

for self-abuse. On multiple occasions, Respondent gained access to patients' homes in order to accomplish the thefts, a particularly heinous *modus operandi* for a trusted family physician.

Respondent also failed to maintain adequate records of controlled substances as required by DEA regulations and finally, was convicted pursuant to his plea agreement of a State misdemeanor involving controlled substances.

While the investigative file reflects Respondent sought treatment for his addiction, albeit while criminal charges were pending, and he has undergone successful follow-up random drug testing, the egregious nature of his misconduct bears directly upon his fitness to possess a DEA registration. In sum, applying factors two through five above, Respondent's abandonment of his patients' medical interests and flaunting of their personal trust to divert controlled substances to his personal use, coupled with his flagrant violations of law and regulation, all lead to the inevitable conclusion that granting this 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 28 CFR 0.100(b) and 0.104, hereby orders that the application of Glenn Anthony Routhouska, D.O., for a DEA Certificate of Registration, be, and it hereby is denied. This order is effective April 14, 2005.

Dated: February 14, 2005.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Margaret Melinda Sprague, M.D.; Revocation of Registration

On September 8, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Margaret Melinda Sprague, M.D. (Dr. Sprague) who was notified of an opportunity to show cause as to why DEA should not revoke her DEA Certificate of Registration BS1464089, pursuant to 21 U.S.C. 824(a)(3) and deny any pending applications under 21 U.S.C. 823(f), on the ground that she lacks State authority to handle controlled substances in the State of California. The Order to Show

Cause also notified Dr. Sprague that should no request for a hearing be filed within 30 days, her hearing right would be deemed waived.

The Order to Show Cause was sent by certified mail to Dr. Sprague at her registered address in La Jolla, California. However that letter was unclaimed. It was then forwarded by the United States Postal Service to 7934 La Jolla Shores Drive, La Jolla, California 92037, an address Dr. Sprague had provided postal authorities as a forwarding address. She had also previously advised DEA investigators to use that address when sending correspondence related to her registration. However, the forwarded letter was also unclaimed and postal authorities returned it to DEA stamped "Notice Left—No Response." Additional efforts by DEA investigators to locate Dr. Sprague's current address were also unsuccessful. DEA has not received a request for hearing or any other reply from Dr. Sprague or anyone purporting to represent her in this matter.

Therefore, the Deputy Administrator of DEA, finding that: (1) Thirty days having passed since the attempted deliveries of the order to Show Cause to the Registrant's address of record and her forwarding address; (2) reasonable and good faith efforts to locate her have been unsuccessful; and (3) no request for hearing having been received, concludes that Dr. Sprague is deemed to have waived her hearing right. *See* James E. Thomas, M.D., 70 FR 3564 (2005); Steven A. Barnes, M.D., 69 FR 51474 (2004); David W. Linder, 67 FR 12579 (2002). After considering material from the investigative file in this matter, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds that Dr. Sprague is currently registered with DEA as a practitioner authorized to handle controlled substances in Schedules II through V under Certificate of Registration BS1464089, expiring on February 28, 2006. According to information in the investigative file on December 3, 2003, the Medical Board of California (Board) issued an Order immediately suspending Dr. Sprague's Physician and Surgeon's Certificate. The suspension was based in part, on the Board's conclusion that Dr. Sprague was unable to safely practice medicine due to a mental or physical condition.

There is no evidence before the Deputy Administrator to rebut a finding that Dr. Sprague's California medical license has been suspended. Therefore, The Deputy Administrator finds Dr. Sprague is currently not authorized to practice medicine in the State of

California. As a result, it is reasonable to infer that she is also without 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 she conducts business. *See* 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. *See* Richard J. Clement, M.D., 68 FR 12103 (2003); Dominick A. Ricci, M.D., 58 FR 51104 (1993); Bobby Watts, M.D., 53 FR 11919 (1988).

Here, it is clear that Dr. Sprague's State medical license was suspended and there is no information before the Deputy Administrator which points to that suspension having been lifted or stayed. As a result, Dr. Sprague is not authorized to practice medicine or handle controlled substances in California, where she is registered with DEA. Therefore, she is not entitled to maintain that registration.

