Order

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

Dated: July 30, 2010.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010–20237 Filed 8–13–10; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08–15]

Hilmes Distributing, Inc.; Dismissal of Proceeding

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

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

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

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

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

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

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

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

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

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

Having considered the entire record in this matter, I adopt the ALJ decision in its entirety except for her findings and conclusion that Respondent has not failed to report suspicious orders. However, because the Government made no such allegation, the relevant evidence cannot be considered as the basis for imposing a sanction. Accordingly, the Order to Show Cause will be dismissed. I make the following findings of fact.

Findings

Respondent is an Illinois corporation, which is owned and operated by Mr. Gary Hilmes, who also serves as its President. ALJ Ex. 4, at 2; Tr. 160. Respondent, which has eight employees including Mr. Hilmes, Tr. 160, is a wholesale distributor of various items to convenience stores, gas stations, and liquor stores. Tr. 15; GXs 22–24. Its customers are located in Illinois, Indiana, Missouri, Ohio, Oklahoma, Wisconsin and Minnesota. Tr. 165. Its product lines include "automotive products, batteries, candies, cigarette papers, meat snacks, salty snacks, novelties, seasonal items, toys, maps," as well as List I chemical products. *Id.* at 13, 162. As for the latter, at the time of the hearing, Respondent distributed ephedrine products under the brand names of Mini Ephedrine 2-Way Action and Rapid Action; these products combine either 12.5 or 25 mgs. of ephedrine with 200 mgs. of guaifenesin. *Id.* at 176 & 202. According to the DI, Respondent did not sell what he called "traditional brand name ephedrine." *Id.* at 18–19.

Respondent, which was then organized as a sole proprietorship, first obtained a DEA registration in 1997. *Id.* at 165. Respondent's registration was renewed every year until the 2007 issuance of the Order to Show Cause. *Id.* at 165. According to its Certificate, Respondent's registration was to expire on October 31, 2007. GX 1. However, on October 8, 2007, Respondent filed a renewal application. *Id.* In accordance with the Administrative Procedure Act and DEA regulations, because Respondent's application was timely filed, I find that Respondent's registration has remained in effect pending the issuance of this Decision and Final Order. *See* 5 U.S.C. 558(c); 21 CFR 1301.36(i).

Ephedrine in combination with guaifenesin is lawfully marketed under the Food, Drug and Cosmetic Act for over-the-counter use as a bronchodilator. GX 15, at 3. However, ephedrine is regulated as a listed chemical under the Controlled Substances Act (CSA) because it is easily extracted from these products and is a precursor chemical used in the illicit manufacture of methamphetamine, a schedule II controlled substance. ALJ Ex. 4, at 1–2; 21 U.S.C. 802(34); 21 CFR 1308.12(d); Tr. 42; GX 4; GX 15, at 8; GX 16, at 7.[1]

Methamphetamine is a highly addictive central nervous system stimulant. Tr. 136. Methamphetamine abuse has destroyed numerous lives and families and ravaged many communities. *Id.* at 136. Moreover, the illicit manufacture of methamphetamine produces toxic and explosive byproducts, including phosphine gas, which is lethal even in low concentrations, and causes serious environmental harms. RX 9, at 27. Individuals have lost limbs and even their lives due to explosions during methamphetamine "cooks." [2] Tr. 136.

Illicit methamphetamine production is comparatively inexpensive, as "with $200," a person "can buy all the chemicals and equipment [she/he] needs to make * * * $2,000, $2,500 worth of methamphetamine." RX 9, at 30. Typically, methamphetamine is sold in "quarter gram, half gram, [and] gram units." Tr. 129. At the hearing in April 2008, a DEA Special Agent (SA) testified that a quarter gram might cost $25–$40 while an ounce would cost anywhere from $850 to $1,200. *Id.* at 129–130.

Respondent distributes products to customers in the States of Missouri, Illinois, Indiana, Ohio, Oklahoma, Wisconsin, and Minnesota. *Id.* at 165. Several of these States have serious problems with methamphetamine abuse as evidenced by the number of clandestine lab incidents. *See* GX 13 (showing that even after the enactment of Federal legislation, there were still nearly 1260 lab incidents in Oklahoma). Due to the development of state laws limiting the sale of List I chemical tablets, at the time of the hearing, Respondent sold combination ephedrine tablets only in Indiana and Wisconsin; elsewhere he sold gel cap ephedrine combination products. Tr. 201.

