

a temporary suspension of a state medical license. For that reason, the Respondent argues that a summary disposition in these DEA proceedings, based on the suspension of his state licensure, “would be inconsistent with [the Agency’s] previous rulings and would create a manifest injustice to Respondent.” While the Respondent’s position is not without some level of facial appeal, it is unsupported by the applicable statutes, regulations and precedent emanating from both the courts and the Agency.

The Controlled Substances Act (CSA) requires that a practitioner must be currently authorized to handle controlled substances in “the jurisdiction in which he practices” in order to maintain a DEA registration. See 21 U.S.C. 802(21) (“[t]he term ‘practitioner’ means a physician * * * licensed, registered, or otherwise permitted, by * * * the jurisdiction in which he practices * * * to distribute, dispense, [or] administer * * * a controlled substance in the course of professional practice”); see also *id.* § 823(f) (“The Attorney General shall register practitioners * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices.”). Therefore, because “possessing authority under state law to handle controlled substances is an essential condition for holding a DEA registration,” this Agency has consistently held that “the CSA requires the revocation of a registration issued to a practitioner who lacks [such authority]” (emphasis supplied). *Roy Chi Lung*, 74 FR 20346, 20347 (2009); *Scott Sandarg, D.M.D.*, 74 FR 17528, 174529 (2009); *John B. Freitas, D.O.*, 74 FR 17524, 17525 (2009); *Roger A. Rodriguez, M.D.*, 70 FR 33206, 33207 (2005); *Stephen J. Graham, M.D.*, 69 FR 11661 (2004); *Dominick A. Ricci, M.D.*, 58 FR 51104 (1993); *Abraham A. Chaplan, M.D.*, 57 FR 55280 (1992); *Bobby Watts, M.D.*, 53 FR 11919 (1988).

Denial of an application or revocation of a registration via a summary disposition procedure is also warranted if the period of a suspension is temporary, or if there exists the potential that Respondent’s state controlled substances privileges will be reinstated, because “revocation is also appropriate when a state license has been suspended, but with the possibility of future reinstatement,” *Rodriguez*, 70 FR at 33207 (citations omitted), and even where there is a judicial challenge to the state medical board action actively pending in the state courts. *Michael G. Dolin, M.D.*, 65 FR 5661, 5662 (2000).

In order to revoke a registrant’s DEA registration, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR 1301.44(e). Once DEA has made its *prima facie* case for revocation of the registrant’s DEA COR, the burden of production then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant’s registration would not be appropriate. *Morall v. DEA*, 412 F.3d 165, 174 (DC Cir. 2005); *Humphreys v. DEA*, 96 F.3d 658, 661 (3d Cir. 1996); *Shatz v. U.S. Dept. of Justice*, 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston*, 45 FR 72311 (1980).

Regarding the Government’s request for summary disposition of the present case, it is well-settled that where no genuine question of fact is involved, or when the material facts are agreed upon, a plenary, adversarial administrative proceeding is not required, see *Jesus R. Juarez, M.D.*, 62 FR 14945 (1997); *Dominick A. Ricci, M.D.*, 58 FR 51104 (1993), under the rationale that Congress does not intend for administrative agencies to perform meaningless tasks. See *Philip E. Kirk, M.D.*, 48 FR 32887 (1983), *aff’d sub nom. Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984); see also *Puerto Rico Aqueduct & Sewer Auth. v. EPA*, 35 F.3d 600, 605 (1st Cir. 1994); *NLRB v. Int’l Assoc. of Bridge, Structural & Ornamental Ironworkers, AFL-CIO*, 549 F.2d 634 (9th Cir. 1977); *United States v. Consol. Mines & Smelting Co.*, 455 F.2d 432, 453 (9th Cir. 1971).

The record evidence in the instant case clearly demonstrates that no genuine dispute exists over the established material fact that Respondent currently lacks state authority to handle controlled substances in Florida, his state of registration with the DEA, since his state osteopathic medical practitioner’s license was suspended on April 28, 2010. Notwithstanding the Respondent’s attempts to distinguish the rationale for revocation in the cases cited by the Government as factually dissimilar to his own circumstances, the dispositive consideration here is that because the Respondent presently lacks state authority, both the plain language of the applicable federal statutory provisions and Agency interpretive precedent set forth herein dictate that the Respondent is not entitled to maintain his DEA registration, and therefore a registration action less than revocation is not appropriate. Simply put, there is no contested factual matter adducible at a hearing that can provide the Agency with authority to continue (or a *fortiori*

for me to recommend) his entitlement to a COR under the circumstances and further delay in ruling on the Government’s motion for summary disposition is not warranted.

Accordingly, the Government’s Motion for Summary Disposition is hereby *granted*, its Motion for Stay of Proceedings is *denied* as moot, and in view of the presently uncontroverted fact that the Respondent lacks state authority to handle controlled substances, it is herein recommended that the Respondent’s DEA registration be *revoked* forthwith and any pending applications for renewal be denied.

Dated: August 12, 2010.

John J. Mulrooney, II,
U.S. Administrative Law Judge.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 09-12]

Bienvenido Tan, M.D.; Denial of Application

On October 31, 2008, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Bienvenido Tan, M.D. (Respondent), of Newhall, California. The Show Cause Order proposed the denial of Respondent’s application for a DEA Certificate of Registration as a practitioner, on the ground that “his registration is inconsistent with the public interest.” ALJ Ex. 1, at 1.

More specifically, the Show Cause Order alleged that on April 12, 2007, Respondent “voluntarily surrendered [his] controlled substances privileges” when he was under investigation for illegally distributing controlled substances, and that in February 2008, he had applied for a new registration. *Id.* The Order alleged that “[l]aw enforcement personnel conducted at least eleven (11) undercover visits” to Respondent’s office between October 2006 and March 2007 and that on several occasions, he had prescribed Lorcet and Vicodin, schedule III controlled substances which contain hydrocodone, as well as alprazolam, a schedule IV controlled substance, to them “with cursory or no medical examinations, and without a legitimate medical purpose.” *Id.* (citing 21 CFR 1306.04).

The Show Cause Order further alleged that a medical expert had reviewed Respondent’s files and “found ‘strong

evidence for inappropriate prescribing of controlled [substances]" and that his "prescribing was 'an extreme departure from the standard of care expected of a licensed practicing physician.'" *Id.* at 2. The Order also alleged that Respondent had admitted to investigators that he "authorized an employee to dispense controlled substances to [his] patients in violation of state law." *Id.* at 1 (citing Cal. Bus. & Prof. Code § 4170).

By letter of November 4, 2008, Respondent timely requested a hearing and the matter was placed on the docket of the Agency's Administrative Law Judges (ALJs). Following pre-hearing procedures, an ALJ conducted a hearing from March 24 through March 26, 2009 in Los Angeles, California. At the hearing, both parties called witnesses to testify and submitted documentary evidence. Thereafter, both parties filed post-hearing briefs.

On January 8, 2010, the ALJ issued her recommended decision (also ALJ). Therein, the ALJ considered the evidence relevant to the five public interest factors. See 21 U.S.C. 823(f).

As to factor one—the recommendation of the appropriate State licensing board—the ALJ found that the Medical Board of California ("the Board") had not made a recommendation in this matter. ALJ at 34. The ALJ then noted that the Board had brought a proceeding against Respondent based on its review of three patient files (which are not at issue in this proceeding), but had found that "cause did not exist to discipline the Respondent's medical license 'for prescribing without a good faith examination and medical indication, as to all three patients.'" *Id.* The ALJ noted, however, that the Board found that "cause did exist to discipline Respondent's medical license 'for maintaining inadequate records' for one of the three patients" and that the Board "publicly reprimanded the Respondent 'for his departures from the standard of care regarding his medical record keeping' of that specific patient." *Id.* at 34. The ALJ did not make a finding as to whether this factor weighed for or against a finding that Respondent's registration was inconsistent with the public interest. See *id.*

The ALJ then considered factors two and four—the applicant's experience in dispensing controlled substances and his compliance with applicable Federal, State, or local laws related to controlled substances—together. Under these factors, the ALJ considered evidence pertaining to various undercover visits by a Special Agent (SA) and Confidential Informant (CI), Respondent's dispensing practices, his

office procedures, and his recordkeeping. *Id.* at 35–39.

With respect to the undercover visits, the ALJ did not make findings as to whether the prescriptions Respondent issued to the SA or CI violated the CSA's prescription requirement. *Id.* at 36–37. Instead, the ALJ observed that "[t]he primary concern regarding the Respondent is his dispensing practices." *Id.* Noting that the evidence showed that "Respondent is dispensing multiple times more dosage units than the patient should consume, if taking the medication as prescribed," the ALJ explained that "either the patient is at risk of taking an overdose of the controlled substances, or the patient is diverting the controlled substances to the illicit market." *Id.* at 37. "Based on this factor alone," the ALJ concluded that "the Government has established a prima facie basis for denying * * * Respondent's application for a DEA registration." *Id.* at 38.

The ALJ further found that Respondent "is allowing unlicensed office staff to fill and dispense controlled substances." *Id.* She also found that Respondent did not require his pain patients to undergo urine or blood screens to determine whether they were actually using the drugs he prescribed and to determine whether they were taking drugs obtained either from other doctors or on the street. *Id.* The ALJ concluded that this "allows diversion of such medications without detection by * * * Respondent." *Id.*

The ALJ also found relevant Respondent's continuing to prescribe controlled substances without obtaining his patient's medical records. *Id.* She further noted that Respondent increased dosages without performing physical examinations, and that in some cases, he continued to prescribe controlled substances to patients for "almost a year" without seeing them. *Id.* at 38–39. Finally, she noted that while in some cases, he had indicated "his desire to decrease the dosage units of controlled substances," he would "oftentimes without even seeing the patient * * * return to the higher dosage without recording his treatment plan or otherwise explaining the higher dosage in the patient's records." *Id.* at 39. The ALJ, therefore, concluded that these factors support a finding that Respondent's registration is inconsistent with the public interest.¹

¹ With respect to factor three—Respondent's record of convictions for offenses related to the dispensing or distribution of controlled substances—the ALJ noted that there is no evidence that he has been convicted of an offense within this factor. ALJ at 39.

Turning to factor five—such other conduct which may threaten the public health and safety—the ALJ reviewed the reports of each party's experts (who had examined various patient records) regarding the standard of care for prescribing controlled substances. *Id.* at 39–43. The ALJ noted that she had "a problem with the conclusions of both expert witnesses." *Id.* According to the ALJ, this was so because the Government's expert had opined that Respondent's care was "markedly below the accepted standards of licensed physicians in the United States today," thus suggesting that he had not applied the standard applicable under California law, *id.* at 40–41, and Respondent's expert had opined that he should be compared against "physicians of similar age, training, and background," which "is not the standard followed in California." *Id.* at 41.

The ALJ noted, however, that in preparing his report, the Government's Expert had relied on the Medical Board of California's "Guidelines for Prescribing Controlled Substances for Pain." *Id.* at 42. Because the Government's Expert's conclusions were "more consistent with the California requirements for determining the standard of care," she found persuasive his findings that Respondent's charting practices were "extremely deficient," that there were "inadequate records of consultation requests for further medical evaluations," and that "it would not be safe [for a patient] to ingest the quantity of controlled substances received in that short of a period of time" as occurred between the dates on which Respondent dispensed controlled substances to the various patients. *Id.* at 40, 43. The ALJ thus found that this "factor * * * weighs in favor of denying the Respondent's application," and that "[i]n total * * * the Government has met its burden of proof in presenting a prima facie case for denying the Respondent's application for a DEA registration." *Id.* at 43.

