

Nolte Drive, West Deptford, New Jersey 08066, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedule II:

| Drug | Schedule |
|-------------------------------------|----------|
| Methadone (9250) | II |
| Methadone Intermediate (9254) | II |

The company plans to use the Methadone Intermediate to produce the Methadone HCL for sale to its customers who are final dosage manufacturers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Johnson Matthey Inc. to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Johnson Matthey Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: May 29, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 07-19]

CRJ Pharmacy, Inc. and YPM Total Care Pharmacy, Inc.; Revocation of Registrations

This is a consolidated proceeding involving two pharmacies under common ownership. On February 2, 2007, I issued an Order to Show Cause and Immediate Suspension of DEA Certificates of Registration, BC9458539, issued to CRJ Pharmacy, Inc., and BY9713276, issued to YPM Total Care Pharmacy, both of Lakeland, Florida. I immediately suspended each

Respondent's registration based on my preliminary finding that they had "diverted and continue to divert massive amounts of controlled substances in violation" of federal law "thereby creating an imminent danger to public health or safety." Show Cause Order at 5. The Show Cause Order further sought the revocation of each Respondent's registration on the ground that its continued registration would be "inconsistent with the public interest." *Id.* at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)).

With respect to CRJ Pharmacy, the Show Cause Order alleged that it was the fourteenth largest retail purchaser of hydrocodone-combination products in the State of Florida, and that "[f]rom January through November 2006, CRJ purchased 1,416,320 dosage units of brand name and generic hydrocodone combination products," a schedule III controlled substance. *Id.* The Show Cause Order further alleged that on March 30, 2006, DEA investigators had inspected CRJ and determined that it filled controlled substance orders placed through a Web site, *yourpainmanagement.com*; that the orders were for persons throughout the United States; and that the orders were authorized by only two physicians. *Id.* at 2. According to the allegations, one of the physicians was licensed to practice only in Florida; the other was licensed only in Minnesota. *Id.*

The Show Cause Order further alleged that on January 22, 2007, DEA investigators executed an administrative search warrant at CRJ and obtained records showing that between July 3, 2006, and January 22, 2007, CRJ had "filled approximately 19,223 controlled substance drug orders and shipped them to customers throughout the United States." *Id.* The Show Cause Order also alleged that these prescriptions were authorized by physicians located in Texas, Wisconsin, Puerto Rico, New York, California, Kansas, and Florida, for persons who did not reside in the same States as the physicians, that the prescriptions were disproportionately for "one or two types of highly addictive and abused controlled substances," that "CRJ filled large quantities of prescriptions per day, per physician," and thus CRJ knew or should have known that the prescriptions it dispensed "were not issued 'for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'" *Id.* at 4 (quoting 21 CFR 1306.04(a)).

The Show Cause Order alleged that CRJ's owner, Mr. Chris Larson, had admitted to investigators that he owned

bestrxcare.com. *Id.* at 2. According to the Show Cause Order, Mr. Larson told investigators that persons seeking controlled substances completed an on-line questionnaire and then faxed their medical records to *bestrxcare.com*, where they were scanned into a database for review by either a physician or a physician's assistant (PA). *Id.* Mr. Larson allegedly told investigators that if the records were "ok," a physician or a PA would then consult with the customer by telephone. *Id.* According to the Show Cause Order, after the customer had paid the Web site and the phone consultation was completed, a "prescription" was issued which CRJ then downloaded from the Internet and dispensed. *Id.*

The Show Cause Order further alleged that a physician employed by Larson had admitted to investigators that Larson was using his DEA "license for pain pills." *Id.* at 3. According to the Show Cause Order, the physician further admitted that "he does not speak with any of the Internet customers or their primary care physicians," and that he "does not diagnose the Internet customers or provide after care services for the Internet customers." *Id.*

With respect to YPM, the Show Cause Order alleged that it was dispensing controlled substances that were ordered through another Web site, *yourpainmanagement.com*, which was also owned by Larson. *Id.* at 4. The Show Cause Order alleged that on August 17, 2005, Larson stated to DEA investigators that a person could order controlled substances for pain management through this Web site by completing a form on which they provided their name, address, billing information, general biographic details and medical complaint. *Id.* Larson allegedly also told investigators that the customers would then fax their medical records to the Web site where they were then reviewed by a PA; if the records appeared "in order," either a physician or the PA would conduct a telephone consultation with the customer. *Id.* The Show Cause Order further alleged that during this interview, one of Larson's employees told DEA investigators that the Web site does not order further testing of its customers and does not contact the physicians named on the customers' medical records. *Id.*

