expect a practitioner who is properly supervising his patients to rarely, if ever, do otherwise, the record establishes numerous instances in which Respondent dispensed both hydrocodone drugs and schedule IV depressants (Xanax and Valium) in quantities which far exceeded his dosing instructions. Indeed, the ALJ's assertion is refuted repeatedly by her own findings which show that the quantities of the various drugs he dispensed greatly exceeded what the patients required in the course of legitimate medical treatment.

Next, the ALJ noted that "Respondent seemed to understand the need for a pain management contract, even though he had not implemented any procedures to verify compliance with that agreement." *Id.* at 44. This, however, does not mitigate his misconduct because, as the latter part of this finding make plain, Respondent's pain management contracts were not worth the paper they were written on as he never enforced them.[55]

Finally, the ALJ noted that Respondent had acknowledged that "he had a problem" because "between February and March of 2007, he was preparing for the Board's proceeding, and after that, he had a major increase of his patients" thus leading "to his failure to keep careful track of the frequency and quantities" of his refills. ALJ at 44. However, Respondent's failure to properly monitor his patients was not limited to the February–March 2007 time frame, as he issued many refills, which were clearly unwarranted, well before then. Indeed, most of the evidence discussed above involved his dispensings prior to this period and he admitted to only a few instances of early refills.[56] I thus conclude that Respondent has not fully accepted responsibility for his misconduct.

It is acknowledged that Respondent testified that, if granted a new registration, he would use the CURES database if he "feel[s]" that a patient is requesting refills "too frequently" and that he would limit his prescribing of drugs to the PDR limits.[57] Tr. 344–45. He also claimed that he would hire additional help and instruct his staff to keep better track of his patients' refill requests. Yet it is entirely unclear at what point he would "feel" that a patient's refill requests were being made "too frequently." As for his promise to not exceed the PDR limits, the record shows that he repeatedly issued refills which were excessive even when evaluated under his own understanding as to a drug's maximum daily safe dosing limit.

Thus, while I have considered Respondent's proposed reforms, the record here does not inspire confidence in his ability or willingness to properly implement them. Indeed, even ignoring the illegality of the prescription he issued to the Special Agent, the record amply demonstrates that Respondent acted with reckless disregard for his obligation to properly supervise his patients to ensure that they were not abusing and/or selling to others the controlled substances he dispensed. His conduct was egregious and likely caused great harm to public health and safety. Accordingly, I hold that Respondent has not rebutted the Government's *prima facie* case. Respondent's application will therefore be denied.[58]

[55] The ALJ also noted that Dr. Norcross stated that Respondent "met the standard of care for a physician of his age and training." ALJ at 44. However, as explained above, the issue is whether Respondent acted in the usual course of professional practice and had a legitimate medical purpose in issuing the prescriptions. *See* 21 CFR 1306.04(a). Moreover, Dr. Chavez provided an extensive explanation for his opinion that Respondent's prescribing practices represented an extreme departure from the accepted standards of medical practice and of medication prescribing.

[56] While Respondent conceded that he dispensed a limited number of early refills to E.A. and S.M., this was only a small portion of the early refills he issued to these two persons. Most significantly, he also failed to accept responsibility for numerous early and unwarranted refills he dispensed to other patients.

[57] While I note this, I agree with Respondent that the record in this matter does not establish that the accepted standard of medical practice requires a physician who prescribes controlled substances to check his patient in a prescription monitoring program database to determine whether he/she is a doctor shopper. *See* Resp. Prop. Findings, at 8–9.

[58] Respondent also contends that the public interest analysis requires the Agency to "balance the need to prevent possible abuse by a few isolated patients against the public harm caused by denying * * * DEA registration privileges to an important provider of healthcare (and pain management) services in a poor, mostly indigent community." Resp. Reply Br. at 2. DEA has previously rejected this contention as unworkable and lacking any support in the statutory factors. *See Gregory D. Owens,* 74 FR 36751, 36757 & n.22 (2009) ("The residents of this Nation's poorer areas are as deserving of protection from diverters as are the citizens of its wealthier communities, and there is no legitimate reason why practitioners should be treated any differently because of where they practice or the socioeconomic status of their patients.").

In his Reply Brief, Respondent also asserts "that the few patients who receive[d] slightly excessive amounts of pain medication were not representative of a larger number, and were a minuscule portion of [his] practice." Resp. Reply Br. at 7. Beyond the fact that Respondent mischaracterizes the evidence regarding the amounts of pain medication he dispensed and entirely ignores the extraordinary number of unlawful Valium and Xanax refills he dispensed, DEA has repeatedly rejected the argument that revocation of a registration or denial of an application is unwarranted where a practitioner's misconduct only involves a small number of patients. *See Jayam Krishna-Iyer,* 74 FR 459, 463 (2009). DEA has revoked a practitioner's registration based on a physician's simultaneous presentation of two fraudulent prescriptions to a pharmacist, *see Alan H. Olefsky,* 57 FR 928, 928–29 (1992), and DEA can revoke based on a single act of diversion. In short, Respondent's misconduct is egregious and he has not rebutted the Government's *prima facie* case.

## Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b) and 0.104, I hereby order that the application of Bienvenido Tan, M.D., for a DEA Certificate of Registration be, and it hereby is, denied. This order is effective April 29, 2011.

Dated: March 22, 2011.

**Michele M. Leonhart,**

*Administrator.*

[FR Doc. 2011–7394 Filed 3–29–11; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 09–40]**

### Scott C. Bickman, M.D.; Revocation of Registration

On March 27, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Scott C. Bickman, M.D. (Respondent), of Anaheim Hills, California. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BB3698632, as well as the denial of any pending applications to renew or modify his registration, on the ground that his "continued registration is inconsistent with the public interest." ALJ Ex. 1, at 1.

The Show Cause Order specifically alleged that "[f]rom December 2007 through October 2008," Respondent allowed his "DEA registration to be used to purchase at least 281,500 dosage units of hydrocodone combination products, in exchange for $2,000 per month," in violation of 21 U.S.C. 843(a)(2) and (3). *Id.* The Show Cause Order also alleged that Respondent had materially falsified his July 25, 2008 application to renew his registration because he failed to disclose that the Medical Board of California had "placed limits on [his] practice and placed [him] on probation for a period of thirty-five (35 months), effective September 18, 2006." *Id.* at 1–2 (citing 21 U.S.C. 824(a)(1)).

Respondent timely requested a hearing on the allegations and the matter was placed on the docket of the

Office of Administrative Law Judges (ALJ). Following pre-hearing procedures, an ALJ conducted a hearing in Los Angeles, California on January 26–27, 2010. At the hearing, both parties introduced documentary evidence and called witnesses to testify. Thereafter, both parties submitted briefs containing their proposed findings of fact, conclusions of law, and arguments.

On May 28, 2010, the ALJ issued her recommended decision (also ALJ). Therein, the ALJ found that Respondent had materially falsified his July 2008 renewal application. ALJ at 31. Based on "Respondent's inconsistent testimony about how the misstatement occurred and his failure to take responsibility for it," the ALJ further found that Respondent had not shown that "the omission was unintentional and that there was no intent to deceive." *Id.* The ALJ thus concluded that this act "constitutes grounds for revoking [Respondent's] registration." *Id.*

The ALJ then turned to whether Respondent had committed acts rendering his registration inconsistent with the public interest. *Id.* (discussing 21 U.S.C. 823(f)). With respect to the first factor—the recommendation of the State licensing authority—the ALJ noted that Respondent's State medical license "is unrestricted and that he is authorized to handle controlled substances in" the State. *Id.* The ALJ thus found that this factor supports a finding that Respondent's "continued registration would be in the public interest." *Id.* at 31–32. However, the ALJ further noted that this factor is not dispositive.

Turning to the second factor—Respondent's experience in dispensing controlled substances—the ALJ noted that this factor was "not at issue in th[e] proceeding." *Id.* at 32. With respect to the third factor—Respondent's record of convictions for offenses related to the manufacture, distribution or dispensing of controlled substances—the ALJ noted that there was no evidence that Respondent has been convicted of such an offense. *Id.* However, the ALJ noted that this factor was also not dispositive. *Id.*

Addressing the fourth factor—Respondent's compliance with applicable Federal and State laws related to controlled substances—the ALJ found that "between December 2007 and October 2008[,] some 120,000 dosage units of hydrocodone were ordered [by another physician who was allowed to use his registration] and shipped from Harvard Drug using Respondent's DEA registration number" and that "Respondent does not deny that this happened, but urges that these orders were made without his authorization or knowledge." *Id.* The ALJ further found that while "[t]he record does not establish that Respondent had actual knowledge of every order placed with Harvard Drug using his DEA number[,] [it] conclusively establishes * * * that [he] had ample reason to suspect that his registration was being misused and that he chose not to act on those suspicions." *Id.* Further finding Respondent's various explanations of his conduct implausible, the ALJ concluded that he "knew or should have known that" his registration was being used "to order controlled substances that were likely to be diverted." *Id.* at 33. The ALJ thus concluded that, by allowing another doctor to use his DEA registration "to order controlled substances," Respondent had unlawfully distributed controlled substances in violation of 21 U.S.C. 841(a) and that this factor supported a finding that his "continued registration would be inconsistent with the public interest." *Id.*

Turning to the fifth factor—other conduct which may threaten public health or safety—that ALJ found it "abundantly clear from Respondent's testimony and his letters to [a DEA Investigator that he] does not admit to any wrongdoing or accept any responsibility for the 120,000 dosage units of hydrocodone that were ordered * * * using his DEA registration number." *Id.* at 33. Concluding "that Respondent's refusal to acknowledge his wrongdoing offers little hope for the prospect that if he retains his DEA registration he will act more responsibly in the future," the ALJ found that this factor also supported a finding that his continued registration would be inconsistent "with the public interest." *Id.* at 34.