The ALJ then discussed various facts she deemed favorable to Respondent. These included that he "was not dispensing controlled substances for monetary gain," that he "refused to prescribe Oxycontin because of its addictive properties," that he "refused to prescribe controlled substances for recreational purposes," and that because he had a major increase in patients, he did not see them as often as necessary and did not keep careful track of his refills. *Id.* at 43–44. The ALJ further noted that "Respondent credibly testified that, if given a DEA registration, he would use the CURES

database² and he would limit his prescribing of controlled substances to the PDR³-defined limits.” *Id.* at 44. The ALJ nonetheless concluded that “this does not go far enough” because Respondent had failed “to address his use of unlicensed individuals to dispense controlled substances,” as well as what “procedures he would put in place to monitor his patients to ensure they were consuming the controlled substances as prescribed.” *Id.* at 44–45. Thus, the ALJ recommended that “Respondent’s application for a DEA registration * * * be denied at this time.” *Id.* at 45.

On January 28, 2010, Respondent filed Exceptions to the ALJ’s Decision; these Exceptions have been considered and are discussed throughout this decision. Respondent also requested that the ALJ reopen the record and admit his Exhibit A, which is a sworn statement signed by him and dated January 27, 2010, addressing the ALJ’s findings that he had failed to address several critical deficiencies identified in the proceedings. Resp. Exceptions at 10.

On February 16, 2010, the ALJ denied Respondent’s request, noting that Respondent should have been aware of “the Agency’s longstanding rule” that where “the Government has made out a *prima facie* case that a practitioner has committed acts which render his registration inconsistent with the public interest, the relevant inquiry is whether a practitioner has put forward ‘sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility carried by such a registration.’” Order Denying Respondent’s Request to Reopen the Record and Include “Exhibit A,” at 2 (citations omitted). The ALJ further explained that “this inquiry looks to whether the registrant has accepted responsibility for his misconduct and undertaken corrective measures to prevent the re-occurrence of similar acts.” *Id.* While noting that “[t]he evidence might have proven material when considering whether or not Respondent’s continued registration would be a threat to the public interest,” the ALJ noted that the evidence was

available at the time of the hearing and that Respondent had the “burden of persuasion” on the issue. *Id.* at 4. She therefore denied Respondent’s request to reopen the record. *Id.* Finding no error, I adopt the ALJ’s ruling denying Respondent’s request to reopen the record.

Thereafter, on February 18, 2010, the ALJ forwarded the record to me for final agency action. Having reviewed the record in its entirety and considered Respondent’s Exceptions, I adopt the ALJ’s findings except as expressly noted herein. I also adopt her recommendation that I deny Respondent’s application. As the ultimate finder of fact, I make the following findings.

Findings

Respondent has been a licensed physician and surgeon in the State of California since 1959; he was 83 years old at the time of the hearing. ALJ Ex. 3, at 1; Tr. 553. Respondent previously held a DEA Certificate of Registration, which authorized him to dispense controlled substances in schedules II through V. GX 2. However, on April 12, 2007, Respondent voluntarily surrendered his registration. *Id.* On February 29, 2008, Respondent applied for a new registration; this application is at issue in this proceeding. ALJ Ex. 3, at 2; GX 1.

Until 1998, Respondent primarily practiced as a surgeon. During this period, he also had a family practice with four offices and operated a dispensary on the premises of his practice for thirty to forty years. Tr. 562, 570, 598. From 1968 through 1998, he owned and operated Newhall Community Hospital, where he was the Medical Director and also a staff surgeon. *Id.* at 599, 602. During the course of his surgical career, Respondent had occasion to prescribe pain medications; while running the hospital he often had discussions with colleagues on pain medicine issues. *Id.* at 597, 602.⁴

In 1998, Respondent opened his current family practice. Tr. 563. While he is not formally trained in pain management, in 2003 he attended a 5-day course on pain management. *Id.* at 564, 638. At that course, he learned about Pain Management Agreements and Patient Comfort Assessment Guide

tools, which he began to utilize in his practice. *Id.* at 307–09.

The State Board Proceeding

On June 20, 2006, the Medical Board of California (the Board) filed a seventeen-count accusation against Respondent’s medical license based on his treatment of patients P.P., D.F., and K.Z. RX A, at 2; RX V. The allegations included, *inter alia*, that Respondent had prescribed various drugs without performing adequate physical examinations and taking adequate histories, that he had committed negligent and incompetent acts, and that he had failed to maintain adequate records. RX V.

On April 2, 2007, a State ALJ rejected all of the allegations except for that which alleged that Respondent’s recordkeeping with respect to K.Z. was inadequate. RX A, at 18. The State ALJ thus recommended that Respondent be “publicly reprimanded * * * for his departures from the standard of care regarding his medical record keeping of patient K.Z.” *Id.* at 22. On May 4, 2007, the Board adopted the State ALJ’s decision. *Id.* at 1. Of note, in this proceeding, the Government does not rely on Respondent’s treatment of any of these three patients.⁵

The DEA Investigation

In either August or September 2006, DEA’s Los Angeles Field Division received information from a confidential source that Respondent was

⁵ In his decision, the State ALJ found that Respondent had told patient K.Z. that he could take Vicodin at the rate of up to twelve tablets per day. RX A, at 6. The ALJ also found that one of the Board’s experts had observed that at one point, K.Z. would have been consuming “approximately nine grams of Acetaminophen” per day and that the expert “considered any quantity over four grams of Acetaminophen [per day] troubling.” *Id.* at 10. While the State ALJ found that the *Physician’s Desk Reference* (“PDR”) states that “[t]he total 24 hour dose [of Vicodin] should not exceed five tablets,” *id.* at 13, he did not make any further finding as to whether there is an appropriate maximum dose of drugs containing acetaminophen such as Vicodin and simply concluded that the Board had failed to show that Respondent’s “off-label dosage instructions departed from the standard of care.” *Id.* at 20. This is not the same as saying—as Respondent testified—that the Board found that the maximum safe dosage of Vicodin ES is twelve tablets per day, and of Lorcet, eighteen tablets per day. Tr. 299–300. Indeed, according to one of the findings of the State ALJ’s decision, “[a]cetaminophen is potentially toxic if between 7.5 to 10 grams are consumed daily for one to two days.” RX A, at 14 (citation omitted).

However, for the purpose of resolving this proceeding, I accept the premise that Respondent had a good faith belief that a patient can safely consume up to 9 to 10 grams per day of acetaminophen. However, even accepting this, there was ample other evidence including an expert’s report establishing the need to perform regular blood tests to determine how ingesting this much of the drug is affecting a patient’s liver function.

² CURES is a database maintained by the State of California, Bureau of Narcotics Enforcement, from which doctors may obtain Patient Activity Reports (PARs) showing a patient’s controlled substance prescriptions and who prescribed them. GX 39; Tr. 104. Dispensers of controlled substances, including pharmacies and physicians who dispense, must report to CURES. *Id.* Thus, the PARs allow a physician to determine whether a patient is receiving controlled substances from other doctors and is thus engaged in doctor shopping. *Id.* at 103.

³ The PDR, or *Physician’s Desk Reference*, contains manufacturers’ recommendations as to the dosing of drug products. RX D, at 3.

⁴ Respondent excepted to the ALJ’s Decision arguing that it “neglect[ed] to recognize Respondent’s medical training as a surgeon and his years of experience with pain management as a surgeon and as the chair of the Newhall Community Hospital and as a participant in hospital peer review proceedings dealing with pain management.” Resp. Exc., at 4.

unnecessarily prescribing hydrocodone to the “younger, mid-twenties population.” Tr. 24. Thereafter, a DEA Diversion Investigator (DI) obtained reports from the Controlled Substance Utilization Review and Evaluation System (CURES), the State’s prescription monitoring program showing prescriptions issued for schedule II through IV controlled substances, as well as ARCOS, a DEA database which monitors the sale of Schedule III and IV controlled substances from manufacturers and distributors. *Id.* at 25–27; GX 39. While the CURES report showed “minimal activit[y],” Tr. 26, the ARCOS report showed that between 2004 and 2006, Respondent’s purchases of hydrocodone had increased from 63,600 tablets to 388,000, and that between January 1 and April 11, 2007, Respondent purchased 221,000 such tablets. *Id.* at 26–27; GX 4.⁶ According to the DI, such large hydrocodone purchases were not consistent with a family practice or even with the operation of a typical family pharmacy, which he estimated might purchase 100,000 hydrocodone tablets per year. Tr. 44. Among physician purchasers of hydrocodone in the Los Angeles area, Respondent ranked second; the ARCOS database could not be queried, however, as to a ranking for physicians who also operate their own dispensaries. *Id.* at 28–30, 34, 43–44.

During the investigation, the DEA sent an undercover special agent (SA) using the name of “Kim Jackson” to Respondent in an attempt to obtain controlled substances. Tr. 51. The SA wore a wire and was monitored by a DI. *Id.* at 52.

At the SA’s first undercover visit with Respondent on October 3, 2006, she told Respondent that she had just moved from Montana and had been getting Vicodin, a Schedule III controlled substance which contains hydrocodone and acetaminophen, from a physician there. Tr. 187, 192 (playing of GX 47 in hearing); GX 47; RX AA, at 1 (transcript of visit); see 21 CFR 1308.13(e). When

Respondent asked her why she was taking the Vicodin, she responded, “It just made me feel better.” Tr. 193; GX 47; RX AA, at 1. Respondent then said, “No, you know, I don’t prescribe Vicodin for recreational purposes or to feel better * * * because Vicodin is a controlled drug and it is specifically for specific pains, you know?” Tr. 193–94; GX 47; RX AA, at 1. The SA then inquired whether “if [her] back hurt” would “be a way to get” the drug. Tr. 194; GX 47; RX AA, at 1. Respondent replied: “Yeah, what happened to your back?” Tr. 194; GX 47; RX AA, at 1. The SA answered: “I don’t really specifically remember anything happening to it. But if it hurt, would Vicodin help it?” Tr. 194; GX 47; RX AA, at 1. Respondent answered in the affirmative.

Respondent then inquired about the doctor in Montana who had prescribed the Vicodin and whether that physician had obtained additional studies given her report of back pain. Tr. 194–95; GX 47; RX AA, at 1–2. The SA indicated that the doctor in Montana performed a physical examination but did not take x-rays or order any other tests. Tr. 195; GX 47; RX AA, at 2. Respondent then noted that it was “unusual” for someone as “young” as the SA to be having back pain, and asked: “where in your back are you having the pains?” Tr. 195; GX 47; RX AA, at 2. The SA answered: “I don’t specifically have it, I was just asking you if that would be a reason someone would have it?” Tr. 195; GX 47; RX AA, at 2. Respondent next stated, “well you know, if it is for that reason for now * * * I can give you a prescription * * * which Vicodin are you using? Extra strength?” Tr. 196; GX 47; RX AA, at 2. The SA told Respondent that she was getting 10 mg. strength. Tr. 196.