The DEA Inspection of Respondent

On November 28, 2006, a DEA Diversion Investigator conducted an inspection of Respondent which included reviewing its physical security, recordkeeping and operating procedures. The Investigator met Mr. Hilmes, who told him that that his firm had 430 customers, which include convenience stores, gas stations and liquor stores; of these, 131 purchased combination ephedrine products. *Id.* at 12–13, 15, 202; GX 36, at 8. *See also* GXs 22–24 (Respondent's sales records for June through August 2006) and 26–28 (copies of Respondent's sales receipts for months of June through August 2006).[3]

Respondent stores the listed chemical products in "the drug room," a room with locked doors that is continually lit and is outfitted with an infra-red camera to guard against theft. Tr. 169. As an additional security precaution, within the room, the List I chemicals are stored in a steel cage. *Id.* The room is also protected by an alarm system with a motion detector; in the event the alarm is triggered, both the County Sheriff and a monitoring service are notified; the latter first calls Respondent's business line, then Mr. Hilmes's cell phone, and, if there is no answer at either, Mr. Hilmes's father. *Id.* at 170. Regarding Respondent's security, the DI (who had also participated in two other inspections of it) testified that DEA "never had any problems with [Respondent's] security." *Id.* at 96; *see also id.* at 178 (testimony of Mr. Hilmes that although DEA has inspected Respondent four or five times, it has never found its security inadequate).

With respect to Respondent's recordkeeping, the DI testified that it is "one of the better distributors as far as record keeping goes." *Id.* at 62–63. The DI further stated that "there was nothing wrong with * * * [Respondent's] recordkeeping and as a matter of fact, [Respondent] is one of the few chemical distributors that we work with that had most of their records on a database, which made it easily accessible." *Id.* at

[1] An ounce of methamphetamine contains 28 grams, and each gram of methamphetamine yields around eight to ten doses. RX 8, at 15, 19; RX 9, at 17. Around 1,000 ephedrine pills will yield approximately one gram of methamphetamine in a clandestine methamphetamine laboratory. Tr. 92. An illicit clandestine laboratory may manufacture anywhere from a 1-ounce to a 4-ounce batch. *Id.* at 125.

[2] While methamphetamine imported from Mexico has taken an increasing share of the domestic market, small toxic and illegal laboratories in the United States continue to pose an enforcement challenge. RX 12, at 1–2. This is true even following the implementation of the Combat Methamphetamine Epidemic Act of 2005 and other state laws restricting the over-the-counter purchase of List I chemical products. Tr. 131.

[3] At the hearing Mr. Hilmes testified that since the passage of the Combat Methamphetamine Epidemic Act of 2005 (CMEA), those of his customers who were "independents" "opted out" of selling List I chemical products "for fear of getting caught in some sort of trouble for not properly" complying with the CMEA's provisions. Tr. 164. Consequently, his current List I customer base consists of only 105 to 110 businesses. *Id.* Respondent's total customer list, however, has grown to around 480 to 500 businesses. *Id.*

96. The DI further described Mr. Hilmes as "very cooperative" at the inspections. *Id.* at 62–63.

Respondent also put on extensive testimony as to its procedures for handling listed chemical products. Upon receipt of the products, Respondent stamps them. *Id.* at 171. Each Friday, Respondent takes an inventory and maintains a record of what products have been taken by each salesman. *Id.* It then compares this figure (prior week's inventory minus the product taken by its drivers) with the new inventory. *Id.* at 171–72.

Each Friday, Respondent requires that each driver account for the merchandise he has taken; if there is a discrepancy, the driver does not leave on his route the next week until it is resolved. *Id.* at 172–73. Respondent also retains a copy of its sales invoices and makes a copy on which its drivers record the product's lot number at the store, "prior to the actual transaction." *Id.* at 174.

Under company policy, Respondent will not sell to customers who seek to buy only List I chemical products. *Id.* at 177. Since the implementation of the Combat Methamphetamine Epidemic Act of 2005, Respondent distributes List I chemical products only to those businesses that have self-certified in compliance with the Act; Respondent also requires its drivers to visually inspect the self-certification and note the expiration date. *Id.* at 189. Some thirty to ninety days prior to the expiration of a customer's certification, Respondent sends a letter notifying it of the upcoming expiration and indicating that Respondent will not continue to sell product to it after the expiration of its certification unless the store re-certifies. *Id.* In addition, since the enactment of the CMEA, Respondent's drivers will not service a new customer until they confirm visually that the customer has a logbook as required by law. *Id.* at 191.

