

Dang, 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. 2011-21062 Filed 8-17-11; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10-4]

Satinder 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 Satinder K. Dang, M.D. (Respondent), of Fountain Valley, California. The Order proposed the revocation of Respondent's DEA Certificate of Registration, AD9234446, as a practitioner, as well as the denial of any pending applications to renew or modify her 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 her husband Surinder 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 her 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.* Continuing, the Order alleged that on March 16, 2006, "DEA Special Agents seized 50,000 dosage units more from this employee's residence." *Id.*

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 her husband "had ordered"; the Order thus also alleged

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.* at 2. Finally, the Order alleged that, when Respondent "made dispensing records," she "frequently failed to indicate whether" she or her husband "actually dispensed the controlled substances as required by 21 CFR 1304.03(b)." *Id.*

By letter of October 2, 2009, Respondent, through her 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 2-3, 2010, in Santa Ana, California.

At the hearing, the Government called two witnesses to testify and introduced documentary evidence. Respondent testified on her own behalf. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law and argument.

On June 18, 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 her registration be revoked. ALJ at 29, 37-38.

As to the first factor—the recommendation of the appropriate State licensing board or professional disciplinary authority—the ALJ found "no evidence that the Medical Board of California has taken any action against the Respondent." *Id.* at 27. 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." *Id.* (citing *Patrick W. Stodola*, 74 FR 20727, 20730 (2009); *Jayam Krishna-Iyer*, 74 FR 459, 461 (2009)). The ALJ then concluded that "this factor does not fall in favor of revocation." *Id.* 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.* at 27-28.

The ALJ then considered factors two and four—Respondent's experience in dispensing controlled substances and her compliance with Federal, State, and

local laws relating to controlled substances—together. *Id.* at 28-29. The ALJ found that the record was "replete with Respondent's lack of oversight concerning the use of her controlled substances registration." *Id.* at 28. Specifically, the ALJ found that: (1) Respondent's clinic was unable to provide a biennial inventory (or an inventory of any kind); (2) "Respondent was unable to account for any of the controlled substances ordered using her DEA registration number"; and (3) Respondent had admitted that "she did not maintain a key to the controlled substance cabinet" at her clinic. *Id.* at 28-29. Further, the ALJ found that an "audit revealed that the approximately 3,870,700 dosage units of hydrocodone were unaccounted for." *Id.* at 29. Based on these findings, the ALJ concluded that "Respondent failed to maintain adequate records." *Id.*

The ALJ rejected Respondent's argument that "the DEA's findings did not distinguish between the controlled substances prescribed or dispensed to Respondent's patients versus the patients of" her husband. *Id.* The ALJ found that "the missing controlled substances were ordered under both DEA registration numbers in a haphazard manner and subsequently mixed into an incoherent *mélange*." *Id.* The ALJ reasoned that if "Respondent maintained some oversight of her controlled substances registration, then DEA would most likely be able to 'distinguish between controlled substances prescribed or dispensed to Respondent's patients versus' those of her husband." *Id.* Based on these findings, the ALJ concluded that "Respondent's circular reasoning does not absolve her [of] culpability." *Id.* The ALJ thus held that the Government's evidence under factors two and four "established prima facie grounds for revocation of * * * Respondent's DEA Certificate of Registration." *Id.*

Turning to factor five—such other conduct as may threaten the public health and safety—the ALJ explained that "[e]ven if Respondent was not directly involved in the illegal diversion of controlled substances * * * she committed acts which constitute 'conduct which may threaten the public health and safety' and which render her registration 'inconsistent with the public interest.'" *Id.* (quoting 21 U.S.C. 823(f)(5), 824(a)(4)). Noting that "[u]nder DEA precedent, a registrant who entrusts [her] registration to another person is strictly liable for the latter's misuse of [her] registration," the ALJ reasoned that "even if there had been no conspiracy amongst Respondent, her husband, and [R.K., the

office manager of the clinic where she practiced with her husband] to unlawfully distribute the drugs, [Respondent] would still be liable for the acts [R.K.] committed while being allowed to use [her] registration.” *Id.* (citations omitted).

The ALJ further found incredible Respondent’s testimony that “she was unaware of [R.K.’s] actions.” *Id.* Noting Respondent’s “admitted lack of supervision” over R.K.—including that Respondent would “tell [R.K.] which drug she wanted to dispense,” R.K. “would retrieve the controlled substances from the steel cabinet and update the logbook,” and “only [R.K.] had a key to the controlled substances cabinet”—placed R.K. in a “position where she could take advantage of the lax security” of Respondent’s controlled substances, the ALJ rejected Respondent’s contention that these were “minor record-keeping violations” and held that she was “responsible for enabling [R.K.’s] acts of unlawful possession and distribution of the controlled substances that [R.K.] obtained under Respondent’s registration.” *Id.* (citing *Harrell E. Robinson, M.D.*, 74 FR 61370, 61376–77 (2010)). The ALJ also found that Respondent is “still engaged in an ongoing working relationship with [R.K.],” *id.* at 32, and held that “[a] practitioner’s failure to properly supervise patients or staff to prevent them from personally abusing controlled substances or selling them to others constitutes conduct ‘inconsistent with the public interest’ and can support * * * the revocation of an existing registration.” *Id.* at 33 (citing *Jeri Hassman, M.D.*, 75 FR 8194, 8227 (2010); *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006)).