Shortly thereafter, Respondent then asked, “Which part of your back are you hurting * * * show me where?” Tr. 196; GX 47; RX AA, at 2. The SA responded, “Here.” Tr. 196; GX 47; RX AA, at 2. She then elaborated, “it’s not really sensitive.” Tr. 196; GX 47; RX AA, at 2. When Respondent asked her how long she had been having the pain, the SA replied, “A couple years I guess.” Tr. 196; GX 47; RX AA, at 2. Respondent indicated that he would write for thirty tablets of 10 mg. Vicodin (Vicodin ES) but that “we have to have more documentation as to * * * why this [sic] controlled drugs * * * are being prescribed for you, you know?” Tr. 196; GX 47; RX AA, at 2.

Regarding her having pointed to her lower back and her statement that she had had pain for a “couple years I guess,” the SA testified that she had told Respondent several times that she “was not in pain” and that she wanted

Vicodin “because it made me feel good.” Tr. 216. The SA further testified that Respondent was trying to provide her “with a story—oh, okay, yes, that works—back pain.” *Id.* The SA also testified that Respondent did not appear to be hard of hearing as she was never asked to repeat herself. *Id.* While the SA acknowledged that Respondent may have been skeptical of whether she had pain, she testified that “right after that, he agreed to give me the Vicodin without further examination or questions.” *Id.* at 217.

Respondent then indicated that he could either give her a prescription or that she could buy the medication from his dispensary. Tr. 197; GX 47; RX AA, at 3. The SA opted to buy her Vicodin from the dispensary. Tr. 197; GX 47; RX AA, at 3. Respondent instructed her to take the Vicodin as one tablet every eight hours. Tr. 198; GX 47; RX AA, at 3. The SA’s visit with Respondent lasted approximately six minutes. Tr. 192, 199.

The SA received a paper bag containing Vicodin from the receptionist. Tr. 201. According to the SA, she did not receive anything in writing from Respondent notifying her that she had the option of obtaining the medication either with a prescription from a pharmacy or from his dispensary. *Id.* at 201. When the DIs later counted the pills, there were thirty-five tablets, not thirty. *Id.* at 202.

According to the patient record, Respondent observed a “muscle spasm.” GX 14, at 4. In her testimony, the SA stated that Respondent examined her back “for maybe five seconds, at which time he touched me two to three times, lightly.” Tr. 200. She also testified that Respondent never mentioned back spasms to her and that she never mentioned that she had back spasms to him. *Id.* The SA further testified that in examining her, Respondent never saw her skin as he did not lift the garment covering her back. *Id.* at 213.

In his testimony, Respondent asserted that when he touched the SA’s back, he noticed muscle spasms, which confirmed his “impression that she did [have] back pain.” Tr. 404. Respondent also testified that usually when he detects muscle spasms in a pain patient, he does not mention it to the patient but only notes it in the patient record as the observation is a “confirmation for [his] own information.” *Id.* at 319. According to Respondent, a physical examination of the back largely “is by palpation of the back muscles.” *Id.* at 486. He further maintained that, in checking for muscle spasms, it is preferable to touch through light clothing rather than to touch skin directly so as to avoid cold hands triggering a muscle spasm. *Id.* at 320.

⁶ Respondent testified that during these years, his practice was growing. Tr. 282. In 2004, he had 1,740 patients; in 2005, he had 1,970 patients; in 2006, he had 2,320 patients; and in 2007, he had 2,353 patients. *Id.* He indicated that the reason for this increase was that prior to his heart surgery in 2003, he had retained a physician’s assistant at his practice. *Id.* at 283. However, on losing patients after the heart surgery, he had dismissed the physician’s assistant. *Id.* He attributed the subsequent growth of his practice to the fact that the patients were able to see him instead of just a physician’s assistant. *Id.* at 284. Respondent further testified that with the increase in patients, he also experienced an increase in pain patients and therefore increased his purchases of Vicodin and other opioids. *Id.* The ALJ “generally found the Respondent’s testimony credible.” ALJ at 10 n.4.

Regarding the SA's visit, Respondent testified that in almost fifty years of practicing medicine he had never had a patient claim to not have pain yet request pain medication; nor had a patient who initially claimed to not have pain later claim to have pain. *Id.* at 404–05. According to Respondent, “I don’t believe, nor do I remember, that she told me that she did not have any back pain.” *Id.* at 405.

The ALJ found that “Respondent credibly testified that he believed she was suffering from back pain for the past two years. He believed he saw muscle spasms, which would be consistent with back pain.” ALJ at 7. The ALJ did not explain how Respondent would have seen muscle spasms given the SA’s testimony that he did not lift the garment that was covering her back. Nor did she reconcile her credibility findings with the actual conversation which was recorded during the visit which shows that Respondent had agreed to provide the Vicodin before the Agent had made any representation that she had back pain.

If taken as instructed, the thirty pills that the SA should have received would have lasted a minimum of ten days. On October 19, the SA phoned Respondent’s office and requested a refill of Vicodin and asked for sixty pills instead of the thirty of her initial prescription. Tr. 202. The receptionist told her to call back after 3:00 to confirm whether the refill was approved. *Id.* When the SA called back, she was told that the refill had been approved; the SA picked up the prescription the following day. *Id.* at 203.

If taken as prescribed, the refill should have lasted a minimum of twenty days. Eighteen days later, on November 7, the SA called for another refill and asked for 120 Vicodin because she was going out of town. *Id.* This time, the SA was not told to call back to verify whether the refill had been approved. *Id.* Two days later, the SA obtained the drugs. *Id.*

At an appointment on December 1, 2006, the SA told Respondent that Vicodin made her nauseous and requested OxyContin. Tr. 203–04; RX Z, at 2. Respondent stated that OxyContin had worse side effects and that he would give her Lorcet (another hydrocodone drug) instead. Tr. 204; RX Z, at 3. He also recommended that she get massaged with warm olive oil and use a heating pad on her back. RX Z, at 3–4. The SA received 120 Lorcet from Respondent’s staff on that day. Tr. 204. The SA also testified that although she had been asked to bring her medical records during the phone call in which

she made her initial appointment, she never did and was never again asked to bring them. *Id.* at 205. On cross-examination, the SA testified that she did not receive early refills. *Id.* at 226.

R.E., who had reported Respondent to the DI, also agreed to wear a wire and visit Respondent; a portion of the recording of his initial visit was played at the hearing. Tr. 55; GX 47. On October 13, 2006, R.E. visited Respondent. GX 12, at 3. R.E. complained of stiffness in his neck which he had had for “a couple of years” duration and said that he had been taking Norco, a drug which contains 10 mg. hydrocodone and 325 mg. acetaminophen. Tr. 60–61, 68; GX 12, at 3, GX 47. R.E. also indicated that he had tried acupuncture and “[a] little yoga.” Tr. 63. He also complained that it was hard for him to fall asleep. *Id.* at 64.

During the visit, Respondent touched R.E. lightly on the neck a couple of times. While Respondent noted the presence of muscle spasms in R.E.’s patient record, the recording of the visit contains no comment by Respondent which indicates that he had found that R.E. had a muscle spasm. GX 12, at 3; Tr. 60–67. The DI also testified that when he interviewed R.E. after the visit, R.E. never mentioned that Respondent had said that he had muscle spasms. Tr. 122. Respondent advised R.E. to use a heating pad and to get someone to massage the muscles for him. *Id.* at 63. Respondent also told R.E. he could either provide, or write a prescription for, 60 Vicodin ES, as well as 60 Xanax (alprazolam) to help him sleep. *Id.* at 64. R.E. opted to buy the drugs from Respondent’s dispensary and Respondent instructed him to take one Vicodin ES every eight hours and one Xanax at night for sleep and another during the day “if you need it.” *Id.* at 65, 174; GX 12, at 3.

If taken as directed, the Vicodin ES thus should have lasted twenty days; the Xanax should have lasted thirty days. On October 20, one week later, R.E. obtained a refill of 120 Vicodin ES. GX 12, at 5. According to R.E.’s patient record, on November 9, R.E. did a follow-up appointment with Respondent at which time Respondent switched him to Lorcet and dispensed to him 120 tablets, with the instruction to take one tablet every six hours. GX 12, at 5.

While this quantity would have provided a thirty-day supply if taken as directed, on December 1 (twenty-two days later), R.E. obtained a refill of 150 Lorcet, 30 tablets more than the previous refill. While if taken as directed, this refill would have lasted thirty-seven days, only six days later on

December 7, Respondent approved refills for another 150 Lorcet with the same dosing instructions, as well as for 60 Xanax. *Id.* at 6.

On February 27, 2007, R.E. received refills for 150 Lorcet (again a thirty seven-day supply) and 60 Xanax, with the same dosing instructions. *Id.* On March 13, R.E. obtained another refill for 150 Lorcet and Respondent changed the dosing instruction to one tablet every four hours. *Id.* However, there are no notes indicating that Respondent had talked with R.E. and learned of any change in his condition that would support an increase in the dosing. Beside Respondent’s initials on the phone message requesting the refill is the message: “Need visit & agreement.” *Id.* at 9. A note saying “No Refill” three times in a row followed by “NEEDS TO BE SEEN,” dated March 19, 2007 appears in R.E.’s patient record. *Id.* at 7.

A CURES Patient Activity Report (PAR) indicates that R.E. received hydrocodone/apap 7.5 mg./300 mg. from another doctor on November 8, 2006; Vicodin ES the following day from another doctor; and Suboxone⁷ from another doctor on November 22. GX 44, at 2. On December 6, 2006, R.E. received more hydrocodone/apap 7.5 mg./300 mg., as well as diazepam, from yet another doctor; on February 13 and March 5, 2007, he received Suboxone from the same physician who had issued the prescription filled on November 22. *Id.*

R.E. had disclosed to DEA Investigators his consumption of Suboxone. Tr. 126. The DI testified that during the time that R.E. worked as a confidential informant, he had no reason to believe that R.E. was improperly consuming controlled substances.⁸ *Id.* at 179.

The investigators subsequently obtained warrants to search Respondent’s office and residence. *Id.* at 70. On April 12, 2007, the warrants were executed and the authorities seized approximately one hundred patient records which were selected based on these persons having received large quantities of hydrocodone, Xanax, and Valium; the DIs also seized the patient files for the SA and CI. *Id.* at 90–91. During the search of Respondent’s residence, the DIs interviewed him. *Id.* at 71.

⁷ Suboxone is a drug which is used to detoxify addicts from narcotics. Tr. 111.

⁸ The record does not indicate at what point DEA became aware that R.E. was obtaining controlled substance prescriptions from other doctors or what course of action investigators took as a result. Because my findings regarding Respondent’s prescribing to R.E. are based on the recording of his visit (which was played into the record) and his patient file, R.E.’s credibility is not in issue.

In the interview, Respondent indicated that he had approximately two thousand patients, including approximately fifty pain patients for whom he either wrote prescriptions or dispensed medication. *Id.* at 72. Respondent related that he took primarily cash patients and some MediCal patients but he did not take patients with private insurance. *Id.* at 90.

