold were suspicious, he did not report any of the six sales to DEA.

Moreover, while I reject the ALJ's finding that most of Respondent's customers were purchasing only twelve to twenty-four bottles, I conclude that these six sales "involved [an] extraordinary quantity" based on both the absolute amount of each sale and that the sales were approximately double to nearly triple what Respondent had sold to this store in a previous month (468 bottles). Any responsible person would have recognized that these sales were suspicious and Mr. Mitchell admitted that they were.[36] Accordingly, these sales involved an "extraordinary quantity" and were subject to reporting under section 830(b)(1)(A).[37] I therefore hold that Respondent violated Federal law and DEA regulations by failing to report these sales.

Alleged Violations of 21 U.S.C. 841(c)(2)

The Government also alleged that Respondent violated 21 U.S.C. 841(c)(2),[38] because "Respondent had 'reasonable cause to believe' that the large quantities of ephedrine products it sold to Fast Stop Covington, Chevron Food Mart[,] * * * [and] Holiday Chevron * * * would be used to manufacture methamphetamine." Gov. Br. at 26. The Government further argues that it "is not required to prove that the products were actually used to manufacture methamphetamine," and that there is no quantity threshold which exempts a merchant from criminal liability under the statute. *Id.* (citing cases). The ALJ agreed with the Government and found that Respondent violated 21 U.S.C. 841(c)(2) because it sold "excessive quantities of listed chemicals" and "it should have known that some of those chemicals were likely to be diverted to the illicit manufacture of * * * methamphetamine." ALJ at 37.

The Government is correct that it need not show that the ephedrine Respondent distributed was actually used to manufacture methamphetamine and that the then-existing threshold that triggered reporting requirements did not

[34] Under the regulation, whether the threshold had been reached (and a regulated transaction had occurred) was based on "the cumulative amount for multiple transactions within a calendar month." 21 CFR 1310.04(f). The thresholds were eliminated by the Combat Methamphetamine Epidemic Act of 2005. *See* USA Patriot Improvement and Reauthorization Act of 2005, Pub. L. 109–177, section 712(b), 120 Stat. 192, 264 (2006). For all transactions occurring after the effective date of the legislation, "the size of the transaction is not a factor in determining whether the transaction meets the definition of a regulated transaction * * *. All such transactions, regardless of size, are subject to recordkeeping and reporting requirements as set forth in * * * part [1310] and notification provisions as set forth in part 1313 * * *." 21 CFR 1310.04(g).

[35] In light of Mr. Mitchell's admission, I deem waived any argument that the sales did not exceed the 1000 gram threshold.

[36] In her discussion of Respondent's obligation to report suspicious orders, the ALJ explained that "Respondent did not controvert [the DI's] testimony that most of its customers purchased twelve or twenty-four bottles per month." ALJ at 35. A review of Respondent's evidence suggests that its average monthly sale was considerably more. Respondent did not, however, provide any statistical analysis to show what its average sale was.

[37] I note Respondent's evidence that the owner of the Holiday Chevron was purportedly buying for two stores. *See* RX 53. This contention is legally irrelevant as the transactions occurred with a single person. Significantly, while Congress exempted "a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person" from the definition of a regulation transaction, it did not exempt the distribution to that regulated person. 21 U.S.C. 802(39)(A) & (A)(i). Indeed, were such transactions exempt from reporting, the purpose of the statute would be seriously undermined.

[38] This provision makes it a felony for "[a]ny person who knowingly or intentionally * * * possesses or distributes a listed chemical knowing, or having reasonable cause to believe, that the listed chemical will be used to manufacture a control substance except as authorized by" the CSA. 21 U.S.C. 841(c)(2).

create a safe harbor which allowed a registrant to distribute a listed chemical product in disregard for the ultimate disposition of those products. *Holloway Distributing,* 72 FR 42118, 42124 (2007) (collecting cases); *see also United States* v. *Kim,* 449 F.3d 933, 941 (9th Cir. 2006) (" '[t]here is no quantity threshold exempting a merchant from criminal liability under section 841(c)(2).' ").

The Government ignores, however, that to establish a violation of this provision it must show that Respondent (or its principal) knew facts that provided "reasonable cause to believe" that the ephedrine it distributed would be used to illicitly manufacture methamphetamine. *Holloway,* 72 FR at 42124. As one court of appeals has explained, the Government must show that Respondent "knew, or knew facts that would have made a reasonable person aware, that the [ephedrine] would be used to make methamphetamine." *United States* v. *Kaur,* 362 F.3d 1155, 1158 (9th Cir. 2004).