The ALJ thus concluded that Respondent had "at least constructively engaged in [the] unlawful distribution of hydrocodone and that he is unwilling or unable to accept the responsibilities inherent in a DEA registration." *Id.* The ALJ thus recommended that Respondent's "registration be revoked and that any pending applications be denied." *Id.*

Thereafter, Respondent filed exceptions to the ALJ's decision. The record was then forwarded to me for final agency action.

Having considered the entire record in this matter, including Respondent's exceptions, I reject the ALJ's legal conclusion that Respondent materially falsified his application. I agree, however, with the ALJ's finding that Respondent has committed acts which render his registration inconsistent with the public interest because he either knew or had reason to know that his registration was being misused and yet did nothing to prevent it. I further agree with the ALJ that Respondent has failed to accept responsibility for his misconduct. Accordingly, I will adopt the ALJ's recommendation that his registration be revoked and pending application be denied. As ultimate fact finder I make the following findings.

**Findings**

Respondent is an anesthesiologist who holds a physician and surgeon license issued by the Medical Board of California (MBC). GX 7, at 1. Pursuant to a Stipulated Settlement and Disciplinary Order (State Order), which became effective on September 18, 2006, the MBC revoked Respondent's license but then stayed the revocation and placed him on probation for a period of thirty-five months subject to various conditions. *Id.* at 2–3. The State Order resolved an Accusation that Respondent had committed acts of gross negligence, negligence, incompetence, and had failed to maintain adequate and accurate records, based on his provision of epidural anesthesia to a patient. *Id.* at 21–25. Notably, the Board did not place any restriction on Respondent's authority to administer, prescribe or dispense controlled substances. *See id.* at 5–15. It was undisputed that Respondent has satisfactorily completed the probation.

Respondent is also the holder of a DEA Certificate of Registration, which authorizes him to dispense controlled substances in schedules II through V as a practitioner. GX 1. Respondent's registration was to expire on July 31, 2008; however, on July 28, 2008, Respondent submitted a renewal application. GX 6, at 3. On the application, Respondent was required to answer the following question: "Has the applicant ever had a state professional license or controlled substance registration revoked, suspended, restricted, or placed on probation, or is any such action pending?" GX 5, at 1. Respondent answered: "No." *Id.*

On September 28, 2005, when Respondent previously renewed his registration, he gave as his registered location his residence on Wilshire Boulevard in Los Angeles, California. GX 6, at 3–4. However, on August 22, 2007, an application was submitted through DEA's registration Web site which changed his registered address from his residence to 145 S. Chaparral Court, Suite 101, Anaheim Hills, California. GX 6, at 3. This address was the location of an outpatient surgery

center which was owned by Dr. Harrell E. Robinson, a plastic surgeon.

According to Respondent, he first met Robinson in 2005 when the latter performed surgery at a surgery center in Beverly Hills. Tr. 471. On some date in either late 2006 or April/May 2007, Robinson began performing outpatient surgery at the Chaparral Court surgery center. *Id.* at 475–76. Robinson told Respondent that he was going to take over the center and asked him if he would be interested in providing anesthesia to the patients who underwent procedures there. *Id.* at 476. Respondent agreed to do so, and Robinson agreed to provide the controlled substances (among them fentanyl and midazolam) that were used to anesthetize the patients. *Id.* at 476–77. Respondent did not order the controlled substances but would tell the clinic's nurse when the supplies were running low, who would then order more. *Id.* at 477–78. Respondent administered anesthesia to patients at the center until sometime in late November 2007. *Id.* at 480, 587.

According to Respondent, the accreditation of Robinson's surgery center, which was issued by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), was due to expire at the end of November 2007 and Robinson had no plans to re-accredit the center. *Id.* at 480. Respondent maintained that he stopped performing anesthesia at the center after its accreditation expired because the State Order prohibited him from practicing at an unaccredited facility and that he had stopped going there.[1] *Id.* at 481.

In mid-November 2007, Robinson asked Respondent to become the center's medical director. *Id.* Respondent declined Robinson's offer. *Id.* at 482. However, because Respondent knew a nurse anesthetist who had previously assisted other surgery centers in obtaining accreditation and who would provide him with the templates necessary to prepare the documents required to do so, as well as because upon the center's obtaining a new accreditation, he would then be able to work there, Respondent offered to help Robinson get the center re-accredited for a fee of $16,000.[2] *Id.* at 482–83; *see also id.* at 347–48. Robinson agreed. *Id.* at 482–83.

Respondent maintained that in addition to preparing the necessary documents, he agreed to allow Robinson to use his DEA registration to order necessary supplies and medications for performing "peri-operative anesthesia services," which he maintained were necessary "to get the center up and running to be accredited." Tr. 496. According to Respondent, this included "gloves, syringes, needles, IVs, IV bags, Bovies and drapes," as well as the drugs used prior to surgery (such as midazolam), during surgery (fentanyl) and post-surgery (Dilaudid and fentanyl). *Id.* at 496–97. Dilaudid (hydromorphone) and fentanyl are schedule II controlled substances, *see* 21 CFR 1308.12(b)(1) & (c); midazolam is a schedule IV controlled substance. *See id.* 1308.14(c).

Respondent also submitted into evidence a November 19, 2007 letter which he asserted he had written to Robinson stating the terms of his agreement for assisting Robinson with getting the center re-accredited. RX DD. According to the letter (which is not signed by either him or Robinson), Respondent agreed to "provide use of my DEA certificate and DEA license for use of supplies and medications related to Peri-operative Anesthesia services." *Id.* The letter further states that "[t]his authorization does not extend to clinic and post-operative services or oral analgesics," and that, "[i]f at any time my * * * DEA is used for other then the narrow range specific [sic] in this letter of understanding then this letter of understanding is nil [sic] and void." *Id.*

Respondent testified that he prepared the letter because he knew that Robinson had started dispensing hydrocodone from his office and he "just wanted to cover [him]self to make sure that [his] DEA in the future was not used for that purpose." Tr. 648. Respondent further denied having written the letter after the fact. *Id.* at 652. However, on either October 19 or 22, 2008, Respondent was interviewed by both a DEA Diversion Investigator (DI) and a DEA Special Agent (S/A) and did not mention the letter. *Id.* at 225, 656–57; GX 23, at 1. Moreover, while Respondent submitted a lengthy written statement to the DI following the interview (as well as two other statements), he did not mention the letter in any of the statements and admitted that he never provided it to the DI.[3] *Id.* at 652, 654, 656–57; *see also* GX 23.

Respondent further maintained that he did not authorize Robinson to use his DEA registration to order oral analgesics such as Vicodin or other controlled substances containing hydrocodone. *Id.* at 644–45. While Respondent testified that Robinson needed his DEA number to order both non-drug supplies and controlled substances from a distributor, *id.* at 496, Samir Shah, Vice-President of Regulatory Affairs for the Harvard Drug Group (hereinafter, either Harvard or HDG), a registered distributor, testified that his company only required a DEA registration if a customer sought to purchase controlled substances. *Id.* at 20–21. The record does not establish whose registration was used by Robinson's clinic to obtain the controlled substances that were needed to anesthetize patients who underwent surgery there in the period prior to the date on which Respondent authorized Robinson to use his registration for this purpose and why Respondent's registration was subsequently required to order the drugs.[4]

According to B.C., who was the front office manager at Robinson's clinic from July through December 3, 2007, when Robinson fired the entire staff, *id.* 410–11, 413–14; in the summer of 2007, she observed Robinson's wife Alinka change Respondent's registered address through the DEA Web site. *Id.* at 416–17. B.C. testified that she asked Alinka Robinson whether Respondent "knew that she was changing his address"; Ms. Robinson stated that Respondent had told her husband that "it was okay." *Id.* at 417. Respondent subsequently denied having authorized this and maintained that he did not become aware that his address had been changed until he attempted to renew his registration in July 2008. *Id.* at 508, 636–40.

In a declaration, B.C. testified that Alinka Robinson had used Respondent's registration to open an account with Ready Rx, another drug distributor, and did so without Respondent's knowledge and consent.[5] RX X. The evidence

[1] However, the State Order contains no such prohibition. *See* GX 7, at 5–16.