Respondent further stated that an employee, H.C., filled the prescriptions at his dispensary. *Id.* at 73. According to the DI, H.C. was not licensed in California to dispense drugs. *Id.* Respondent told the DIs that those patients who wanted refills would call his office, that he reviewed the requests, and that where appropriate, he approved a refill. *Id.* He further stated that he would authorize a refill approximately once a month. *Id.* The DI testified that Respondent's statement as to the frequency of his authorizing of refills was not consistent with what he observed in the patient files. *Id.* at 73–74.

As discussed below, the various patient records include slips memorializing the refill requests his patients phoned in. Respondent testified that upon reviewing these slips, he would instruct his staff to note on the slip when the patient had last received a refill (indicated by "LR") and/or the date when he/she had last been seen (indicated by "LS"). *Id.* at 337–38. He further testified that he used follow-up visits to obtain "information as to how that patient is doing at the particular moment" which he would use "either to keep the medications the same, lower it, or increase it." *Id.* at 337.

Respondent further testified that H.C. repackages pain medications into smaller bottles and labels them with pre-labeled dosing instructions. *Id.* at 306, 328. H.C. then brings the pain medication to "the girl in front who in turn gives them to the patient who pays [for the drug] up front." *Id.* at 328.⁹

Respondent admitted, however, that he did not personally supervise the receptionist as she delivered the controlled substances to his patients. *Id.* at 593. He also testified that his pharmacy, including his manner of dispensing medication to patients, was inspected by the Medical Board on two separate occasions and that he was not cited for any infractions. *Id.* at 328–29. Respondent was not present during one of the inspections. *Id.* at 329.

The DI also obtained additional PARs from CURES. These reports showed that four additional patients whose prescriptions were at issue in the proceeding obtained controlled substances from other physicians during the same period in which they obtained controlled substances from Respondent. *Id.* at 108–11; GXs 41, 42, 44, 45. California authorizes a licensed physician to obtain PARs "so that well-informed practitioners can and will use their professional expertise to evaluate their patients' care and assist patients who may be abusing controlled substances." GX 39, at 2.

Respondent testified that he was unaware of the availability of PARs until he saw the documents the Government was presenting in this proceeding. Tr. 343. He testified that, should his registration be restored, he would use the database when a patient is requesting refills too quickly, when a patient reports at his initial visit that he has already been on controlled substances, as well as thirty days after having prescribed controlled substances to a patient. *Id.* at 344, 557–58.

The Expert Reports on the Standard of Care and Usual Course of Professional Practice

At the hearing, neither party offered the testimony of an expert witness. However, each party submitted into evidence a report from a physician who had reviewed at least some of the patient files in question. GX 6; RX D. While neither party's witness was formally qualified as an expert (as would likely be the case if they had been called to testify), both parties referred to the physicians as experts and the ALJ treated them as such, as do I.

The Government's Expert was Rick Chavez, M.D. Dr. Chavez, who holds a B.A. from Stanford University and obtained his M.D. from the U.C.L.A. School of Medicine, is the founder and Medical Director of The P.A.I.N. Institute and is an Assistant Clinical Professor of family medicine at the U.C.L.A. School of Medicine. GX 6, at 33; GX 5. Dr. Chavez holds board certifications in family practice, pain management, and addiction medicine. GX 5, at 1. He is a member of the American Academy of Pain Management, the Society for Pain Management, the American Society of Interventional Pain Physicians, the American Pain Society, and the American Academy of Addiction Psychiatry. *Id.* at 8.

In addition to his medical practice, since 2001 Dr. Chavez has served as a Consultant/Physician Reviewer for the California Board of Medical Quality

Assurance. *Id.* In this capacity, he reviews cases involving pain management, family medicine, addiction medicine, and general medical quality.¹⁰ *Id.*

Respondent's Expert was William A. Norcross, M.D. Dr. Norcross received a B.S. from Ursinus College and his M.D. from the Duke University School of Medicine and holds board certification in family practice and geriatric medicine. RX D, at 5. At the time of the hearing, he was the Director of the University of California—San Diego's Physician Assessment and Clinical Education (PACE) Program and a Professor of Clinical Family Medicine at the University's School of Medicine. *Id.* at 6. However, Dr. Norcross is not board-certified in pain management.

In their respective reports, Dr. Chavez reviewed fifteen patient files;¹¹ Dr. Norcross reviewed four patient files. See GX 6; RX D. In their reports, both Dr. Chavez and Dr. Norcross opined as to whether Respondent had met the standard of care. However, Dr. Chavez provided an extensive discussion of what steps Respondent was required to take in order to meet the standard of care and discussed the Medical Board of California's *Guidelines for Prescribing Controlled Substances for Pain (Guidelines)*, which were first adopted in 1994.¹² GX 6, at 16. By contrast, Dr.

¹⁰ Dr. Chavez also has extensive experience in conducting utilization review and case management, which involves monitoring the activities of primary care physicians for excessive or unwarranted use of services in pain management, neurosurgery, plastic surgery, orthopedics, podiatry, and general surgery. GX 5, at 3–4. He has also "developed guidelines for surgical, orthopedic, plastic surgery and pain management procedures to ensure appropriate utilization and quality of care." *Id.* at 4.

¹¹ Dr. Chavez reviewed the patient records of W.C., J.D., R.A., M.T., B.W., S.M., M.H., D.M., "Kim Jackson," R.E., E.A., J.N., M.D., J.W., and S.R. GX 6, at 2. Dr. Norcross reviewed the patient files of W.C., J.D., R.A., and M.T.; these files include three of the patients who, according to the PARs obtained by the Government, had obtained controlled substances from other physicians during the period in which Respondent prescribed to them. RX D, at 1; GX 41–43.

¹² In his discussion of the standard of care, Dr. Chavez noted that the Board has promulgated *Guidelines for Prescribing Controlled Substances for Pain*, a copy of which was attached to the Government's Post-Hearing Brief. Gov't Post. Hrng. Br., App. E. These were adopted by the Board in 1994, GX 6, at 16, and were subsequently revised in 2003. *Id.* at 16; App. E, at 1. I take official notice of the fact that the Board adopted the revised *Guidelines* on August 1, 2003. The *Guidelines* are intended "to improve effective pain management in California, by avoiding under treatment, over treatment, or other inappropriate treatment of a patient's pain and by clarifying the principles of professional practice that are endorsed by the Medical Board so that physicians have a higher level of comfort in using controlled substances, including opioids, in the treatment of pain." *Id.* at 1 (emphasis added).

⁹ Respondent later identified this individual as the receptionist, who first takes a patient's payment. Tr. 592.

Norcross's report discussed only whether he believed Respondent's "charting and clinical decision making," as well as his prescribing of drugs beyond the maximum recommended daily dosage listed in the *Physician Desk Reference*, met the standard of care. RX D.

According to Dr. Chavez, "[a]ccepted standards of medical practice require that physicians obtain a sufficient history and perform a focused physical exam when evaluating patients in chronic pain." GX 6, at 17. Furthermore, "[b]efore prescribing narcotic analgesic medications[,] the physician should have an understanding as to the probable diagnosis and a picture of the overall general health of the patient." *Id.*

Dr. Chavez explained that a physician must obtain a history of the condition, which includes determining the onset of the pain, the "[e]xact location and character of pain" and use either "a visual analogue" or a "1–10 scale" to measure the pain level. *Id.* The physician must assess the degree of the patient's functional and physical impairment, which includes the patient's physical and psychological function, documentation of the presence of recognized medical indications for the use of controlled substances, and a substance abuse history with the latter being "a basic requirement." *Id.* at 17–18. In addition, the physician should do a review of prior pain treatment and medications and determine the patient's "response to previous treatment," as well as review the patient's medical records and test results from prior treatment. *Id.* Moreover, the physician must determine whether the patient has any coexisting or underlying conditions. *Id.* at 18.

Dr. Chavez further explained that "[b]ased on the patient's complaints, the physician must determine the most likely reasons for the patient's pain complaint" and that "[d]etermining the exact Pain Generator or source of pain requires a thorough focused exam which correlates with historical data." *Id.* Continuing, Dr. Chavez observed that "[h]alf of all patients in chronic pain suffer from 1 or more other medical conditions and thus, may have multiple

different diagnoses. Therefore, assessment of cardiac, renal, hepatic, GI, pulmonary, and psychiatric status are imperative before prescribing opiate analgesics and other medication which may not be indicated in particular medical conditions, or which may affect end-organ function." *Id.* Moreover, "[i]t is of utmost importance that the physician keep an accurate and complete medical record with thorough documentation at every visit for each chronic pain patient." *Id.* Dr. Chavez also explained that a patient may require further testing to verify a presumed diagnosis and to assess major organ systems because prescribing certain drugs, including those containing Tylenol (acetaminophen), "in a patient who may develop end organ damage may be contraindicated." *Id.* at 19.

In this regard, Dr. Chavez further observed that "[p]atients on large doses of medications which might cause serious side effects must have regular blood chemistries drawn in order to assess end-organ function and a baseline measurement of function. It is crucial for the treating physician to recognize early on whether any evidence of medication induced organ dysfunction is present." *Id.* at 29.

According to Dr. Chavez, once the physician makes a diagnosis, a treatment plan should be created which lists, *inter alia*, the objectives of treatment, how the success of the treatment plan will be evaluated, and whether any further tests or consultations with specialists are required. *Id.* at 20–21. In addition, "the prescribing physician should have discussed the risks and benefits of the use of controlled substances with the patient and have [obtained] a signed medication agreement with the patient, within the first [three] visits, which spells out the requirement for continued opioid therapy." *Id.* at 20–21. Dr. Chavez further noted that "[c]hronic pain treatment requires more than the use of opiate analgesic medications." *Id.* at 30.

Dr. Chavez observed that "[i]t is not considered good medical practice to allow refills on addictive medications in pain patients unless they have been under the care of the physician for [a] long-term and/or are well-known to the prescribing physician." *Id.* at 20. Continuing, he explained that "[f]requent visits and re-evaluation of the situation are necessary" and that "[i]t is prudent to see the opiate treated chronic pain patient once every 1 to 3 months." *Id.* He also explained that a "[p]eriod of titration of medication and physician follow-up is necessary to determine [the] effectiveness of therapy

or [to] re-evaluate whether the presumed diagnosis is correct." *Id.* at 22.

In his review of the patient files, Dr. Chavez found that "for each patient receiving opiate analgesic(s), anti-anxiety, muscle relaxant(s), or sleep agents for chronic pain therapy," Respondent's "charts did not exhibit [the] clear presence of" "[a] thorough history," "[a] thorough focused physical exam," and "[a] thorough past historical review." *Id.* at 30. Moreover, not one of the charts had evidence that Respondent had "[b]egun a diagnostic work-up or thoughtful discussion to verify the presumed diagnosis and probable pain generator(s)," ¹³ or that the patients had "been placed on a multi-modality pain treatment and management program with appropriate use of other non-addictive medications" and consideration of other treatment modalities. *Id.*

According to Dr. Chavez, "[c]hronic pain treatment requires more than use of opiate analgesic medication and, therefore, on chart review, one should see evidence of discussion of other therapies and offer recommendations regarding behavioral therapy, psychological therapy and support, physical therapy, exercise, weight loss, and other modalities." *Id.* There should also "be plans for appropriate specialty consultation, diagnostic studies * * * and drug screens to rule out illicit drug use or diversion," as well as "medication contracts or agreements." *Id.*

Dr. Chavez observed that "the patient medication agreement that [Respondent] did have in the chart did not seem to be followed like it should have been." *Id.* at 30. More specifically, the terms of Respondent's pain management agreement included that the patient "will submit to a blood or urine test if requested by my doctor to determine my compliance with my program of pain control medicine," and that the patient "will use [his] medicine at a rate no greater than the prescribed rate and that use of * * * medicine at a greater rate will result in * * * being without medication for a period of time." GX 7 at 10.

