

Motion for Summary Disposition (Motion). In that Motion the Government asserted the Medical Licensure Commission of Alabama (Alabama Commission), had indefinitely suspended Respondent's Alabama State Medical License and, as a result, he was no longer authorized to handle controlled substances in the state where he is registered with DEA. Attached to the Government's Motion was a copy of the Alabama Commission's Order dated October 30, 2003, indefinitely suspending Respondent's medical license.

On January 31, 2005, Judge Randall issued an order allowing Respondent until February 22, 2005, to respond to the Government's Motion. Respondent did not file any response and on March 25, 2005, Judge Randall issued her Order, Opinion and Recommended Decision of the Administrative Law Judge (Opinion and Recommended Decision). In it, she granted the Government's Motion, finding Respondent lacked authorization to handle controlled substances in his state of DEA registration and recommended that his registration be revoked.

No exceptions were filed by either party to the Opinion and Recommended Decision and on April 26, 2005, the record of these proceedings was transmitted to the Office of the DEA Deputy Administrator.

The Deputy Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues her final order, based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, in full, the Opinion and Recommended Decision of the Administrative Law Judge.

The Deputy Administrator finds Respondent currently holds DEA Certificate of Registration BG2476186 as a practitioner and that on October 30, 2003, the Alabama Commission indefinitely suspended his license to practice medicine in that State. The suspension was predicated on the Commission's findings that Respondent engaged in unprofessional conduct, had staff privileges terminated, revoked or restricted by a hospital and was "unable to practice medicine with reasonable skill and safety to patients by reason of illness or as a result of a mental or physical condition."

The Deputy Administrator's therefore finds Respondent is currently not licensed to practice medicine in Alabama and lacks authorization to handle controlled substances in that state.

DEA does not have statutory authority under the Controlled Substances Act to

issue or maintain a registration if the applicant or registrant is without state authority to handle controlled substances in the state in which he conducts business. See 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. See Stephen J. Graham, M.D., 69 FR 11,661 (2004), Dominick A. Ricci, M.D., 58 FR 51,104 (1993); Bobby Watts, M.D., 53 FR 11,919 (1988). Denial or revocation is also appropriate when a state license has been suspended, but with the possibility of future reinstatement. See Paramabalo Edwin, M.D., 69 FR 58,540 (2004); Alton E. Ingram, Jr., M.D., 69 FR 22,562 (2004); Anne Lazar Thorn, M.D., 62 FR 847 (1997).

Here, it is clear Respondent is not currently licensed to handle controlled substances in Alabama, the jurisdiction in which he holds a DEA registration. Therefore, he is not entitled to registration in that state.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.014, hereby orders that DEA Certificate of Registration BG2476186, issued to Carlin Paul Graham Jr., M.D., be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This order is effective July 7, 2005.

Dated: May 25, 2005.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03-35]

Joy's Ideas, Revocation of Registration

On June 13, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Joy's Ideas (Joy's Ideas/Respondent) proposing to revoke its DEA Certificate of Registration 003278JIY as a distributor of list I chemicals and deny its pending application for renewal under 21 U.S.C. 824(a)(4) and 823(h) as being inconsistent with the public interest. The Order to Show Cause alleged, in sum, that Respondent was distributing list I chemicals to what DEA has

identified as the "gray market" and that a September 2001 audit by DEA Diversion Investigators showed the company had serious record keeping deficiencies.

Respondent requested a hearing on the issues raised by the Order to Show Cause and the matter was docketed before Administrative Law Judge Gail A. Randall. Following pre-hearing procedures, a hearing was held in Memphis, Tennessee, on March 11 and 12, 2004. At the hearing, both parties called witnesses to testify and introduced documentary evidence. Subsequently, both parties filed Proposed Findings of Fact, Conclusions of Law, and Argument.

On September 29, 2004, Judge Randall issued her Recommended Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (Opinion and Recommended Ruling), recommending that Respondent's registration to distribute pseudoephedrine and ephedrine products be continued and its application for renewal be granted, subject to enumerated monitoring conditions. She recommended denying the request to distribute phenylpropanolamine. The Government filed Exceptions to the Opinion and Recommended Ruling, to which Respondent submitted a Reply and on November 8, 2004, Judge Randall transmitted the record of these proceedings to the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues her final order based upon findings of fact and conclusions of law hereinafter set forth. Except as otherwise set forth in this final order, the Deputy Administrator adopts the findings of fact and conclusions of law of the Administrative Law Judge. The Deputy Administrator agrees with the recommendation that Respondent be denied registration to distribute phenylpropanolamine, but disagrees with Judge Randall's recommendation that Respondent be registered to distribute ephedrine and pseudoephedrine, even under close monitoring conditions.

Respondent is a sole proprietorship owned and operated by Ms. Joy Carter which is located in Memphis, Tennessee. It has been a DEA registrant since March 1998 and holds DEA Certificate of Registration 003278JIY. On November 10, 2003, Ms. Carter filed an application for renewal of that registration, which was due to expire on December 31, 2003. In it, she sought registration to distribute list I products

containing pseudoephedrine, ephedrine and phenylpropanolamine. Having filed a timely application for renewal, Respondent has been allowed to continue distributing listed chemicals during the pendency of these proceedings. See 21 CFR 1309.45.

In September 2001, DEA Diversion Investigators conducted a routine regulatory investigation of Respondent and met Ms. Carter at her residence, which is also the registered premises. The physical security and monitoring systems were found to be adequate and Ms. Carter testified at the hearing that she had never had any listed chemical products stolen or lost.

As a part of their investigation, the Diversion Investigators conducted a two day accountability audit. However, the results were hampered by Respondent's lack of an accurate inventory and investigators assigned a beginning inventory of zero as their starting inventory. Ms. Carter was cooperative and provided investigators all purchase and sales records for the period covering March 1, 2001 to September 12, 2001. At the conclusion of the audit, investigators found there were overages of four listed chemical products and shortages of two such products. Ms. Carter was unable to account for 15 100-count bottles of "Efedrin" and 557 60-count bottles of "Mini-thins." The overages involved 6-count packages and 60-count bottles of "Efedrin," 60-count bottles of "Max Brand Two Way" and 6-count packages of "Mini Thins."

Evidence was introduced that overages can be anticipated when a zero starting inventory is used and/or they may be attributable to improperly maintained records. Shortages can result from improperly maintained records or from theft or loss of the product. At the hearing, a mathematical error impacting the overage of one product was discovered and a former DEA Diversion Investigator testified that more often than not, these audits do not result in perfectly balanced inventories, particularly when a zero opening balance is used.

At the hearing Ms. Carter testified that before receiving the Order to Show Cause, she was unfamiliar with procedures for ensuring accountability of listed chemicals or how to conduct an audit. After receiving that Order, she began working with her attorney and certified public accountant to establish procedures for accurately recording purchase and sales data and initiated weekly physical inventories of listed chemicals. This system was put into operation in November 2003 and records introduced at the hearing

showed that Ms. Carter was adhering to the improved accountability procedures.

The Respondent is a wholesale distributor of about 200 sundry products to convenience stores and gas stations. Seven of her approximately 60 customers are located in Arkansas and Mississippi and the balance are in Memphis. Each of these customers buy listed chemicals from Joy's Ideas, which makes up between 20 to 30 percent of Respondent's total sales. Most customers purchase approximately \$100.00 of list I chemical products from Respondent each month.

Ms. Carter, the sole employee, testified she personally delivers the listed chemicals and places them on customer's shelves. As a result, she believed she could monitor her customers' stocks and tell if she was their only supplier of listed products. Affidavits from several long term customers were also introduced which affirmed they only purchased listed chemicals from Respondent and their retail customers did not buy more than two weeks packets or bottles of listed chemicals at a time. According to records introduced at the hearing, Respondent also did not exceed the threshold quantities of sales to a single purchaser which are established by the Comprehensive Methamphetamine Control Act of 1996. Ms. Carter further testified that she instructed her customers to not sell more than two bottles of ephedrine products to any single customer.

Ms. Carter has never been charged or convicted under Federal or state law of any crime involving controlled substances or listed chemicals. Joy's Ideas is her only source of income and she expressed fear that if she were not able to provide customers listed chemicals, they would take their entire business to other wholesalers, who could provide "one stop" shopping.

List I chemicals are those that may be used in the manufacture of a controlled substance in violation of the Controlled Substance Act. 21 U.S.C. 802(34); 21 CFR 1310.02(a). Pseudoephedrine and ephedrine are list I chemicals which are legitimately manufactured and distributed in single entity and combination forms as decongestants and bronchodilators, respectively. Both are used as precursor chemicals in the illicit manufacture of methamphetamine and amphetamine.

Phenylpropanolamine, also a list I chemical, is a legitimately manufactured and distributed product used to provide relief of symptoms resulting from inflammation of the sinus, nasal and upper respiratory tract tissues and for weight control.

Phenylpropanolamine is also used as a precursor in the illicit manufacture of methamphetamine and amphetamine. In November 2000, the United States Food and Drug Administration issued a public health advisory requesting drug companies to discontinue marketing products containing phenylpropanolamine, due to risk of hemorrhagic stroke. As a result, pharmaceutical companies have stopped using phenylpropanolamine as an active ingredient. See, Gazaly Trading, 69 FR 22,561 (2004).

As testified to by government witnesses and as addressed in previous DEA final orders, methamphetamine is an extremely potent central nervous system stimulant and its abuse is a persistent and growing problem in the United States. See, e.g., Direct Wholesale, 69 FR 11,654 (2004); Branex, Inc., 69 FR 8,682 (2004); Denver Wholesale, 67 FR 99,986 (2002); Yemen Wholesale Tobacco and Candy Supply, Inc., 67 FR 9,997 (2002).

The Government introduced documentary and testimonial evidence regarding the rapid proliferation of clandestine methamphetamine laboratories in Tennessee and its adjoining states and described local methods of production, as well as the multiple health hazards and social costs stemming from production and abuse of methamphetamine. As discussed in several recently published final orders, Tennessee leads the DEA Atlanta Region in the number of clandestine laboratories seized. See, e.g., Elk International Inc., d.b.a. Tri City Wholesale (Elk International), 70 FR 24,615 (2005); Prachi Enterprises, Inc., 69 FR 69,407 (2004); CWK Enterprises, Inc., 69 FR 69,400 (2004). Further, DEA has found that local "[d]istributors or retailers serving the illicit methamphetamine trade observe no borders and trade across state lines." *Id.* 69 FR at 69,401.

A DEA Special Agency credibly testified that the list I chemical product of choice found in about eighty percent of illicit laboratories in Tennessee is distributed under the off-name brand "Max Brand" label and is usually obtained from convenience stores. Judge Randall found Respondent has distributed this product. However, there was no direct evidence showing a known diversion of Respondent's products to illicit manufacturing.

By written declaration, a DEA Diversion Investigator contrasted the "traditional" market for list I chemicals with what DEA has termed the "gray market" for these products. The traditional market, characterized by a short distribution chain from

manufacturer to distributor to retailer, typically includes large chain grocery stores, chain pharmacies, large convenience stores and large discount stores. The gray market is characterized by additional layers of distribution and includes such non-traditional retailers as small convenience stores, gas stations and other retail establishments where customers do not usually purchase over-the-counter medications. These non-traditional retailers typically sell higher-strength products in larger package sizes, such as 60, 100 or 120-county bottles of 60 mg. pseudoephedrine. The Diversion Investigator also identified the off-name brands found in disproportionate numbers during clandestine laboratory seizures. These included Max Brand, Mini Two Way, MiniThin and Action-Pseudo products.

In previous final orders DEA has identified convenience stores as the "primary source" for the purchase of "Max Brand products, which are the preferred brand for use by illicit methamphetamine producers." * * * See, Elk International, *supra*, 70 FR 24,615; Express Wholesale, 69 FR 62,086, 62,087 (2004); *see also*, RAM, Inc. d/b/a American Wholesale Distribution Corp., 70 FR 11,693 (2005).

By declaration, the Government introduced evidence regarding ephedrine and pseudoephedrine sales and the convenience store market from Mr. Jonathan Robbin, a consultant in marketing information systems and databases, who is an expert in statistical analysis and quantitative marketing research.