The Show Cause Order also alleged that from May 2006 through November 2006, YPM had purchased 841,800 units of hydrocodone-combination products. *Id.* Relatedly, the Show Cause Order alleged that YPM records showed that it had dispensed 17,336 controlled substance orders to internet customers throughout the United States and that

98 percent of the orders were authorized by three physicians. *Id.* The Show Cause Order further alleged that two of these physicians were licensed to practice medicine in Florida; moreover, between June 1, 2006, and January 19, 2007, the third physician, who was licensed in Minnesota, had authorized 15,050 orders. *Id.* The Show Cause Order thus alleged that YPM “knew or should have known that the ‘prescriptions’ [it] dispensed were not issued ‘for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice’” and violated federal law. *Id.* at 4 (quoting 21 CFR 1306.04(a)).

On February 5, 2007, both CRJ and YPM were served with the Order to Show Cause and Immediate Suspension of Registrations. On February 22, 2007, both Respondents, who were represented by the same counsel, requested a hearing on the allegations. The matters were assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner.

On March 12, 2007, the Government moved for summary disposition. The basis for the Government’s motion was that Respondents had closed their businesses on February 12, 2007, and had “transferred all prescription records, inventory, and required DEA records to other DEA registrants.” Gov. Mot. for Summ. Disp. at 1. The Government’s motion further asserted that on February 27, 2007, Respondent CRJ had surrendered its Florida Board of Pharmacy License to the Florida Board of Pharmacy. *Id.* The Government further asserted that Respondent YPM had “signified its intent to surrender its Florida Board of Pharmacy License in its letter to DEA dated February 22, 2007.” *Id.* at 2. The Government thus asserted that both “Respondents are currently without authority under Florida law to dispense controlled substances” and therefore are not entitled to maintain their DEA registrations. *Id.*

In support of its motion, the Government attached copies of letters from both YPM (dated Feb. 27, 2007) and CRJ (dated Feb. 28, 2007) to the DEA Miami Office; each letter advised that the pharmacy had closed, that it was in the process of surrendering its state license, and sought permission to act as a one-time wholesaler to sell the controlled substances (which apparently were still in their possession) to another pharmacy. See Appendices I & II to Gov. Mot. The Government also attached a copy of the letter from CRJ to the Florida Board of Pharmacy, by which it surrendered its state license. See Appendix III to Gov. Mot. The

Government’s submission did not, however, include a similar letter from YPM.

Respondent did not oppose this motion. Response to Gov. Motion for Summ. Disp. at 1. However, on March 16, 2007, the Government had also filed a motion to supplement the motion for summary disposition. The Government based its motion on my decision in *William R. Lockridge, M.D.*, 71 FR 77,791 (2006). In *Lockridge*, I reviewed the propriety of an immediate suspension in a case in which the Respondent’s registration had expired, in part, because of the collateral consequences which attached with the issuance of the suspension. The Government thus moved to submit several affidavits of DEA investigators to support “the basis for the immediate suspensions.” Gov. Mot. to Supp. at 1.

Thereafter, on March 19, 2007, the ALJ afforded Respondents the opportunity to respond to the Government’s motion by April 2, 2007. Subsequently, on March 22, 2007, the ALJ granted the Government’s motion for summary disposition to the extent it sought the revocation of Respondents’ DEA registrations on the ground that CRJ and YPM were without authority under Florida law to handle controlled substances and therefore were not entitled to maintain their DEA registrations. ALJ Dec. at 3. The ALJ thus recommended that Respondents’ registrations be revoked. *Id.*

The ALJ also granted the Government’s motion to supplement its original motion for summary disposition and submit into the record the two affidavits. The ALJ, however, also afforded Respondents the opportunity to submit additional documents including affidavits.¹

On April 2, 2007, Respondents filed their response which vigorously opposed the Government’s motion. Respondents contended that there is “no dispute” that they “can no longer hold DEA registrations.” Response at 3. Respondents maintained, however, that the Government’s reliance on *Lockridge* was misplaced because in there, a full hearing had been held and “[m]ootness was implicated only when the respondent’s registration expired *after the hearing.*” *Id.* at 4.

Respondents further argued that “[t]he Government itself has claimed that this case is moot and therefore no hearing should be held,” and that this precludes a “ruling on the immediate suspension as the Government seeks.”

¹ The ALJ did not, however, rule on the Government’s alternative basis for summary disposition.