Dr. Chavez noted, however, "that there is no consistent refill rate" in the charts, and that "[s]ome refills occurred within two days of the last refill which would mean that large quantities of opiates had * * * been ingested during that time." GX 6, at 30. He also observed that "not one of the patients had a urine

¹³ The *Guidelines* state that "[t]he Medical Board expects physicians and surgeons to follow the standard of care in managing patients." *Id.* Under the heading "History/Physical Examination," it provides that "[a] medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; an assessment of underlying or coexisting diseases or conditions; and the documentation of the presence of a recognized medical indication for the use of a controlled substance." *Id.* at 2 (emphasis added).

¹³ Dr. Chavez stated that while it is not expected that a physician can conduct all the "recommended evaluations on the first visit," "by the 2nd, 3rd, or 4th visit patient charts should have many of the basic standards of care during the course of treatment." GX 6, at 30.

drug screen done to verify that they were indeed ingesting the medication as opposed to diverting it.” *Id.* at 30–31. He also further found that Respondent “did not do any significant medical workup on any of the patients.” *Id.* at 31.

Dr. Chavez also noted that while under the California guidelines “there is no maximum or minimum of medication limitations as long as [the] amounts provided match a safe dosing schedule,” he further opined that “if the maximum exceeds the manufacturer’s (pharmaceutical company; PDR) recommendations, then, generally, one may conclude that misuse or diversion of opiates or other addictive drugs may be occurring.” *Id.* at 31–32. Dr. Chavez then explained that “the normal maximum dosage of Norco would be two tablets every four hours or a maximum of 12 tablets per day, and for Vicodin ES 7.7/750[,] a maximum of 4–6 per day because of the amount of Tylenol [acetaminophen] involved,” which “generally should not exceed 4000 milligrams per day.” *Id.* at 32.

According to Dr. Chavez, while “most of the quantities [Respondent] prescribed” would be “reasonable and appropriate” if “given on a monthly interval,” he noted that “[m]any of the refills occurred within 2 to 7 days of the last refill” and that “[i]n many cases, it would have been impossible * * * to use this quantity of controlled medications within that short of period of time.” *Id.* at 32. In Dr. Chavez’s opinion, “[t]his should have been a red flag for possible drug diversion and/or abuse.” *Id.*

Dr. Chavez opined that “[b]ased on the types and quantities of medications prescribed, the younger age range of many of [Respondent’s] patients,¹⁴ the frequency of prescriptions, the excessive quantities of medications, and irregular refill dates, there is substantial evidence to indicate the probability of abuse or diversion of opiate medications in the majority of the patient charts reviewed.” *Id.* at 31. He also opined that “[t]he fact that [Respondent] so freely prescribed these drugs without a thorough evaluation of these patients is not an acceptable approach to pain management.” *Id.*

Continuing, Dr. Chavez noted that “[n]ot one chart had evidence of the physician undertaking a workup in evaluation of the underlying medical problem” and “[t]he 15 charts reviewed

lacked any objective evidence or chart notes justifying the use of opiate therapy to the level exhibited on the charts evaluated.” *Id.* at 32. Dr. Chavez also observed that the charts demonstrated no “effort to try nonaddictive medications or offer alternative modalities of treatment.” *Id.* Dr. Chavez then opined that “[t]he medical care and treatment provided by [Respondent] are markedly below the accepted standards of treatment for licensed physicians in the United States today. The represents an EXTREME DEPARTURE from the standard of care expected of a licensed practicing physician in the U.S. today.” *Id.* at 33 (caps in original).

In addition to the four patient records indicated above, Dr. Norcross reviewed Dr. Chavez’s report on Respondent and the Board’s decision referenced above. RX D, at 1. Dr. Norcross indicated he had formed certain opinions based on these materials and also on his “personal knowledge” of Respondent in that he had known Respondent “for almost 4 years in [Dr. Norcross’s] capacity as a teacher, helping [Respondent] to improve the quality of his prescribing and record-keeping.” *Id.* Further, Dr. Norcross had “also served as a witness in [Respondent’s] Medical Board of California matter.” *Id.*

Dr. Norcross concurred with Dr. Chavez that Respondent’s “medical record-keeping still has room for improvement” and that his “charting of the patient history and physical examination would not be ‘thorough’ by the standards Dr. Chavez cite[d].” *Id.* at 2. However, he then asserted that Respondent should be “judge[d] * * * against the standard of care defined by ‘the community of licensees,’ and within that group, against physicians of similar age, culture, experience, training background, and clinical environment.” *Id.* at 2. Continuing, Dr. Norcross opined that “if compared to other older generation general practitioners who were not the beneficiaries of a full 3-year residency training program and were providing care to an underserved patient population, I believe [Respondent’s] charting and clinical decision making are well within the middle of that Bell Curve.” *Id.*

Dr. Norcross further opined that as to the four patients whose medical records he reviewed, “there was a plausible source of pain, and [Respondent] provided enough history and enough examination, that the diagnosis was clear in all cases.” *Id.* With respect to Dr. Chavez’s criticism as to the lack of “laboratory tests and imaging studies” as well as consultations with specialists, Dr. Norcross explained that he understood the costs of these were a

“deterrent[] * * * for a significant portion of [Respondent’s] patient population” because they do not have insurance. *Id.*

Respondent, however, produced no credible evidence that any of the specific patients whose files were reviewed by Dr. Chavez lacked the financial resources to pay for these tests and/or consultations.¹⁵ Moreover, given that some of these patients had the ability to purchase more drugs (and sometimes multiple drugs) on numerous occasions within a month, it seems likely that they had the ability to pay for some tests and/or consultations.

Dr. Norcross did, however, agree with Dr. Chavez’s “point that physicians should, as a general rule, limit their prescribing habits, for all drugs, not just opiates, to the manufacturer’s prescribing limits, even though responsible physicians can, and do, prescribe medications, including pain medications, ‘off label’ in appropriate cases.” *Id.* at 3. Dr. Norcross further noted that he had advised Respondent that “it was [his] strong recommendation [to] limit his prescribing to the * * * recommended daily maximum dosage, even though other reasonable physicians do engage in ‘off label’ prescribing in appropriate cases” and that “there are epidemiological studies regarding liver toxicity supporting the PDR dosage recommendations.” *Id.* According to Dr. Norcross’ report, he had “reviewed this” with Respondent, who had “committed himself to doing this henceforth, notwithstanding the ‘off label,’ dosage levels discussed in the [Board’s] decision.” *Id.*

While the ALJ “ha[d] a problem with the conclusions of both of the expert[s],” she held that Dr. Chavez’s findings were entitled to more weight because “they are more consistent with the California requirements for determining the standard of care to be levied against the Respondent’s practices.” ALJ at 43. I agree with the ALJ’s conclusion although I disagree with her reasoning to the extent it suggests that Dr. Chavez erroneously “seemed to infer that there

¹⁵ On this issue, Respondent’s testimony was generally vague. With respect to patient M.T. (GX 19), who complained of lower back pain, Respondent stated that he did not do any additional diagnostic studies because “actually in talking to him it sounds like he’s a patient of very limited means and to get the x-rays and all of the other studies would cost him a lot of money which he cannot afford.” Tr. 384. Yet M.T.’s record contains no indication that Respondent discussed this issue with him. See generally GX 19. With respect to M.H. (GX 13), who complained of migraines, Respondent acknowledged that “there could have been a lot more studies” but the patient “would have to incur considerable expense.” Tr. 397. Here again, there is no evidence in M.H.’s record that Respondent discussed the issue with him.

¹⁴ According to Dr. Chavez, “[p]atients between the ages of 21 and 39 who suffer with chronic pain and who are on chronic opiate therapy are not that prevalent, even in a busy ‘Pain Practice.’” GX 6, at 32. Moreover, the majority of patients “in this age group can be treated with non-opiate and non-addictive medications for the most part.” *Id.*

is a national standard of care.” *Id.* at 40; see also *id.* (noting that “[i]n California * * * a doctor is held to the standard of skill or care prevailing in the medical profession in the locality in which he practices”) (citing *Inouye v. Black*, 238 Cal.App.2d 31, 33 (Cal. Ct. App. 1965)).

In his Exceptions, Respondent contends that the ALJ “completely ignore[d] the standard of care set by the California Supreme Court and ratified by the California Medical Board” that “a physician is required to possess and exercise, in both diagnosis and treatment, that reasonable degree of knowledge and skill which is ordinarily possessed and exercised by other members of his profession in similar circumstances.” Resp. Exceptions at 7 (quoting *Landeros v. Flood*, 17 Cal. 3d 399, 408 (1976)). According to Respondent, the standard applied by the ALJ “has long been repudiated * * * in favor of the ‘similar circumstances’ standard articulated by” his expert. *Id.* at 7–8.

Both the ALJ’s reasoning and Respondent’s contention ignore, however, that the standard applicable under Federal law is whether the prescriptions were “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a). In *United States v. Moore*, 423 U.S. 122, 138–39 (1975), the Supreme Court upheld the conviction of a physician for unlawful distribution of methadone based on a jury instruction that allowed the jury to find him guilty if he dispensed the drug “other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States.” (emphasis added).

Moreover, even after *Gonzalez v. Oregon*, 546 U.S. 243 (2006), several courts of appeals “have applied a general-practice standard when determining whether the practitioner acted in the ‘usual course of professional practice.’” See *United States v. Smith*, 573 F.3d 639, 647–48 (8th Cir. 2009); see also *id.* at 648 (discussing *Moore*; “Thus informed by the Supreme Court and other controlling and persuasive precedent, we believe that it was not improper to measure the ‘usual course of professional practice’ under § 841(a)(1) and [21 CFR] 1306.04 with reference to generally recognized and accepted medical practices. * * * ”); see also *United States v. Merrill*, 513 F.3d 1293, 1306 (11th Cir. 2008) (quoting *Moore*, 423 U.S. at 139) (“The appropriate focus is not on the subjective intent of the doctor, but

rather it rests upon whether the physician prescribes medicine ‘in accordance with a standard of medical practice generally recognized and accepted in the United States.’”).

Of further significance, post-*Gonzales*, the Ninth Circuit has expressly recognized that “both the Supreme Court and this Circuit have previously approved jury instructions that refer to a national standard of care.” *United States v. Feingold*, 454 F.3d 1001, 1009 (9th Cir. 2006).—As these cases make clear, the opinion of the Government’s Expert that Respondent’s treatment of the patients whose files he reviewed was “markedly below the accepted standards of treatment for licensed physicians in the United States today” and “represents an EXTREME DEPARTURE from the standard of care expected of a licensed practicing physician in the U.S. today” is clearly admissible and probative of whether Respondent’s prescriptions were “issued for a legitimate medical purpose” and whether he acted “within the usual course of professional practice.” 21 CFR 1306.04(a).¹⁶

In any event, the record establishes that Dr. Chavez serves as a consultant/physician reviewer to the California Board on pain management and is thus clearly familiar with the standards of medical practice related to prescribing controlled substances to treat chronic pain patients in California. Moreover, in his report, Dr. Chavez made clear that he had analyzed Respondent’s prescribing pursuant to the California guidelines.¹⁷ See GX 6, at 31.