Noting that Respondent blamed her husband and R.K. for her misconduct, the ALJ further found that “Respondent’s acceptance of responsibility has been minimal” and “weighs heavily against her continuing registration.” *Id.* at 35. The ALJ further held that Respondent’s “lack of cooperation with the DEA investigation nominally weighs against her continued registration.” *Id.* at 36–37.

The ALJ also found that “the fact that [Respondent] still works alongside [R.K.] is an aggravating factor.” *Id.* at 35. While noting Respondent had offered to file quarterly reports of her prescriptions with the Agency, the ALJ found that “Respondent’s careless use of her DEA Certificate of Registration coupled with her lack of assurances that she will no longer enable others such as [R.K.] and her husband to abuse her controlled substances registration

weighs heavily against her continuing registration.” *Id.* at 37. The ALJ therefore recommended that “Respondent’s DEA Certificate of Registration be revoked.” *Id.* at 38.

On August 9, 2010, Respondent filed Exceptions to the ALJ’s Decision, and on August 18, the ALJ forwarded the record to me for Final Agency Action. On September 10, 2010, the Government filed a motion with my Office to accept its response to Respondent’s Exceptions. In its motion, the Government stated that Respondent’s counsel had consented to its filing. Accordingly, by this Order I grant the Government’s motion.

Having considered the entire record, I adopt the ALJ findings of fact and conclusions of law except as expressly noted herein. I further adopt the ALJ’s ultimate conclusion that Respondent’s “continued registration is not in the public interest,” ALJ at 38, and her recommendation that her registration be revoked. As ultimate factfinder, I make the following findings:

Findings

Respondent is the holder of DEA Certificate of Registration, AD9234446, which authorizes her to dispense controlled substances in schedules II through V, as a practitioner, at the registered location of 17150 Euclid #200, Fountain Valley, California. GX 1. While Respondent’s registration was to expire on June 30, 2007, *id.*, on June 4, 2007, Respondent filed an application to renew her registration. GX 2. Accordingly, her registration remains in effect pending the issuance of this Decision and Final Order. 5 U.S.C. 558(c); *see also* ALJ Ex. 3, at 2 (Prehearing Order; Stipulations).

Respondent currently holds a medical license issued by the Medical Board of California. Moreover, the Board has not taken any formal action to limit her ability to practice medicine or to prescribe controlled substances. ALJ Ex. 3, at 3. Also, Respondent has not been convicted of an offense related to the manufacture, distribution, or dispensing of controlled substances. *Id.*

Respondent is married to Surinder Dang, M.D.¹ He and Respondent practice medicine at Complete Medical Care, Inc. (“CMC”). Tr. 188–189; GX 6, at 20. Their son, Sameer Dang, also works in the CMC office. Tr. 58, 188. At all relevant times (including through the date of the hearing), CMC’s office

¹ Dr. Surinder Dang holds DEA Certificate of Registration AD6122143; he is registered at the same address as Respondent. ALJ Ex. 3, at 2, GX 2 at 2.

manager was Ms. Rani K. (R.K.).² *Id.* at 190–91, 194–95, 203–04.

In November 2005, a Diversion Group Supervisor (GS) in DEA’s Riverside Diversion Group reviewed ARCOS³ records which showed that large amounts of controlled substances, including hydrocodone,⁴ were being ordered under the DEA registration numbers of both Respondent and her husband.⁵ Tr. 30–32; GXs 3 & 4. Upon reviewing the ARCOS data, the GS contacted several of the firms that were distributing controlled substances to Respondent. *See, e.g.*, GX 6, at 7. At several points throughout the investigation, these firms provided the GS with copies of various documents, including sales records, invoices, statements of account, delivery information, applications for credit, and correspondence. *See generally* GX 5 (records from Moore Medical, L.L.C.),⁶ GX 6 (record from Henry Schein, Inc.), GX 9 (records from ParMed Pharmaceuticals, Inc.).

The majority of the controlled substances ordered under Respondent’s DEA registration were obtained from Anda Pharmaceuticals. GX 3; Tr. 130, 139. The GS obtained purchase records from Anda showing hydrocodone and other controlled substances purchases by both Respondent and her husband between 2000 and 2005. GX 8; Tr. 47–49. However, there is no evidence that Respondent ever personally ordered these controlled substances. Tr. 140.

CMC also ordered controlled substances, primarily hydrocodone, from another drug distributor, Henry Schein, Inc. GX 6; Tr. 44. The Schein records show that the orders were placed under Respondent’s husband’s name, but a number of the invoices note Respondent’s name as well as her husband’s. GX 6, at 8–9, 11, 14–15, 17–18, 29. R.K.’s name was also listed as

² In various documents R.K.’s first name was spelled as both Rani and Roni. *Compare* GX 5, at 7, with GX 6, at 1, 5, 9, 14–15, 18, 29; *see also* GX 10 at 1.

³ Pursuant to 21 CFR 1304.33(c), manufacturers and distributors of various controlled substances including schedule III narcotics are required to report their distributions of controlled substances to DEA through the Automated Records and Consolidated Orders System (ARCOS). *See also* Tr. 33.

⁴ As a combination product, hydrocodone is a schedule III controlled substance. 21 CFR 1308.13(e)(1)(iv).

⁵ The ARCOS system reports the registration number used, but not necessarily the person who actually ordered the drugs. Tr. 114–16.

⁶ Moore Medical Supply reported to DEA that CMC ordered excessive amounts of hydrocodone. Tr. 32–34; GX 5. The order to Moore was placed under Respondent’s husband’s DEA registration and R.K.’s name appears on a fax sheet sent to Moore Medical and related to CMC’s account number. GX 5, at 7; Tr. 131.

the contact person for the Henry Schein account. Tr. 132–34.