Id. Respondents also contended that because of the collateral consequences that attach with the issuance of an immediate suspension, “to the extent the Deputy Administrator seeks to uphold the suspension, CRJ and YPM have a right to a hearing.” *Id.* Respondents thus maintained that granting the Government’s supplemental motion would “violate [their] hearing rights” because the Government’s affidavits are “conclusory” and cannot support the “factual findings” sought by the Government. *Id.* at 4–5 (citing 21 CFR 1316.41). Finally, Respondent contended that *Lockridge* “does not, and cannot, hold that a decision on the merits may issue after a summary disposition.” *Id.* at 5. Respondents did not, however, submit any affidavits of their own.

Neither party filed exceptions to the ALJ’s decision. Thereafter, the ALJ forwarded the record to me for final agency action. Having considered the record as a whole, I hereby issue this final order. I adopt the ALJ’s recommendation that each Respondent’s registration be revoked on the ground that it no longer has authority to handle controlled substances in the State of Florida and thus is not entitled to hold a DEA registration in that State. I further conclude that my decision in *Lockridge* is not controlling and that the issue of the validity of the immediate suspensions is now moot because each Respondent has surrendered its Florida pharmacy license and closed its business. Moreover, neither the Government nor Respondents have pointed to any non-speculative collateral consequence which a ruling on the merits of the immediate suspension order would resolve. I make the following findings.

Findings

On April 21, 2006, Respondent YPM Total Care Pharmacy, Inc., was issued DEA Certificate of Registration, BY9713276, as a retail pharmacy, with an expiration date of May 31, 2009. On some date not specified in the record, Respondent CRJ Pharmacy, Inc., was issued DEA Certificate of Registration, BC9458539, with an expiration date of August 31, 2008.

On February 7, 2007, DEA investigators served both YPM Total Care Pharmacy, Inc., and CRJ Pharmacy, Inc., with the above described Order to Show Cause and Immediate Suspension of Registration. Shortly thereafter, on February 12, 2007, YPM closed its pharmacy. Moreover, on February 26, 2007, YPM transferred its prescription records to another DEA registrant, and

on February 28, 2007, YPM transferred its records and inventory of controlled substances (with the Agency's approval) to that registrant. YPM subsequently surrendered its Florida Pharmacy License. I take official notice of the online records of the Florida Department of Health which confirm that YPM Total Care Pharmacy has closed.²

According to the record, on February 12, 2007, CRJ Pharmacy, Inc., also closed its pharmacy. On February 26, 2007, CJR transferred its prescription records to another DEA registrant, and on February 28, 2007, transferred its records and inventory of controlled substances to that registrant. CJR subsequently surrendered its Florida Pharmacy License. I also take official notice of the online records of the Florida Department of Health which confirm that CRJ Pharmacy has closed.

Discussion

Under the Controlled Substances Act, a practitioner must be currently authorized to handle controlled substances in "the jurisdiction in which [it] practices" in order to maintain its DEA registration. See 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.* section 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."). As numerous agency orders have held, "a registrant may not hold a DEA registration if it is without authority under the laws of the state in which it does business." *Bourne Pharmacy, Inc.*, 72 FR 18273, 18274 (2007) (quoting *Oakland Medical Pharmacy*, 71 FR 50100, 50102 (2006)). *Accord Rx Network of South Florida, LLC*, 69 FR 62,093 (2004); *Wingfield Drugs, Inc.*, 52 FR 27,070 (1987).

Each Respondent having surrendered its State license, neither now disputes "that summary disposition and

revocation are appropriate." Response to Gov. Mot. to Supplement at 3. Respondents do, however, object to the Government's submission of the two affidavits and my ruling on the merits of the immediate suspension.

Respondents assert that *Lockridge* is distinguishable because there, a full evidentiary hearing had been held, and here, no such hearing has been held. Respondents further argue that the validity of the immediate suspensions is now a moot issue although they contend—inconsistently—that they are entitled to a hearing "before bearing the adverse collateral consequences" that would arise were I to issue a ruling upholding the immediate suspension orders.

I conclude that *Lockridge* is not controlling and that the issue of the validity of the immediate suspensions in this case is now moot. It is fundamental that the issuance of an immediate suspension imposes a deprivation of a property interest which gives rise to the protections of the Due Process Clause. See, e.g., *FDIC v. Mallen*, 486 U.S. 230, 240 (1988). Subsequent events may nonetheless make clear that there is no longer a live controversy between the parties even when the Government has yet to provide the constitutionally required process. Cf. *City News and Novelty, Inc.*, v. *City of Waukesha*, 531 U.S. 278 (2001).