Since it first became registered, Respondent has provided its customers with acrylic cases for storing the combination ephedrine products. *Id.* at 193. The cases which Respondent currently provides have keyed locks on the back thus preventing a customer from acquiring the product without the assistance of a store clerk. *Id.*

Since the enactment of the CMEA's requirement that retailers self-certify, Respondent has provided a print-out of the training materials from the DEA website which follows the online self-certification process prior to his first delivery to new customers. *Id.* at 194; RX 6. The training materials include such information as the single-day (3.6 grams) and thirty-day (9 grams) limits on an individual's purchase of combination ephedrine products. *Id.* at 194; RX 6, at 12. Mr. Hilmes testified that while his drivers cannot by law examine a customer's logbook, if it were proven that a customer violated those limits, Respondent would no longer sell List I chemical products to that customer. Tr. 195.

The DI, who had worked on two prior inspections of Respondent, testified that he was not aware of Respondent's ever having been cited for regulatory infractions by DEA, including after the inspection of November 2006. *Id.* at 60–61. Similarly, Mr. Hilmes testified that he had no knowledge of any regulatory infractions by his firm. *Id.* at 178.

Respondent's total sales volume of all products from January 1, 2004 through the close of business October 13, 2006, was $6,336,943.18. GX 21. According to the DI, Mr. Hilmes told him at the 2006 inspection that thirty percent of his gross sales were attributable to combination ephedrine products. Tr. 15, 83. However, at the hearing, Mr. Hilmes contested this, testifying that he "specifically recall[ed] stating" that the percentage of gross sales attributable to List I chemical products "was 20 percent or less." *Id.* at 197.

Mr. Hilmes testified that he ran the figures for June through August 2006 (the time period referenced in the Show Cause Order) and found that the percentage of sales attributable to List I chemical products was 19.39 percent. *Id.* at 198. Mr. Hilmes further testified that, at the time of the hearing, the quantity of List I chemical product it was selling was down but, due to price increases, its total sales remained about the same.[4] *Id.* at 196.

The Government entered into evidence a spreadsheet created by the DI which showed Respondent's sales of combination ephedrine products to its various customers during the period of June through August 2006. GX 35; Tr. 21. The DI testified that Respondent's customer's monthly retail sales of ephedrine products exceeded $15 a month, an amount which the Government maintained represents the normal expected retail sales range of these products at convenience stores for legitimate uses. *Id.* at 31; *see also* ALJ Ex. 1, at 2 (Show Cause Order ¶ 6).

As for the stores specifically identified in paragraph 7 of the Show Cause Order, the Government produced evidence showing that, between June 8 and August 24, 2006, the FISCA Oil Co. of West Alton, Mo., had purchased ephedrine products with a total retail value of approximately $15,600. GX 35, at 7–8. Mr. Hilmes testified that this customer is a gas station, liquor store and smoke shop that benefits from being just over the border in Missouri where taxes are lower on gasoline and cigarettes than they are in Illinois. Tr. 181. He also indicated that during this time period, Illinois law limited purchases of ephedrine gel caps to one package of 6-count or 12-count blister packs, while under Missouri law, an individual could buy two 36-count packages. *Id.* According to Mr. Hilmes, the store "sell[s] a lot of pills because [it] sell[s] a lot of everything else." *Id.* at 182.

The Government's evidence showed that between June 7 and August 23, 2006, the Gas Mart #11 of St. Louis, Mo., had purchased ephedrine products with a total retail value of $8,573. GX 35, at 9. Mr. Hilmes testified that this customer is a high-volume store located so as to draw both local and interstate traffic and also "sell[s] a lot of everything." Tr. 182.

The Government's evidence showed that between June 13 and August 22, 2006, Blue Goose Liquor of Centralia, Ill., purchased ephedrine products with a total retail value of $5,079. GX 35, at 2. Mr. Hilmes testified that Blue Goose Liquor is "the number one Anheuser-Busch retailer in that county," was his "largest dollar [customer] overall," "that it's like a country WalMart liquor store," and is even outfitted with a "drive-up window." Tr. 183. Moreover, the store is located in an industrial area and there are "three shifts of people coming in there 24 hours a day." *Id.* at 184.