In a letter dated November 7, 2005, Respondent's husband explained to Henry Schein that CMC would begin ordering controlled substances so that CMC's physicians could dispense medications directly to CMC's patients. GX 7; Tr. 46. This letter listed the CMC physicians as Surinder Dang, M.D.; Satinder Dang, M.D.; Robert Belanger, D.O.; Huey Lin, M.D.; and Davinder Singh, M.D. GX 7. The letter also stated: "We dispense medications to our patients only. Our practice has been growing." *Id.* However, none of the records obtained in the investigation show that controlled substances were ordered from Schein under the registrations of any of the doctors besides those of Respondent and her husband. GX 6, at 7; Tr. 176–79.

The DEA registration numbers of both Respondent and her husband were used to order controlled substances from Darby Medical Supply and ParMed Pharmaceuticals. GX 16; GX 9, 11; Tr. 51, 61–62. The Darby records show that Respondent ordered hydrocodone fourteen times. GX 16, at 1, 5, 7, 11. The ParMed records show that between December 29, 2005 and January 4, 2006, 88,800 dosage units of hydrocodone were ordered under Respondent's registration. GX 9, at 2. At one point, D.L., ParMed's Regulatory Affairs officer, reported to the GS that CMC's orders were "excessive and suspicious"; D.L. also identified R.K. as the point of contact for the clinic and that R.K. had opened the CMC accounts. Tr. 51–53.

According to ARCOS records, while in 2004, Respondent purchased 157,100 dosage units of hydrocodone, in 2005, she purchased 2,272,800 dosage units. GX 3, at 2–13. ARCOS data further showed that in 2005, Respondent and her husband had ordered a combined total of 3,626,400 tablets of hydrocodone. GX 3 at 13; GX 4, at 6; *see also* Tr. 93–94 (GS's testimony that between January 1, 2005 and March 16, 2006, Respondent and her husband purchased approximately 4 million tablets of hydrocodone).⁷

Throughout the investigations, several of the firms also provided the GS with information regarding when various deliveries were to be made to Respondent's clinic. On December 14, 2005, the GS, who had received information from two different distributors (Henry Schein and Moore Medical) that controlled substances

deliveries were to be made that day, conducted surveillance at the [Dangs'] clinic from approximately 9:00 a.m. until 6:00 p.m. Tr. 43, 67–68, 75. During the surveillance, the GS observed both deliveries and noted that "approximately no more than a dozen" people entered the clinic that day. *Id.* at 75.

On January 13, 2006, the GS conducted a second surveillance from approximately 9:00 a.m. until 3 p.m. *Id.* at 76–77. During the surveillance, the GS saw R.K. "tak[ing] boxes from the office and plac[ing] them in the trunk of her * * * SUV." *Id.* at 77.

On January 17, 2006, the GS, who had received notice of a controlled substance delivery from another distributor (ParMed Pharmaceuticals, Inc.), conducted another full-day surveillance. *Id.* at 77–78. Once again, Investigators observed R.K. "place numerous boxes in her vehicle that had been delivered to the clinic" and "put them in the back of her * * * SUV." *Id.* at 78. The GS observed R.K. drive away and notified the California Highway Patrol (CHP). *Id.* at 78, 80, 147–48. After observing R.K., who was driving forty miles per hour, operate her vehicle within five feet of the vehicle in front of her, the CHP officer conducted a traffic stop. *Id.* at 78; GX 10, at 2.

As he approached R.K., the CHP officer observed "cardboard boxes that were taped shut in the rear cargo area." GX 10, at 2. The CHP officer advised R.K. of the reason for the stop and requested her license, registration, and insurance. *Id.* He then asked R.K. "what the boxes were." *Id.* R.K. stated that the boxes held Vicodin, a schedule III controlled substance which contains hydrocodone. *Id.*; ALJ Ex. 3, at 1; 21 CFR 1308.13(e)(iv). When the CHP officer asked R.K. if she was a doctor, she stated that "she was the president of a medical facility and that she was going to give the Vicodin to the doctor at her facility." GX 10, at 2. The CHP Officer asked R.K. a second time if she was a doctor; R.K. again said "no" and became "extremely nervous." *Id.*

After the CHP Officer asked R.K. to step out of her car, he asked "why she had cases of Vicodin." *Id.* R.K. answered that she ran a medical office and handed him a business card listing her name and her position as "president." *Id.* R.K. further stated that "she received a delivery of Vicodin from a delivery company at about 1100 hours and that she needed to give it to" Respondent. *Id.* When the Officer asked R.K. if the Vicodin had been delivered "to her car or to her office," R.K. stated that it had been delivered to the office. *Id.* When the Officer asked if her office

had a locker in which to store the Vicodin, R.K. answered "yes," but that she had to personally give the drugs to Respondent. *Id.*

The CHP Officer then asked how the Vicodin had ended up in her vehicle; R.K. stated that "she [had] carried the boxes to her vehicle around noon time and left them there," and that she had stayed in her office until about 5 p.m., at which point "she left * * * to get something to eat." *Id.* When the Officer told R.K. that he was "concerned that she was in possession of so much of a controlled substance," she said she would return it to the office. *Id.* R.K. then stated that Respondent was "doing a procedure at an unknown hospital and he would be returning at an unknown time to the office" and that she would then give him the Vicodin. *Id.*

