Respondent denied that he engaged in some of the conduct for which he was convicted, including providing addictive medications to patients who abused them, and also testified that he felt that the patients needed the diagnostic examinations he ordered for them. I also note that in his resume Respondent ''steadfastly assert[s]'' his innocence, and that he testified that although he was guilty, he had no ''criminal intent to commit a crime.''

Based on the record, Judge Bittner could not ''find that Respondent recognizes his own misconduct, or that he is yet in a position to accept the responsibilities inherent in a DEA registration.'' She therefore concluded that granting Respondent's application for DEA registration would not be consistent with the public interest and recommended that the application be denied. The Deputy Administrator agrees.

Respondent filed exceptions to the Opinion and Recommended Ruling. First, he asserted the ruling was arbitrary and capricious in comparison to prior decisions in which grants of restricted registration were recommended by the Administrative Law Judge and approved by the agency. However the facts and circumstances of the five cases cited by Respondent are distinguishable from the facts and circumstances of this matter. *See, Mark Binette, M.D.*, 64 FR 42977 (1999); *Michael Alan Patterson, M.D.*, 65 FR 5682; *Robert M. Golden, M.D.*, 65 FR 5663; *Nick M. Higgins, D.D.S.*, 54 FR 53388 (1989); *Jane W. Wuchinich, M.D.*, 56 FR 4081 (1991).

As opposed to several cases cited by Respondent, he engaged in his criminal misconduct for pecuniary gain, not because he suffered from an addiction or dependency which was later demonstrated to have been successfully mitigated by rehabilitation, therapy or careful monitoring. While neither is desirable, depending on the facts, greed can be viewed as a more serious personal motivator for criminal activity than addiction or dependency. Respondent's reasons for violating the law and risking reputation and his growing livelihood also reflect a cavalier attitude toward his responsibilities as a physician and DEA registrant.

As opposed to other cases relied upon by Respondent, he has also failed to adequately acknowledge personal responsibility for the actions leading to his convictions and lengthy prison sentence. He also knowingly made material misrepresentations on his DEA application and was excluded from participating in Federal health care programs for 15 years, both of which are additional independent grounds for denying registration.

Finally, DEA has previously revoked registrants for actions and on grounds comparable to Respondent's. *See, Johnnie Melvin Turner, M.D.*, 67 FR 71203 (2002) (revocation based on exclusion from Medicare program after Federal fraud conviction); *Stanley Dubin, D.D.S.*, 61 FR 60727 (1996) (revocation for exclusion from Federal health programs after State fraud conviction).

In sum, the facts of this matter are unique and the cases cited by Respondent simply do not demonstrate that the recommended action is a departure from agency practice and policy or was rendered either arbitrarily or capriciously.

Respondent also contends in numerous exceptions that the Administrative Law Judge's ruling ''failed to take into account'' or ''ignores'' or ''disregards'' or ''erroneously discounted'' or ''failed to credit'' or ''refused to consider'' or ''placed improper emphasis'' on certain evidence in reaching her findings and recommendations. These include: Respondent's degree of contrition and acceptance of responsibility; the opinions of several witnesses as to Respondent's prescribing activities; his monitoring of the physician assistant at the secondary clinic; his post-incarceration medical education; his value to the local, humanitarian efforts and opinions of charter witnesses; his professed intended limited use of the registration were it to be granted; the nature of his current and intended medical practice; and the adverse impact denying registration will have upon Respondent and his practice.

The Opinion and Recommended Ruling clearly demonstrates that the Administrative Law Judge admitted and carefully considered Respondent's evidence on all of the foregoing issues. While Respondent would prefer Judge Bittner arrived at a different outcome, his objectives are really just a re-argument as to the weight which should be assigned certain testimony and documentary evidence introduced during the hearing and the credibility which the fact finder should give Respondent's explanations for his misrepresentations, the extent and sincerity of his remorse and his acceptance of personal responsibility. Given the record supporting Judge Bittner's conclusions, these arguments are insufficient to alter the outcome.

Finally, in the letter received by the Deputy Administrator after the Opinion and Recommended Ruling was transmitted to this office by Judge Bittner, Respondent notes recent changes in TennCare Products which will have the effect of limiting his ability to prescribe even non-controlled substances for TennCare patients, should DEA registration be denied. He submits this ''hardship could neither have been intended, nor anticipated by Judge Bittner's Report.''

However, while this particular consequence was not addressed at the hearing, when Judge Bittner recommended denial she was well aware of the multiple hardships befalling any physician denied DEA registration. She was also aware of numerous specific hardships that would impact Respondent and practice, were the application denied. Nevertheless, these consequences were insufficient for Judge Bittner to warrant recommending the application be granted and the Deputy Administrator does not consider the additional information on adverse collateral consequences sufficient to alter the conclusion that registration would not be in the public interest.

The Deputy Administrator has examined the record and finds that the facts and credibility determinations of Judge Bittner are well supported by the evidence. Respondent materially falsified his application for DEA registration and has been excluded from participating in Federal health care programs for fifteen years, both of which constitute independent grounds for denying registration. It has also been sufficiently established that Respondent's registration would not be in the public's 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 the Respondent's pending application for registration be, and it hereby is, denied. This order is effective December 29, 2004.