The Government's evidence showed that between June 9 and August 25, 2006, the Hit-n-Run #8 of Bethalto, Ill., purchased ephedrine products with a total retail value of $4,699. GX 35, at 18. Mr. Hilmes testified that "[i]t's always been an extremely high dollar ephedrine account" because no other store in Bathalto, Illinois, with the exception of the pharmacy and Walgreen's, carries ephedrine. *Id.* He added that when Walgreen's opened, his ephedrine sales to this account dropped by half. *Id.*

The Government's evidence showed that between June 7 and August 23, 2006, the 7–11 #19889 of St. Louis, Mo., purchased ephedrine products with a total retail value of $2,916. GX 35, at 1.

[4] Mr. Hilmes testified that Respondent had not purchased gel caps since the preceding September "when the industry ran out nationwide, because the company that makes gel caps shut their operation down." Tr. 175. At the time of the hearing, Respondent no longer stocked 6-count, 12-count, and 24-count gel cap packages but only 12-tablet and 24-tablet blister packs. *Id.* at 176. Lacking gel caps in its inventory, Respondent had only twelve active List I customers, all located in either Indiana or Wisconsin; but Mr. Hilmes stated that he intended to supply a total of 108 customers once gel caps were again available. *Id.* at 201.

Mr. Hilmes testified that, similar to Gas Mart, the store is located in a high population density area of South St. Louis and is open twenty-four hours per day, seven days per week. *Id.* at 185. Summarizing his sales to all the above-mentioned stores, Mr. Hilmes testified that "they bought a whole lot of" other products besides ephedrine. *Id.*

During January and February 2008, a DI went to eight Moto Marts (which are chain gas stations and convenience stores) in southern Illinois to verify whether they were Respondent's customers and to review their logbooks. *Id.* at 30–31 & 69. The DI found that "the same people were buying similar products at—within the component of eight [stores] we worked on, various stores within that component." *Id.* at 31, 69. Moreover, the same four "individuals accounted for 42 percent of the total monthly sales" of combination ephedrine products at Moto Mart #3111 for the period October 9, 2007 through February 29, 2008. *Id.* at 34. Of the logbook review, he commented that the customer establishments were running close to CMEA limits but not exceeding them. *Id.* at 70–71.

The Government also entered into evidence two affidavits prepared by an expert witness[5] for other proceedings regarding the normal expected sales range of ephedrine products at convenience stores in legitimate commerce. In one of these affidavits, the expert opined that in August 2007, he "analyzed national sales data for over-the-counter non-prescription drugs that contain ephedrine (Hcl)." GX 36, at 4. Based on his review of data from various sources, the affidavit asserts that during the year 2006, "about $172 per year or about $14 per month of in-store sales [at convenience stores] could be attributed to combination ephedrine/guaifenesin tablet products." *Id.* at 5. The expert further opined that "the normal expected retail sale of ephedrine (Hcl) tablets in a convenience store ranges between $0 and $29, with an average of $14.39 and a standard deviation of $5.76." *Id.* at 7–8. In addition, the expert opined that "[a] monthly retail sale of $60 of ephedrine/guaifenesin (Hcl) tablets would be expected to occur about once in a million times in random sampling." *Id.* at 8.

However, during a proceeding which was litigated simultaneously with this matter, the methodology used by the Government's expert to determine the expected sales range was found to be unreliable. *See Novelty Distributors, Inc.,* 73 FR 52689, 52694 (2008). As I have noted in other cases, even though Respondent did not challenge the methodology of the Government's expert,[6] "the Agency cannot . . . ignore the ultimate finding in *Novelty* which rejected the expert's conclusions as to the expected sales range of ephedrine products" at convenience stores. *Gregg & Son Distributors,* 74 FR 17517, 17520 (2009). *See also Mr. Checkout North Texas,* 75 FR 4418, 4421 (2010); *CBS Wholesale Distributors,* 74 FR 36746, 36748 (2009). Accordingly, I again conclude that the Government's figures for the monthly expected sales by convenience stores of combination ephedrine products for legitimate uses, as well as for the statistical probability of various sales levels in legitimate commerce, are not supported by substantial evidence.

