

methamphetamine. *See id.* at 9, 11–13. The Order also alleged that Respondent's employees knew that the KPD was arresting Respondent's customers, that customers would often complain about the police, and that the police would sometimes enter the pharmacy to look for a suspect. *See id.* at 16. In addition, many of Respondent's customers were from out of town. *See id.*

The Show Cause Order also recounted the facts surrounding a complaint that had been filed with the Louisiana Board of Pharmacy against Respondent. The complainant alleged that on both January 17 and February 3, 2004, her 19 year old son had obtained from Respondent a combination prescription of 90 hydrocodone 10 mg., 90 carisoprodol 350 mg., and 30 alprazolam 2mg. *See id.* at 16. On February 5, 2004, the complainant's son died of respiratory failure due to acute and chronic drug use. *Id.* The autopsy's toxicology tests found elevated levels of hydrocodone and alprazolam. *See id.*

Finally, the Show Cause Order alleged that the majority of prescriptions filled by Respondent were for the aforementioned drug combination and were issued by a small group of doctors. *See id.* at 17. The Order alleged that "[b]ased upon the sheer volume of duplicate prescriptions from the large volume of customers written by the same group of doctors, and the knowledge that [Respondent's] customers were routinely being arrested * * * after leaving" the pharmacy, Respondent "knows or should know that the combination prescriptions it fills are not valid prescriptions." *Id.* The Order thus alleged that Respondent and its pharmacists were diverting "massive amounts of controlled substances" in violation of 21 U.S.C. 841(a)(1), and 21 CFR 1306.04. *Id.* at 17.

On May 5, 2005, Respondent requested a hearing; the case was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner. On May 25, 2005, the Government sought to stay the proceeding and moved for summary disposition. The basis for the motion was that on April 28, 2005, Respondent had entered into a consent agreement with the Louisiana Board of Pharmacy. Pursuant to the agreement, Respondent surrendered its Louisiana Controlled Dangerous Substances License. The Government thus contended that because Respondent no longer had authority under state law to engage in the distribution of controlled substances, *see* 21 U.S.C. 824(a)(3), it was no longer entitled to hold a Federal registration. The Government further

contended that Respondent's request for a hearing should be dismissed.

On June 9, 2005, Respondent filed a response. Respondent advised that it did not oppose the Government's motion. Respondent further acknowledged that it had voluntarily surrendered its state license and was thus not eligible to hold a DEA registration.

On July 1, 2005, the ALJ granted the Government's motion for summary disposition. The ALJ observed that, under longstanding agency precedent, "a registrant may not hold a DEA registration if it is without appropriate authority under the laws of the state in which it does business." ALJ Dec. at 2 (citing, *inter alia*, *Rx Network of South Florida, LLC*, 69 FR 62,093–01 (2004); *Wingfield Drugs, Inc.*, 52 FR 27,070 (1987)). The ALJ further noted that Respondent had admitted that it was no longer licensed in Louisiana and thus was not entitled to hold a DEA registration. *Id.* Because there were no material facts in dispute, the ALJ granted the Government's motion and recommended that I revoke Respondent's registration and deny any pending applications for renewal or modification of its registration. *See id.* at 2–3.

Having considered the record as a whole, I hereby issue this decision and final order. I adopt in its entirety the ALJ's opinion and recommended decision. Because the facts are straightforward and not in dispute, I conclude that there is no need to elaborate on them. As the ALJ found, Respondent is no longer authorized to distribute controlled substances under State law. Therefore, under our precedents, Respondent is not entitled to maintain its DEA registration. *See, e.g., Rx Network of South Florida*, 69 FR at 62095.

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b) and 0.104, I hereby order that DEA Certificate of Registration, No. BM8291572, issued to Michael's Discount Pharmacy, 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 September 25, 2006.