In support of her conclusion that Respondent was selling excessive quantities, the ALJ cited the DI's testimony that Respondent was selling only twelve to twenty-four bottles a month to most of its customers (Tr. 143). The DI's testimony was based on his review of an exhibit (GX 21), which purports to be a record of Respondent's monthly sales to each customer. The record is, however, clearly incomplete and was missing data (for every month no less) for most of Respondent's customers. While it is unclear why this record is incomplete, what is clear is that this evidence is not reliable and does not satisfy the substantial evidence test. *See* 5 U.S.C. 556(d) ("A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence.").[39] I therefore conclude that the Government has not met its burden and that this allegation is not proved.

Alleged Sales of Drug Paraphernalia

The Government further alleged that Respondent sold Love Roses, a product consisting of a small glass tube which contains a plastic flower and has removable ends. It is undisputed that this item is "commonly used" to smoke crack cocaine, and that it has no legitimate purpose. Tr. 191. It is also undisputed that during the June 2005 inspection, the DI told Respondent that this item was used to smoke crack and yet Respondent continued to sell the product and was still doing so at the time of the hearing. The ALJ did not, however, address the allegation in her decision. *See* ALJ at 36–38.

Under Federal law, "[i]t is unlawful for any person * * * to sell or offer for sale drug paraphernalia." 21 U.S.C. 863(a). As relevant here, this statute defines "[t]he term 'drug paraphernalia' [to] mean[] any equipment, product, or material of any kind which is primarily intended or designed for use in * * * ingesting, inhaling, or other introducing into the human body a controlled substance, possession of which is unlawful under the" CSA. *Id.* section 863(d). Section 863(d) further provides that drug paraphernalia "includes items primarily intended or designed for use in ingesting, inhaling, or otherwise introducing marijuana, cocaine, hashish, hashish oil, PCP, methamphetamine, or amphetamines into the human body, such as * * * metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls." *Id.* section (d) & (1).

The Supreme Court has explained that Section 863(d) "identifies two categories of drug paraphernalia: those items 'primarily intended * * * for use' with controlled substances and those items 'designed for use' with such substances." *Posters 'N' Things, Ltd.* v. *United States,* 511 U.S. 513, 518 (1994).[40] With respect to the latter category, the Court explained that "[a]n item is 'designed for use' * * * if it 'is principally used with illegal drugs by virtue of its objective features, *i.e.,* features designed by the manufacturer.' " *Id.* (quoting *Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.,* 455 U.S. 489, 501 (1982)).

In construing the "primarily intended * * * for use" language, the Court acknowledged that the phrase "could refer to the intent of nondefendants, including manufacturers, distributors, retailers, buyers or users." *Id.* at 519. Based on its analysis of the statute's text and structure, the Court concluded that the term "is to be understood objectively and refers generally to an item's likely use." *Id* at 521. The Court further explained that where an item has multiple uses, "it is the likely use of customers generally, [and] not [of] any particular customer, that can render a multiple-use item drug paraphernalia." *Id.* at 522 n.11.

While the Court construed section 863 as imposing a scienter requirement of knowledge, the Court held that "the knowledge standard in this context [does not] require knowledge on the defendant's part that a particular customer actually will use an item of drug paraphernalia with illegal drugs." *Id.* at 524. The Court further explained that "[i]t is sufficient that the defendant be aware that *customers in general are likely to use the merchandise with drugs.* Therefore, the Government must establish that the defendant knew that the items at issue are likely to be used with illegal drugs." *Id.* (emphasis added) (citing *United States* v. *United States Gypsum Co.,* 438 U.S. 422, 444 (1978) ("knowledge of 'probable consequences' sufficient for conviction")).[41]

The evidence establishes that a Love Rose's likely use is to smoke illicit drugs, and that Respondent sold this item knowing that they were "likely to be used with illegal drugs." *Id.* As explained above, Congress expressly included in the definition of "drug paraphernalia," a list of items which "constitute[e] *per se* drug paraphernalia." *Id.* at 519. Of relevance here, Congress included in this list "metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens." 21 U.S.C. 863(d). As the record shows, a Love Rose is nothing more than a small and fake flower inserted in a glass pipe; that the pipe contains a flower does not make it any less a pipe. Tr. 118; *See also Posters 'N' Things,* 511 U.S. at 518 (observing that certain items "including bongs, cocaine freebase kits, and certain kinds of pipes, have no other use besides contrived ones (such as use of a bong as a flower vase)"). The item thus falls within the statutory definition of "drug paraphernalia." *See* 21 U.S.C. 863(d).