Finally, the DI testified that he was not aware that Respondent's sales exceeded the then-existing threshold of 1,000 grams per thirty-day period. Tr. 68; *see also* 21 CFR 1310.04(f)(1)(ii)(2006).[7] Moreover, the record contains no evidence that either Respondent's owner or any of its employees have ever been convicted of an offense related to related to controlled substances.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) 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 an applicant to distribute a list I chemical unless the Attorney General determines that the registration of the applicant is inconsistent with the public interest." *Id.* § 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 listed chemicals into other than legitimate channels;

(2) compliance by the [registrant] with applicable Federal, State and 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.

"These factors are considered in the disjunctive." *Gregg & Son,* 74 FR at 17520; *see also Joy's Ideas,* 70 FR 33195, 33197 (2005). I may rely on any one or a combination of factors, and I may give each factor the weight I deem appropriate in determining whether to revoke an existing registration or deny an application for renewal of a registration. *Gregg & Son,* 74 FR at 17520; *Jacqueline Lee Pierson Energy Outlet,* 64 FR 14269, 14271 (1999). Moreover, I am not required to make findings as to all of the factors. *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

The Government bears the burden of proof. 21 CFR 1309.54. However, where the Government has made out a *prima facie* case, the burden shifts to the Respondent to show why its continued registration is consistent with the public interest.

Having considered the Government's evidence and the relevant factors, I conclude that the Government has not satisfied its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest. Accordingly, Respondent's renewal application will be granted and the Order to Show Cause will be dismissed.

The Government did not challenge the adequacy of Respondent's physical security, its recordkeeping, or its procedures for monitoring its receipt and distribution of listed chemicals, all of which are relevant in assessing the adequacy of its diversion controls. *See, e.g., Gregg & Son,* 74 FR at 17520. Instead, the Government's sole basis for seeking the revocation of Respondent's registration was the allegation that it sold combination ephedrine products in quantities which "greatly surpass the expected sales range [by convenience stores] to meet legitimate demand for combination ephedrine products" and that these stores constitute a gray market which is the "primary source for precursors that are diverted to illicit

[5] The expert did not testify in this proceeding.

[6] Respondent did, however, challenge the expert's credibility.

[7] To make clear, the 1,000 gram threshold for sales (within a thirty-day period) of combination ephedrine products by a distributor to a retail store triggered various recordkeeping and reporting requirements. The provision neither prohibited sales in excess of the threshold nor provided a safe harbor for sales when a distributor had reason to know that the products were likely to be diverted. *See United States* v. *Kim,* 449 F.3d 933, 944 (9th Cir. 2006); *Sunny Wholesale, Inc.,* 73 FR 57655, 57665 (2008); *Rick's Picks,* 72 FR 18275, 18278 (2007). This remains the case with respect to those chemicals for which thresholds remain in place.

methamphetamine laboratory operators." ALJ Ex. 1 (¶¶ 6 & 3).

As found above, the Government's figures for the expected sales range and the statistical probability of certain sales level of ephedrine products in legitimate commerce at convenience stores are not supported by substantial evidence. Accordingly, there is no basis for concluding that Respondent's sales of these products "greatly surpass the expected sales range to meet legitimate demand." *Id.* at 2 (¶ 6).

The ALJ also acknowledged that when compared to Respondent's average monthly sales to its other customers ($454), Respondent's sales to the FISCA Oil Company and some other stores seem excessive. ALJ at 21–22. While this evidence is disturbing, I agree with the ALJ's conclusion that this evidence only creates a suspicion that diversion was occurring.[8] *Id.* at 22.

Finally, based on the DI's testimony, the ALJ also found that there is no evidence that Respondent failed to report any suspicious transactions. ALJ at 6 & 18. Notwithstanding the DI's testimony, this finding is erroneous.

On March 9, 2006, the Combat Methamphetamine Epidemic Act of 2005 was signed into law. *See* USA PATRIOT Improvement and Reauthorization Act of 2005, Public Law 109–177, Title VII, 120 Stat.192, 256–77. Section 712(b) of the Act eliminated the 1,000 gram threshold for combination ephedrine products. 102 Stat. 264. While Congress provided an effective date for other provisions of the Act, *see, e.g.,* section 711(b)(2) & (c)(3), 120 Stat. 261, it provided no effective date for section 712(b).