In *Lockridge*, I held that the proceeding was not moot notwithstanding that the practitioner had allowed his registration to expire following the hearing and there was no existing registration to act upon. In so holding, I relied on several factors. These included the collateral consequences that attached with the issuance of the immediate suspension, in particular the harm to the practitioner's reputation, and the additional disability imposed by the Agency's requirement to report the suspension on any subsequent application for a DEA registration.

I also noted that the practitioner had not moved to dismiss the proceeding on mootness grounds and that he had submitted no evidence showing that he "intend[ed] to permanently cease the practice of medicine." 71 FR at 77797. I thus concluded that Respondent might apply for a new registration and seek to engage in the same practices which had prompted the immediate suspension. Thus, it was not "absolutely clear that [the practitioner's] allegedly wrongful behavior could not reasonably be expected to recur." *Id.* (quoting *Friends of the Earth, Inc.*, v. *Laidlaw Env. Servs.*,

Inc., 528 U.S. 167, 189 (2000) (other quotations and citations omitted)).³

Here, by contrast, the record establishes that each Respondent has not only surrendered its State license, but has also gone out of business. Moreover, in contrast to the registrant in *Lockridge*, each Respondent has not only engaged in affirmative acts showing that it was ending its business activities, it has also expressly communicated these facts to the Agency. Relatedly, neither Respondent opposes the revocation of its registration nor seeks to litigate the validity of the suspension orders.

Finally, neither Respondent has asserted that it plans to re-enter the business of pharmacy at some future date. The speculative possibility that either Respondent will seek a new registration at some point in the future is not enough to conclude that sufficient collateral consequences exist to render the issue of the suspension orders' validity a live dispute. See, e.g., *City News*, 531 U.S. at 285; *Spencer v. Kemna*, 523 U.S. 1, 16 (1998). Indeed, were either Respondent to apply for a new registration in the future, it would nonetheless be required to disclose on its application the revocation being ordered below. Under these circumstances, the suspension orders impose on Respondents no additional consequence beyond what they will be required to disclose because of the revocations of their registrations.⁴ Accordingly, the issue is now moot.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824, as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, BC9458539, issued to CRJ Pharmacy, Inc., and DEA Certificate of Registration, BY9713276, issued to YPM Total Care Pharmacy, Inc., be, and they hereby are, revoked. I further order that pending applications for renewal or modification of either registration be, and they hereby are, denied. This order is effective July 5, 2007.

³ I also noted the extensive resources committed by both parties in litigating the case and the potential prejudice to the public interest were I to dismiss the proceeding without making findings.

⁴ Finally, in this proceeding, the Government apparently did not place under seal the controlled substances possessed by either Respondent at the time of the suspensions. See 21 U.S.C. 824(f). Accordingly, title to the controlled substances is not a collateral issue which would be resolved in this proceeding.

² Under the Administrative Procedure Act (APA), an agency "may take official notice of facts at any stage in a proceeding—even in the final decision." U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is "entitled on timely request, to an opportunity to show to the contrary." 5 U.S.C. 556(e); see also 21 CFR 1316.59(e). Respondent can dispute these facts by filing a properly supported motion for reconsideration within fifteen days of service of this order, which shall begin on the date this order is mailed.

Dated: May 21, 2007.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 06-4]

Trinity Health Care Corp., D/B/A/ Oviedo Discount Pharmacy; Affirmance of Immediate Suspension

On August 19, 2005, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Trinity Healthcare Corporation, d/b/a/ Oviedo Discount Pharmacy (Respondent) of Oviedo, Florida. The Order immediately suspended Respondent's Certificate of Registration, BT2863668, as a retail pharmacy, based on my preliminary finding that Respondent was filling large quantities of prescriptions for controlled substances that were issued through an internet site, iPharmacy.MD, by physicians who did not have a legitimate doctor-patient relationship with the individuals who ordered the drugs. See Show Cause Order at 5-10. Based on my preliminary finding that Respondent was "responsible for the diversion of large quantities of controlled substances," and that its participation in this scheme "invites the fraudulent procurement of controlled substances on a vast scale," I concluded that Respondent's continued registration pending these proceedings "would constitute an imminent danger to the public health and safety," and therefore immediately suspended its registration. *Id.* at 10.