Furthermore, even if the Love Rose does not fall strictly within the "list of * * * items constituting *per se* drug

[39] Moreover, while months before the hearing, Respondent provided the Government with additional sales records, the Government offered no statistical analysis of the data to show why, based on its sales level alone, Respondent had "reasonable cause to believe" that the products it distributed would be used to manufacture methamphetamine. 21 U.S.C. 841(c)(2).

[40] While *Posters 'N' Things* addressed the prior version of the Federal drug paraphernalia statute, the Court explained that "[t]he language of § 863 is identical to that of former § 857 except in the general description of the offense." 511 U.S. at 516 n.5. Of note, section 863 expanded the scope of prohibited acts with respect to drug paraphernalia and did not alter the definition of the term "drug paraphernalia." See id. Accordingly, the Court's interpretation of the term remains lawful authority.

[41] *See also* 511 U.S. at 524 n.13 (quoting *United States* v. *Mishra,* 979 F.2d 301, 307 (3d Cir. 1992) ("Government must prove that defendant 'contemplated, or reasonably expected under the circumstances, that the item sold or offered for sale would be used with illegal drugs' ") and *United States* v. *Schneiderman,* 968 F.2d 1564, 1567 (2d Cir. 1992) ("Government must prove that defendant 'knew there was a strong probability the items would be so used.' ")).

paraphernalia," 511 U.S. at 519, there was ample evidence establishing that the item's "likely use" is to ingest illicit drugs. *Id.* at 521. The DI testified that Love Roses are "commonly used" to smoke crack and that the product has no legitimate purpose.[42] Tr. 191; *see also Gregg & Son Distributors,* 74 FR 17517, 17522 (2009) (quoting Sharon Tubbs, "A Crack Pipe by Any Other Name," St. Petersburg Times (Aug. 10, 2001) (Floridian Section) ("The outsider assumes the rose tubes are meant to attract the impulse buyer who picks up a chintzy gift for his sweetie. But for addicts, the buy is anything but an impulse. Addicts go to stores looking for rose tubes, calling them 'stems'—street talk for [a] crack pipe.")). The DI further testified as to how the product is adapted for use to smoke crack by removing the cork. Tr. 118.

Moreover, it is undisputed that Mr. Mitchell was told by the DI during the June 2005 inspection that the product was used to smoke crack. Mr. Mitchell was thus "aware that customers in general [we]re likely to use the merchandise with drugs." *Posters N' Things,* 511 U.S. at 524. Yet Mr. Mitchell admitted that Respondent continued to sell the product and was still doing so at the time of the inspection. I thus conclude that Respondent violated Federal law by selling drug paraphernalia. 21 U.S.C. 863(a).

In conclusion, I find that Respondent violated Federal law and DEA regulations by failing to report six regulated transactions which were suspicious and by knowingly selling drug paraphernalia. These findings further support the conclusion that Respondent's continued registration is inconsistent with the public interest.

Factor Five—Other Factors Relevant to and Consistent With Public Health and Safety

The illicit manufacture and abuse of methamphetamine have had pernicious effects on families and communities throughout the nation. This is especially so in States such as Tennessee and Kentucky, which, notwithstanding the enactment of laws at both the state and Federal level which more closely regulate or restrict the sale of certain listed chemical products, still have an extraordinarily serious problem with illicit methamphetamine production and its abuse. As the record demonstrates, in 2008, law enforcement authorities in Tennessee and Kentucky still seized 553 and 416 illegal meth. lab sites respectively. The illicit production of methamphetamine thus remains a grave threat to public health and safety in both States. Cutting off the supply source of methamphetamine traffickers is of critical importance in protecting the citizens of Tennessee and Kentucky (as well as the citizens of adjoining States) from the devastation wreaked by this drug.

While listed chemical products containing ephedrine can still be lawfully marketed for over-the-counter use as a bronchodilator, numerous DEA orders have found (and the record here establishes) that convenience stores and gas stations constitute the non-traditional retail (or gray) market for legitimate consumers of products containing these chemicals. *See, e.g., Tri-County Bait Distributors,* 71 FR 52160, 52161–62 (2006); *D & S Sales,* 71 FR at 37609; *Branex, Inc.,* 69 FR 8682, 8690–92 (2004); Resp. Br. 13 ("Respondent's evidence demonstrates that it sold List I chemical product to non-traditional retailers."). DEA has further found 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 Sunny Wholesale, Inc.,* 73 FR 57655, 57667 (2008) (noting testimony of special agent, who had debriefed more than 200 individuals involved in the illicit manufacture of methamphetamine, that gas stations, convenience stores, and other small retailers "were the primary and preferred source of" list I chemicals used by smaller meth. labs); *TNT Distributors, Inc.,* 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").[43] *See also Joy's Ideas,* 70 FR at 33199 (finding that the risk of diversion was "real" and "substantial"); *Jay Enterprises of Spartanburg, Inc.,* 70 FR 24620, 24621 (2005) (noting "heightened risk of diversion" if application to distribute to non-traditional retailers was granted).

For this reason, DEA has closely scrutinized the adequacy of the diversion controls and the compliance records of those entities which distribute listed chemicals into this market. Moreover, even where a distributor's violations are not extensive and/or identified inadequacies in its diversion controls might be redressed through compliance conditions, DEA may still conclude that revocation is necessary to protect the public interest based on evidence that a registrant and/or its principals do not take seriously their responsibility either to prevent diversion or to comply with the CSA. *See, e.g., Novelty Distributors, Inc.,* 73 FR 52689, 52703 (2008) (revoking registration and rejecting ALJ's recommendation to impose compliance conditions based, in part, on registrant's failure to enforce its own policies), *pet. for review denied,* 571 F.3d 1176 (D.C. Cir. 2009); *Holloway Distributing,* 72 FR at 42126 (revoking registration and noting that while registrant had "taken corrective actions, these measures [were] still not adequate to protect against the diversion of its products").[44]

As found above, Respondent's diversion controls are inadequate for four reasons: (1) Its practice of storing products on the trucks overnight, both at Respondent's facility and while the salesmen are servicing their routes; (2) it could not account for all of each product that was audited and did not have a contemporaneous record of products it destroyed; (3) its employees

[42] Indeed, even if one is cheap, if one is intent on expressing his/her affection for a loved one, there are plenty of other ways of doing so such as buying a real flower and not a fake one inside a small glass pipe. Mr. Mitchell's testimony proved this point. When asked on cross-examination what he understood the product was used for, Mr. Mitchell initially testified: "Well they take them home to their wives to keep from getting beat up." Tr. 390–91. Before the Government's counsel could even ask his next question, Mr. Mitchell added: "I don't know. I'd get beat up if I took one home." Tr. 391. Mr. Mitchell then acknowledged that he had been told that the product was used as drug paraphernalia. *Id.*

[43] *See 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 an 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").

[44] Under the Administrative Procedure Act, an Agency is not required to give a licensee the "opportunity to demonstrate or achieve compliance with all lawful requirements" prior to revoking a license "in cases of willfulness or those in which public health, interest, or safety requires otherwise." 5 U.S.C. 558(c). While this exception likely applies here given the continued scope of the methamphetamine problem, especially in the States where Respondent distributes its products, I apply DEA's longstanding precedent that where "the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must present sufficient mitigating evidence to assure the Administrator that [it] can be entrusted with the responsibility carried by such a registration." *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting cases). *See also id.* ("DEA has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct.").

do not ask their customers whether they are purchasing from other distributors; and (4) Mr. Mitchell acknowledged that he continued to sell to stores even when he knew they were obtaining "large quantities" from other distributors. Regarding these four deficiencies, Mr. Mitchell addressed only one of them—the storage of products on its trucks—and did so only with respect to when the trucks were at his facility.[45]

The evidence also showed that Respondent failed on six occasions to report suspicious monthly sales to a store as required by Federal law even though Mr. Mitchell acknowledged that the transactions were suspicious. Here again, Respondent did not offer any evidence that it has instituted a program to identify and report suspicious orders.

Relatedly, when asked whether he had "ever pause[d] to think" that the ephedrine products his firm distributes could be resold to traffickers, Mr. Mitchell explained: "I've guess I've taken the attitude that I have no control on what the retail public does with the product." Tr. 404. As noted above, consistent with this attitude, Mr. Mitchell admitted that his firm had continued to sell to stores even when he knew the stores were buying large quantities from other distributors. And as if further evidence of Mr. Mitchell's and his firm's indifference to their obligations to comply with the law is needed, the record further showed that Respondent violated the CSA by selling a product whose likely use is as drug paraphernalia, and did so even after the DI told Mr. Mitchell that the product was used for this purpose.