Dated: August 15, 2006.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 05–15]

Oakland Medical Pharmacy; Revocation of Registration

On October 27, 2004, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and further ordered the immediate suspension of DEA Certificate of Registration, AO6837477, issued to Oakland Medical Pharmacy (Respondent) of Madison Heights, Michigan. The Show Cause Order proposed to revoke Respondent's pharmacy registration and to deny any pending applications for renewal or modification of its registration on the ground that Respondent's continued registration would be inconsistent with the public interest. *See* 21 U.S.C. 823(f) and 824(a). The Order of Immediate Suspension was based on my preliminary finding that Respondent's continued registration "would constitute an imminent danger to the public health and safety because of the substantial likelihood" that Howard Applebaum, Respondent's owner and chief pharmacist would "continue to divert controlled substances to persons who will abuse them." Show Cause Order at 3. The Show Cause Order also notified Respondent of its right to a hearing. *Id.*

The Show Cause Order specifically alleged that between February 2002 and October 2004, Mr. Applebaum had "[o]n many occasions * * * provided [two undercover] agents with refills of controlled substance prescriptions when refills had not been authorized by a physician." *Id.* at 2. The Show Cause Order further alleged that Mr. Applebaum had "also provided the agents with excessive amounts of controlled substances that had not been authorized by a physician" by providing the agents with refills when he dispensed the initial prescriptions. *Id.* The Order also alleged that Mr. Applebaum had provided refills to the agents long before their original prescriptions would have been used up. *Id.*

The Show Cause Order alleged that on July 26, 2004, Mr. Applebaum filled a controlled substance prescription for an agent "with no authorization from her physician." *Id.* The Order also alleged that on the same day, the agent observed Mr. Applebaum provide another customer with two refills for a controlled substance. *Id.*

The Show Cause Order further alleged that a review Respondent's records for

the period January 2003 through May 2004 indicated that “Mr. Applebaum routinely dispenses unauthorized controlled substances by providing early refills * * * and multiple refills of prescriptions for the same controlled substances on the same date.” *Id.* The Order also alleged that Respondent’s records show that “Mr. Applebaum dispenses narcotic to drug addicts and to individuals obtaining treatment for narcotic addiction.” *Id.*

The Show Cause Order alleged that “Mr. Applebaum was “routinely dispens[ing] contraindicated controlled substances at the same time to the same patient,” and that he was also “routinely dispens[ing] controlled substances” to doctor shoppers. *Id.* Finally, the Show Cause Order alleged that from October 2003 through April 2004, Respondent had purchased 350,000 units of hydrocodone products and that 46 percent of the hydrocodone prescriptions it dispensed were issued by the same physician. *Id.* at 3. The Order thus alleged that there was a “substantial likelihood that Mr. Applebaum will continue to divert controlled substances to” drug abusers and that Respondent’s continued registration “would constitute an imminent danger to public health and safety.” *Id.*

On December 13, 2004, the Office of the Administrative Law Judges received Respondent’s request for a hearing. The case was assigned to Administrative Law Judge (ALJ) Gail A. Randall.

On December 22, 2004, the Government moved for summary disposition. The basis for the motion was that on November 16, 2004, the Michigan Board of Pharmacy had filed an Administrative Complaint against Respondent and had also summarily suspended Respondent’s state pharmacy license. The State’s Order of Summary Suspension was effective immediately. The Government thus contended that because Respondent no longer had authority under state law to distribute or dispense controlled substances, see 21 U.S.C. 824(a)(3), it was not entitled to hold its Federal registration. The Government further contended that there was no factual matter in dispute.¹

On January 21, 2005, Respondent filed an opposition to the Government’s motion. While Respondent acknowledged that the State had summarily suspended its registration, it contended that the State’s action “was predicated in large part on the

immediate ex-parte suspension of respondent’s DEA registration * * * and the facts developed by the DEA.” Resp. Answer to Motion for Summary Disp. at 1. Respondent further contended that the hearing before the State ALJ was ongoing and that the state order was not final. See *id.* Respondent argued that for DEA to rely on the State’s summary suspension when the State’s action was based on the original DEA proceeding “is a case of bootstrapping extraordinaire.” *Id.* at 2.

Respondent thus contended that it would be “fundamentally unfair” to grant the Government’s motion. *Id.* Respondent further contended that revocation was not required by the statutory language of 21 U.S.C. 824(a)(3). See *id.* (quoting 21 U.S.C. 824(a)(3) (“a registration * * * may be suspended or revoked by the Attorney General upon a finding that the registrant has had his State license or registration suspended, revoked or denied by competent State authority”). According to Respondent, “[t]he action is not mandatory nor is it warranted in this situation where the respondent has specifically requested a hearing on the merits and is currently in the midst of” a State hearing “on the issue of whether * * * Respondent’s conduct merits [an] order of summary suspension of the licenses by the State.” *Id.* at 2–3. Respondent thus requested that the ALJ deny the Government’s motion for summary disposition and that the Federal proceeding be stayed until the State issued a decision on the merits.