More specifically, the Show Cause Order alleged that Respondent was filling prescriptions for phentermine, a schedule IV controlled substance, which were issued to the customers of iPharmacy.MD by Richard Carino, a physician located in Port Richey, Florida. *Id.* at 5. The Show Cause Order alleged that Dr. Carino issued prescriptions for phentermine to persons located "throughout the country" based solely on a questionnaire. *Id.* The Show Cause Order further alleged that DEA investigators interviewed various individuals who had been prescribed controlled substances by Dr. Carino; each of these persons stated that they were not patients of Dr. Carino and had not provided him with their medical records. *Id.* at 6.

The Show Cause Order also alleged that on May 6, 2004, DEA investigators conducted an inspection of Respondent during which they obtained its prescription records for the period January 1 through May 6, 2004. *Id.* at 7. The Show Cause Order alleged that between January and May 5, 2004, Respondent had filled 2,196 internet prescriptions for phentermine issued by Dr. Carino to persons located throughout the United States. *Id.* at 7-8.

Finally, the Show Cause Order alleged that on April 15, 2005, a DEA Special Agent (S/A) had accessed the iPharmacy.MD Web site, completed a questionnaire, and ordered 90 tablets of phentermine. *Id.* at 9. The Show Cause Order further alleged that on April 21, 2005, the S/A received a bottle of phentermine which had been filled by Respondent.

Respondent, through its counsel, requested a hearing. The matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who conducted a hearing on May 30 through June 2, 2006, in Arlington, Virginia. At the hearing, both parties called witnesses to testify and introduced documentary and/or demonstrative evidence. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law, and argument.

On October 2, 2006, the ALJ issued her decision. In that decision, the ALJ concluded that Respondent's continued registration would be inconsistent with the public interest and recommended that I revoke Respondent's registration and deny any pending applications for renewal or modification. ALJ Dec. (hereinafter ALJ) at 32. Neither party filed exceptions.

On November 13, 2006, the ALJ forwarded the record to me for final agency action. Having carefully reviewed the record as a whole, I hereby issued this decision and final order. I adopt the ALJ's findings of fact and conclusions of law except as noted herein. Furthermore, while Respondent's registration expired on November 30, 2006, and Respondent did not submit a renewal application, I nonetheless conclude that this case is not moot. See *William R. Lockridge*, 71 FR 77791, 77797 (2006). Accordingly, while I do not adopt the ALJ's recommendation that Respondent's registration be revoked, I will review the propriety of the immediate suspension under section 304(a) of the Controlled Substances Act, 21 U.S.C. 824(a), and make the following findings.

Findings of Fact

Respondent is a corporation, which is owned and operated by Mr. Obi Enemchukwu, a pharmacist, and does business as Oviedo Discount Pharmacy in Oviedo, Florida. ALJ at 2; ALJ Ex. at 3. Respondent held DEA Certificate of Registration, BT2863668, which authorized it to dispense controlled substances in Schedules II through V, from September 1991 until the expiration of its registration on November 30, 2006. ALJ Ex. 3, at 1. Respondent last renewed its registration on October 24, 2003. *Id.* I take official notice of the fact that Respondent did not submit a renewal application prior to the expiration of its registration.¹ Accordingly, I find that Respondent is no longer registered with the Agency. See 5 U.S.C. 558(c).

DEA's 2001 Policy Statement on Internet Prescribing and Dispensing

In April 2001, several years before the events at issue here, DEA published in the **Federal Register** a guidance document entitled "Dispensing and Purchasing Controlled Substances over the Internet." 66 FR 21181 (2001); see also Gov. Ex. 18. DEA issued this document to advise "the public concerning the application of current laws and regulations as they relate to the use of the Internet for dispensing [and] purchasing * * * controlled substances." 66 FR at 21181.

More specifically, the guidance document advised that "[o]nly practitioners acting in the usual course of their professional practice may prescribe controlled substances. * * * A prescription not issued in the usual course of professional practice * * * is not considered valid. Both the practitioner and the pharmacy have a responsibility to ensure that only legitimate prescriptions are written and filled." *Id.*

The guidance document also discussed the legality under existing law of prescribing controlled substances based on an on-line questionnaire. After noting DEA's regulation that a prescription for a controlled substance is not effective unless it is "'issued for

¹ Under the Administrative Procedure Act (APA), an agency "may take official notice of facts at any stage in a proceeding—even in final decision." U.S. Dept. of Justice *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is "entitled on timely request to an opportunity to show to the contrary." 5 U.S.C. 556(e); see also 21 CFR 1316.59(e). To allow Respondent the opportunity to refute this fact, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall commence with the mailing of the order.