Mr. Mitchell's and his firm's clear disregard of their responsibility to protect against diversion and comply with the law "is fundamentally inconsistent with the obligations of a DEA registrant." *Holloway,* 72 FR at 42124; *see also D & S Sales,* 71 FR 71 FR at 37610 (noting that a registrant is "required to exercise a high degree of care in monitoring its customers' purchases") (int. quotations and citations omitted). Because it is clear that Mr. Mitchell does not understand the nature of his firm's obligations, I conclude that Respondent's continued registration "would be inconsistent with the public interest." 21 U.S.C. 823(h). Accordingly, Respondent's registration will be revoked and any pending application will be denied.

[45] It is acknowledged that Respondent undertook to ensure that its customers obtained the necessary certifications required by the CMEA. Tr. 399. Yet this is only one of many factors that are properly considered in assessing whether Respondent's registration is consistent with the public interest.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h) and 824(a), as well as by 28 CFR 0.100(b) and 0.104, I order that DEA Certificate of Registration, 004413RAY, issued to R & M Sales Company, Inc., be, and it hereby is, revoked. I further order that any pending application of R & M Sales Company, Inc., for renewal or modification of its registration, be, and it hereby is, denied. This order is effective January 18, 2011.

Dated: December 3, 2010.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08–43]

Ronald Lynch, M.D.; Revocation of Registration

On April 4, 2008, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Ronald Lynch, M.D. (Respondent), of Sanford, Florida. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BL6686541, and the denial of any pending applications to renew or modify his registration, on the ground that Respondent's "continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(f), 824(a)(4)." ALJ Ex. 1, at 1.

The Show Cause Order alleged that Respondent "authorized controlled substance prescriptions for Internet customers throughout the United States from approximately June 2002, through September 2004, on the basis of online questionnaires and/or telephone consultations." *Id.* The Order alleged that Respondent "issued these prescriptions without a legitimate medical purpose and outside the usual course of professional practice, in violation of 21 CFR 1306.04(a) and 21 U.S.C. 841(a)(1)." *Id.* The Order further alleged that, while Respondent authorized controlled substance "drug orders" for "online customers throughout the United States," he is only licensed to practice medicine in the State of Florida and that he "violated state laws that prohibit the unauthorized practice of medicine, including unlicensed, out-of-state physicians issuing controlled substance prescriptions to state residents." *Id.* at 2 (citations omitted). Finally, the Order alleged that Respondent "violated Florida law and regulation prohibiting licensed physicians from issuing controlled substance prescriptions in excessive or inappropriate quantities, and from issuing prescriptions via the Internet without a documented patient evaluation and discussion between the physician and patient regarding treatment options." *Id.* (citing Fla. Stat. § 458.331(q) and Fla. Admin. Code Ann. r. 64B8–9.014).

On May 7, 2008, Respondent's counsel requested a hearing on allegations, ALJ Ex. 2, and the matter was placed on the docket of the Agency's Administrative Law Judges (ALJs). On March 24–25, 2009, a hearing was held in Arlington, Virginia.

At the hearing, the Government called several witnesses (including the Respondent) to testify and introduced documentary evidence. Respondent also testified on his own behalf. Following the hearing, both parties filed briefs containing their proposed findings of fact, conclusions of law, and argument.

On September 18, 2009, the ALJ issued her recommended decision (also ALJ). Therein, the ALJ, after considering the five public interest factors, *see* 21 U.S.C. 823(f), concluded that "Respondent has misused his DEA registration [in] the past and has not shown any indication that he will not do so in the future." ALJ at 46. The ALJ thus recommended that Respondent's "registration be revoked and that any pending applications be denied." *Id.*

As to the first factor—the recommendation of the appropriate state licensing board—the ALJ found that Respondent's continued licensure by the State of Florida "throughout the relevant time period" weighed "in favor of a finding that his continued registration would not be inconsistent with the public interest." *Id.* at 34. However, the ALJ also noted that "state licensure is a necessary but not sufficient condition for [holding a] DEA registration" so that "this factor is not dispositive." *Id.*

Examining factors two and four together—Respondent's experience in handling controlled substances and his compliance with applicable Federal, State or local laws—the ALJ determined that "both the Controlled Substances Act and the Florida telemedicine standards require that the prescribing physician or a provider under his supervision personally conduct a physical examination." *Id.* at 38–39. The ALJ found that because Respondent failed to perform such examinations, "he did not establish a proper doctor-patient