Using the 1997 United States Economic Census of Retail Trade, Mr. Robbin tabulated data indicating that over 97% of all sales of non-prescription drug products, including non-prescription cough, cold and nasal congestion remedies, occur in drug stores and pharmacies, supermarkets, large discount merchandisers, mail-order houses and through electronic shopping. He characterized these five retail industries as the traditional marketplace where such goods are purchased by ordinary customers.

Analyzing national sales data specific to over-the-counter, non-prescription drugs containing pseudoephedrine, Mr. Robbin's research and analysis showed that a very small percentage of the sales of such goods occur in convenience stores; only about 2.6% of the Health and Beauty Care category of merchandise or 0.05% of total in-store (non-gasoline) sales. He determined that the normal expected retail sales of pseudoephedrine tablets in a convenience store would range between \$10.00 and \$30.00 per month, with an

average monthly sales figure of about \$20.00 and that sales of more than \$100.00 in a month would be expected to occur in a random sampling about once in one million to the tenth power.

According to Mr. Robbin, after evaluating Tennessee convenience store sales data, half of the Tennessee stores analyzed showed implied sales over ten times expectation, with ten of them over twenty times expectation. These differences were extremely significant statistically and in his expert opinion, "[t]he implausible nature of such exceptionally large hypothetical sales at retail leads to a virtually incontrovertible conclusion that the goods are not actually being purveyed at retail to ordinary customers in the store's trading area at all, but are being diverted to some other channel 'under the counter.'" He concluded that many small Tennessee convenience stores were not selling pseudoephedrine and ephedrine products for their intended purpose as non-prescription drugs in the legitimate market and the assumption that they were supplying a "gray market" was statistically supported "many times over * * *"

Pursuant to 21 U.S.C. 823(h), the Deputy Administrator may deny an application for a Certificate of Registration if she determines that granting the registration would be inconsistent with the public interest, as determined under that section. Section 823(h) requires the following factors be considered in determining the public interest:

- (1) Maintenance of effective controls against diversion of listed chemicals into other than legitimate channels;
- (2) Compliance with applicable Federal, State, and local law;
- (3) Any prior conviction record under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
- (4) Any past experience in the manufacture and distribution of chemicals; and
- (5) Such other factors as are relevant to and consistent with the public health and safety.

As with the public interest analysis for practitioners and pharmacies pursuant to subsection (f) of section 823, these factors are considered in the disjunctive; the Deputy Administrator may rely on any one or combination of factors, and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. *See, e.g.*, Direct Wholesale, *supra*, 69 FR 11,654; Energy Outlet, 64 FR 14,269 (1999); Henry J. Schwartz, Jr., M.D., 54 FR 16,422 (1989).

As to factor one, maintenance by the applicant of effective controls against diversion, the Deputy Administrator agrees with Judge Randall that Respondent's physical security system is adequate. With regard to the 2001 accountability audit's results, Judge Randall found the statistics "questionable" and based on the statistics alone, could not conclude that any listed chemical products distributed by Respondent had been diverted. She also concluded that Ms. Carter had a faulty accountability system at the time of the audit. However, that was mitigated by the significant accountability improvements crafted by her certified public accountant after receipt of the Order to Show Cause. Judge Randall also found Ms. Carter had a long standing relationship with her customers and personally delivered their listed chemical products and placed them on the shelves, allowing her to monitor whether or not they were obtaining listed chemicals from other wholesalers. Judge Randall concluded this factor weighted in favor of registration.

The Deputy Administrator agrees with the Government's Exceptions that the shortages established by the 2001 inventory would normally show up as overages, given that a zero opening balance was used, and that diversion may be inferred from such shortages. However, given the apparent good faith of Ms. Carter to avoid diversion and the inadequate accountability systems she was using at the time of the audit, under the facts of this case the inference of diversion attributable to the audit is not strong.

On the other hand, given the number of Respondent's retail customers and imprecise and unrecorded "eyeball" monitoring of what is on their shelves, the Deputy Administrator has concern over Ms. Carter's ability to know, with an acceptable degree of certainty, whether or not her customers are obtaining products from other distributors. DEA has previously found that gray markets retailers supplying chemicals for illicit use regularly acquire their product from multiple distributors in order to mask their acquisition of large amounts of listed chemicals. *See*, Elk International Inc., *supra*, 70 FR 24,615; Titan Wholesale, Inc., 70 FR 12,727 (2005).