[2] According to Respondent, the nurse anesthetist recommended that the center seek accreditation from a different entity, the Institute for Medical Quality (IMQ).

[3] Respondent also submitted a lengthy document, which was a draft of a Policy and Procedure Manual he prepared for Robinson because the Chaparral Court clinic would need it to obtain accreditation. *See* RX E; Tr. 485, 492. Respondent further admitted that this document was only "a draft * * * a rough copy," and was "not intended to be sent in time for approval, or even to request somebody to come [to] the center." Tr. 674. Respondent then explained: "It's a rough draft, as a skeleton, so to speak, for him to have in place something that when he decided * * * then that was not for me to even know that he was going to get it ready. Then he had a rough draft that would have been cleaned up as it needed to be." *Id.* at 674–75. To similar effect, Respondent's fiancé, who helped prepare the document, acknowledged that the document was not final "in any way, shape or form," but rather was "a work in progress." Tr. 376.

[4] While B.C. testified that Robinson would place requests for various controlled substances which she would then order, Tr. 415, it is not clear whether the drugs were ordered under Robinson's, Respondent's, or someone else's registration.

[5] The Government submitted a report it compiled from DEA's ARCOS database of hydrocodone

shows that Alinka and Harrell Robinson used the account to order oral controlled substances such as Vicodin. Tr. 433, 506, 548–49. While B.C. testified that she did not tell Respondent about the account "at the time that [it] was set up," she further stated that after she was laid off she called Respondent to "let him know everything that was going on." *Id.* at 445. According to B.C., Respondent "seemed very shocked when I told him." *Id.* Respondent maintained, however, that while he knew in November 2007, "before [he] left the center that [Robinson] had actually been dispensing medicines out of the office," he had "never even heard of [Ready Rx] until today." *Id.* at 506. He also testified that he was never told by anyone at "Robinson's office that oral controlled substances had been ordered using [his] DEA" registration. *Id.* at 548.

The ALJ did not specifically address this factual dispute. However, as ultimate fact finder, I find that B.C., who was called as Respondent's witness, had no reason to testify falsely as to her having told Respondent about the Ready Rx account following her termination in early December 2007.[6] I therefore credit this testimony.

In December 2007, Dr. Robinson, who had previously purchased controlled substances from HDG for a clinic he owned in Santa Ana, California, contacted the company to set up an account and obtain controlled substances for the Anaheim Hills clinic. Tr. 21. Robinson represented to HDG that Respondent was the medical director of the Anaheim Hills clinic. *Id.* at 22; GX 10, at 1 (Jan. 25, 2008 memorandum from Harrell Robinson to HDG).

According to Mr. Shah, HDG required three documents to open up an account in Respondent's name and to ship controlled substances to the Anaheim Hills clinic: 1) a copy of his medical license, 2) a copy of his DEA registration, and 3) a document, which Mr. Shah called "the DEA affidavit," a copy of which was submitted into evidence.[7] Tr. 29–30; *see also* GX 11. The affidavit reads as follows:

(1) This is to attest that *BICKMAN, SCOTT COLEMAN MD,* located at *145 S. CHAPARRAL COURT, ANAHEIM HILLS, CA 92808,* is not engaged in, nor has ever engaged in conducting business as an internet pharmacy or internet pharmacy supplier of controlled substances, nor do we dispense prescriptions by mail to patients.

(2) DEA# is *BB3698632.*

(3) *BICKMAN, SCOTT COLEMAN MD* Harvard Drug Group/Major Pharmaceuticals Acct.# is *P4840.*

(4) *BICKMAN, SCOTT COLEMAN MD* is located in an area that is accessible to the public and walk-in customers are welcomed.

GX 11, at 1.

According to Respondent, Robinson faxed him the affidavit and asked him to sign it and return it to HDG. Tr. 527. Upon reviewing the affidavit, Respondent discussed it with Mr. Shah because he wanted to know why he was being asked to sign it. Tr. 34. Mr. Shah told Respondent that HDG was doing "due diligence to make sure that [the] pharmaceuticals [it sold were] not being dispensed through [an] internet pharmacy." *Id.* In his testimony, Respondent maintained that he interpreted the language—"This is to attest that *BICKMAN, SCOTT COLEMAN MD,* located at *145 S. CHAPARRAL COURT, ANAHEIM HILLS, CA 92808*"—to mean he was "credentialed there, I'm located there," but not to mean that it was "my clinic that I'm doing business out of." *Id.* at 531.

It is undisputed that Respondent signed the affidavit and wrote that his title was "Practitioner"; he also signed the accompanying California Jurat with Affiant Statement, which was sworn to by him on January 15, 2008. GX 11, at 2; Tr. 529, 585. It is undisputed that the affidavit was faxed to HDG after Respondent's conversation with Mr. Shah. Tr. 35.

However, on the same day that Respondent signed the affidavit, he sent a letter to HDG which stated: "This letter is to prohibit further use of my DEA license number unless there is a verbal confirmation from myself, Scott, Coleman Bickman, M.D. I can be reached at the following numbers[,]" and listed two phone numbers and a fax number. GX 12, at 1; Tr. 532–33. According to Respondent, he sent the letter because he "was bothered by the openness of the located question and the internet pharmacy business" and he "wanted to be very clear in [his] wording to Harvard that anything that was going to be ordered under [his] DEA license, [he] wanted to be notified to give confirmation, so that there was going to be a check and balance system in place." Tr. 533.

However, the HDG invoices show that by the date Respondent signed the affidavit, HDG had already shipped 34,500 dosage units of various hydrocodone combination drugs to the Anaheim Hills Clinic listing his registration number as the "Customer DEA." GX 17, at 1–13. According to Respondent, he "had no idea that anything had ever been ordered by any[one] via my DEA besides myself," and if he had known he would have terminated his relationship with Robinson and "turned him in." Tr. 534.

On January 24, 2008, Robinson prepared a credit application for HDG, which listed "Physicians and Surgeons d/b/a Scott Bickman" as both the legal name of the business and the buyer's name. RX G, at 5. While the document listed Robinson as the owner, it then listed Respondent as the Guarantor of the account. *Id.* Robinson called Respondent and asked him to sign the application which he then faxed to him. Tr. 521. Respondent, however, did not sign the document because it listed three trade references with whom he had no relationship. *Id.* at 521–22.

The same day, Robinson then completed a new credit application in which he listed the legal name and buyer's name as "Physicians & Surgeons of O.C., d/b/a Harrell E. Robinson." GX 9, at 1. Robinson signed the application as Guarantor and faxed it to HDG the next day. *Id.* Robinson also faxed a memo to HDG which stated that he was the "owner of Physicians and Surgeons of Orange County Inc."; and that he had

purchases made in 2007 using Respondent's registration and which were shipped to Robinson's Anaheim Hills clinic. GX 18; *see also* 21 CFR 1304.33(a). While this report does not list any purchases as having been made from a firm named Ready RX, the report does list multiple distributions of hydrocodone by Top RX, Inc., which occurred between October 8 and November 19, 2007. GX 18, at 8–9. These distributions totaled 38,000 tablets. *See id.*

Respondent also submitted various documents including a Top Rx credit application (which listed Respondent's DEA registration number and listed "Bickman, Coleman Scott MD" as the "legal name" and "Orange County Surg." as the "trade name") and a Top Rx "DISPENSING PHYSICIAN QUESTIONNAIRE." RX LL, at 1, 2–4. The latter document is dated as having been completed on "9/20/07." *Id.* at 2. The DI acknowledged that the signature on the documents did not look like Respondent's, Tr. 249, and conceded that the documents were a fraudulent application. *Id.* at 255.

[6] B.C. also testified that twice a week, she would be told by one of the Robinsons not to come to the clinic because one Maggie Annan would be coming in. Tr. 426. B.C. further testified that Annan would pay Alinka Robinson between $9,000 and $10,000 in cash each month to use the clinic. *Id.* at 427–28.

[7] Invoices show, however, that HDG commenced filling orders for combination hydrocodone drugs using Respondent's DEA registration as early as December 18, 2007, nearly a month before Respondent executed the affidavit. GX 17, at 1. The invoices also listed Respondent and the Anaheim Hills office in the "ship to" block. *Id.* According to Mr. Shah, HDG did not require a customer to submit a credit application before it shipped controlled substances; HDG also allowed a customer a grace period of "two to three weeks for providing" the affidavit. Tr. 82. Thus, HDG actually only required a copy of a customer's State license and DEA registration before it would ship. *Id.* at 82–83, 87.

two clinics, one in Santa Ana and the other at 145 S. Chaparral Ct., Suite 101, in Anaheim Hills. GX 10, at 1. The memo also stated that "Dr. Bickman, MD, serves at [sic] my Medical Director at the Anaheim Hills' office[,]" that "our accounts payable office Dept covers both offices," and that the invoices should "go through the channels originally set up." *Id.*

On February 7, 2008, Respondent faxed a letter (which was dated January 30, 2008) to HDG. GX 13. Respondent wrote that "[t]his letter is to authorize the Physicians and Surgeons of Orange County dba Harrell Robinson, MD to order the necessary supplies for the center without having The Harvard Drug Group notify me for approval only for the next sixty days." *Id.* According to Respondent, he wrote this letter because Robinson had called him and said that "it was too difficult" to order the supplies this way. Tr. 537. Respondent maintained that he wrote the letter "not to undo my previous order, but to say, okay, they [HDG] don't have to contact me for supplies * * * not for the necessary supplies for the center," which he deemed to include syringes, needles, and gloves but "absolutely not" controlled substances. *Id.* at 538.

