

the Darvocet?" The Agent answered "yes," but Registrant did not even ask her if she had pain, let alone ask her any questions regarding the nature and intensity of the pain, whether the Darvocet was helping to alleviate her pain, or how the pain was affecting her physical and psychological function. Accordingly, with respect to the Agent's second visit, I again conclude that Registrant failed to establish a doctor-patient relationship with her. I also conclude that Registrant lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing Xanax and Darvocet-N to her and violated Federal law. See 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1).

As the forgoing demonstrates, Registrant has committed acts which "render his registration * * * inconsistent with the public interest." 21 U.S.C. 824(a)(4). I will therefore order that his registration be revoked and that any pending applications be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as by 28 CFR 0.100(b), I hereby order that DEA Certificate of Registration, BF7430781, issued to Joe C. Fermo, M.D., be, and it hereby is, revoked. I further order that any pending application of Joe C. Fermo, M.D., to renew or modify his registration be, and it hereby is, denied. This Order is effective September 19, 2011.

Dated: August 5, 2011.

Michele M. Leonhart,
Administrator.

[FR Doc. 2011-21061 Filed 8-17-11; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Ideal Pharmacy Care, Inc., D/B/A Esplanade Pharmacy; Revocation of Registration

On November 12, 2010, I, the then Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Ideal Pharmacy Care, Inc., d/b/a Esplanade Pharmacy (Registrant), of New Orleans, Louisiana. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration FF1125651, which authorizes it to dispense controlled substances in schedules II through V as a retail pharmacy, on the ground that it has

committed acts which render its registration "inconsistent with the public interest." Show Cause Order at 1 (citing 21 U.S.C. 824(a)(4)). The Show Cause Order also proposed the denial of any pending applications to renew or modify Registrant's registration. *Id.*

The Show Cause Order specifically alleged that on October 14, 2010, investigators conducted an accountability audit of Registrant and found that it had "significant shortages" of various controlled substances. *Id.* The Order alleged that these included shortages of: (1) 3,891 dosage units of hydrocodone 7.5/650 mg, 78 percent of the accountable total; (2) 27,179 dosage units of hydrocodone 7.5/750 mg, 59 percent of the accountable total; (3) 5,514 dosage units of hydrocodone 10/500 mg, 48 percent of the accountable total; (4) 114,826 dosage units of hydrocodone 10/650 mg, 96 percent of the accountable total; (5) 83,254 dosage units of alprazolam 2 mg, 96 percent of the accountable total; and (6) 1,616,420 ml of promethazine with codeine, 99 percent of the accountable total. *Id.* at 1-2. Based on the audit results, the Order alleged that the Registrant had violated 21 U.S.C. 827(a)(3) and 842(a)(5), as well as 21 CFR 1304.03, 1304.04, and 1304.21. *Id.* at 2.

Next, the Show Cause Order alleged that various distributors make deliveries of controlled substances to Registrant when it "is closed," and that the "deliveries are received and signed for by" non-employees who work "at the grocery store in which [it] is located," and that the deliveries are then "diverted in violation of 21 U.S.C. 843(a)(3)." *Id.* The Order thus alleged that Registrant "has failed to provide effective controls" against theft and diversion of controlled substances. *Id.* (citing 21 CFR 1301.71).

The Show Cause Order also alleged that Registrant had violated a Memorandum of Agreement (MOA) it entered into with DEA. *Id.* The Order alleged that in the MOA, Registrant agreed that it would not employ its former owners "in any capacity relating to [its] business," and that it would not permit its former owners to have "access to any area of [it] where controlled substances are kept, stored, or maintained." *Id.* The Order alleged that Registrant "has permitted [its former owners] to enter the pharmacy where controlled substances are present in violation of" the MOA and 21 CFR 1301.72(d). *Id.*

Based on the matters set forth above, I concluded that Registrant's continued registration during the pendency of the proceeding would constitute "an imminent danger to public health and

safety." *Id.* (citing 21 U.S.C. 824(d)). I, therefore, ordered the immediate suspension of Registrant's registration. *Id.*

On November 17, 2010, the Order to Show Cause and Immediate Suspension of Registration, which also notified Registrant of its right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedures for doing either, and the consequences for failing to do either, *id.* at 3 (citing 21 CFR 1301.43(a) & (c)), was personally served on Registrant's Pharmacist-in-Charge. GX 2. Since the date of service of the Order, more than thirty days have now passed, and neither Registrant, nor anyone purporting to represent it, has requested a hearing or submitted a written statement. Accordingly, I find that Registrant has waived its right to a hearing or to submit a written statement in lieu of a hearing. 21 CFR 1301.43(a), (c) & (d). I, therefore, issue this Decision and Final Order based on relevant material contained in the record submitted by the Government. 21 CFR 1301.43(e).

Findings

Registrant is the holder of DEA Certificate of Registration FI1125651, which authorizes it to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered address of 1400 Esplanade Ave., New Orleans, Louisiana. Registrant's registration does not expire until November 30, 2011. Registrant is apparently located in a building which also contains a grocery store. Affidavit of DI, at 8 (GX 22).

On October 14, 2010, DEA Investigators conducted an audit of Registrant's handling of controlled substances. *Id.* at 9. The audit covered the period of October 22, 2008, on which date Registrant had no controlled substances on hand, through the beginning of business on October 14, 2010, at which time the closing inventory for the audit was taken. *Id.* According to the DI, she obtained invoices provided by Registrant's suppliers to determine the total amount of the controlled substances it had purchased during the audit period and was accountable for; the DI also obtained Registrant's records (including the prescriptions on file), as well as data from the state's prescription monitoring program showing the pharmacy's dispensings, and added the amount of its dispensings to the closing inventory to determine the total amount of each drug which it could account for. *Id.* Upon comparing the two amounts, the DI found that Registrant had large

shortages of six different drugs. These included:

1. A shortage of 3,891 dosage units of hydrocodone/apap 7.5/650 mg, which was 78 percent of the total amount for which it was accountable;

2. A shortage of 27,179 dosage units of hydrocodone/apap 7.5/750 mg, which was 59 percent of the total amount for which it was accountable;

3. A shortage of 5,514 dosage units of hydrocodone/apap 10/500 mg, which was 48 percent of the total amount for which it was accountable;

4. A shortage of 114,826 dosage units of hydrocodone/apap 10/650 mg, which was 96 percent of the total amount for which it was accountable;

5. A shortage of 83,254 dosage units of alprazolam 2 mg., which was also 96 percent of the total amount for which it was accountable; and

6. A shortage of 1,616,420 ml of promethazine with codeine, a shortage of 99 percent of the total amount for which it was accountable.

Id. at 9.

While pharmacy employees told the DI that they were the only persons who accepted controlled substance deliveries, based on the records obtained from one of Registrant's distributors, the DI determined that many of the shipments had been delivered on Saturdays, a day when the pharmacy was closed, and that a number of the shipments were signed for by non-pharmacy employees who worked in the grocery store. *Id.* at 7–8, 10. Moreover, while Registrant's employees had told the DI that McKesson was the only distributor it purchased controlled substances from, Registrant was also purchasing from ANDA and Smith Drug Company. *Id.* at 7–8.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to “dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section.” 21 U.S.C. 824(a)(4). In making the public interest determination, the CSA requires that the following factors be considered:

(1) The recommendation of the appropriate state licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing * * * controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the

manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

These factors are considered in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors, and I may give each factor the weight I deem appropriate in determining whether to revoke an existing registration. *Id.* Moreover, I am “not required to make findings as to all the factors.” *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall v. DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). The Government bears the burden of proof. 21 CFR 1316.56.

Having considered all of the factors, I conclude that the evidence pertinent to Registrant's compliance with applicable laws related to controlled substances (factor four) is dispositive and supports a finding that it has committed acts which render its registration “inconsistent with the public interest.” 21 U.S.C. 824(a)(4).

As found above, DIs conducted an audit of Registrant's handling of various controlled substances and found that it could not account for extraordinary quantities of four different formulations of hydrocodone, a schedule III controlled substance, and alprazolam 2 mg (generic for Xanax), a schedule IV controlled substance; both of these drugs are highly popular with drug abusers. See 21 CFR 1308.13(e); 13018.14(c). More specifically, approximately 150,000 dosage units of various hydrocodone drugs and 83,000 dosage units of alprazolam (96% of the amount purchased) were purchased by Registrant and could not be accounted for. In addition, 1.6 million mls of promethazine with codeine (99% of the amount purchased), another highly-abused controlled substance, was purchased by Registrant and could not be accounted for.