The CHP Officer then "asked R.K. to open the boxes" to confirm that they contained Vicodin. *Id.* R.K. opened six boxes containing a total of 70 bottles of hydrocodone bitartrate/acetaminophen (hereinafter, hydrocodone/apap or hydrocodone). *Id.* at 2–3. Each of the bottles contained between 100 and 500 tablets (for a total of "approximately 31,000 tablets") in 7.5/500 mg, 10/500 mg, and 10/325 mg strengths. *Id.* The Officer then seized the Vicodin and gave R.K. a receipt for it. *Id.* at 3. After giving R.K. a citation, the officer allowed her to leave. *Id.*

The CHP Officer then contacted a DEA Task Force Officer (TFO) and arranged to transfer custody of the drugs to DEA; upon the TFO's arrival at the Officer's location, the drugs were transferred to the TFO. *Id.* The TFO gave the CHP Officer a receipt which confirms the figures in the latter's report.⁸ *Id.* at 6.

R.K. then drove to her residence in Anaheim Hills; Investigators followed her there in order to question her about the drugs that were found in her vehicle. Tr. 82. R.K. told the Investigators that she had taken the hydrocodone with her for safekeeping because Respondent was out of the office; she also maintained that she intended to return them to the office after she ate. *Id.* at 83. While R.K. initially claimed that this was the first time she had done this, upon being confronted with the fact that Investigators had on another occasion observed her placing boxes in her vehicle, R.K. admitted that this was the second time she had done so. *Id.*

⁸ More specifically, there were 14 bottles of 500 count of hydrocodone/apap 7.5/500 mg; 10 bottles of 500 count hydrocodone/apap 10/500 mg; 36 bottles of 500 count hydrocodone/apap 10/325 mg; and 10 bottles of 100 count hydrocodone/apap 10/500 mg. GX 10, at 6.

⁷ The GS stated that he analyzed ARCOS data, distributors' sales records, audit inventories, patient files and dispensing logs when creating GX 15. Tr. 92–97.

R.K. stated that there were about five physicians who worked at Respondent's clinic, that they dispensed the pills in 30- and 60-count bottles, and that the clinic had approximately twenty to twenty-five patients per day. *Id.* at 84. R.K. further said that she used her personal credit card to purchase drugs from wholesalers and that Respondent would reimburse her. *Id.*

The Investigators then asked R.K. if she would consent to a search of her residence; she agreed. *Id.* According to the GS, the Investigators found approximately \$69,500 in cash in an upstairs closet, a "quantity of hydrocodone and lorazepam in the house" (2000 lorazepam tablets and 1400 hydrocodone tablets), "money order receipts," and receipts of "payments made to the credit card companies by [R.K.]." *Id.* To explain the cash found at her residence, R.K. claimed the sum was a combination of money received from the sale of a house in India and a home-based business she had previously run. *Id.* at 85–86.

On February 24, 2006, Respondent's husband wrote a letter to CHP requesting the return of the hydrocodone which had been seized during the traffic stop of R.K. Tr. 88–89; GX 12. The letter asserted that R.K. was the clinic's "office manager," and had "informed CHP that the property was not hers, and instead belonged to her employer, Complete Medical Care Inc." GX 12.

On March 16, 2006, DEA executed search warrants at both Respondent's clinic and R.K.'s residence. Tr. 90, 104. At the clinic, the Investigators took an inventory of the controlled substances on hand and found 48,000 tablets of hydrocodone, which they seized; the Investigators also seized CMC's controlled substance purchasing records and dispensing log. Tr. at 90, 95. Later that day, Investigators went to Respondent's residence and sought consent to search her house. Tr. 103. Respondent declined to provide consent and refused to talk with Investigators without an attorney present. *Id.*

R.K. was present during the search of her residence and was interviewed. *Id.* at 104. R.K. stated that since January 17, 2006, she had stopped purchasing the drugs on her own, and that the drugs were being purchased by Respondent's husband, Dr. Surinder Dang. *Id.* at 105. R.K. stated that Respondent's husband was the clinic's "primary dispenser" of the drugs and that she "dispensed drugs to the patients under the direction of * * * Dr. Surinder Dang." *Id.*

On March 16, 2006, the Diversion Investigator (DI) interviewed several

CMC employees, including A.N.,⁹ C.G.,¹⁰ L.Y.,¹¹ and S.B.¹² In April 2006, the GS interviewed Dr. B., a physician who had worked at CMC on a part-time basis since approximately 2004. *Id.* 109–110. Dr. B. also worked at a facility for the local county government, but he saw some of his patients at CMC. *Id.* at 110. Dr. B. stated that while he worked at CMC, he rarely, if ever, prescribed or dispensed controlled substances to his patients. *Id.* at 111. He also stated that the patient load at CMC did not justify the quantities of controlled substances that were being purchased by the clinic. *Id.* at 114.

Using the records seized during the search of Respondent's clinic and its patient files, ARCOS data, and information provided by several of the distributors,¹³ the GS conducted an audit of the hydrocodone ordered under both Respondent's and her husband's registrations between January 1, 2005 and March 16, 2006. Tr. 93–96, 67; GX 15. Because CMC did not maintain records of their inventory (notwithstanding Federal law requiring

⁹ A.N. stated that Respondent, her husband, and R.K. handled drug deliveries when they came into CMC. *Id.* at 238–39. A.N. further stated that both Respondent and her husband kept records of dispensed drugs in the patient files and dispensing logs; she identified the writing in the patient log as R.K.'s. *Id.* at 239–40.

¹⁰ The transcript notes the coworker's initials as C.G.; however, other documents suggest that her initials are K.G. See Resp. Brief at 8. C.G. stated that both R.K. and Respondent's husband ordered the drugs for CMC. Tr. 241, 249–250. R.K. usually accepted deliveries of drug orders; however, sometimes C.G. would sign for the delivery but not open the boxes. *Id.* at 241–42. C.G. further stated that she witnessed R.K. writing in the dispensing log the day before the search warrant was executed and heard R.K. comment that CMC's drug procedures had changed. *Id.* at 242.

¹¹ According to L.Y., the clinic saw twenty to twenty-five patients per day. *Id.* at 244. L.Y. also stated that R.K. handled the drugs once they arrived. *Id.* at 243. When shown the dispensing log, L.Y. identified the handwriting as belonging to R.K. *Id.* at 243–44. She further stated that Respondent only wrote prescriptions. *Id.* at 250.

¹² S.B. stated that R.K. and Respondent's husband handled the drugs that were dispensed directly to patients and that R.K. handled the drug inventory and payment for the drugs that were ordered. *Id.* at 246. S.B. also stated that R.K. handled the dispensing log. *Id.* at 247. S.B. further stated that CMC had approximately twenty-five patients per day, of whom ten saw Respondent. *Id.* According to S.B., both Sameer Dang and R.K. paid for the drugs. *Id.* She also stated that R.K. had access to the controlled substances received at the CMC office. *Id.* at 248.

¹³ Moore Medical provided DEA with sales records under Respondent's registration for hydrocodone from late 2005 to early 2006. Tr. 34, 43; GX 5. ANDA provided DEA with a spreadsheet listing all sales under the registrations of Respondent and her husband from May 2000 through mid-October 2005. Tr. 47–49; GX 8. DEA also acquired sales records and a sales summary from ParMed which show Respondent's purchases of controlled substances between November 28, 2005 and January 4, 2006. Tr. 51–52; GX 9.

them to do so, see 21 U.S.C. 827(a) & (b)), the GS chose January 1, 2005 as the starting date and assumed that no controlled substances were then on hand; for the closing inventory, the GS used the inventory taken (48,000 tablets) when the search warrant was executed.¹⁴ Tr. 92–93, 95; GX 15. To this latter figure, the GS added the hydrocodone that was seized during the January 17, 2006 traffic stop of R.K. (31,000 tablets) and the 1,200 tablets¹⁵ found during the search of R.K.'s residence which occurred later that day. Tr. 95; GX 12, 15.

Using both the ARCOS data and distributor invoices, the GS determined that 4,037,900 tablets of hydrocodone had been ordered during the audit period. Tr. 94; GX 15. The clinic's dispensing logs, which did not identify which doctor had authorized the various dispensings, see GX 14, showed that only 12,000 tablets had been dispensed;¹⁶ in addition, the GS reviewed the clinic's patient files and credited another 75,000 tablets as having been dispensed.¹⁷ Tr. 95–96; GX 15. Accordingly, CMC could only account for approximately 167,000 tablets of hydrocodone.¹⁸ Tr. 96–97; GX 15. While the DI combined the purchases of Respondent and her husband, the ARCOS data and distributor invoices did list whose registration was used to place the various orders. See, e.g., GXs 3 & 4. This evidence shows that in 2005 alone, 2,272,800 dosage units of hydrocodone were ordered under Respondent's registration. Accordingly, Respondent still could not account for more than two million dosage units.¹⁹ GX 3, at 13.

Respondent testified that she had no knowledge that her "DEA registration

¹⁴ If any controlled substances were in fact on hand on the starting date of the audit period, assigning a zero starting inventory would reduce the size of any shortage.

¹⁵ I acknowledge that this figure differs from the quantity of 1,400 tablets which, according to the GS's testimony, was found in R.K.'s house. The difference, however, is inconsequential given the result of the audit.

¹⁶ The dispensing logs also did not contain the name of the dispensing physician, the initials of the person dispensing the drugs, and the patient's address as required by 21 CFR 1304.22(c). Tr. 90; see also GX 14. Moreover, while there were some dispensing logs from 2003, the remaining logs only covered the period from February 28 through March 15, 2006. See GX 14.

¹⁷ The GS credited CMC with dispensing a total of 87,000 hydrocodone tablets; this calculation counted the prescriptions issued by Respondent or her husband, because the prescriptions may have been filled in the office. Tr. 100; GX 15.

¹⁸ Neither Respondent nor her husband had reported to DEA any thefts, losses, or destructions of controlled substances. Tr. 99–101.

¹⁹ This calculation gives Respondent credit for all of the 167,000 tablets for which the GS could account.

number was being used to order large quantities of hydrocodone that were being delivered to CMC." Tr. 192. She asserted that she did not order any controlled substances between 2002 and March 16, 2006, and that she did not order any controlled substances after that period. *Id.* at 195–96. Specifically, she testified that she did not order Lorazepam in October 2006. *Id.*

Respondent testified that while during this time period, she was aware that her husband was ordering drugs for his pain management practice, she did not know how much he was ordering. *Id.* at 201. Respondent stated that she had no knowledge of the controlled substances being delivered to CMC during this time period; while she admitted to having seen boxes being delivered to the clinic, she claimed to not know what they contained. *Id.* 197–198. Respondent further stated that R.K. would open the boxes after they were delivered. *Id.* at 200.