Further, convenience store operators engaged in this illicit trade could be obtaining products from other wholesalers, yet not be displaying them on retail shelves, also compromising Ms. Carter's efforts to ensure she was the only supplier. Accordingly, so long as Respondent services this suspect

market, even the most sincere efforts by Ms. Carter to self-regulate her customers cannot guarantee that current and/or future customers will not be obtaining precursor chemicals from other distributors, as well as from Respondent, and then resell them for illicit purposes.

Nevertheless, given Ms. Carter's commendable actions to improve her accountability systems and her honest and credible desire to avoid contributing to the scourge of methamphetamine, in a "close call," the Deputy Administrator agrees with Judge Randall that factor one weighs in favor of continued registration.

With regard to factor two, Respondent's compliance with applicable Federal, state and local law, Judge Randall concluded this factor also weighs in favor of registration. However, the significance for this factor and factor five as well, the Deputy Administrator notes that state legislatures throughout the United States are actively considering legislation designed to impede the ready availability of precursor chemicals. Many of these proposals are similar to legislation enacted by the State of Oklahoma, titled the "Oklahoma Methamphetamine Reduction Act of 2004." Under that measure, as of April 6, 2004, pseudoephedrine tablets were designated as Schedule V controlled substances and may be sold only from licensed pharmacies within that state.

As a result, it is prohibited in Oklahoma to sell these products from gray market establishments, such as independent convenience stores, which have contributed so much to the methamphetamine abuse problem. *See, e.g.,* Express Wholesale, *supra*, 69 FR at 62,809 [denying DEA registration to an Oklahoma gray market distributor, in part, because of new state restrictions].

A review of data for 2004 reveals the Oklahoma law has resulted in an apparent reduction in the number of seizures involving clandestine methamphetamine laboratories in that state. These developments are encouraging and represent an important step in the ongoing battle to curb methamphetamine abuse in the United States. State legislation, such as Oklahoma's, reflects a positive trend and growing recognition that the diversion of precursor chemicals through the gray market insidiously impacts public health and safety. *See, e.g.,* Tysa Management, d/b/a Osmani Lucky Wholesale, 70 FR 12,732, 12,734 (2005) [denying registration to intended Oklahoma distributor, in part, on basis of enactment of recent state legislation];

Express Wholesale, *supra*, 69 FR at 62,089.

Of particular relevance to Joy's Ideas and similarly situated Tennessee applicants and registrants, after Judge Randall signed her Opinion and Recommended Ruling, legislation was enacted by the State of Tennessee patterned after the Oklahoma initiative. That legislation (Senate Bill 2318/House Bill 2334), collectively known as the "Meth-Free Tennessee Act of 2005," was signed into law by Governor Phil Bredeson on March 31, 2005, and makes it unlawful for establishments, other than licensed pharmacies, to sell tableted pseudoephedrine products in Tennessee after April 1, 2005. This included both name brand and off-name brand products. *See, e.g.,* Elk International Inc., *supra*, 70 FR 24,615.

According to evidence introduced at the hearing, approximately 53 of Respondent's 60 customers are convenience stores and gas stations located in Tennessee. Therefore, with only a few exceptions, Respondent's entire customer base is now prohibited by state law from selling the pseudoephedrine products Respondent seeks DEA registration to distribute. Thus, factor two weighs heavily against registration. *See, Elk International, supra*, 70 FR at 24,618; Tysa Management, d/b/a Osmani Lucky Wholesale, *supra*, 70 FR at 12,734; Express Wholesale, *supra*, 69 FR at 62,089.

As to factor three, any prior conviction record relating to listed chemicals or controlled substances, the Deputy Administrator concurs with Judge Randall that there is no evidence of any prior convictions of Respondent or its owner relating to listed chemicals or controlled substances. Accordingly, this factor weighs in favor of registration.