As the Supreme Court has explained, "absent a clear direction by Congress to the contrary, a law takes effect on the date of its enactment." *Gozlon-Peretz* v. *United States,* 498 U.S. 395, 404 (1991) (other citations omitted). And "'where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'" *Id.* at 404–05 (quoting *Russello* v. *United States,* 464 U.S. 16, 23 (1983) (internal quotations omitted)).

It is therefore clear that the provision eliminating the threshold for combination ephedrine products became effective with the Act's enactment on March 9, 2006. Accordingly, thereafter every transaction in a combination ephedrine product by a distributor became a regulated transaction under the CSA, and thus, all transactions became subject to the recordkeeping and reporting requirements of 21 U.S.C. 830, including the requirement to report "any regulated transaction involving an extraordinary quantity of a listed chemical." 21 U.S.C. 830(b).

Respondent's sales to the FISCA Oil Company, which occurred after the threshold was eliminated and which were more than ten times its average monthly sale (as well as its sales to several other stores which were also multiple times greater than its average sale) involved an "extraordinary quantity" within the meaning of the statute. While the evidence does not establish that the products Respondent sold in these transactions were diverted, it cannot be seriously disputed that the transactions were suspicious and should have been reported to the Agency. *See* ALJ at 25 ("[T]he Respondent should remain more vigilant in determining when a customer is purchasing listed chemical products in suspicious amounts.").

It is acknowledged that the Government did not allege that Respondent violated Federal law by failing to report these transactions. Accordingly, consistent with the Due Process Clause, the Agency cannot impose a sanction on Respondent for these violations. *See, e.g., Darrell Risner, D.M.D.,* 61 FR 728, 730 (1996). However, while the Order to Show Cause must be dismissed, Respondent is now on notice that its failure to report similar transactions in the future may give rise to further proceedings seeking the revocation of its registration.

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 hereby order that the application of Hilmes Distributing, Inc., for renewal of its DEA Certificate of Registration be, and it hereby is, granted. I further order that the Order to Show Cause be, and it hereby is, dismissed. This order is effective immediately.

Dated: August 4, 2010

Michele M. Leonhart,

Deputy Administrator.

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[8] The record does not establish the standard deviation for Respondent's sales. Nor did the Government rebut Respondent's evidence regarding the stores which purchased the largest quantities such as their locations and the nature of their businesses.

Moreover, the Government did not file a brief at any stage of this matter. I thus conclude that the Government does not rely on the disparity between Respondent's average sale and its sales to stores such as FISCA to prove that Respondent's products were being diverted.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Hung Thien Ly, M.D.; Revocation of Registration

On August 28, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Hung Thien Ly, M.D. (Respondent), of McRae, Georgia. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BL8586147, which authorizes him to dispense controlled substances as a practitioner, and the denial of any pending applications to renew or modify his registration on two grounds. Show Cause Order at 1–2.

First, the Order alleged that, on August 6, 2009, the Georgia Composite Medical Board (Board) revoked his license to practice medicine in Georgia, the State in which he holds his DEA registration, and that therefore, he is not entitled to maintain his registration. *Id.* (citing 21 U.S.C. 824(a)(3)). Second, the Order alleged that on August 14, 2008, Respondent was convicted of 129 counts of violating 21 U.S.C. 841(a)(1), by dispensing controlled substances "outside the usual course of professional practice and for no legitimate medical purpose." *Id.* at 2; *see also id.* at 1 (citing 21 U.S.C. 824(a)(2)).

On September 30, 2009, Respondent was served with a copy of the Order to Show Cause. Thereafter, on November 2, 2009, Respondent filed letter waiving his right to a hearing and responding to the Show Cause Order. Waiver of Hearing and Written Response to Order to Show Cause at 1. Therein, Respondent does not dispute either that he has been convicted by a United States District Court of violations of 21 U.S.C. 841 or that the Board has revoked his medical license. *Id.* Rather, he maintains that the Board's action "was based entirely" on his conviction and that his "trial was fundamentally flawed" because he was "denied appointed counsel by the District Court and represented himself at trial." Moreover, he "is confident that the Eleventh Circuit will grant a new trial with appointed counsel and expert medical testimony that will demonstrate that his practice was consistent with the good faith treatment of chronic pain." *Id.* at 1–2. Accordingly, he "requests that good cause is shown to suspend his registration [rather than revoke it] * * * until such time as the appeal [of his conviction] and any subsequent proceedings are complete." *Id.*