Dated: November 10, 2004.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 04–26310 Filed 11–26–04; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Prachi Enterprises, Inc.; Denial of Registration

On July 23, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Prachi Enterprises, Inc. (Prachi) proposing to deny its September 9, 2003, application for DEA

Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting Prachi's application would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(h) and 824(a). The order also notified Prachi that should no request for a hearing be filed within 30 days, its hearing right would be deemed waived.

According to the DEA investigative file, the Order to Show Cause was sent by certified mail to Prachi at its proposed registered location at 1516 Kalamazoo Drive, Suite 5A, Griffin, Georgia 30224. It was received on August 2, 2004, and DEA has not received a request for a hearing or any other reply from Prachi or anyone purporting to represent the company in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) Thirty days have passed since delivery of the Order to Show Cause, and (2) no request for a hearing having been received, concluded that Prachi has waived its hearing right. *See Aqui Enterprises,* 67 FR 12576 (2002). After considering relevant material from the investigative file, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1309.53 (c) and (d) and 1316.67. The Deputy Administrator finds as follows.

List I chemicals are those that may be used in the manufacture of a controlled substance in violation of the Controlled Substances Act. 21 U.S.C. 802(34); 21 CFR 1310.02(a). Pseudoephedrine and ephedrine are list I chemicals commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance. As noted 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 11654 (2004); *Branex, Inc.,* 69 FR 8682 (2004); *Yemen Wholesale Tobacco and Candy Supply, Inc.,* 67 FR 9997 (2002); *Denver Wholesale,* 67 FR 99986 (2002).

The Deputy Administrator's review of the investigative file reveals that on or about September 9, 2003, an application was submitted by an officer of Prachi, Mr. Ashish Patel, seeking registration to distribute ephedrine, pseudoephedrine and phenylpropanolamine list I chemical products. Subsequently Mr. Patel notified DEA the company did not intend to sell any products containing phenylpropanolamine.

In connection with the pending application, an on-site pre-registration investigation was conducted. Mr. Patel advised investigators that Prachi was a wholesale distributor of over-the-counter items to convenience stores, liquor stores, gas stations and grocery stores. He proposed to sell Mini-Thins and Max-Brand pseudoephedrine and Two-Way products, but was unable to articulate any other intended products containing listed chemicals the company might sell. He also failed to provide DEA with a requested list of intended products. He furthermore failed to provide DEA with a list of intended customers for the list I chemical products, although he had 350 customers purportedly awaiting his registration. DEA was unable to conduct customer verifications without that information.

DEA is aware that small illicit laboratories operate with listed chemical products often procured, legally or illegally, from non-traditional retailers of over-the-counter drug products, such as gas stations and small retail markets. Some retailers acquire product from multiple distributors to mask their acquisition of large amounts of listed chemicals. In addition, some individuals utilize sham corporations or fraudulent records to establish a commercial identity in order to acquire listed chemicals.

The illegal production of methamphetamine continues unabated within the Southwest region. The adjacent State of Tennessee leads the region in the number of clandestine laboratories seized, accounting for approximately 50 percent of the clandestine laboratories seized during the second quarter of 2002. When compared with the third quarter of 2001, the increase in clandestine laboratory seizures is notable.

According to records for the DEA Atlanta region, 360 clandestine laboratories were seized during the third quarter of 2002. Of these, 207 were located in Tennessee, 103 in Georgia, 35 in South Carolina and 15 in North Carolina. In Georgia, there has been a consistent increase in the number of illicit laboratories and enforcement teams continue to note a trend toward smaller capacity laboratories. This is likely due to the ease of concealment associated with smaller laboratories, which continue to dominate seizures and cleanup responses.

The adjacent State of Florida has a substantial methamphetamine abuse problem in Northeast and Central Florida, and DEA is aware of a past history of trafficking in precursors in these areas. Distributors or retailers serving in the illicit methamphetamine trade observe no borders. In fact, where precursor laws are stringent, out-of-state distributors often make direct shipments to retailers without observing state requirements.

DEA knows by experience that there exists a ''gray market'' in which certain high strength, high quantity pseudoephedrine; and ephedrine products are distributed only to convenience stores and gas stations, from where they have a high incidence of diversion. These grey market products are not sold in large discount stores, retail pharmacies or grocery stores, where sales of therapeutic over-the-counter drugs predominate. Mini-Thins and Max Brand products are prime products in this gray market industry and are rarely found in any retail store serving the traditional therapeutic market.

DEA also knows from industry data, market studies and statistical analysis that over 90% of over-the-counter drug remedies are sold in drug stores, supermarket chains and ''big box'' discount retailers. Less than one percent of cough and cold remedies are sold in gas stations or convenience stores. Studies have indicated that most convenience stores could not be expected to sell more than $20.00 to $40.00 worth of products containing pseudoephedrine per month. The expected sales of ephedrine products are known to be even smaller. Convenience stores handling gray market products often order more product than what is required for the legitimate market and obtain chemical products from multiple distributors.