Pursuant to DEA regulations, all “registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.” 21 CFR 1301.71(a). Among the factors DEA considers in assessing whether a registrant maintains effective controls against theft and diversion, is “[t]he adequacy of the registrant's * * * system for monitoring the receipt * * * distribution, and disposition of controlled substances in its operations.” *Id.* 1301.71(b)(14).

Moreover, under Federal law and DEA regulations, “every registrant

under this subchapter * * *

distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance * * * received, sold, delivered, or otherwise disposed of by [it].” 21 U.S.C. 827(a)(3). See also 21 CFR 1304.03; 1304.04, 1304.21, 1304.22(c). A registrant is required to maintain these records for at least two years. *Id.* § 827(b) (“every inventory or other record required under this section * * * shall be kept and be available, for at least two years, for inspection and copying”). See also 21 CFR 1304.03 (“Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section.”); *id.* § 1304.04 (mandating that records be maintained for at least two years and be available for inspection and copying). See also *Paul H. Volkman*, 73 FR 30630, 30644 (2008) (“Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.”).

Whether the shortages are attributable to outright diversion by either pharmacy or store employees, theft, or the failure to maintain accurate records, does not matter. What is clear is that Registrant purchased several hundred thousand dosage units of highly abused controlled substances which cannot be accounted for and that it has committed acts which render its registration “inconsistent with the public interest.” 21 U.S.C. 824(a)(4). Accordingly, I will order that Registrant's registration be revoked and that any pending application be denied.¹

¹ On November 17, 2010, the Louisiana Board of Pharmacy issued an Active Suspension Notice to Registrant, which placed its Louisiana Pharmacy Permit in active suspension pending further proceedings. Thus, Registrant also no longer meets the CSA's requirement for holding a registration that it be “authorized to dispense * * * controlled substances under the laws of the State in which [it] practices.” 21 U.S.C. 823(f); see also *id.* § 824(a)(3) (authorizing revocation where registrant's “[s]tate license or registration [has been] suspended * * * by competent State authority and [registrant] is no longer authorized by State law to engage in the * * * dispensing of controlled substances”); *id.* § 802(21) (defining “[t]he term ‘practitioner’ [to] mean[] a * * * pharmacy * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which [it] practices * * * to dispense * * * a controlled substance in the course of professional practice”).

Registrant's loss of state authority thus provides an additional ground to revoke its registration. See *Bourne Pharmacy, Inc.*, 72 FR 18273, 18274 (2007). However, the State's suspension was not cited as a basis for Agency action in the Order to Show Cause (as it occurred five days after the latter was issued) and there are no pleadings establishing that the Agency subsequently gave notice of its intent to rely

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), I order that DEA Certificate of Registration FI1125651, issued to Ideal Pharmacy Care, Inc., d/b/a/Esplanade Pharmacy, be, and it hereby is, revoked.

I further order that any pending application to renew or modify this registration, be, and it hereby is, denied.

Dated: August 5, 2011.

Michele M. Leonhart,
Administrator.

[FR Doc. 2011-21060 Filed 8-17-11; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE**Drug Enforcement Administration**

[Docket No. 10-2]

Surinder Dang, M.D.; Revocation of Registration

On August 31, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Surinder Singh Dang, M.D. ("Respondent"), of Fountain Valley, California. The Order proposed the revocation of Respondent's DEA Certificate of Registration, AD6122143, as a practitioner, as well as the denial of any pending applications to renew or modify his registration "for reason that [Respondent's] continued registration[] would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f) and 824(a)(4)." ALJ Ex.1, at 1.

The Order specifically alleged that between January 2004 and July 2007, Respondent and his wife, Dr. Satinder Dang, "who also possesses a DEA registration and shares [Respondent's] registered location," ordered "more than 5,000,000 dosage units of hydrocodone" and that Respondent "failed to properly account for, secure, and otherwise handle these controlled substances." *Id.* The Order alleged that on January 17, 2006, one of Respondent's "employees removed 30,000 dosage units of controlled substances" from his registered location and "attempted to take them to her residence." *Id.* The Order further alleged that on the same day, "DEA Special Agents seized another 10,000 dosage units of controlled substances from this employee's residence." *Id.* at 1-2. Continuing, the Order alleged that on March 16, 2006, "DEA Special Agents

seized 50,000 dosage units more from this employee's residence." *Id.* at 2.