On February 4, 2005, the ALJ issued an Order for Status Report. In the order, the ALJ notified the parties that she had taken the matter under advisement and that the proceedings would remain stayed. The ALJ also ordered Respondent to file a status report with respect to its State license on or before April 18, 2005. The ALJ further notified Respondent that if it failed to file the report, the ALJ would rule on the government’s motion based on the information then before her. See Order for Status Report at 1.

As of May 27, 2005, Respondent had not filed a status report. The ALJ therefore issued her order, opinion and recommended decision. In her order, the ALJ granted the Government’s motion for summary disposition, denied the Respondent’s request for a continued stay of the proceedings and recommended the revocation of Respondent’s registration on the ground that Respondent lacked State authority to handle controlled substances. See ALJ Dec. at 5–7.

The ALJ specifically found that “Respondent did not deny that it is

currently without state authorization to handle controlled substances.” ALJ Dec. at 5. The ALJ further noted that Respondent had failed to file a report advising her of the status of the state proceeding. See *id.* Because state authorization is an essential prerequisite to a DEA registration, see *id.* at 4, and it was undisputed that “that the Respondent does not have authority to handle controlled substances in the jurisdiction where it seeks to maintain its DEA registration,” the ALJ granted the Government’s motion for summary disposition. *Id.* at 5.

The ALJ acknowledged Respondent’s argument that it was “unfair” for DEA to revoke its registration based on the Michigan suspension, because it had been based on the DEA Order to Show Cause and Immediate Suspension of Registration. *Id.* at 5–6. The ALJ further noted that “such an action is circular and may result in the Respondent being denied an opportunity to adjudicate the facts.” *Id.* at 6.

The ALJ also denied Respondent’s request for a stay until the conclusion of the state proceeding. According to the ALJ, “[t]he fact remains that the Respondent currently lacks state authorization to handle controlled substances, and therefore *cannot* remain registered with the DEA.” *Id.* The ALJ thus concluded that she had “no choice but to grant summary disposition at the present time, and to deny” Respondent’s motion for a stay. *Id.*

Thereafter, Respondent sought reconsideration of the ALJ’s recommended decision. The basis for Respondent’s motion was that he had not intentionally failed to file a Status Report but had erroneously believed, based on a phone conversation with Government counsel that occurred on April 11, 2005, that Government counsel “was going to investigate the matter and confirm with Respondent’s counsel whether it was still necessary for him to file anything additional in writing given the status of the” state hearing. Resp. Req. for Recon. at 2. Respondent’s counsel stated that when he did not hear back from Government counsel, he “wrongly assumed that the issue had been resolved.” *Id.* Respondent further informed the ALJ that the state proceedings were continuing and that the proceeding had been “an elongated and vigorously contested hearing,” which had been held on five different dates with one additional date to follow, at which the State’s “expert pharmacy witness” was to testify. *Id.* at 3.

The Government responded that while it did not object to the late filing of the status report, it did object to

¹ Upon receipt of the Government’s motion, the ALJ ordered that the proceedings be stayed pending a decision on the motion and further order Respondent to file a reply.

reconsideration of the ALJ's decision. *See* Govt. Resp. at 2. While the Government counsel did not remember the aforementioned telephone conversation, he did not dispute that Respondent's counsel may have asked him whether he had to file anything. *Id.* The Government further pointed out that Respondent's counsel did not contend that he had not received the ALJ's Order for Status Report, and that the Order, which the Government had not received, presumably clearly stated the deadline for filing the Status Report. *See id.* at 2–3.

The Government contended that whether Respondent should be permitted to file a status report was irrelevant because Respondent's state license had been suspended in November 2004 and had remained so since then. The Government further argued that "Respondent still does not know when the state proceedings will end, and there is no assurance that Respondent will regain its state authority." *Id.* at 3. According to the Government, "[t]he ALJ based her Decision on the fact that Respondent had no state authority to handle controlled substances at the time of the Decision. That fact was true at the time of the deadline for the status report, at the time of the Decision and is true at the present." *Id.* Therefore, the Government argued that there was no basis for the ALJ to reconsider her decision.