With regard to factor four, the applicant's past experience in distributing listed chemicals, Judge Randall found that Ms. Carter's lack of knowledge concerning how to conduct accountability audits and lack of inventory control, which were uncovered in the 2001 audit, weighed against Respondent's continued handling of listed chemical products. However, this was balanced by Ms. Carter's aggressive actions to improve her inventory and accountability practices. She was also familiar with listed chemical products, as well as her customers, and never sold over-the-threshold quantities.

The Administrative Law Judge concluded that while "a close matter," because of Ms. Carter's willingness to create and maintain a viable inventory

system and her familiarity with her customers' operations, factor four weighed in favor of continued registration, especially if close monitoring was maintained by DEA over Respondent. The Deputy Administrator disagrees with this conclusion.

The evidence showed Respondent was selling most of her convenience store customers about \$100.00 of list I chemicals per month. As established by Mr. Robbin's expert opinion evidence, this far exceeds the amount of expected sales of these products for legitimate therapeutic purposes. Even though, as Judge Randall concluded, there was no direct evidence that Respondent contributed to the diversion of listed chemical products, she did find the record contained "abundant statistical evidence that, without further explanation, would logically lead to the conclusion that the Respondent distributed more listed chemical products to its convenience store customers than could reasonably be sold at resale for legitimate use."

The Deputy Administrator cannot find a plausible explanation in the record for this deviation from the expected norm, other than diversion at the retail level. Accordingly, while Ms. Carter may have been an unknowing and unintentional contributor to Tennessee's methamphetamine problem, it is logical to infer that the listed products she was distributing to area convenience stores were being diverted to illicit purposes. Accordingly, the Deputy Administrator finds that factor four weighs against Respondent's continued registration.

With regard to factor five, other factors relevant and consistent with the public health and safety, Judge Randall acknowledged earlier DEA precedent applying this factor to deny registration to a gray market distributor based on statistical evidence. *See, Xtreme Enterprises, Inc.*, 67 FR 76,195 (2002); *Branex, Inc.*, *supra*, 69 FR 8,682, 8,693. However, based on the amounts of listed products being distributed by Respondent, their wholesale prices and Ms. Carter's apparent good faith and willingness to adhere to DEA requirements, given the facts of the case, Judge Randall was unwilling to conclude that Respondent's listed chemical products were being diverted or would likely be diverted in the future. She therefore found factor five weighed in favor of continued registration to distribute ephedrine and pseudoephedrine.

In Xtreme Enterprises, the Deputy Administrator found its owner had only a rudimentary knowledge of what

would constitute a suspicious order and no experience in the manufacture or distribution of listed chemicals. While given Ms. Carter's past experience, those findings do not apply to Respondent. However, most significant for this and similar cases, the Deputy Administrator also found that "[v]irtually all of the Respondent's customers, consisting of gas station and convenience stores, are considered part of the grey market, in which large amounts of listed chemicals are diverted to the illicit manufacture of amphetamine and methamphetamine." Xtreme Enterprises, Inc., *supra*, 67 FR at 76,197.

DEA has expansively applied Xtreme Enterprises to a multitude of applicants and registrants seeking to do business in the gray market. *See e.g.*, Express Wholesale, *supra*, 69 FR 62,086; Value Wholesale, 69 FR 58,548 (2004); K & Z Enterprises, Inc., 69 FR 51,475 (2004); William E. "Bill" Smith d/b/a B & B Wholesale, 69 FR 22,559 (2004); Branex Incorporated, *supra*, 69 FR 8,682; Shop It for Profit, 69 FR 1,311 (2003); Shani Distributors, 69 FR 62,324 (2003).

As in those cases, Ms. Carter's lack of a criminal record, previous general compliance with the law and regulations and willingness to comply with regulations and guard against diversion, are far outweighed by her intent to continue selling ephedrine and pseudoephedrine exclusively in the gray market. Unlawful methamphetamine production and use is a growing public health and safety concern throughout the United States and specifically in the locality where Respondent does business. Pseudoephedrine and ephedrine are the precursor products used to manufacture methamphetamine and area laboratory operators have predominantly acquired their precursor chemicals from the customer base Respondent seeks to continue serving. While Ms. Carter may intend to avoid contributing to this problem, the risk of diversion once her listed chemicals enter the gray market is real, substantial and compelling.