Respondent further testified that she was unaware that R.K. had taken drugs from CMC to her residence until learning of it through these proceedings; she also stated that she was not sure if her husband had instructed R.K. regarding taking drugs to her residence. *Id.* at 204–205. However, the ALJ did not find credible Respondent's testimony that she was unaware of R.K.'s activities. ALJ at 30.

Regarding the controlled substance drug storage area, Respondent stated that she had "no idea" how the drugs were organized. Tr. 198–99. Respondent testified that she did not pay attention to what was in that storage area, but then stated there was a basic cabinet that was locked at night and that she did not have a key. *Id.* at 200–01. According to Respondent, the key was either kept by R.K. or in a place where her husband could find it; Respondent also did not know if the storage cabinet was locked during the day. *Id.* at 234.

While Respondent testified on direct examination that she had not dispensed drugs at CMC, on cross-examination, she stated "I don't recall. I might have dispensed but I dispensed rarely." *Id.* at 195. Respondent then admitted dispensing, stating "maybe I might have given [hydrocodone] once or twice to my patients only." *Id.* She stated that other people had ordered these drugs that she dispensed. *Id.* at 229. On the occasions that she did dispense, Respondent asked R.K. for the drug. *Id.* at 230. R.K. would retrieve the controlled substances from the cabinet and give them to Respondent to hand to the patient. *Id.* In these instances, R.K. would record the dispensed controlled

substances in a "separate log." *Id.* at 228.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that "[a] registration pursuant to section 823 of this title 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 [her] 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 in the case of a practitioner, Congress directed 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).

"[T]hese factors are considered in the disjunctive." *Robert A. Leslie*, 68 FR 15227, 15230 (2003). I may rely on any one factor, or a combination of factors, and may give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application. *Id.* Moreover, I am "not required to make findings as to all of the factors." *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005) (citing *Morall v. DEA*, 412 F.3d 165, 173–74 (DC Cir. 2005)).

With respect to a practitioner's registration, the Government bears the burden of proving by a preponderance of the evidence that the continuation of a registration would be inconsistent with the public interest. 21 CFR 1301.44(d). However, where the Government satisfies its *prima facie* burden by showing that a registrant has committed acts which are inconsistent with the public interest, the burden then shifts to the applicant to demonstrate why he can be entrusted with a registration. *Medicine Shoppe-Jonesboro*, 73 FR 364, 380 (2008).

In this matter, having considered the entire record and all of the factors, I agree with the ALJ's conclusions that the Government's evidence under factors two, four, and five makes out a *prima facie* that Respondent has committed acts which render her

registration inconsistent with the public interest.²⁰ ALJ at 29. I further agree with the ALJ's conclusion that Respondent has not accepted responsibility for her misconduct and has thus not rebutted the Government's *prima facie* case.

Factors Two, Four, and Five—Respondent's Experience in Dispensing Controlled Substances, Compliance With Applicable Laws Related to Controlled Substances, and Other Conduct Which May Threaten Public Health and Safety

The Government's case implicates each of these factors. As found above, during an approximately fifteen-month period, more than four million tablets of highly abused combination drugs containing hydrocodone, a schedule III controlled substance, were purchased by R.K., Respondent's office manager, using her and her husband's DEA registrations, approximately 2.3 million of which were ordered under her registration during 2005 alone. When DEA Investigators audited Respondent's and her husband's handling of the hydrocodone, they could account for only 167,000 tablets, leaving Respondent with over two million

²⁰I acknowledge that Respondent holds a valid medical license from the State of California. Moreover, the State Board has not taken action against her, nor made any recommendation in this matter (factor one). ALJ at 27.

Be that as it may, in enacting the CSA, Congress vested this Agency with "a separate oversight responsibility [apart from that which exists in state authorities] with respect to the handling of controlled substances." *Mortimer B. Levin*, 55 FR 8209, 8210 (1990). DEA has therefore long recognized that it has "a statutory obligation to make its independent determination as to whether the [continuation] of [a registration] would be in the public interest." *Id.* Accordingly, "a State's failure to take action against a registrant's medical license is not dispositive in determining whether the continuation of a registration is in the public interest." *Jayam Krishna-Iyer*, 74 FR 459, 461 (2009); see also *Levin*, 55 FR at 8210 (holding that practitioner's reinstatement by state board "is not dispositive" in public interest inquiry). Thus, that the Medical Board of California has taken no action with respect to Respondent's medical license is not dispositive in determining whether her continued registration is consistent with the public interest.

There is also no evidence that Respondent has been convicted of an offense related to the manufacture, distribution, or dispensing of controlled substances under either Federal or state law (factor three). ALJ at 27–28. However, while a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of (or even prosecuted for) such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry. *Krishna-Iyer*, 74 FR at 461; *Edmund Chein*, 72 FR 6580, 6593 n.22 (2007). Accordingly, that Respondent has not been convicted of an offense related to the distribution or dispensing of controlled substances is not dispositive of whether the continuation of her registration is consistent with the public interest.

tablets unaccounted for. In addition, law enforcement authorities found that R.K. had large quantities of hydrocodone in her possession during both a traffic stop and a search of her residence; Investigators also found a large quantity of cash in R.K.'s home.

At a minimum, the evidence clearly shows that Respondent violated the CSA's various recordkeeping provisions. Under Federal law, as soon as Respondent "first engage[d] in the * * * distribution[] or dispensing of controlled substances, and every second year thereafter," she was required "to make a complete and accurate record of all stocks thereof on hand." 21 U.S.C. 827(a)(1) (emphasis added); see also 21 CFR 1304.03(a)-(b), 1304.04(a), (g), 1304.11. However, as found above, during the audit, Respondent could not produce an inventory record for any of the controlled substances that were purchased under her registration.