Next, the Order alleged that on March 16, 2006, DEA conducted an accountability audit of Respondent's handling of hydrocodone and that Respondent "could not account for more than 3,500,000 dosage units" that Respondent and his wife "had ordered," and that Respondent "failed to keep accurate and complete records of each controlled substance received, sold, delivered, or otherwise disposed of as required by 21 U.S.C. 827(c) and 21 CFR 1304.01 *et seq.*" *Id.* Finally, the Order alleged that when Respondent "made dispensing records," he "frequently failed to indicate whether" he or his wife "actually dispensed the controlled substances as required by 21 CFR 1304.03(b)." ¹ *Id.*

By letter of October 2, 2009, Respondent, through his counsel, requested a hearing on the allegations. ALJ Ex. 2. The matter was then assigned to an Administrative Law Judge (ALJ), who conducted a hearing on March 3, 2010, in Santa Ana, California.

At the hearing, the Government called one witness to testify and introduced documentary evidence. Respondent did not call any witnesses and introduced a single exhibit, this being a letter from the counsel for Respondent's employee R.K. stating that she intended to assert her Fifth Amendment privilege if called to testify. *See* RX 1. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law and argument.

On May 19, 2010, the ALJ issued her Recommended Decision (also ALJ). Therein, the ALJ considered the five public interest factors, *see* 21 U.S.C. 823(f), and concluded that Respondent's continued registration would be inconsistent with the public interest and recommended that his registration be revoked. ALJ at 26, 30-31.

As to the first factor—the recommendation of the appropriate State licensing board or professional disciplinary authority—the ALJ found that the California Medical Board "has not taken any formal action to limit Respondent's right to practice medicine nor has it recommended limiting his ability to prescribe controlled substances." *Id.* at 23. However, the ALJ recognized that under Agency precedent "the fact that the Medical Board of California has currently authorized * * * Respondent to practice medicine is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest." ALJ at 22-23 (citing *Patrick W. Stodola*, 74 FR 20727, 20730 (2009); *Jayam Krishna-*

Iyer, 74 FR 459, 461 (2009)). The ALJ thus concluded that "this factor does not fall in favor of revocation." *Id.* at 23. Likewise, with respect to factor three—Respondent's record of convictions for offenses relating to the manufacture, distribution, or dispensing of controlled substances—the ALJ found that Respondent has not been convicted of such an offense and that this factor also did not "fall in favor of revocation." *Id.*

The ALJ then considered factors two and four—Respondent's experience in dispensing controlled substances and his compliance with Federal, State, and local laws relating to controlled substances—together. *Id.* at 23-26. The ALJ specifically found that: (1) "Respondent authorized" his employee R.K. "to purchase large amounts of hydrocodone using his DEA registration and that of his wife"; (2) another physician who practiced at Respondent's clinic had "stated that the patient load" at the clinic "would not justify such large purchases of controlled substances"; (3) R.K. remained in Respondent's employ even after "drugs were discovered in [her] personal vehicle by the California Highway Patrol"; (4) "[l]arge bundles of cash, controlled substances, and other * * * evidence, such as receipts and money order stubs were discovered at [her] home"; and (5) "[a]fter being questioned, [R.K.] stated that she was ordering and transporting controlled substances all at the direction of the Respondent." *Id.* at 24. Based on these findings, the ALJ concluded that "either [Respondent] is personally involved in hydrocodone diversion or he is facilitating such diversion on the part of his employee." *Id.*

The ALJ further found that Respondent "prescribed Vicodin," a schedule III controlled substance, to patient B.R. "on many occasions without a thorough examination." *Id.* Based on Cal. Bus. & Prof. Code § 2242(a), which provides that it is "unprofessional conduct" to "[p]rescrib[e], dispens[e] or furnish[] dangerous drugs as defined in Section 4022 without an appropriate prior examination and a medical indication," the ALJ concluded that Respondent prescribed Vicodin to B.R. without an "appropriate prior examination." *Id.* at 25. The ALJ thus concluded that Respondent "prescribed controlled substances without establishing a bona-fide patient relationship" and violated both Federal and state law. *Id.* at 24-25.

Next, the ALJ found that Respondent did not have any inventories for the controlled substances his clinic dispensed, that he "failed to maintain accurate records of the controlled

on the State's suspension. *See* 5 U.S.C. 554(b). I therefore do not rely on it.