This reasoning has also been applied by the Deputy Administrator in a series of final orders published after Judge Randall issued her Opinion and Recommended Ruling in the matter. *See*, Elk International, *supra*, 70 FR 24,615; TNT Distributors, Inc., *supra*, 70 FR 12,729; Titan Wholesale, Inc., *supra*, 70 FR 12,727; RAM, Inc. d/b/a American Wholesale Distribution Corp., *supra*, 70 FR 11,693; Al-Alousi, Inc., 70 FR 3,561 (2005); Volusia Wholesale, 69 FR 69,409, (2004); Prachi Enterprises, Inc., *supra*, 69 FR 69,407; CWK Enterprises, Inc. 69 FR 69,400 (2004); J & S Distributors, 69 FR 62,089 (2004);

Express Wholesale, *supra*, 69 FR 62,086; Absolute Distributing, Inc., 69 FR 62,078 (2004).

In any event, Judge Randall's recommendation that Respondent be allowed to continue distributing listed chemicals to convenience stores in Tennessee, albeit with close monitoring by DEA through the submission of a monthly log and consent to inspection without an administrative inspection warrant, has been mooted by Tennessee's recent enactment of legislation requiring that all pill and tablet pseudoephedrine products, including those marketed under traditional brand names, be sold only through registered pharmacies. As this state statute, discussed more fully under factor two, effectively bars distribution of those products throughout Tennessee's gray market, it is also relevant under factor five and weighs heavily against Respondent's continued registration. *See, e.g.*, Elk International, *supra*, 70 FR at 24,618.

Finally, as recommended by Judge Randall, due to the apparent lack of safety associated with the use of phenylpropanolamine, factor five is also relevant to Respondent's initial proposal to distribute that product. DEA has previously determined that such a request constitute a ground under factor five for denial of an application for registration. *See* J & S Distributors, *supra*, 69 FR 62,089; Gazaly Trading *supra*, 69 FR 22,561; William E. "Bill" Smith d/b/a B & B Wholesale, *supra*, 69 FR 22,559; Shani Distributors, *supra*, 69 FR 62,324. However, it is noted that after the hearing and the Government's filing of its Exceptions to the Opinion and Recommended Ruling, Respondent's Reply indicated that it did not intend to carry products containing phenylpropanolamine.

Based on the foregoing, the Deputy Administrator concludes that continuing Respondent's registration and granting its pending application for renewal would be inconsistent with the public interest.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, 003278JIY, issued to Joy's Ideas, be, and it hereby is, revoked. Further, the pending application for renewal of said Certificate of Registration submitted by Joy's Ideas should be, and hereby is, denied.

This order is effective July 7, 2005.

Dated: May 25, 2005.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 04-62]

Kennard Kobrin, M.D., Revocation of Registration

On June 28, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Kennard Kobrin, M.D., (Respondent) of Fall River, Massachusetts, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration AK8615013 as a practitioner pursuant to 21 U.S.C. 824(a)(2), (3) and (4), and deny any pending applications for renewal or modification of that registration pursuant to 21 U.S.C. 823(f). As a basis for revocation, the Order to Show Cause alleged that Respondent had been convicted of three state felony counts, which involved illegal prescribing of a controlled substance and Medicaid fraud. As a part of his sentence, the court ordered Respondent to cease prescribing any medications for two years, effective August 28, 2003. Therefore, the Government alleged that Respondent was no longer authorized to handle controlled substances in Massachusetts, his state of practice and DEA registration.

Respondent, through counsel, timely requested a hearing in this matter and Presiding Administrative Law Judge Mary Ellen Bittner (Judge Bittner) issued an Order for Prehearing Statements. After various motions had been filed and addressed by Judge Bittner, on November 22, 2004, the Government filed its Request for Stay of Proceedings and Motion for Summary Disposition (Motion). In that Motion it was asserted that the Massachusetts Board of Registration in Medicine (Medical Board) had revoked Respondent's license to practice medicine in that state, effective December 17, 2004, and that as a result, he was no longer authorized to handle controlled substances in the state where he is registered with DEA. Attached to the Government's Motion was a copy of the Medical Board's Final Decision & Order, dated November 17, 2004, revoking Respondent's Massachusetts medical license as of December 17, 2004.