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 0.104, hereby orders that DEA Certificate of Registration, BS1464089, issued to Margaret Melinda Sprague, M.D., be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal or modification of the aforementioned registration be, and hereby are, denied. This order is effective April 14, 2005.

Dated: February 14, 2005.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Titan Wholesale, Inc.; Denial of Registration

On October 13, 2004, the Deputy Assistant Administrator, Office of Division Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Titan Wholesale, Inc. (Titan) proposing to deny its August 14, 2003, application for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting Titan'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 Titan

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 Titan at its proposed registered location at 4995 Outland Center Drive, Building E, Suite 107, Memphis, Tennessee 37075. It was received on October 18, 2004, and DEA has not received a request for a hearing or any other reply from Titan 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 Titan has waived its hearing right. See *Aqui Enterprises*, 67 FR 12,576 (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 11,654 (2004); *Branex, Inc.*, 69 FR 8,682 (2004); *Yemen Wholesale Tobacco and Candy Supply, Inc.*, 67 FR 9,997 (2002); *Denver Wholesale*, 67 FR 99,986 (2002).

The Deputy Administrator's review of the investigative file reveals that on or about August 18, 2003, an application was submitted by Mr. Chris Pelt, owner and operator of Titan, seeking registration to distribute ephedrine and pseudoephedrine list I chemical products.

In connection with the pending application, a pre-registration investigation was conducted by investigators for DEA's Nashville, Tennessee District Office. It was determined Titan was incorporated in Tennessee on February 2, 2000. The company's stock is owned entirely by Mr. Pelt and Titan has a total of seven employees, including its owner. There is no evidence that any of Titan's employees or owner had experience in distributing list I chemicals.

Mr. Pelt advised investigators that Titan was a wholesale grocery broker which engaged in nationwide searches for opportunities to purchase in-transit shipments of grocery products which were not needed by their intended recipients, usually because of overstocking or over-supply. The shipments would be purchased at a discount and resold, ideally, while still in transit to another purchaser at a higher price. Titan had no fixed customer list, but apparently dealt with sellers and purchasers as opportunities presented themselves.

According to Mr. Pelt, if Titan was registered, it would acquire and distribute listed chemicals in the same manner as its grocery products, *i.e.*, they would not necessarily be stored at the registered premises but could be "diverted in-transit" to locations wherever prospective purchasers might be. The products might be shipped from a point of purchase to a point of sale without Titan ever physically handling or possessing them and it is unknown whether or not the distributions would take place among and between DEA registrants.

When Mr. Pelt was advised by investigators that Titan's proposed business methods apparently ran counter to DEA regulations intended to prevent diversion and ensure safe handling of listed chemicals, he rejected that suggestion. He also represented that two specific DEA registrants were already operating in the manner he proposed. However, inquiries by investigators refuted that claim.

DEA has previously found there is a substantial methamphetamine abuse problem and history of trafficking in precursors in the area covered by DEA's Atlanta Field Division, which includes Tennessee, Georgia, North Carolina and South Carolina. DEA is aware distributors or retailers serving in the illicit methamphetamine business observe no borders and trade across state lines. In fact, where precursor laws are stringent, out-of-state distributors often make direct shipments to retailers without observing state requirements.

DEA is also 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 convenience stores. 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.

In Tennessee, there has been a consistent increase in the number of illicit laboratories and enforcement teams have noted 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 in that state. In the second quarter of 2002, Tennessee led in the number of clandestine laboratories seized in the area, accounting for approximately 50 percent of these seizures. See *CWK Enterprises, Inc.*, 69 FR 69,400 (2004).

DEA has found there exists a "gray market" in which certain high strength, high quantity pseudoephedrine and ephedrine products are distributed 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. 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 station or convenience stores. The expected sales of ephedrine products are known to be even smaller. Furthermore, 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. See *Prachi Enterprises, Inc.*, 69 FR 69,407 (2004); *Volusia Wholesale*, 69 FR 69,409 (2004), *CWK Enterprises, Inc.*, *supra*, 69 FR 69,400.

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 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 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 14,269 (1999). See also, Henry J. Schwartz, Jr., M.D., 54 FR 16,422 (1989).

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

As to factor one, maintenance of effective controls against diversion of listed chemicals into other than legitimate channels, the Deputy Administrator has previously held that this factor and 21 CFR 1309.71(b)(8) encompass more than mere physical security of listed chemicals while in storage or transit. See e.g., *Al-Alousi, Inc.*, 70 FR 3,561 (2005) [inability of applicant to adequately verify location and identities of prospective customers considered under factor one]; *OTC Distribution Company*, 68 FR 70,538, 70,542 (2003); see also *Aqui Enterprises*, supra 67 FR 12,276; *Alfred Khalily, Inc.*, 64 FR 31,289 (1999).

Titan's proposed process of purchasing in-transit shipments of listed chemicals and redirecting them to other buyers fails to provide adequate protection and safeguards for preventing listed chemicals from diversion into other than legitimate channels. The company's methods would not require it to ever have physical control of the chemicals, nor would it ensure compilation of adequate inventories or complete and accurate records. It also fails to provide for the consistent and accurate verification of identities of the persons and entities which would ultimately be receiving the listed chemicals.

In sum, Titan's proposed methods run counter to the distribution and accountability safeguards envisioned under the Controlled Substances Act and its implementing regulations and fail to provide effective controls against diversion of listed chemicals. Accordingly, factor one weighs against granting the pending application.

With regard to factor four, the applicant's past experience in the distribution of chemicals, the Deputy Administrator finds this factor relevant based on the applicant'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 has been a factor in denying pending

applications for registration. See, e.g., *Direct Wholesale*, supra, 69 FR 11,654; *ANM Wholesale*, 69 FR 11,652 (2004); *Extreme Enterprises, Inc.*, 67 FR 76,195 (2002).

With regard to factor five, other factors relevant to and consistent with the public safety, the Deputy Administrator finds this factor also weighs 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 decision, have been identified as constituting the grey market for list I chemical products. 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 11,652; *Xtreme Enterprises, Inc.*, supra, 67 FR 76,195; *Sinbad Distributing*, 67 FR 10,232 (2002); *K.V.M. Enterprises*, 67 FR 70,968 (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 76,197.

Because of its proposed methods, Titan could not identify the specific ephedrine and pseudoephedrine products it intended to distribute or their quantities and strengths. It also could not identify any specific customers or suppliers. While Titan did not state whether or not it would enter the grey market, it is reasonable to infer its business practices would invite eventual participation in that sector. The company intends to search nationwide for bulk quantities of chemicals becoming available for sale while in-shipment. It would buy them at a discount and redirect them to new purchasers, ideally without ever exercising physical possession of the product. Titan would thus be engaging

in apparently random transactions, occurring whenever it discovers an opportunity to buy low and resell at a profit.

Mr. Pelt did tell investigators that if Titan's application was granted, he would try to develop business relationships with large chain drug stores. However, given his company's lack of specific prospective buyers and suppliers, its inability to identify products, quantities and strengths and its aggressive business practices, coupled with the absence of effective controls described under factor one above, the Deputy Administrator views the risk of Titan entering the gray market as real and significant, once it discovers buyers from that sector willing to purchase listed chemicals at prices yielding Titan large profits.

The Deputy Administrator is also concerned with Mr. Pelt's refusal to consider alternative business methods and his inaccurate representations regarding the purportedly similar business practices of two other registrants. This suggests that Mr. Pelt and Titan would either be unwilling or unable to successfully fulfill the significant 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 824 and 28 CFR 0.100(b) and 0.104, hereby orders the pending application for DEA Certificate of Registration, previously submitted by Titan Enterprises, Inc., be, and it is hereby is, denied. This order is effective April 14, 2005.

Dated: February 14, 2005.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03-24]

TNT Distributors, Inc., Denial of Application

On March 31, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to TNT Distributors, Inc., (Respondent/TNT) proposing to deny its