Mr. Shah testified, however, that after HDG received the letter, he asked G.B., a salesperson, "to contact [Respondent] and notify him that we intend[ed] to close the account as our system [was] not capable of handling his request for [the] next 60 days for holding all orders." *Id.* at 45. The salesperson called Respondent, who, upon being told that HDG "would be closing the account," asked to speak to Mr. Shah. *Id.* at 46–47. The salesperson then transferred the call to Mr. Shah. *Id.* at 48.

Mr. Shah testified that during the call, he explained to Respondent that HDG would "not be able to handle [his] request" because its system lacked the capability of "holding orders" for a "certain time period." *Id.* Mr. Shah further told Respondent that HDG could either "continue to ship or not ship." *Id.* Respondent then told Mr. Shah to "reinstate the account" and Shah stated that he could not do so until he received "a written confirmation from" Respondent. *Id.*

According to Mr. Shah, during the conversation Respondent asked "what kind of products" were being shipped. *Id.* Shah testified that he told Respondent that "we are shipping hydrocodone products." *Id.* Shah further testified that Respondent appeared "shocked" by this information and asked: "Oh is that right? We are ordering hydrocodone from you?" *Id.* at 49. Shah replied: "That is correct." [8] *Id.*

In his testimony, Respondent acknowledged that he had spoken to Mr. Shah and that Shah had said that "he couldn't conduct business like this" and that "he wasn't going to call [him] every time" because HDG's system was not "set up * * * to handle verbally notify[ing] me about my DEA usage." [9] *Id.* at 544. However, Respondent maintained Mr. Shah did not "mention one item of any drugs being ordered from [HDG] on my DEA." *Id.* Respondent also stated that he did not "understand why [Shah] was so adamantly violently yelling at [him] on the phone" and that he "really was taken aback." *Id.* at 545. Respondent further testified that he never asked Shah (or Ms. B., the HDG sales rep.) what was

[8] On cross-examination, Respondent's counsel asked Shah whether he had ever contacted Respondent to "tell him that a very large quantity of hydrocodone was being ordered." Tr. 88. Shah responded: "I don't recollect having a conversation with [Respondent] that the orders that we have been shipping has [sic] hydrocodone in it that is being shipped. I don't remember anything else other than what quantity and so forth." *Id.* Shah further testified that he did not document the conversation in which he told Respondent that HDG was shipping hydrocodone because "we did receive a confirmation on February 27, 2008 signed by Dr. Bickman [to] disregard all previous instructions and communications." *Id.* at 93.

Respondent contends that Shah's testimony on cross-examination is inconsistent with his testimony on direct. Resp. Br. 24. However, Shah was asked two different questions; on direct, he testified that Ms. Brooks had initially contacted Respondent to notify him that HDG could not "continue shipping products based on his instructions," that Respondent asked to speak with him, and that during the ensuing conversation, Respondent asked what HDG was shipping and Shah told him hydrocodone. Tr. 45–48. On direct examination, Shah did not maintain that he had contacted Respondent to tell him that his registration was being used to order a large quantity of hydrocodone, but rather to tell him that HDG would not comply with his instructions. Moreover, on cross-examination, Shah maintained that he had two conversations with Respondent, one in which HDG's "DEA affidavit" was discussed and the second one in which he told Respondent that HDG was going to close the account. Tr. 89–90.

In his Exceptions, Respondent notes that on June 15, 2010, DEA immediately suspended HDG's registration based on its distributions of oxycodone products over a two year period. Resp. Exc. at 1. Respondent argues that Shah's testimony is tainted because the Government knew and concealed from him that "HDG was under investigation for massive diversion of millions of doses of controlled oral drugs," and that the Government "posited that one of the reasons [R]espondent should have knew [sic] or should have know [sic] of the hydrocodone purchases is because HDG was a responsible drug wholesaler." Exc. at 3. Respondent further argues that because he did not have "the benefit of knowing that he [Shah] and HDG conducted an unlawful business," he was denied "an opportunity for impeachment." *Id.* Respondent thus contends that Shah's testimony should be stricken; he also argues that "[t]he concealment of the investigation, and the offering of Mr. Shah's testimony may also represent the equivalent misconduct so contumacious in degree that dismissal of the section 841(a) charge would be an appropriate remedy." *Id.*

I reject Respondent's Exceptions for the reasons stated in the ALJ's ruling. I further note that there is no support in the record for Respondent's contention that the Government's theory was that he should have known about the hydrocodone purchases because HDG "was a responsible drug wholesaler." While the Government's case was based in part on Shah's testimony that he told Respondent that HDG was shipping hydrocodone, the Government also relied, *inter alia,* on the various letters Respondent sent to HDG, as well as the material inconsistencies in his testimony and written statements. I also note that Respondent had ample opportunity to cross-examine Shah, who admitted that HDG shipped large quantities of hydrocodone even though it was "very unusual" to get a letter (such as Respondent's Jan. 15, 2008 one) telling HDG not to ship without first getting verbal confirmation and that this was "all the more reason" why HDG should have then contacted Respondent. Tr. 96–97. I further note that while Shah testified that a customer had only two to three weeks to submit the affidavit HDG required, HDG had been shipping controlled substances to the Chaparral Court clinic for nearly four weeks before it obtained the affidavit from Respondent and had already shipped more than 34,000 dosage units. Respondent thus demonstrated several ways in which HDG did not act in a responsible manner, and I have considered this in making my findings.

[9] At the time of the conversation, Respondent was attending the Physician Assessment and Clinical Education (PACE) Program at the University of San Diego pursuant to the probation imposed by the State Board. Tr. 542–43; GX 7, at 9.

In a letter Respondent wrote to the DI, he maintained that while attending the PACE program, he received a phone call from both Dr. Robinson and Harvard during which "[t]hey both complained that they could not do business with all of this notification." GX 23, at 8. Respondent further asserted that he "was extremely preoccupied at the time and again Dr. Robinson pleaded with me that he could not get orders filled for the operating room and that he would have to cancel surgeries as a result." *Id.* Continuing, Respondent wrote: "[a]gain, I trusted Dr. Robinson that he was just ordering supplies and anesthesia drugs and wrote the second letter to Harvard[.]" *Id.*

Yet earlier in the same letter, Respondent wrote that he "was unaware of whether or not Harvard had knowledge that they were sending drugs to a center that was unaccredited and not legally performing surgery. In no way did it even occur to me that my allowing Dr. Robinson to order his supplies and anesthesia related drugs could lead to this deception because any law abiding company would have confirmed the status of Dr. Robinson's center and questioned why they were using my DEA to supply an unaccredited center not performing surgery and therefore having no need for the quantities of narcotics they were shipping to Dr. Robinson." *Id.* at 7.

On cross-examination, the Government asked Respondent why he had written the letter "authorizing Dr. Robinson to place orders as needed so he wouldn't have to cancel his surgeries at the unaccredited center?" Tr. 625. Respondent replied that he had not said in the letter that the center was unaccredited. *Id.* The Government then asked Respondent if "the center was unaccredited?" *Id.* Respondent answered: "for all I know, he took the supplies with him to the place next door that was accredited. I have no idea. But I did not give him authorization for him to order supplies to do surgery in an unaccredited surgery center. I don't know [what] he did with the supplies. He could have taken them down * * * the street and used them." *Id.* at 625–26.

being ordered on the account. *Id.* at 571–72.

The ALJ did not resolve the factual dispute as to whether Mr. Shah told Respondent that hydrocodone or other drugs were being ordered with his registration. However, I credit Shah's testimony given that Respondent admitted that the conversation concerned his "DEA usage," and it seems strange that Respondent would not have asked what type of drugs were being ordered.

In addition, the ALJ generally found Respondent to be a less than credible witness. ALJ at 34. For example, while Respondent testified that he did not give Robinson authorization "to order supplies to do surgery in an unaccredited surgery center," Tr. 625–26, he had previously written to the DI that the reason he told HDG to reinstate the account was because Robinson "pleaded with me that he could not get orders filled for the operating room and that he would have to cancel surgeries as a result." GX 23, at 8. Likewise, Respondent denied that he had ever been told that his registration was being used to order controlled substances, Tr. 534, a statement which was contradicted by B.C., who was his own witness, and who had no reason to testify falsely.

After the conversation, Respondent wrote a new letter[10] which he apparently faxed to Robinson, who then faxed it to HDG. *See* GX 15; Tr. 50. This letter, which is dated February 27, 2008, and which is on stationary of the University of California San Diego Medical Center reads: "Please Disregard *All* Previous Faxes Regarding Management of My Account and Allow Dr. Robinson's Office to Place Orders as Needed. Thank You for Reinstating the Account At This Time." GX 15. Respondent testified that he "had no problem writing this" because "no one had told me that there was any problem from the ordering standpoint, that they [the Robinsons] were ordering anything" with his DEA registration.[11] Tr. 545.

In his testimony Respondent also maintained that until he was interviewed by a DEA Diversion Investigator,[12] he was unaware that "some inordinate amount of Vicodin had been ordered on my DEA through the Harvard Drug Group," that this was "absolutely quite shocking" because "no one had ever said to me, 'Is this okay,' when I had actually put everything in place along the way for that not to happen." *Id.* at 546. Respondent further testified that during the relevant time period, he never "dispensed Vicodin to a patient," and that the last time he had been to the Anaheim Hills clinic was in "later November of 07." *Id.* at 547. As noted above, Respondent also testified that he was unaware that his registration was being used to order oral controlled substances from other companies. *Id.* at 548. However, the ALJ found that Respondent knew or had reason to know that his registration was being misused. ALJ at 34.

Regarding the events surrounding the submission of his renewal application, Respondent testified that he knew his registration was about to expire because several of the surgery centers where he worked (and which required that he submit his credentials) had told him so. *Id.* at 550–51. Respondent added that because he procrastinated in renewing his registration, he asked A.R., his fiancé, to go online and fill out the form. *Id.* at 551. Respondent's fiancé made several unsuccessful attempts to access the Web page (apparently because she inputted the zip code of Respondent's registered address before it was changed by Alinka Robinson,[13] *see id.* at 382–83) at which the renewal application is submitted. *Id.* at 379; 552.

Both Respondent and his fiancé testified that the impending expiration of Respondent's registration prompted several phone calls from Alinka Robinson. *Id.* at 380 (testimony of A.R; "Alinka Robinson started calling * * * and saying that his DEA license is going to expire, his DEA license is going to expire"). According to Respondent, "we had Alinka Robinson, Harrell Robinson calling incessantly asking why it hadn't been renewed * * * It became * * * a state of almost * * * panic for us to get it done." *Id.* at 552; *see also id.* at 640 ("Alinka was blowing up the phone night and day, 'Where's my renewal?'"). When asked whether it concerned him that Alinka Robinson "was in a state of panic," Respondent replied that he was "very busy" doing anesthesia and did not think twice about it. *Id.* at 644.

Respondent maintained that he trusted A.R. "to be very diligent" in completing the on-screen application and that while he did "check it over for a second before [he] sent it," he "didn't catch" the false answer to the question about whether his State license had been sanctioned. *Id.* at 564. Respondent further testified that he was "[a]bsolutely not" trying "to deceive anybody." *Id.*

As noted above, Respondent maintained that he did not learn that his registered address had been changed until July 2008, when he renewed his registration. *Id.* at 640. While Respondent maintained that his registered address had been changed without consent, he admitted that he did not report this to DEA, *id.* at 641, even though "it was unfathomable to" him. *Id.* at 642. Nor, according to his own testimony, did he visit the Anaheim Hills clinic after he authorized Robinson to use his registration, to see what was going on there. *Id.* at 643.

Respondent also admitted that at the time he agreed to allow Respondent to use his DEA number, he "absolutely" knew that Harrell Robinson had been accused of being involved in million dollar insurance fraud ring. *Id.* at 628. *See also* GX 23, at 5 (Respondent's Oct. 27, 2008 letter to DI; "[A]ll I knew about him was some information that I came across on the Internet. Specifically, allegedly Dr. Robinson was involved in some major insurance fraud ring and received more than one million dollars illegally. However, according to the article, Dr. Robinson has never been found guilty due to his non cooperation and evasion of prosecutors."). According to Respondent, he did not ask Robinson "about his fraud and all the stuff related to it" because it did not "concern [him] when [he] did anesthesia for him." Tr. 656.

According to a report obtained from DEA's ARCOS system,[14] approximately

[10] The record also contains a February 21, 2008 letter which Respondent faxed to HDG the same day. *See* GX 14, at 2; Tr. 541. Therein, Respondent wrote: "Please change the previous ordering arrangement for my account to holding all orders until I have been notified and give verbal authorization for them to be honored by The Harvard Group." GX 14, at 2. According to Respondent, he wrote the letter because Robinson "had skipped a month in paying me" and he "wasn't willing to continue any sort of a relationship at all with him in any capacity until he was going to go ahead and honor * * * what I was working for him for. So I wasn't going to extend the courtesy of trying to get his center accredited with him using my DEA * * * to get any supplies or anything without using me to accreditate him." Tr. 541.

[11] In his October 27, 2008 letter to the DI, Respondent stated that he wrote the February 27 letter because both HDG and Robinson "complained that they could not do business with all of this notification. I was extremely preoccupied at the time and again Dr. Robinson pleaded with me that he could not get orders filled for the operating room and that he would have to cancel surgeries as a result. Again, I trusted Dr. Robinson that he was just ordering anesthesia drugs and wrote the * * * letter to Harvard." GX 23, at 8.

[12] According to a DEA DI, the interview occurred on October 22, 2008. Tr. 225.

[13] The Chief of the DEA Registration Unit testified that in order to log in and complete a renewal application, an applicant must type in seven items of information including the zip code of the registered address which must match exactly the information in the registration database. Tr. 129–30.

[14] Pursuant to Federal Regulations, all registered manufacturers and distributors of various

Continued

250,000 dosage units of hydrocodone drugs were purchased under Respondent's registration and distributed to the Anaheim Hills location during 2007 and 2008. *See* GX 18, at 1 & 3 (showing 193,500 units in 2008 and 53,800 in 2007); *see also* Tr. 194. The ARCOS report further shows that while most of the drugs were obtained from HDG, 20,000 dosages units were purchased from A.F. Hauser, Inc., and 38,500 units were purchased from Top Rx. *See* GX 18, at 5–9; *see also* GX 8 (Top Rx invoices) and GX 20 (A.F. Hauser, Inc. Invoices). Most of the drugs were purchased after Respondent was told by B.C. that his registration was being used to order controlled substances. *See id.* Moreover, numerous purchases were made even after the February 2008 phone call during which Mr. Shah told Respondent that the clinic was ordering hydrocodone from HDG. *See id.* at 6–8; *see also* GX 17, at 22–52. The purchases continued even after July 2008, when Respondent became aware that his registered address had been changed without his consent and Alinka Robinson was "in a state of panic" because he had not renewed his registration. GX 17, at 40–52; GX 18, at 8.

As part of his investigation, the DI obtained delivery information from HDG and conducted surveillance of several deliveries that were made to the Anaheim Hills office. Tr. 215–16. On three occasions, the DI observed the deliveries being made, and several hours later, either Robinson or his wife remove the packages from the office and take them either to their home or to a parking lot. *Id.* at 218. According to the DI, the drugs were eventually delivered to Maggie Annan, who was previously identified by B.C. as an associate of the Robinsons. *Id.* at 426–27.

Thereafter, search warrants were obtained and executed at five premises including Robinson's Santa Ana clinic, the Anaheim Hills clinic, Robinson's residence in Yorba Linda, and Ms. Annan's residence in Santa Ana. *Id.* at 219. While during the search of the Anaheim Hills clinic, 6,000 hydrocodone tablets were delivered from HDG, no other hydrocodone was found in the office and there were no records such as invoices or a dispensing log. *Id.* at 220–21. However, at Ms. Annan's house, the search party found six to ten invoices for hydrocodone purchases of about "6,000 pills each," "as well as 6,000 tablets of hydrocodone." [15] *Id.* at 221–22. With respect to the disposition of the drugs, the DI testified that while Robinson had claimed that Annan asked him to order the drugs to give to poor people in Mexico, there were no records to support this claim and the DI had no idea what Ms. Annan did with the drugs. *Id.* at 223.

The DI further testified that he had interviewed Harrell Robinson, who told him that Annan had "asked him to obtain a second registration to order these drugs," and that "he contacted Dr. Bickman and asked him to allow him to use the registration to order drugs and supplies for the office and [that] he would pay [Bickman] $2,000 a month to do this." *Id.* at 224. However, when asked by the Government whether Robinson had talked to Respondent "about using his DEA registration for ordering controlled substances," the DI replied: "Yes. During the interview it was based upon Dr. Robinson being asked by Maggie [Annan] to order more hydrocodone products in order to get more purchase[s] made other than the one registration so [Respondent's] license was needed for that purpose." *Id.* Beyond the fact that Robinson's hearsay statement is of dubious reliability, I find that the DI's testimony is too vague to conclude that Respondent had knowledge that Robinson's purpose in initially obtaining his registration was to enable Annan to obtain more drugs.

Regarding the Robinsons' use of his registration, Respondent testified that he was not "okay with it" and that he felt "that the numbers that it escalated to could have been totally avoided had I been notified even up front as early as when * * * the relationship started with Harvard." Tr. 565. He further testified that "it's so irresponsible to have let that happen * * * for people that knew," and that with the amounts that were being ordered, he would have thought that there would have been "a check and balance * * * from Shamir[sic] Shah or whoever in a compliance role," who would "have called to verify * * * that these amounts [were] being ordered." *Id.* at 566–67. He further asked: "Where am I supposed to get the information from, when the companies [and DEA] aren't telling me?" *Id.* at 567. *See also* GX 23, at 6 (Resp. Ltr. to DI; "There was no mention by either Dr. Robinson or Harvard Group about consenting for Dr. Robinson or Alinka Robinson to knowingly order excessive quantities of oral pain medication on a regular basis with my DEA. Furthermore, it is incomprehensible that Harvard Drug Group would not have notified me that another person was using my DEA in a reckless and illegal manner.").

Respondent further maintained that he told HDG that he "wanted to be notified" of the orders, but that HDG "didn't notify me" and asked "what else are you supposed to do?" *Id.* Yet on cross-examination, Respondent testified that he did not ask either Shah or Ms. B., the HDG sales rep., what Robinson was ordering with his registration. *Id.* at 571–72.

Finally, the Government asked Respondent whether he had designated anyone to maintain records of Dr. Robinson's purchases. *Id.* at 580. Respondent stated that he "did not," but that he assumed that Robinson would be doing it because "he owns a surgical center and knows the rules and regulations about how controlled substances * * * need to be logged and receipts need to be kept for a certain amount of time." *Id.*

**Discussion**

Section 304(a) of the 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 materially falsified any application filed pursuant to or required by this subchapter," or "has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(1) & (4). With respect to the latter inquiry, 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

controlled substances including schedule III narcotics such as combination hydrocodone drugs are required to report their distributions on a quarterly basis to DEA. 21 CFR 1304.33.

[15] According to the DI, "[a]t Ms. Annan's house we found about 6,000 tablets of hydrocodone. At Ms. Annan's house we found about 10 bottles of hydrocodone in her garage." Tr. 222. The DI then explained that each bottle contained about 500 tablets. *Id.* It is not clear, however, whether the drugs found in the garage were all of the total found in Ms. Annan's home or were in addition to those found in her house.

15227, 15230 (2003). I may rely on any one 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 for a registration. *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); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (DC Cir. 2005).

The Government has "the burden of proving that the requirements for * * * revocation or suspension pursuant to section 304(a) * * * are satisfied." 21 CFR 1301.44(e); *see also* 21 CFR 1301.44(d) (Government has "the burden of proving that the requirement for [a] registration pursuant to section 303 * * * are not satisfied"). However, where the Government satisfies its *prima facie* burden, the burden then shifts to the registrant to demonstrate why he can be entrusted with a new registration. *Medicine Shoppe-Jonesborough,* 73 FR 363, 380 (2008).

**The Material Falsification Allegation**

The Government argues, and the ALJ found, that Respondent materially falsified his 2008 renewal application because he provided a "no" answer to the question: "[h]as the applicant ever had a State professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?" Gov. Br. 24; ALJ at 31. It is undisputed that this answer was false because Respondent's State medical license had previously been placed on probation based on what was, in essence, a case of malpractice. The ALJ further concluded that Respondent's false answer was material, reasoning that "'[a]nswers to the liability question[s] are always material because DEA relies on the answers to these questions to determine whether it is necessary to conduct an investigation prior to granting an application.'" ALJ at 31 (quoting *Theodore Neujahr, D.V.M.,* 65 FR 5680, 5681 (2000); other citations omitted). Contrary to the ALJ's understanding, the Supreme Court (and this Agency) have held otherwise.

"The most common formulation" of the concept of materiality is that "a concealment or misrepresentation is material if it 'has a natural tendency to influence, or was capable of influencing, the decision of' the decisionmaking body to which it was addressed." *Kungys* v. *United States,* 485 U.S. 759, 770 (1988) (quoting *Weinstock* v. *United States,* 231 F.2d 699, 701 (DC Cir. 1956) (other citation omitted)) (quoted in *Samuel S. Jackson,* 72 FR 23848, 23852 (2007)); *see also United States* v. *Wells,* 519 U.S. 482, 489 (1997) (quoting *Kungys,* 485 U.S. at 770). Most significantly for this proceeding, the Supreme Court has explained that "[i]t has never been the test of materiality that the misrepresentation or concealment would more likely than not have produced an erroneous decision, *or even that it would more likely than not have triggered an investigation*." *Kungys,* 485 U.S. at 771 (emphasis added). Rather, the test is "whether the misrepresentation or concealment was predictably capable of affecting, *i.e.,* had a natural tendency to affect, the official decision." *Id.* "'[T]he ultimate finding of materiality turns on an interpretation of substantive law,'" *id.* at 772 (int. quotations and other citation omitted), and must be met "by evidence that is clear, unequivocal, and convincing." [16] *Id.*

As the above makes clear, the relevant decision for assessing whether a false statement is material is not the decision to conduct an investigation, but rather the decision as to whether an applicant is entitled to be registered. The Government's evidence does not, however, establish that Respondent's failure to disclose that the State Board had placed him on probation was capable of influencing the decision to grant his renewal application.

Notably, at the time he submitted the application, Respondent had a current State medical license and was authorized under California law to dispense controlled substances; he thus met the CSA's statutory requirement for holding a registration that he be "authorized to dispense * * * controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(f); *see also id.* § 824(a)(3) (authorizing the suspension or revocation of a registration upon a finding that "the registrant * * * has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the * * * dispensing of controlled substances"). Nor had the State Board recommended that his State or Federal controlled substance authority be suspended or revoked. *Id.* § 823(f)(1).

Moreover, the conduct which was the basis of the State Board's order does not implicate any of the other grounds provided for in the CSA for revoking a registration or denying an application. More specifically, the Board Order was not based on Respondent's having been convicted of a felony related to controlled substances under either State or Federal law, his having diverted or abused controlled substances, his failure to comply with other State or Federal controlled substance regulations, or his having committed an act of health care fraud resulting in his exclusion from participating in a program pursuant to 42 U.S.C. 1320a–7(a). *See* 21 U.S.C. 824(a)(2), (4), (5); *see also* 21 U.S.C. 823(f).

Rather, the only evidence in the record is that Respondent failed to properly administer anesthesia to a patient. DEA does not, however, have authority to revoke a registration or deny an application simply because a physician has committed an act of medical malpractice.[17] *See generally Gonzales* v. *Oregon,* 546 U.S. 243 (2006). Short of the Medical Board's having concluded that Respondent's conduct posed such a risk to patients as to warrant the suspension or revocation of his medical license (and authority to prescribe controlled substances under State law), DEA could not have denied his renewal application. Thus, Respondent's falsification was not "capable of influencing" the Agency's decision and was thus not material. *Kungys,* 485 U.S. at 772. Accordingly, I concluded that the Government has failed to prove this allegation.

**The Public Interest Allegations**

The Government argues that the evidence relevant to factors two (Respondent's experience in dispensing controlled substances), four (Respondent's compliance with applicable laws related to controlled substances), and five (such other conduct which may threaten public health and safety) supports the revocation of Respondent's registration. Gov. Br. 18, 22. Specifically, the Government argues that Respondent unlawfully distributed several hundred thousand dosage units of hydrocodone, a schedule III controlled substance, to

[16] While *Kungys* involved a denaturalization proceeding, in other civil proceedings, courts have required that a party establish that a falsification is material by "clear, unequivocal, and convincing evidence" and not simply by a "preponderance of the evidence." *Driscoll* v. *Cebalo,* 731 F.2d 878, 884 (1984). In any event, the Government's evidence on materiality would not even meet the preponderance standard.

[17] This is not to say that every case of medical malpractice is not material to the Agency's registration decision. Where, for example, there is evidence that a physician committed malpractice while being under the influence of a an illegally obtained controlled substance, the failure to disclose a State proceeding would be a material falsification even where a State board has imposed only a period of probation. However, here there is no evidence that Respondent was unlawfully under the influence of a controlled substance when he committed the acts which were the basis of the MBC proceeding.

an unknown and unregistered person. *Id.* at 18–19.

The Government argues that even if Harrell Robinson and Maggie Annan "operated without his knowledge or consent, Respondent still violated the [CSA] by failing to supervise their activities." *Id.* at 20 (citing 21 CFR 1301.71(a) & (b)(14)). The Government further argues that under agency precedent, Respondent is strictly liable for the misuse of his registration because he entrusted his registration to these persons. *Id.* at 23 (quoting *Harrell Robinson, M.D.,* 74 FR 61370, 61377–78 (2009) (citing *Rose Mary Jacinta* Lewis, *M.D.,* 72 FR 4035 (2007)). Finally, the Government argues that Respondent violated the CSA (and California law) because he failed "to maintain dispensing records as required by 21 CFR 1304.22(c)." *Id.* at 20 (also citing 21 U.S.C. 827(b) and 21 CFR 1304.04(a)); *see also id.* at 21 (citing Cal. Health & Safety Code § 11190(c)(1) & (G.2)).

Citing the CSA's provisions defining the terms "distribute" and "deliver," the ALJ reasoned that the "constructive transfer of a controlled substance is included in the meaning of distribution." ALJ at 32 (citing 21 U.S.C. 802(8) & (10)). While acknowledging that "[t]he record does not establish that Respondent had actual knowledge of every order placed with Harvard Drug using his DEA number," the ALJ found that "[t]he record conclusively establishes * * * that Respondent had ample reason to suspect that his registration was being misused and that he chose not to act on those suspicions." *Id.* Finding that his testimony as to why he had authorized Robinson to use his DEA registration number and his explanations of his various instructions to Harvard lacked credibility, *id.* at 32–33, the ALJ further found "that Respondent knew or should have known that Dr. Robinson was using [his] DEA registration number to order controlled substances that were likely to be diverted," that "Respondent engaged in [the] distribution of those [controlled] substances," and that these distributions violated the CSA. *Id.* at 33 (citing 21 U.S.C. 841(a)).

I need not decide whether the evidence is sufficient to support the ALJ's finding that Respondent constructively transferred controlled substances and thus distributed them in violation of 21 U.S.C. 841(a).[18] Under the public interest standard, DEA can consider a broader range of conduct than that which supports a finding of a criminal violation of the CSA. *See* 21 U.S.C. 823(f).

Here, the evidence is clear that at least from November 19, 2007, Respondent expressly authorized Robinson to use his DEA registration to order controlled substances. Respondent offered no explanation as to why Robinson, beginning on that date, then needed to use Respondent's registration (as opposed to his own) to obtain controlled substances for the clinic; indeed, Respondent's testimony that he had been performing anesthesia at the clinic for at least four months at that time begs the question: whose registration had been previously used to obtain the controlled substances which Respondent used to anesthetize patients at the clinic?[19]

Moreover, were I to credit Respondent's testimony that: (1) He had only authorized Robinson to use his registration to order controlled substances necessary to perform anesthesia; and (2) he did not create the November 19, 2007 letter memorializing this after the fact (as the Government suggests); it is significant that B.C., who was his own witness, testified that after she was terminated by the Robinsons, an event which occurred only two weeks after he wrote the letter, she called Respondent and told him about the Ready Rx[20] account and "everything that was going on," which "shocked" Respondent. Respondent's testimony that he had never heard of this account until the hearing or that his DEA registration was being used to order oral controlled substances (*i.e.,* hydrocodone drugs) is simply not credible.

Likewise, Mr. Shah testified that during a February 2008 phone conversation with Respondent, the latter asked Shah "what kind of products" Harvard was shipping and Shah told him hydrocodone, which again shocked Respondent. ALJ at 16 (citing Tr. 48–49). While Respondent again professed that Shah said no such thing, even after Shah told him that HDG was not able "to verbally notify me about my DEA usage," Respondent authorized Robinson's office to "place orders as needed."

Yet at no time thereafter did Respondent go to the Chaparral Court clinic to determine whether Robinson was actually complying with the Nov. 19 letter by ordering only peri-operative anesthesia drugs and not oral analgesics, as well as whether Robinson was, notwithstanding the clinic's lack of accreditation, still performing surgeries and had a need for any controlled substances. Indeed, Respondent's various statements and testimony regarding why he wrote the letter to HDG which authorized Robinson to "place as orders as needed" are fundamentally inconsistent.

For example, in his October 2008 letter to the DI, Respondent initially wrote he "was unaware of whether or not Harvard had knowledge that they were sending drugs to a center that was unaccredited and not legally performing surgery." GX 23, at 7. Continuing, he wrote that "[i]n no way did it even occur to me that my allowing Dr. Robinson to order his supplies and anesthesia related drugs could lead to this deception because any law abiding company would have confirmed the status of Dr. Robinson's center and questioned why they were using my DEA to supply an unaccredited center not performing surgery." *Id.*

Given Respondent's statements that the center "was not legally performing surgery," Robinson had no lawful need to order any controlled substances.[21]

[18] The Government did not argue that Respondent is liable for Robinson's unlawful conduct under either a conspiracy or aiding and abetting theory.

[19] Under a DEA regulation, "[a] separate registration is required for each principal place of * * * professional practice at one general physical location where controlled substances are * * * dispensed by a person." 21 CFR 1301.12(a); *see also* 21 U.S.C. 822(e). While the regulation exempts from the separate registration requirement "[a]n office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no such supplies of controlled substances are maintained," 21 CFR 1301.12(b)(3), it is clear that controlled substances were maintained at the clinic and that someone had to have been registered there for it to lawfully obtain the controlled substances that were used to anesthetize patients even when it was still accredited.

[20] I acknowledge that B.C. testified that the account was with Ready RX, but various documents show that the account was with Top RX. I conclude, however, that this inconsistency is not material as the substance of B.C.'s testimony was to relate the conduct of the Robinsons and not to identify the specific company from which they were purchasing controlled substances.

[21] In his exceptions, Respondent contends that the ALJ erred because she concluded "that California law prohibits surgery in an ambulatory surgery center unless it is accreditated [sic]." Exc. at 12. Respondent further contends that Cal. "Health and Safety Code section 1204(b) applies only to ambulatory surgery centers that are partially or totally owned by physicians," that California law does not prohibit the performance of ambulatory surgery at a surgery center, which is not owned by a physician but which is licensed "pursuant to Health and Safety Code sections 1200 *et* seq.," and that there is no evidence as to who was the actual owner of the Chaparral Court clinic, even though "it was clearly operated by Harrell Robinson." *Id.*

Respondent misstates California law, which clearly provides that "[a] surgical clinic does not include any place or establishment owned or leased *and operated* as a clinic or office by one or more physicians * * * in individual or group practice, regardless of the name used publicly to identify the place or establishment." Cal. Health & Saf. Code § 1204(b)(1) (emphasis added). Moreover, if, as Respondent now contends in his exceptions (and in contrast to his position he took in his October 2008

Moreover, even if it is the case—as contended by Respondent but without any credible support in the record, *see* Resp. Exc. at 12—that the center would have had to have stocks of anesthesia drugs on hand prior to obtaining re-accreditation, Respondent offered no evidence that the center was even close to obtaining re-accreditation. To the contrary, Respondent testified that the accreditation documents had yet to be finalized and submitted.

Moreover, even if the clinic was required to have stocks of anesthesia drugs on hand prior to obtaining re-accreditation, it is not clear why this would have required that Robinson have authority to use Respondent's registration for at least eight months. Indeed, given that the controlled substances that Respondent testified were necessary to perform anesthesia (fentanyl and midazolam) are widely available, it seems that any drugs the clinic would have needed to have on hand as part of the re-accreditation process could have been obtained through a single order from HDG and at a time shortly before any inspection by the accreditation authority.

Even were I to credit Respondent's testimony that he only authorized Robinson to order controlled substances used as peri-operative anesthesia drugs, because these drugs were being ordered under his registration, Respondent was required to maintain records showing the receipt and disposition of the drugs as well as initial inventories of them. *See* 21 U.S.C. 827(a) ("every registrant * * * shall * * * as soon * * * as such registrant first engages in the * * * dispensing of controlled substances * * * make a complete and accurate record of all stocks thereof on hand"); *id.* § 827(a)(3) ("every registrant * * * 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 him"). Yet again, Respondent never went to the Chaparral Court clinic to determine whether the required records were being maintained.

Also, while Respondent asserted that his registered address had been changed to the Chaparral Court address without his consent; that he did not learn of this until July 2008, when he submitted his renewal application; and that "it was unfathomable to him"; he did not report this to DEA. He likewise stated that he did not think twice about the phone calls he received from Alinka Robinson, who was in a state of "panic" because he had yet to renew his registration.

Accordingly, I conclude that even if Respondent was initially unaware that Robinson was using his registration for unlawful purposes, the evidence clearly shows that at various junctures (including within weeks of his authorizing Robinson to use the registration), Respondent clearly had reason to know that his registration was being misused and did nothing to prevent it. *See* 21 CFR 1301.71(a). In any event, under DEA precedent, a registrant is strictly liable for the misconduct of those persons who he authorizes to act under his registration.[22] *See Paul Volkman,* 73 FR 30630, 30644 n.42 (2008); *Rose Mary Jacinta Lewis,* 72 FR at 4041.

Moreover, Respondent was responsible for maintaining records for the controlled substances and yet did nothing to ensure that the records were being kept. Accordingly, I conclude that the evidence pertinent to factors four (Respondent's compliance with applicable controlled substance laws) and five (other conduct which may threaten public health and safety), establishes that Respondent has committed acts which render his registration inconsistent with the public interest. 21 U.S.C. 824(a)(4).

**Sanction**

Under Agency precedent, where, as here, the Government has made out a *prima facie* case that a registrant has committed acts which render his "registration inconsistent with the public interest," he must " 'present[] sufficient mitigating evidence to assure the Administrator that [he] 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 [his] actions and demonstrate that [he] will not engage in future misconduct." *Medicine Shoppe-Jonesborough,* 73 FR 364 (2008). As the Sixth Circuit has recognized, this Agency "properly consider[s]" a registrant's admission of fault and his candor during the investigation and hearing to be "important factors" in the public interest determination. *See Hoxie,* 419 F.3d at 483.

The ALJ found that it "is abundantly clear from Respondent's testimony and his letters to [the DI, that] Respondent does not admit to any wrongdoing or accept any responsibility for the 120,000 dosage units of hydrocodone that were ordered from [HDG] using his" registration, and that "Respondent knew or should have known that his * * * registration was being misused." ALJ at 33. The ALJ thus concluded that "Respondent's refusal to acknowledge his wrongdoing offers little hope for the prospect that if he retains his registration he will act more responsibly in the future." *Id.*

I agree with the ALJ. Respondent's testimony was riddled with material inconsistencies, including his explanation as to why Robinson needed to use his registration to order drugs for nearly a year if the facility was not legally authorized to perform surgery. Moreover, his claim that he lacked knowledge that the Robinsons were misusing his registration to obtain hydrocodone was contradicted even by his own witness.

Finally, Respondent's attempt to shift responsibility from himself to HDG is wholly unpersuasive. Whatever responsibility HDG bears for the diversion which likely occurred here is irrelevant. As found above, Respondent authorized Robinson to use his registration and then did nothing to determine how it was being used. He did not go to the clinic to see whether Robinson was maintaining records for even those drugs which would be used to provide anesthesia, or to see whether Robinson was, in fact, still performing surgery after the clinic lost its accreditation and could no longer legally do so. And even had I credited his testimony that HDG's personnel did not notify him that Robinson was ordering hydrocodone with his registration, his assertion that there was nothing else he could do to obtain this information is patently absurd given his admission that he never asked either Mr. Shah or Ms. B. what drugs were being ordered from HDG.

Thus, I conclude that Respondent's assertion that he was not "okay" with

letter), it was legal to perform surgery at the Chaparral Court clinic, because, notwithstanding its loss of accreditation, the clinic was licensed as a specialty clinic, *see id.;* this begs the question of why Respondent stopped providing anesthesia for the surgeries that Robinson performed there and why he purportedly was helping Robinson to obtain a new accreditation. *See also* Cal. Health & Safety Code (listing criteria for operating in "an outpatient setting"). Respondent did not address this inconsistency.

[22] To make clear, this is not a case where a practitioner simply provided his DEA registration to a health care facility as part of the credentialing process and a person at the facility subsequently used his registration for unlawful purposes. Rather, Respondent affirmatively authorized Respondent to use his registration to obtain controlled substances, and is thus strictly liable for the misuse of his registration.

what happened is simply a case of crying crocodile tears. Because Respondent has not accepted responsibility for his misconduct and that misconduct manifests an egregious disregard for his responsibilities as a DEA registrant, I hold that Respondent has not rebutted the Government's *prima facie* showing that his continued registration is "inconsistent with the public interest." 21 U.S.C. 824(a)(4). Accordingly, Respondent's registration will be revoked and any pending application will be denied.

**Order**

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a)(4), as well as by 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, BB3698632, issued to Scott C. Bickman, M.D., be, and it hereby is, revoked. I further order that any application for renewal or modification of such registration be, and it hereby is, denied. This Order is effective April 29, 2011.

Dated: March 22, 2011.

**Michele M. Leonhart,**

*Administrator.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Roger A. Pellmann, M.D.; Revocation of Registration

On January 29, 2010, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration (Order) to Roger A. Pellmann, M.D. (Respondent), of Germantown, Wisconsin. The Order proposed the revocation of Respondent's registration, AP1892822, on the ground that his "continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f) and (g)(2)(E)(i)." Order, at 1.

The Order alleged that Respondent "possessed and dispensed controlled substances at 3129 S. Ridge Crest, New Berlin, Wisconsin," an unregistered location, in violation of 21 U.S.C. 841(a)(1). Order, at 1. The Order further alleged that beginning "in approximately June 2009," Respondent "prescribed controlled substances to an employee for other than legitimate medical purposes," in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04. *Id.* at 2. The Order also alleged that at Respondent's "request," a local pharmacy dispensed controlled substances which were "returned" to Respondent for his "personal use," in violation of 21 U.S.C. 843(a)(3). *Id.*

Next, the Order alleged that an "accountability audit performed at [Respondent's] office in November 2009" found "an unexplained shortage of approximately 10,470 fentanyl citrate 0.05 mg/ml (2 ml ampule) during the first audit and an unexplained shortage o[f] approximately 9,556 fentanyl citrate 0.05 mg/ml (2 ml ampule) during the second audit." *Id.* The Order also alleged that "accountability audits for morphine sulfate indicated a shortage of approximately 780 units of morphine sulfate injection 15 mg/ml (20 ml vial); 1825 units of morphine sulfate injection 10 mg/ml (1 ml vial); 550 units of morphine sulfate injection 8 mg/ml (1 ml vial); and 200 units of morphine sulfate injection 5 mg/ml (1 ml vial)." *Id.* Finally, the Order alleged that "[n]o initial inventory was taken upon the establishment of the registered location, nor was a biennial inventory taken of the controlled substances on the premises of the registered location every two years" and that "records were not properly maintained for the dispensed controlled substances." *Id.* (citing 21 CFR 1304.11, 1304.11(b) & (c), and 1304.22(c)). Based on the above, I concluded that Respondent's continued registration during these proceedings "constitutes an imminent danger to the public health and safety" and immediately suspended his registration. *Id.* (citing 21 U.S.C. 824(d)).

On February 24, 2010, Respondent timely filed a request for a hearing on the allegations. The matter was placed on the docket of the DEA Administrative Law Judges (ALJ) and was set for hearing on June 22, 2010. Order Terminating Proceeding, at 1. However, on June 7, 2010, counsel for Respondent notified the ALJ that following Respondent's criminal conviction after trial "on facts related to the allegations set forth" in the Order, he "no longer wished to pursue a hearing." *Id.* The same day, Respondent's Counsel also wrote a letter to the ALJ stating that he was "waiving his opportunity to participate in the hearing" and submitting his statement of facts and his position. Letter from Adam C. Essling (June 7, 2010), at 1 (citing 21 CFR 1301.43(c)).

Mr. Essling's letter additionally stated that Respondent "maintains that his registration is not inconsistent with [the] public interest under 21 U.S.C. 823(f)." *Id.* More specifically, the letter related that Respondent "maintains that [J.E.] has been a patient of his since 2005" and that "[a]ll of the controlled substances provided to [J.E.] were for a legitimate purpose." *Id.* However, the letter conceded that Respondent "did not maintain a proper inventory or records for the controlled substances dispensed within the scope of his practice." *Id.*

By order of June 8, 2010, the ALJ terminated the proceeding. Order Terminating Proceeding, at 2. Thereafter, the Investigative Record was forwarded to me for Final Agency Action.

Based on relevant evidence contained in the Investigative Record, I conclude that Respondent has committed acts which render his registration "inconsistent with the public interest." 21 U.S.C. 824(a)(4). I will therefore, order that Respondent's registration be revoked and that any pending applications to renew or modify his registration be denied. I make the following findings of fact.

**Findings**

Respondent is a physician licensed by the State of Wisconsin who practices radiology. Respondent also holds DEA Certificate of Registration, AP1892822; the registration, which does not expire until March 31, 2011, authorizes him to dispense controlled substances as a practitioner at the registered location of CMI—Center for Medical Imaging, W178 N9912 Rivercrest Drive, Suite 102, Germantown, Wisconsin ("CMI," or "Germantown clinic"). Certificate of Registration Status (March 11, 2010). However, on January 29, pursuant to my authority under 21 U.S.C. 824(d), I ordered that Respondent's registration be immediately suspended; Respondent was served with the Order on February 2, 2010.

On September 4, 2009, a confidential source (CI) informed a DEA Diversion Investigator (DI) that Respondent had "been providing [J.E.] with large quantities of liquid Fentanyl and morphine sulfate, both of which are Schedule II controlled substances,[1] for

[1] *See* 21 CFR 1308.12(b)(1)(ix) & (c)(9). According to the FDA-approved package insert for fentanyl citrate injection, a dosage of 0.1 mg in 2 ml. solution is "approximately equivalent in analgesic activity to 10 mg of morphine"; fentanyl is thus approximately 100 times more powerful than morphine. Its approved uses are primarily for analgesic action "during anesthetic periods, premedication, induction and maintenance, and in the immediate postoperative period" as needed, and also as "a narcotic analgesic supplement in general or regional anesthesia." Other uses include "administration with a neuroleptic such as droperidol injection as an anesthetic premedication, for the induction of anesthesia, and as an adjunct in the maintenance of general and regional anesthesia," and "as [an] anesthetic agent with oxygen in selected high risk patients, such as those undergoing open heart surgery or certain complicated neurological or orthopedic procedures."