The ALJ denied Respondent's motion for reconsideration. Again, the ALJ noted that "under the Controlled Substances Act it is clear that the DEA does not have statutory authority to maintain a registration if the registrant is without state authority to handle controlled substances in the state in which the registrant conducts business." Order Denying Resp. Req. for Recon. at 2. The ALJ then transmitted the record to me.²

Having considered the record as a whole, I hereby issue this decision and final order. I adopt the ALJ's findings of fact and conclusions of law. I further adopt the ALJ's recommended decision to revoke Respondent's registration. I do not, however, adopt the opinion to the extent it suggests that it was "unfair" for this agency to revoke Respondent's Federal registration based on the State proceeding and that "such an action is circular and may result in the Respondent being denied an

opportunity to adjudicate the facts." ALJ Dec. at 6.

I acknowledge that the State's Administrative Complaint relied in part on my Order to Show Cause and Immediate Suspension of Registration. *See* Admin. Complaint at 3. But the state complaint did not rely solely on my action. The state complaint cited a variety of grounds under Michigan law for imposing sanctions including "failing to comply with applicable Federal laws," *id.* at 2 (citing Mich. Comp. Laws § 333.7311(1)(f)); dispensing of "controlled substances for other than legitimate medical purposes," *id.* (citing Mich. Comp. Laws § 333.7311(1)(g)); and "if an officer or stockholder of the pharmacy lacks good moral character." *Id.* at 2–3 (citing Mich. Comp. Laws § 333.17768(2)(a)). The complaint further alleged that Respondent had violated these provisions of state law. *Id.* at 3–4. Furthermore, the State's Order of Summary Suspension was based on the "careful consideration of the documentation filed" in the State's administrative proceeding including the complaint. Order of Summary Suspension 1. The State's Order also provided a procedure for Respondent to petition for dissolution of the state suspension. *See id.*

I take the State on its word and conclude that its decision to summarily suspend Respondent's state license was not based solely on my order but was also based on its own evaluation of the evidence. Furthermore, as Respondent itself pointed out, the State proceeding has been "an elongated and vigorously contested hearing," which included at least six days of hearings with the State putting on an expert witness. It is hard to imagine why a proceeding would take so long to litigate and require expert testimony if it did not involve an adjudication of the underlying facts. Thus, I do not accept the ALJ's conclusion that it is "circular" for this agency to revoke Respondent's registration based on the State's summary suspension order and that doing so "may result in * * * Respondent being denied an opportunity to adjudicate the facts." ALJ Dec. at 6. Quite the opposite, it appears that the State entered its suspension order based on its own examination of the evidence; it further appears that Respondent has had a full and fair opportunity to litigate the facts in the State proceeding.

DEA's regulations make clear that the ALJ's decision is only a recommendation; it is not the final agency action. The revocation of Respondent's Federal registration

becomes final only with this order. Yet in the interval between the ALJ's decision and the publication of this order, Respondent has submitted no evidence to show that the State has lifted its suspension.

As the ALJ correctly recognized, DEA has consistently held that a registrant may not hold a DEA registration if it is without appropriate authority under the laws of the state in which it does business. *See, e.g., Rx Network of South Florida, LLC*, 69 FR 62,093 (2004); *Wingfield Drugs, Inc.*, 52 FR 27,070 (1987). Respondent does not have authority under Michigan law to handle controlled substances. Therefore, it is not entitled to maintain its DEA registration. *See Rx Network of South Florida*, 69 FR at 62095.

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b) and 0.104, I hereby order that DEA Certificate of Registration, No. AO6837477, issued to Oakland Medical Pharmacy be, and it hereby is, revoked. I further order that any pending applications for renewal or modification of its registration be, and they hereby are, denied. This order is effective September 25, 2006.

Dated: August 15, 2006.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Sujak Distributors; Denial of Application

On May 18, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Sujak Distributors (Respondent). The Show Cause Order proposed to deny Respondent's application for a DEA Certificate of Registration as a distributor of List I chemicals on the ground that Respondent's registration would be inconsistent with the public interest. *See* U.S.C. 823(h).

The Show Cause Order specifically alleged that Respondent was proposing to sell ephedrine and pseudoephedrine products, which are precursors used in the manufacture of methamphetamine, to convenience stores, gas stations and liquor stores in the Davenport, Iowa area. *See* Show Cause Order at 2. The

² I emphasize that there is no provision in DEA's regulations for either party to request reconsideration of an ALJ's recommended decision. *See* generally 21 CFR Subpart D. The appropriate means of challenging the ALJ's decision is to file exceptions. *See* 21 CFR 1316.66.