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. Section 823(h) requires that 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 of the applicant in the manufacture and distribution of chemicals; and

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

As with the public interest analysis for practitioners and pharmacies pursuant to subsection (f) of section 823, these factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a 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., Energy Outlet*, 64 FR 14269 (1999). *See also, Henry J. Schwartz, Jr., M.D.*, 54 FR 16422 (1989).

The Deputy Administrator finds factors four and five relevant to the pending application for registration.

With regard to factor four, the applicant's past experience in the distribution of chemicals, the Deputy Administrator finds this factor relevant based on Mr. Patel's lack of knowledge and experience regarding the laws and regulations governing handling of list I chemical products. In prior DEA decisions, this lack of experience in handling list I chemical products has been a factor in denying pending applications for regristration. *See, e.g., Direct Wholesale, supra,* 69 FR 11654; *ANM Wholesale*, 69 FR 11652 (2004); *Xtreme Enterprises, Inc.*, 67 FR 76195 (2002).

With regard to factor five, other factors relevant to and consistent with the public safety, the Deputy Administrator finds this factor weights heavily against granting the application. Unlawful methamphetamine use is a growing public health and safety concern throughout the United States and Southeast. Ephedrine and pseudoephedrine are precursor products needed to manufacture methamphetamine and operators of illicit methamphetamine laboratories regularly acquire the precursor products needed to manufacture the drug from convenience stores and gas stations which, in prior DEA decisions, have been identified as constituting the grey market for list I chemical products. It is apparent that Prachi intends on being a participant in this market.

While there are no specific prohibitions under the Controlled Substances Act regarding the sale of listed chemical products to these entities, DEA has nevertheless found these establishments serve as sources for the diversion of large amounts of listed chemical products. *See, e.g., ANM Wholesale, supra*, 69 FR 11652; *Xtreme Enterprises, Inc., supra*, 67 FR 76195; *Sinbad Distributing*, 67 FR 10232 (2002); *K.V.M. Enterprises*, 67 FR 70968 (2002).

The Deputy Administrator has previously found that many considerations weighed heavily against registering a distributor of list I chemicals because, ''[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 76197. As in *Xtreme Enterprises, Inc.*, Mr. Patel's lack of a criminal record and stated intent to comply with the law and regulations are far outweighed by his lack of experience and the company's intent to sell ephedrine and pseudoephedrine exclusively to the gray market.

The Deputy Administrator is further troubled by Mr. Patel's reticence to provide requested information to DEA, indicating his company cannot be trusted to handle the responsibilities of a registrant.

Based on the foregoing, the Deputy Administrator concludes that granting the pending application 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 823 and 28 CFR 0.100(b) and 0.104, hereby orders the pending application for DEA Certificate of Registration, previously submitted by Prachi Enterprises, Inc., be, and it hereby is, denied. This order is effective December 29, 2004.

Dated: November 10, 2004.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Volusia Wholesale; Denial of Registration

On July 23, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Volusia Wholesale (Volusia) proposing to deny its December 12, 2003, application for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting Volusia's application would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(h). The order also notified Volusia that should no request for a hearing be filed within 30 days, its hearing right would be deemed waived.

According to the DEA investigative file, the Order to Show Cause was sent by certified mail to Volusia at its then-proposed registered location at 917 Daytona Avenue, Daytona Beach, Florida 32117. It was received on August 2, 2004, and DEA has not received a request for a hearing or any other reply from Volusia or anyone purporting to represent the company in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days have passed since delivery of the Order to Show Cause, and (2) no request for a hearing having been received, concludes that Volusia has waived its hearing right. *See Aqui Enterprises*, 67 FR 12576 (2002). After considering relevant material from the investigative file, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1309.53(c) and (d) and 1316.67. The Deputy Administrator finds as follows.

List I chemicals are those that may be used in the manufacture of a controlled substance in violation of the Controlled Substances Act. 21 U.S.C. 802(34); 21 CFR 1310.02(a). Pseudoephedrine and ephedrine are list I chemicals commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance. As noted 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 11654 (2004); *Branex, Inc.*, 69 FR 8682 (2004); *Yemen Wholesale Tobacco and Candy Supply, Inc.*, 67 FR 9997 (2002); *Denver Wholesale*, 67 FR 99986 (2002).

The Deputy Administrator's review of the investigative file reveals that on or about September 9, 2003, an application was submitted by the owner of Volusia, Mr. Anwar Khrino, seeking registration to distribute ephedrine and pseudoephedrine list I chemical products. The application initially listed the proposed registered location as Mr. Khrino's then-residence, 1420 N. Grandview Avenue, Daytona Beach, Florida 32118. He subsequently moved to 917 Daytona Avenue, Daytona Beach, Florida 32117, which was to be Volusia's registered address.

In connection with the pending application, an on-site pre-registration investigation was conducted at the Daytona Avenue proposed premises. The location was Mr. Khrino's residence. There were no security measures in place and his intent was to store the chemical products overnight in a locked delivery van in the driveway.

Mr. Khrino advised investigators Volusia is a sole proprietorship and wholesale distributor of approximately 60 to 80 sundry and novelty items to convenience stores and gas stations. He proposed to distribute ''two packs'' of