Under Federal law, Respondent was also required to "maintain, on a current basis, a complete and accurate record of each such substance * * * received, sold, delivered, or otherwise disposed of by [her]." 21 U.S.C. 827(a)(3) (emphasis added). With respect to a practitioner who engages in dispensing, DEA regulations require that the record include "the number of units or volume of such finished form dispensed, * * * the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed and the written or typewritten name or initials of the individual who dispensed * * * the substance on behalf of the dispenser." 21 CFR 1304.22(c); see also *id.*; 21 CFR 1304.03(a)-(b), 1304.04(a), (g), 1304.21. However, as found above, while large quantities of controlled substances were purchased under her registration throughout 2004 and 2005, Respondent had no dispensing logs for these years and the 2006 logs covered only from February 28 through March 15. Moreover, the logs that were maintained lacked required information such as the name of the dispensing doctor, the initials/name of the person doing the dispensing, and the address of the patient. GX 14.

Recordkeeping is one of the central features of the CSA's closed system of distribution. See *Paul H. Volkman*, 73 FR 30630, 30644 (2008), *pet. for rev. denied* 567 F.3d 215, 224 (6th Cir. 2009). "[A] registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances." *Id.* Given that millions of dosage units of a highly abused controlled substance that were ordered under Respondent's

registration cannot be accounted for, her failure to comply with the CSA's recordkeeping requirements is egregious. This finding provides reason alone to conclude (with respect to factors two and four) that her continued registration "is inconsistent with the public interest." 21 U.S.C. 823(f); see also *Volkman*, 73 FR at 30644 (holding that recordkeeping violations alone supported denial of practitioner's application).

In her Exceptions to the ALJ's decision, Respondent argues that "she had no knowledge that her DEA Registration was being used by her husband or [R.K.] to order controlled substances" until DEA executed the search warrant on March 16, 2006. However, DEA has long held that a registrant is strictly liable for the misuse of her registration by a person to whom she entrusts her registration. See also *Harrell E. Robinson*, 74 FR 61370, 61377 (2009); *Paul H. Volkman*, 73 FR 30630, 30644 n.42 (2008); *Rose Mary Jacinta Lewis*, 72 FR 4035, 4041 (2007) (citing *Anthony L. Capelli*, 59 FR 42288 (1994)); *Leonard Merkow*, 60 FR 22075, 22076 (1995); *Capelli*, 59 FR at 49288. The record clearly supports the conclusion that Respondent entrusted her registration number to R.K. Thus, even if it were the case that Respondent was unaware of R.K.'s illegal activities, she is still strictly liable for R.K.'s misuse of her registration and her failure to properly monitor how her registration was being used. See *Jacinta Lewis*, 72 FR at 4041-42; *Robinson*, 74 FR at 61377; *Volkman*, 73 FR at 30644 n.42; *Capelli*, 59 FR at 49288.

Contrary to Respondent's understanding, the purpose of this proceeding is to protect the public interest, and in determining whether a registrant has committed acts which render her registration "inconsistent with the public interest," 21 U.S.C. 824(a)(4), the standards of *mens rea* for imposing criminal liability are not controlling. Accordingly, the Government is not required to show that Respondent had knowledge that her DEA Registration was being used by her husband or R.K. to order controlled substances.

In any event, the ALJ did not find credible Respondent's testimony that she was unaware of R.K.'s activities. ALJ at 30. I agree. Given the duration and scope of R.K.'s activities, Respondent's denial of knowledge is implausible.

In her Exceptions, Respondent also argues that the ALJ's decision "fails to distinguish between the drugs ordered under Respondent's DEA Registration and the drugs ordered under her husband's." Res. Exc. at 22. This is true.

However, as ultimate factfinder, I have reviewed the evidence and found that the ARCOS data shows that in 2005 alone, more than 2.27 million dosage units of hydrocodone were ordered under Respondent's registration, and that at most, 167,000 dosage units can be accounted for. Thus, Respondent is responsible for more than two million dosage units that cannot be accounted for and were likely diverted.

Respondent's misconduct thus clearly threatened public health and safety. See 21 U.S.C. § 823(f)(5). Moreover, the scope of the diversion is egregious. I therefore conclude that the Government has satisfied its *prima facie* burden of showing that Respondent has committed acts which render her registration is "inconsistent with the public interest." 21 U.S.C. 824(a)(4); 823(f).

Sanction

Under Agency precedent, where the Government has made out a *prima facie* case that a registrant has committed acts which render her "registration inconsistent with the public interest," she must "present[] sufficient mitigating evidence to assure the Administrator that [she] can be entrusted with the responsibility carried by such a registration." *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988)). "Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs., Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), this Agency has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [her] actions and demonstrate that [she] will not engage in future misconduct." *Medicine Shoppe-Jonesborough*, 73 FR at 387.

During her testimony, Respondent continued to deny that she was responsible for the unaccounted-for hydrocodone and blamed her husband and R.K. Furthermore, the ALJ found incredible Respondent's denial that she had knowledge of R.K.'s illegal activities. DEA has repeatedly held that a registrant's lack of candor is a highly relevant consideration in determining the appropriate sanction. See *Hoxie v. DEA*, 419 F.3d 477, 483 (6th Cir. 2005); *Robert F. Hunt*, 75 FR 49995, 50004 (2010); *Rosemary Jacinta Lewis*, 72 FR 4035, 4042 (2007). Respondent's lack of candor further supports the revocation of her registration.