Most importantly, in his report, Dr. Chavez provided an extensive discussion of the accepted standards of medical practice for diagnosing, treating, and monitoring chronic pain patients. By contrast, Dr. Norcross is not even board certified in pain

management. With the exception of his conclusory assertion that Respondent had done enough of a history and examination so that his diagnosis was clear with respect to the four patient files he reviewed (in contrast to the fifteen files Dr. Chavez reviewed), he did not otherwise identify how Dr. Chavez had misstated the accepted standards of medical practice. Indeed, Dr. Norcross apparently agreed with Dr. Chavez’s opinion regarding the inappropriateness of prescribing controlled substances containing acetaminophen in quantities exceeding the manufacturer’s recommended limits, as well as Dr. Chavez’s opinion as to the inadequacy of Respondent’s medical records. Finally, Dr. Norcross failed to address numerous other deficiencies identified by Dr. Chavez such as Respondent’s failure to do blood chemistries to assess organ function, his failure to discuss the risks and benefits of taking controlled substances, his failure to create treatment plans, his failure to recommend other treatment modalities, his failure to require frequent visits to re-evaluate his patients and the efficacy of the therapy, his failure to take substance abuse histories, the frequency of his refills, and his failure to enforce his pain management agreements. Thus, I conclude that Dr. Chavez’s report is entitled to significant weight and Dr. Norcross’s report is entitled to little weight.

The Patient Files and Respondent’s Testimony Regarding Them

Before discussing the patient file evidence, several issues must be resolved. The ALJ found that “Respondent expects his patients to rely upon his verbal dosing information, [and] not the instructions found on the prescription labels on the bottle, for controlled substances.” ALJ at 12. The ALJ further that Respondent “credibly testified that ten grams of acetaminophen is the safe limit for daily intake” and presumably credited his testimony that “the maximum safe dose of Vicodin-ES [which contains 750 mg. of acetaminophen] is 12 tablets per day” and that the maximum safe dose of Lorcet, which contains 500 mg. of acetaminophen,¹⁸ “18–20 tablets per day.” *Id.*

¹⁸ While in his testimony, Respondent asserted that Lorcet contains only 500 mg. of acetaminophen per tablet, Tr. 301–02, the Government attached to its post-hearing brief a copy of the PDR listing for the drug which shows that each tablet contains 650 mg. of acetaminophen. Gov. Br. at Appendix A. In his Reply Brief, Respondent conceded that “Lorcet contains 650 mg. of acetaminophen.” Resp. Reply Br. at 7. For the purpose of this decision, I assume that Respondent had a good faith but mistaken

¹⁶ State Board regulations and/or guidelines are, of course, relevant in determining what practices are necessary for a physician to act in the usual course of professional practice. See *Volkman v. DEA*, 567 F.3d 215 (6th Cir. 2009). This, however, is not a case where a State rule or guideline expressly allows a physician to act in a manner which is in conflict with the accepted standards of medical practice throughout the country. Nor is it a case in which the Attorney General seeks to declare illegal conduct which is clearly permitted under State law. See *Gonzalez*, 546 U.S. at 258.

¹⁷ While Respondent argues that the *Guidelines* do not have the “force of law,” Exceptions at 5, they are nonetheless relevant in assessing what practices are necessary to dispense controlled substances for a legitimate medical purpose and in the usual course of professional practice. Moreover, Federal courts have repeatedly upheld convictions under 21 U.S.C. 841 based on expert testimony as to the accepted standards of professional practice even though these standards may not have been promulgated in State board regulations. I thus reject Respondent’s exception.

In his testimony, Respondent maintained that, notwithstanding the dosing instructions for the prescriptions which were on the bottles and presumably recorded in his patient files, he actually expected his patients to take more than this because they would develop tolerance and require more of the drug to achieve pain relief. Tr. 310, 567. According to Respondent, the dosing instruction written on the bottle was “the least number of pills * * * that [his patients are] supposed to take,” and he expected his patients to rely on what he told them they could safely take, which was up to nine to ten grams of acetaminophen per day, an amount which equates to twelve Vicodin ES tablets (a tablet containing 750 mg. of acetaminophen) and 18–20 tablets of Lorcet (a tablet containing 500 mg. of acetaminophen). *Id.* at 298–302, 305, 569. However, when asked why he did not just put his oral instruction on the prescription vials, he gave the rather evasive answer that it was because he did not “know what is the effect of tolerance in all that.” *Id.* at 568.

It is not clear whether the ALJ found this specific testimony credible.¹⁹ On the one hand, as noted above, the ALJ found that “Respondent expect[ed] his patients to rely upon his verbal dosing information” and not the instructions on the label of the bottle containing the drugs he dispensed. ALJ at 12. She also found credible his testimony “that ten grams of acetaminophen is the safe limit for daily intake,” and apparently, also his testimony as to the maximum daily amount of Lorcet (18–20 tablets) and Vicodin-ES (12 tablets) which can be safely taken. *Id.*

On the other hand, the ALJ devoted an extensive portion of her decision to analyzing the quantities of drugs Respondent dispensed to specific patients, how long these drugs should have lasted “if taken as instructed” or if “taken as prescribed.” *See, e.g.,* ALJ at 13–14 (“The Respondent instructed [R.A.] to take one pill every four hours. If taken as instructed, this amount of pills [2,850 dosage units of Vicodin ES] would have lasted 475 days. Therefore, 475 days worth of medication was distributed over 267 days.”). Apparently, the ALJ based her finding that “Respondent instructed [R.A.] to take one pill every four hours” on the notations in R.A.’s chart. *See* GX 8, at 10. It also appears that she relied on the dosing information contained in the charts for the other patient files she

analyzed and for which she concluded that Respondent had dispensed controlled substances in quantities that far exceeded the amounts which he prescribed to them. *See* ALJ at 37 (“when data is compiled concerning investigated patients, the Respondent is dispensing multiple times more dosage units than the patient should consume, if taking the medication as prescribed.”).

Respondent excepts to these findings, noting that the ALJ found that he “‘credibly testified’ that ten grams of acetaminophen is the maximum daily safe dosage” and thus the maximum safe daily dosage of Vicodin ES “should be corrected to 12 * * * rather than 5” tablets; he further argues that the ALJ failed to acknowledge his testimony “that he did not expect the patients to follow the label directions, but to consume the medication dispensed over the period of time between refills” and that it is therefore “not fair to characterize the[] labels as “‘instructions to patients.’” *Id.* at 2–4.

Respondent is correct that there is an inconsistency between the ALJ’s finding regarding the amounts of Lorcet and Vicodin he told his patients they could take and her analysis of Respondent’s dispensings. I conclude, however, that it is not necessary to resolve the issue because even assuming that Respondent’s testimony regarding his instructions to the patients was credible,²⁰ he offered no similar testimony with respect to his prescribing of Xanax and Valium (*i.e.*, that he told them they could take more than what he prescribed). Thus, in determining whether he was dispensing excessive amounts of Xanax and Valium, I base my findings on the dosing regime which he noted in the respective patient’s chart. Moreover, even with respect to his dispensing of Lorcet and/or Vicodin, there is still evidence that he failed to properly monitor the amount of these drugs his patients were receiving.

E.A.

E.A. was a food server and plumber who complained of back pain. Tr. 497; GX 7, at 3. He was twenty-two years old

at the start of his treatment with Respondent. GX 7, at 2. The patient record bears no indication that Respondent took a substance abuse history. *See id.* Beginning on September 15, 2005, E.A. saw Respondent eight times at roughly monthly intervals. Tr. 503;²¹ GX 7, at 3, 5, 13, 27, 29, 32, 33, 34.

At the initial appointment, Respondent noted that E.A. had fallen about one year earlier and that he had no x-rays or other studies from that time. GX 7, at 3. Respondent observed “lumbar area muscle spasms and tenderness” and jotted down “chronic back pain? intractable?” *Id.* He prescribed Lorcet, to be taken once every four hours, and dispensed 90 tablets, a fifteen-day supply if taken in accordance with the dosing instruction recorded in the patient file. *Id.* Respondent testified that at the exam the following month, E.A.’s condition remained unchanged and that this “fortified[]” his earlier assessment that the pain was “intractable” and “chronic.” Tr. 504.

Respondent testified that he advised E.A. to use a heating pad and also to lose weight. Tr. 505, 510. He did not, however, document this in E.A.’s chart. *See generally* GX 7. He also testified that while other tests could have been administered to E.A., they probably would not have yielded information that would have altered his treatment of the patient. Tr. 618.

On September 19, only four days after E.A.’s initial visit, Respondent provided a refill for 90 Lorcet. GX 7, at 3. If taken according to the instructions in E.A.’s chart, the initial prescription should have lasted fifteen days. If, however, E.A. actually took eighteen to twenty tablets per day, the initial prescription would have lasted four to five days.

E.A. received refills of 120 Lorcet with the same dosing instruction on September 26, October 4, 14, 21 and 28; November 23; December 1, 8, 15, 22 and 29; January 5, 12, 18 and 26; and February 2 and 7, 2006. GX 7, at 5, 31–34. Yet, throughout this period, there is no evidence that Respondent ever performed tests on E.A. to determine whether the high amount of acetaminophen he was supposedly consuming was affecting his liver function.

On November 23, 2005, E.A. signed a Pain Management Agreement. *Id.* at 9–

belief that a Lorcet tablet contains 500 mg. of acetaminophen.

¹⁹ It is noted that the ALJ “generally [found] the Respondent’s testimony credible.” ALJ at 10 n.4.

²⁰ There is reason to question the credibility of Respondent’s testimony regarding the amounts of drugs he told his patients they could take. During the Special Agent’s undercover visit, Respondent told her to take one Vicodin ES “every eight hours.” Tr. 198. When the Agent repeated this instruction, Respondent replied: “Yeah. Take one every eight hours, if necessary.” *Id.* At no time did he tell her that she could safely take up to twelve tablets. *See id.* Likewise, the recording of R.E.’s visit indicates that Respondent told him to take one tablet of the Vicodin “every eight hours.” *Id.* at 65. Here again, there is no indication that Respondent told R.E. that he could take up to twelve tablets.

²¹ Respondent testified that there were five monthly examinations; the chart however indicates that there were eight: on September 15, October 14, November 23, and December 22, 2005, as well as on January 18, February 27, April 17, 2006, and one on which the date is undecipherable. GX7, at 3, 5, 13, 27, 29, 32, 33, 34.

10. Also, at some unknown date, E.A. completed a Patient Comfort Assessment Guide in which he indicated that Lorcet gave him complete relief of his pain. *Id.* at 7. He further indicated that he was at that time experiencing pain of 9 on a scale of 1 to 10, that Lorcet relieved his pain, and that not taking Lorcet exacerbated his pain. *Id.*

On February 2, 2006, E.A. received a refill for 150 Lorcet, an increase in the quantity with the same dosage noted in his file of one tablet every four hours. *Id.* at 31. Based on Respondent's claim that he expected his patients to take up to 18–20 tablets per day in accordance with his oral instructions, the refill would have lasted a minimum of seven days. E.A. obtained additional refills for 150 Lorcet on February 7 and 13. *Id.* Yet E.A. did not obtain another refill until February 27, two weeks later, which suggests that E.A. was not consuming 18–20 Lorcet per day. *Id.* His next refill of 150 Lorcet (7.5 to 8 1/3-day supply) came ten days later on March 6. *Id.*

On March 13, in addition to dispensing 150 Lorcet, Respondent dispensed 60 Valium, a thirty-day supply based on the dosing noted in the chart of one tablet every twelve hours. Respondent did not see E.A. on this day and the medical record contains no indication of Respondent's medical justification for dispensing Valium.

At approximately weekly intervals through mid-April, E.A. obtained 150 Lorcet.²² On April 17, E.A. had an appointment with Respondent, who noted in his chart that he "Need[s] reduction in the amount of meds." *Id.* at 27. On that date, Respondent dispensed only 60 Lorcet to E.A. with the usual dosage instruction of one every four hours. *Id.*

There is no record of a further appointment or refill until December 8, 2006, nearly eight months later. On this date, E.A. obtained 150 Lorcet, to be taken once every six hours (a decrease in dosage from the previous refill; however, a 7.5 to 8-day supply based on Respondent's testimony of the maximum daily safe amount), as well as 120 Valium (a sixty-day supply). *Id.* at 17. Through January 22, 2007, E.A. obtained refills of each of these drugs in the same amounts at 3–4 day intervals for a total of twelve refills of each.²³ *Id.* at 15–17. These refills were clearly early, especially in the case of the Valium, with a sixty-day supply being

obtained every three to four days. E.A. was therefore consuming hydrocodone and Valium in amounts far in excess of the maximum daily dosage, or he was diverting a substantial portion, if not all of the medication.

On January 25, Respondent dispensed a refill of 150 Lorcet but no Valium. On both January 29 and February 2, Respondent dispensed refills for 150 Lorcet and 80 Valium; and on February 5, he dispensed another 150 Lorcet. *Id.* at 14, 16. An entry in the chart for February 8, 2007 reads: "Refill Refused per [Respondent], Lorcet #150 * * * available 2/19/07." *Id.* at 14.

Notwithstanding the note in the chart, on February 16, E.A. again received another 150 Lorcet (7.5 to 8 1/3-day supply) and 30 Valium (a fifteen-day supply). *Id.* E.A. apparently attempted to obtain more Lorcet on February 20, as a note in the chart reads "Too soon Per [Respondent]." *Id.* Three days later, one week from his last Valium refill, he obtained another 30 Valium, thus receiving the refill one week early. *Id.* at 11.

On March 20, E.A. obtained another 150 Lorcet, this time at the dosage of two tablets every four hours. *Id.* The chart does not indicate any reason for the increase in the dosage. E.A. obtained additional refills of 150 Lorcet on March 29 and April 2. *Id.* On April 6, he obtained a further 120 Lorcet (six-day supply), and on April 9, another 150 Lorcet, at which point the prescribing record ends. *Id.* at 12.

In his testimony, Respondent conceded that E.A. received early refills on April 2, 6, and 9. Tr. 524. However, as the above indicates, even assuming that E.A. consumed the Lorcet at the rate of 18 to 20 tablets a day, E.A.'s record is replete with instances of early refills. Although at times Respondent limited the refills (mostly during the period leading up to the MBC proceeding), Respondent repeatedly dispensed Lorcet in amounts that were well in excess of what he stated was the maximum safe daily dose and Valium in amounts that were well in excess of his dosing regime.

Of ninety-eight refills E.A. ordered by telephone, only eleven bore any notation suggesting that Respondent had actually checked to see when E.A. had last been seen or when he had last obtained a refill. GX 7, at 37–53. Moreover, there is no evidence that Respondent ever required E.A. to submit to a urine or blood test to ensure that he was consuming the medication prescribed for him. Nor is there evidence that Respondent ever tested E.A. to ensure that the drugs were not damaging his liver.

M.D.

M.D., who was then twenty years old, first consulted with Respondent on June 29, 2006, complaining of back and ear pain. Tr. 440–41; GX 10, at 7. M.D. had worked in the film industry as a fighter and at some point had been kicked in the left ear. Tr. 440–441; GX 10, at 7. Respondent diagnosed M.D. as having "chronic back pain intractable and otitis external." Tr. 441; GX 10, at 7. According to the patient record, M.D. had previously taken Lorcet for pain relief. Tr. 440–41; GX 10, at 7. The patient history contains no indication that Respondent took a substance abuse history. *See generally* GX 10.

Respondent dispensed 90 Lorcet to be taken once every four hours and advised M.D. to have his left ear canal irrigated. *See id.* at 7. According to Respondent's testimony, the Lorcet was for relief of the "chronic back pain which was intractable." Tr. 441. M.D. did not see Respondent again until sometime in mid-February 2007, more than eight months later.²⁴ GX 10, at 15. However, he received refills of Lorcet throughout this period. *Id.* at 9–16.

By August 1, 2006, Respondent had increased the quantities of the refills from 90 to 120 tablets, and shortly thereafter, a clear pattern of early refills indicative of diversion or abuse/overconsumption developed. *Id.* at 9. Under Respondent's assumption that a patient could safely take eighteen to twenty Lorcet per day, the refill of 120 Lorcet should have lasted at least six days. However, on both August 4 and 7, M.D. sought and obtained refills. *Id.* at 9–10. While M.D. then obtained three refills at roughly one-week intervals, beginning in September, he obtained refills on September 1, 5, 11, 15, 19, 22, and 26; October 6, 10, 16, 19, 24, 27, and 31; and November 3, 7, and 10. GX 10, at 10–12 & 14.

Although M.D. obtained his next two refills at a slower rate (on November 17 and 27), he then obtained refills on December 1, 5, 8, 12, 15, 18 and 21. GX 10, at 13–14. After two refills at approximately a weekly interval over the Christmas and New Year's period (on December 28 and January 5, 2007),²⁵ he then obtained refills on January 9, 12, 15, 18, 22, 23, 25, and 29; as well as on February 5 and 8. GX 10, at 16.

Then, on some date prior to February 19 (likely February 15, but which is not

²² The dates of these refills were March 20 and 27; April 3 and 10, 2006. GX 7, at 27 & 30.

²³ The dates of these refills were December 11, 15, 18, 19, 26, and 29; January 2, 8, 12, 15, 19, and 22. GX 7, at 15–17.

²⁴ *See* GX 10, at 17. The date of this appointment is not decipherable.

²⁵ The dates of these refills were December 28 and January 5, 2007. GX 10, at 13.

clear from the record,²⁶) E.A. came in for an examination and received his usual 120 Lorcet, as well as 60 Xanax, with one tablet to be taken twice a day (and thus a thirty-day supply). *Id.* at 6. In the Pain Management Agreement he signed on February 15, M.D. agreed to submit to urine or blood testing. *Id.* at 5–6.

On February 19, M.D. obtained 120 Lorcet and 60 Xanax (a thirty-day supply based on the dosing of one tablet every twelve hours) from Respondent. And on March 1 and 9, M.D. received 120 Lorcet and 90 Xanax (a forty-five-day supply based on the same dosing). *Id.* at 17.

M.D.'s file contains a phone message date March 13, which states: "Deputy Drake, regarding [M.D.], 3–10–07, was detain[ed] [with] large amount of pain meds." *Id.* at 19. On the same date, under Respondent's initials is a note written out on a prescription form: "Per Deputy Drake= Narcotics detective will be calling—what [M.D.] had was legally dispensed/given to him. May last 10 days supply." *Id.* From this note, it is clear that Respondent did not believe that M.D. was consuming eighteen to twenty Lorcet per day, but rather only twelve tablets, thus making the early refills even more pronounced.

Neither the phone message nor the note makes mention of Xanax, which M.D. had also obtained at a frequent rate. In his testimony, Respondent indicated that he could not remember what the maximum daily dosage for Xanax was. Tr. 578.

Of fifty-five refill requests M.D. called in, only twelve of the messages bore any information suggesting that Respondent had bothered to check either the last time he had seen M.D. or the last time he had approved a refill for him. GX 10, at 20–29. Nor is there any evidence that Respondent ever requested a urine or blood test from M.D. to confirm whether he was consuming his medication or to check his liver function.

S.M.

S.M., who was then twenty-three years old, first saw Respondent on July 21, 2006, complaining of neck and shoulder pain and indicating a history of concussion. Tr. 525–26; GX 15, at 2. Respondent diagnosed him as having arthropathy of the left shoulder, cervical muscle spasm with pain, possible whiplash, and anxiety. Tr. 527; GX 15, at 2. The patient record bears no indication that Respondent's patient history took a substance abuse history. *See generally* GX 15.

At the initial visit, Respondent dispensed 90 Lorcet to be taken once every six hours and 60 Xanax, 1 mg., one tablet to be taken twice a day. *Id.* at 2. S.M. obtained refills of 90 Lorcet on July 27, as well as on August 1 and 7. *Id.* at 25.

S.M. provided records from prior physicians indicating whiplash and a concussion in 1995 and neck and back pain going back to 2002 along with treatment with Vicodin. *Id.* at 9, 13, 23.

On August 11, S.M. saw Respondent again and Respondent dispensed 120 Lorcet. *Id.* at 25. From August 2006 through February 2007, S.M. did not display a pattern of receiving early refills (if the length of time a refill should last is calculated based on Respondent's oral instruction that a patient could take eighteen to twenty Lorcet per day). *See id.* at 26–29. However, a different picture emerges after S.M.'s appointment of February 16, 2007.

On that day, S.M. signed a Pain Management Agreement and completed a Patient Comfort Assessment Guide. *Id.* at 4–7. In his Patient Comfort Assessment Guide, S.M. indicated that he obtained "Complete Relief" from pain with the Lorcet. *Id.* at 4. At this visit, Respondent dispensed 120 Lorcet but with a written dosing instruction of one every four hours instead of one every six hours. *Id.* at 29.

S.M. did not obtain a refill for nearly another two weeks, on March 1. *Id.* at 30. However, he obtained his next eleven refills on March 5, 9, 12, 16, 19, 23, 26, and 30; and April 2, 6, and 9. GX 15, at 30–31. There is no evidence that Respondent ever requested that S.M. undergo a urine or blood test to determine whether he was consuming the controlled substances or to assess whether the medication was affecting his liver function.

In his testimony, Respondent admitted that this patient chart exhibited early refills. Tr. 542. Of forty-five telephonic requests for refills, only sixteen message slips bore any notation related to the last time the patient had been seen or the last time the patient had received a refill. GX 15, at 32–42.

D.M.

D.M., who was then twenty-two years old, first saw Respondent on July 7, 2005. GX 16, at 3. D.M. complained of pain in his left knee caused by a torn meniscus and reported that he had taken Vicodin for it. *Id.*; Tr. 412. It is not clear from the chart whether D.M. had undergone surgery. GX 16, at 3. Respondent testified that he was not sure whether D.M. had had surgery on the knee and that it could have been

repaired surgically. Tr. 415.²⁷ D.M. also reported insomnia. Tr. 413; GX 16, at 3. Again, the patient history bears no indication that Respondent took a substance abuse history. *See generally id.*

At the initial visit, Respondent dispensed 60 Vicodin ES, one tablet to be taken every six hours, and 30 Xanax, 1 mg., to be taken twice a day. GX 16, at 3. Based on Respondent's testimony that twelve tablets of Vicodin ES was the maximum safe dose and assuming that D.M. consumed them at this rate, the Vicodin ES prescription would have lasted a minimum of five days.

On July 11 (four days later) D.M. returned for a second examination and reported that the Vicodin ES was causing abdominal pain. *Id.* Respondent switched him to Lorcet and dispensed 120 tablets with the dosing instruction to take one tablet every six hours. *Id.* D.M. also obtained a refill of his Xanax prescription, even though the previous prescription should have lasted for another eleven days. *Id.* Respondent dispensed additional refills of 30 Xanax to D.M. on July 15, 22, and 29; August 4, 11, 16, 22, and 26; and September 1. *Id.* at 16, 23. Beginning on September 6, Respondent doubled the quantity of the Xanax refills to 60 tablets; however, he did not change the dosing of one tablet twice per day and thus this refill should have lasted thirty days. *Id.* at 24.

Nonetheless, Respondent dispensed 60-tablet refills to D.M. on September 12, 19, and 26. *Id.* at 21, 24. This was followed by refills for 90 tablets on October 3, and refills for 60 tablets on October 10, 17, and 24. *Id.* at 21–22.

On October 13, D.M. requested more Lorcet, claiming he had broken a toe. GX 16, at 53. While initially Respondent wrote "too soon," he ultimately approved the refill. *Id.* Respondent did not, however, order x-rays or require that D.M. come in for a visit to confirm that he had, in fact, broken his toe.

On November 7, 2005, D.M. received a refill for 120 Lorcet at the increased dosage of two tablets to be taken every four hours. *Id.* at 20. However, Respondent did not examine D.M., and no reason was documented in the record to support the increase in dosage. *Id.*

²⁷ A telephonic refill request indicates that D.M. had knee surgery; Respondent wrote "Need copy of knee surgery 1½ years ago done in San Diego." GX 16, at 56. However, the patient file contains no indication that this information was ever received. Respondent excepted to the ALJ's finding that Respondent was unclear on this point, maintaining that it was "unfair to characterize this testimony as indicating uncertainty that surgery had occurred" in view of "Respondent's acknowledged hearing difficulties." Resp. Exc., at 4–5. I find no reason to disturb the ALJ's finding as his testimony is clear on this point. *See* Tr. 415.

²⁶ On this date, E.A. signed a Pain Management Agreement. GX 10, at 6.

D.M. also received 60 Valium, to be taken twice a day, instead of Xanax. *Id.* The phone message from this date indicates that “Xanax hurts his stomach.” *Id.* at 54. D.M. continued to receive refills of the Lorcet and Valium at approximately weekly intervals through his next two examinations which occurred on November 17, 2005 and January 4, 2006. *Id.* at 18–20.

According to D.M.’s record, he received 60 Valium on November 17, 23, and 29, as well as on December 6, 13, 22, and 27. *Id.* at 19–20. Respondent testified that he dispensed only the 10 mg. strength of Valium and that the maximum daily dosage of this strength is two tablets per day. Tr. 579. D.M. was obtaining refills for a thirty-day supply of Valium at approximately weekly intervals.²⁸

D.M. obtained more refills of 120 Lorcet and 60 Valium on January 10, 16, 23, and 30; February 6, 13, 20, and 27; March 7, 13, 20, 27, and 31; and April 4 and 7, 2006.²⁹ GX 16, at 17–18, 25. Even crediting Respondent’s testimony regarding his instructions to his patients as to the maximum daily dosage of Lorcet, D.M. still received numerous refills of Valium which were weeks early.

On April 14, 2006, Respondent examined D.M.³⁰ *Id.* at 25. Respondent recorded “left knee pain on flexion extension” and a diagnosis of “[h]ypertension” and “arthropathy” of the left knee. *Id.* Respondent additionally noted, “Reduce pain med dosage,” and dispensed only 60 Lorcet to be taken once every six to eight hours as well as the usual 60 Valium to be taken twice per day. *Id.*

On April 20 and 27, D.M. obtained refills of 60 Lorcet and 60 Valium. *Id.* at 28. Moreover, on May 5, 11, 18, 19, and 23, D.M. obtained 120 Lorcet, suggesting that Respondent had already ended his plan to reduce the amount of Lorcet that D.M. was to take; D.M. also received 60 Valium tablets on each of these dates. *Id.* Here again, even

ignoring the Lorcet refills, it is clear that the Valium refills were weeks early.

Respondent dispensed more refills for Lorcet (120 tablets) and Valium (60 to 90 tablets) to D.M. on June 9, 15, 23, 27, and 30; and July 5, 7, 11, 14, 18, 21, 25, 28, and 31. *Id.* at 29–30, 40.³¹ Notably, each of the Valium refills from June 30 through July 28 was for 90 tablets, and thus each refill provided a 45-day supply. *Id.*

On August 8,³² D.M. obtained 120 Lorcet but no Valium, and on August 12, he obtained 150 Lorcet.³³ *Id.* at 40. On August 21, he obtained only 120 Lorcet, and the following day, 60 Valium. *Id.* On August 24 and 29, as well as on September 5, he obtained refills of 120 Lorcet, but no Valium. *Id.*

On September 7, D.M. received refills of both Valium (twelve days early based on the last refill) and Lorcet, the latter being only two days after his previous Lorcet refill.³⁴ *Id.* at 39. This was followed by refills of 120 Lorcet on September 11 and 14; on the latter date, he also received 60 Valium even though he had received his previous refill only seven days earlier. *Id.*

On both September 18 and 21, D.M. obtained 150 Lorcet; instead of Valium, he obtained 60 Xanax.³⁵ *Id.* D.M.’s file contains no evidence pertaining to the shift from Valium to Xanax, which he had previously complained hurt his stomach. On September 22, D.M. obtained 120 Lorcet; on September 25, he obtained 150 Lorcet as well as 60 Valium. *Id.*

D.M. received further refills of 120 Lorcet on October 2, 5, and 9; on the latter date, he also obtained 60 Valium. *Id.* at 38. Yet only three days later on October 12, he obtained another 150 Lorcet and 60 Valium. *Id.*

While the dates of the next two dispensings are indecipherable, they appeared to have occurred sometime before October 23. On these occasions, D.M. obtained 120 Lorcet and 60 Valium

and 150 Lorcet and 60 Valium. *Id.* Thereafter, D.M. did not obtain another Valium prescription until January 2007. *Id.* at 33. However, in this period, he obtained refills of either 150 Lorcet or 120 Lorcet at largely three to four-day intervals.³⁶

On January 18, 2007, D.M. obtained another 150 Lorcet and 30 Valium (fifteen-day supply). *Id.* at 33. Seven days later, on January 25, he again obtained refills of 150 Lorcet and 30 Valium. *Id.* This was followed by refills for 120 Lorcet on January 29, February 1 and 5, as well as refills of 30 Valium on both January 29 and February 5. *Id.*

Only three days later on February 8, he obtained 150 Lorcet, and on February 15, he obtained 90 Lorcet and another 30 Valium. *Id.* The next day, Respondent dispensed 30 Xanax to D.M., to be taken twice a day. *Id.* at 13.

On February 27, D.M. obtained another 90 Lorcet. *Id.* On March 5, D.M. received a refill for 60 Xanax (thirty-day supply) and the next day, another 90 Lorcet. *Id.* On March 12, he obtained another 120 Lorcet, with the new dosing instruction to take two tablets every four hours. *Id.* This was followed by additional refills on March 16 for 90 Lorcet; on March 20, 23, and 30 for 120 Lorcet; on April 2 for 150 Lorcet; and on April 5 and 9, for 120 Lorcet. *Id.* at 13–14.

In all, D.M. phoned in for refills 146 times. On only twenty message slips is there a notation regarding the last time D.M. had been seen or had received a refill. GX 16, at 41–63. Although on rare occasions, Respondent denied D.M.’s request for a refill, there is no evidence that he ever required D.M. to undergo a urine or blood test.

The CURES Report for D.M. indicates that he received controlled substances and Suboxone from other prescribing physicians while he was treated by Respondent. Specifically, on October 10, November 11 and 27, December 12, 2006, and January 8, 2007, D.M. obtained Suboxone from three different prescribing physicians. GX 45. Moreover, on February 12 and 15, 2007, he obtained hydrocodone/apap from yet another physician. *Id.* However, Dr. Chavez did not offer any opinion as to whether (or under what circumstances) checking the CURES database is required to meet the accepted standard of medical practice.

²⁸ Respondent excepted to the use of two tablets of Valium per day as the maximum daily dosage, based on two occasions in the hearing where Respondent indicated that a patient could actually take more than two per day. Resp. Exc., at 4. However, I reject the exception because Respondent did not testify that he told his patients that they could take more Valium than what he noted as his dosing instruction.

²⁹ The message slip for March 31, however, indicates that D.M. reported his medication as stolen. GX 16, at 42. I note that there is no indication that Respondent requested that D.M. present a police report in confirmation of this allegation.

³⁰ D.M. apparently called in for another refill on this date, and Respondent refused it with the note, “No—I want to talk to him.” GX 16, at 43.

³¹ According to a phone message, D.M. also requested a refill on June 19, which was denied as “[t]oo soon.” GX 16, at 57.

³² This follows on a request for a refill on an unidentified date, where Respondent wrote that it was “[t]oo soon for refill” but “ok for Monday %/.” GX 16, at 44.

³³ D.M. apparently requested a refill on August 10, which Respondent refused, saying that August 14 would be okay. GX 16, at 45.

³⁴ D.M. apparently requested a refill on September 1, but Respondent indicated, “No. Too soon for refill ok on %/ Tues.” GX 16, at 45.

³⁵ The record of phone requests indicates that D.M. requested a refill on September 20 but that Respondent refused, because it was too early. GX 16, at 50. On September 22, just two days later and one day after receiving a refill, D.M. phoned in another request indicating that he “[h]a[d] no more meds.” *Id.* Respondent approved that request although no explanation was provided as to why D.M. had run out of medication. *Id.*

³⁶ D.M. obtained these refills on October 23 (120 tablets), 26 (150), and 30 (120); November 2 (150), 6 (120), 9 (150), 13 (120 plus 60 Xanax), 20 (120), 22 (120), and 30 (150); December 3 (120), 7 (150), 11 (120), 14 (150), 18 (150), 21 (150), and 28 (150); January 2 (120), 8 (120), 11 (150), and 15 (120). GX 16, at 33, 35, 37–38.

J.N.

J.N., who was then twenty-four, first saw Respondent on May 18, 2006. GX 17, at 3. J.N. complained of lower back pain radiating down into his thigh. Tr. 484; GX 17, at 3. Although he had no history of trauma, he also indicated that he had taken Lorcet for his back in the past. Tr. 484; GX 17, at 3. Upon physical examination, Respondent observed muscle spasms and diagnosed J.N. as having a “muscular ligament strain lumbar back muscles.” