

in *T. Young*, “experience has taught DEA that in the aftermath of every major piece of legislation addressing the illicit manufacture of methamphetamine, traffickers have quickly found ways to circumvent the restrictions.” 71 FR at 60573; *see also* Tr. 63–64. This Agency is not required to wait until the diversion of gelcap and liquid forms of pseudoephedrine reaches epidemic proportions before acting to protect the public interest. Therefore, I reject the ALJ’s finding that factor five supports the continuation of Respondent’s registration.¹⁶

In conclusion, the record establishes that Respondent’s products have been diverted. While Respondent has taken corrective actions, these measures are still not adequate to protect against the diversion of its products. Furthermore, Respondent violated federal law by knowingly distributing listed chemical products when it had reasonable cause to believe that the products would be used to manufacture methamphetamine. Finally, studies show that pseudoephedrine can be easily extracted from gelcap and liquid forms of pseudoephedrine and anecdotal evidence establishes that methamphetamine traffickers are already using these products. Factor five does not require that DEA wait until the diversion of these products becomes widespread before acting to protect the public interest. Therefore, I conclude that Respondent’s continued registration is “inconsistent with the public interest.” 21 U.S.C. 823(h).

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(h) & 824(a), as well as 28 CFR 0.100(b) 7 0.104, I order that DEA

¹⁶In her analysis of factor five, the ALJ concluded that the Government had not proved that “Respondent’s continued distribution of liquid and gelcap forms of List I chemical products poses a threat to the public health and safety.” ALJ at 40. The ALJ erred, however, because she applied the wrong legal standard.

As I have previously explained, the Government is not required to prove that Respondent’s conduct poses a threat to public health and safety to obtain an adverse finding under factor five. *See T. Young*, 71 FR at 60572 n.13. Rather, the statutory text directs the consideration of “such other factors as are relevant to and consistent with the public health and safety.” 21 U.S.C. § 823(h)(5). This standard thus grants the Attorney General broader discretion than that which applies in the case of other registrants such as practitioners. *See id.* § 823(f)(5) (directing consideration of “[s]uch other conduct which may threaten the public health and safety”).

Accordingly, while proof of a threat to public health and safety clearly satisfies the standard of subsection 823(h)(5), it is not required. Distributing a product, which studies show can be easily used to make methamphetamine, clearly satisfies this standard even in the absence of evidence showing widespread diversion of the products.

Certificate of Registration, 003219HIY, issued to Holloway Distributing, Inc., be, and it hereby is, revoked. I further order that the pending application of Holloway Distributing, Inc., for renewal of its registration, be, and it hereby is, denied. This order is effective August 31, 2007.

Dated: July 20, 2007.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 07–23]

Newcare Home Health Services; Revocation of Registration

On February 21, 2007, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Newcare Home Health Services (Respondent), of Baltimore, Maryland. The Show Cause Order proposed the revocation of Respondent’s DEA Certificate of Registration, BN3795892, as a retail pharmacy, on the ground that the Maryland State Board of Pharmacy had suspended Respondent’s state pharmacy license.¹ *See id.*

On or about February 23, 2007, the Show Cause Order was served on Respondent. On March 9, 2007, Respondent, through its counsel, requested a hearing. The matter was assigned to Administrative Law Judge (ALJ) Gail Randall, who, on March 15, 2007, ordered the parties to file pre-hearing statements.

On March 19, 2007, the Government moved for summary disposition and to stay the filing of pre-hearing statements. The basis for the Government’s motion was that on January 5, 2007, the Maryland Board of Pharmacy had summarily suspended Respondent’s state pharmacy and distributor permits. Mot. for Summ. Disp. at 2. In support of its motion, the Government attached a

¹The Show Cause Order also alleged that Respondent had committed acts which rendered its registration “inconsistent with the public interest.” Show Cause Order at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)). More specifically, the Show Cause Order alleged that Respondent “illegally distributed vast quantities of hydrocodone and other controlled substances” by filling prescriptions that were issued over the internet and which were issued by physicians who did not establish “a doctor-patient relationship with the customers.” *Id.* In light of the disposition of this case, a more detailed recitation of the allegations of the Show Cause Order is not necessary.

copy of the Maryland Board’s Order for Summary Suspension. Upon receipt of the motion, the ALJ granted the Government’s motion to stay the proceeding and ordered Respondent to reply to the motion for summary disposition. *See* Order Staying Proceedings at 1–2.

On March 29, 2007, Respondent submitted its reply. Respondent acknowledged that summary disposition would be appropriate but asked the ALJ “to stay all proceedings * * * while the criminal prosecution of [its] owners proceeds through the U.S. District Court.” Resp.’s Reply at 1. Respondent further argued that “[i]f the outcome of the criminal case is favorable to [its] owners, then the posture and merits of this matter * * * will be substantially different than if one or more convictions are obtained.” *Id.* at 2. Respondent further stated that it had appealed the State Board’s suspension of its pharmacy license and had “asked the Board to defer any hearing on the appeal until the criminal case concludes.” *Id.* Respondent further stated that it would agree to the suspension of its registration in the interim. *Id.*

On April 3, 2007, the ALJ issued her recommended decision. Noting that state authority is “a prerequisite to DEA registration,” the ALJ held that Respondent was not entitled to maintain its registration because there was no dispute that Respondent currently lacks “authority to handle controlled substances in the jurisdiction where it seeks to maintain its DEA registration.” ALJ at 4. The ALJ also denied Respondent’s request for a stay. The ALJ thus granted the Government’s motion for summary disposition, lifted her stay order, and denied Respondent’s request for a continued stay of the proceeding. The ALJ also recommended that Respondent’s registration be revoked and forwarded the record to me for final agency action.

Having considered the record as a whole, I adopt the ALJ’s decision and recommended order in its entirety. As the ALJ found, Respondent does not currently possess authority under the laws of Maryland to handle controlled substances.

Under the Controlled Substances Act (CSA), “a practitioner must be currently authorized to handle controlled substances in ‘the jurisdiction in which [it] practices’ in order to maintain its DEA registration.” *Bourne Pharmacy, Inc.*, 72 FR 18273, 18274 (2007) (quoting 21 U.S.C. 802(21)). *See also* 21 U.S.C. 802(21) (“[t]he term ‘practitioner’ means a * * * pharmacy * * * licensed, registered, or otherwise permitted, by * * * the jurisdiction in which [it]

practices * * * to * * * dispense * * * a controlled substance in the course of professional practice"). See also *id.* 823(f) ("The Attorney General shall register practitioners * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which [it] practices.").

State authority is thus an essential prerequisite to maintaining a DEA registration.² Moreover, this Agency has repeatedly revoked the DEA registrations of those registrants who no longer hold state authority to handle controlled substances, regardless of whether that authority has been revoked or suspended pending further proceedings. See *Bourne Pharmacy*, 72 FR at 18274; *The Medicine Shoppe*, 71 FR 42878, 42879 (2006); *Rx Network of South Florida, LLC*, 69 FR 62093 (2004); *Wingfield Drugs, Inc.*, 52 FR 27070 (1987). Because Respondent is not currently authorized to handle controlled substances in the State in which it engages in the practice of pharmacy, it is not entitled to maintain its DEA registration.³ Therefore, its registration will be revoked and any pending applications for renewal or modification of its registration will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) and 0.104, I hereby order that DEA Certificate of Registration, BN3795892, issued to Newcare Home Health Services, be and it hereby is, revoked. I further order that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This order is effective August 31, 2007.

Dated: July 20, 2007.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Alan H. Olefsky, M.D.; Denial of Application

On May 25, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Alan H. Olefsky, M.D. (Respondent), of Chicago, Illinois. The Show Cause Order proposed to revoke Respondent's DEA Certificate of Registration, BO3661104, as a practitioner, and to deny any pending applications for renewal or modification of his registration, on the ground that the Illinois Department of Financial and Professional Regulation had suspended his state medical license and state controlled substance license. Show Cause Order at 1. The Show Cause Order thus alleged that Respondent was not authorized to handle controlled substances in the State where he was registered and was thus not entitled to maintain his registration. *Id.* (citing 21 U.S.C. 824(a)(3)).

The Show Cause Order also alleged that Respondent had committed acts which rendered his registration inconsistent with the public interest. *Id.* (citing 21 U.S.C. 824(a)(4)). More specifically, the Show Cause Order alleged that from December 2002 through October 2004, Respondent had "issued false prescriptions for controlled substances in the names of" three individuals, and that the prescriptions were for his "personal use." *Id.* The Show Cause Order also notified Respondent of his right to request a hearing on the allegations.

On June 8, 2005, the Show Cause Order was served on Respondent by certified mail as evidenced by the signed return receipt card. Neither Respondent, nor anyone purporting to represent him, requested a hearing on the allegations within the time period set forth in 21 CFR 1301.43(a) and the Show Cause Order.

The matter was held in abeyance after the State restored Respondent's medical license. On March 30, 2007, the State again suspended Respondent's medical license. Accordingly, on May 10, 2007, the investigative file was forwarded to my Office for final agency action.

As an initial matter, I find that because Respondent did not request a hearing within thirty days of receipt of the Show Cause order he has waived his right to hearing. See 21 CFR 1301.43(d). I therefore enter this Final Order without a hearing based on relevant

material in the investigative file and make the following findings.

Findings

Respondent was the holder of DEA Certificate of Registration, BO3661104, which authorized him to handle schedule II through V controlled substances as a practitioner. Respondent's registration expired on December 31, 2004. According to the investigative file, Respondent did not submit a renewal application until February 24, 2005, nearly two months after his registration expired. Accordingly, I find that Respondent's renewal application was not timely submitted and his registration expired on December 31, 2004. See 5 U.S.C. 558(c) (requiring submission of a "timely and sufficient application for a renewal" in order for a registration to be continued until the Agency makes a "final determin[ation]" on the application). I further find, however, that Respondent does have an application pending before the agency.

According to the investigative file, on February 18, 2005, the Illinois Department of Financial and Professional Regulation summarily suspended Respondent's state medical license and controlled substance registrations. In support of the suspension, the State alleged, *inter alia*, that "Respondent issued false prescriptions for controlled substances under other names for personal use." Pet. For Temp. Susp. 1. The petition was supported by the sworn affidavit of Larry G. McClain, M.D., the Chief Medical Coordinator of the Illinois Department of Financial and Professional Regulation. In his affidavit, Dr. McClain averred that "the Department has learned that Respondent has repeatedly issued false prescriptions for Xanax, Dilaudid and Viagra. He calls in these prescriptions in the names of [M.G., V.G. and T.C.] He obtains these prescriptions for personal use and pays cash to remain untraceable." Dr. McClain further averred that "Respondent was arrested for a DUI in June of 2004 and * * * has an extensive criminal history."

In September 2006, Respondent and the State entered into a consent order under which his medical license was restored based on his having entered a treatment program and an Aftercare Agreement. Consent Order at 2. In the order, "Respondent admit[ted] the allegations raised by the Department." *Id.* The consent order, which became effective on November 21, 2006, placed Respondent on "Indefinite Probation," and also imposed various conditions including that he comply with the terms

² The ALJ properly rejected Respondent's request for a stay. It is not DEA's policy to stay proceedings under section 304 while registrants litigate in other forums. See *Bourne Pharmacy, Inc.*, 72 FR 18273 (2007); *Oakland Medical Pharmacy*, 71 FR 50100 (2006); *Kennard Kobrin, M.D.*, 70 FR 33199 (2005). As the ALJ explained, Respondent can always apply for a new registration if it prevails in the pending state administrative proceeding.

³ Based on this Agency's records, I find that Respondent is the holder of DEA Certificate of Registration, BN3795892, which does not expire until October 31, 2008.