Given the scope of the diversion which likely occurred here and what the ALJ characterized as Respondent's minimal acceptance of responsibility

(which was limited to the statements of counsel in a post-hearing brief and which do not constitute evidence, see *INS v. Phinpathya*, 464 U.S. 183, 186 n.6 (1984)), I conclude that none of the “favorable facts” cited by the ALJ provide any reason to impose a sanction less than revocation. *Jayam Krishna-Iyer*, 74 FR 459, 463 (2009). Indeed, none of Respondent’s proposed remedial measures mitigate the egregious harm Respondent has caused to public health and safety.

I therefore conclude that it would be inconsistent with the public interest to grant her even a restricted registration. Accordingly, I will order that Respondent’s registration be revoked and that any pending application 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, AD9234446, issued to Satinder K. Dang, M.D., be, and it hereby is, revoked. I further order that any pending application of Satinder K. Dang, M.D., to renew or modify her registration be, and it hereby is, denied. This Order is effective September 22, 2011.

Dated: August 9, 2011.

Michele M. Leonhart,
Administrator.

[FR Doc. 2011–21065 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Roots Pharmaceuticals, Inc.; Revocation of Registration

On September 9, 2010, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Roots Pharmaceuticals, Inc. (Registrant), of American Fork, Utah. The Show Cause Order proposed the revocation of Registrant’s DEA Certificate of Registration BR9610571, which authorizes it to dispense controlled substances as a retail pharmacy, on the ground that Registrant’s state pharmacy and controlled substance licenses had expired on September 30, 2009, and that it therefore lacks authority under the laws of the State in which it is registered with DEA to dispense controlled substances. Show Cause Order at 1 (citing 21 U.S.C. 823(f) and 824(a)(3)). The Show Cause Order 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 consequence for failing to do either. *Id.* at 2.

The Government’s initial attempt to serve Registrant by certified mail was unsuccessful. Thereafter, as evidenced by the signed return receipt card, on January 14, 2011, the Government accomplished service by mailing the Show Cause Order to Registrant’s Registered Agent. On January 11, 2011, the Government also sent an electronic version of the Show Cause Order to Registrant’s Registered Agent at the e-mail address he had previously provided to the Agency. However, since the date of service of the Show Cause Order, no person has requested a hearing, or submitted a written statement in lieu of a hearing, on behalf of Registrant. Because thirty days have now passed since service of the Show Cause Order, I find that Registrant has waived its right to request a hearing or to submit a written statement in lieu of a hearing. See 21 CFR 1301.43(a), (c), and (d). I therefore issue this Decision and Final Order without a hearing based on relevant evidence contained in the record submitted by the Government. *Id.* § 1301.43(e).

Findings

Registrant is the holder of DEA Certificate of Registration BR9610571, which authorizes it to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered location of 12 W 100N, Suite 201B, American Fork, Utah. GX A. Registrant’s registration does not expire until April 30, 2012. *Id.*

According to a Pharmacy Licensing Specialist with the State of Utah, Department of Commerce, Division of Occupational and Professional Licensing, Registrant’s Utah Pharmacy License and Utah Controlled Substance Dispensing License expired on September 30, 2009. GX B. Registrant did not renew either license. *Id.*

Discussion

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 a 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.* § 823(f) (The Attorney General shall

register practitioners * * * to dispense * * * controlled substances * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which [it] practices.”). As these provisions make plain, possessing authority under state law to handle controlled substances is an essential condition for obtaining and maintaining a DEA registration.

The CSA further authorizes the Agency to revoke a registration “upon a finding that the registrant * * * has had [its] State license or registration suspended [or] revoked * * * and is no longer authorized by State law to engage in the * * * distribution [or] dispensing of controlled substances.” 21 U.S.C. 824(a)(3). Moreover, because holding state authority is a statutory requirement for registration as a practitioner, see 21 U.S.C. 802(21) and 823(f), DEA has held that revocation is warranted even when a registrant has merely allowed his state licenses to expire. *James Stephen Ferguson*, 75 FR 49994, 49995 (2010); *Mark L. Beck*, 64 FR 40899, 40900 (1999). See also *Anne Lazar Thorn*, 62 FR 12847, 12848 (1997) (“the controlling question is not whether a practitioner’s license to practice medicine in the state is suspended or revoked; rather, it is whether the Respondent is currently authorized to handle controlled substances”).

As found above, Registrant allowed its state pharmacy and controlled substance licenses to expire, and thus, it no longer holds authority under Utah law to dispense controlled substances. See Utah Code Ann. §§ 58–17b–302(1); 58–37–6(2)(a)(i). Accordingly, Registrant no longer satisfies the CSA’s requirement that it be currently “authorized to dispense controlled substances” under Utah law. 21 U.S.C. 823(f). Accordingly, its DEA registration will be revoked. *Id.* § 824(a)(3).

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a)(3), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BR9610571, issued to Roots Pharmaceuticals, Inc., be, and it hereby is, revoked. I further order that any pending application of Roots Pharmaceuticals, Inc., to renew or modify its registration, be, and it hereby is, denied. This Order is effective September 19, 2011.

Dated: August 5, 2011.

Michele M. Leonhart,
Administrator.

[FR Doc. 2011–21063 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P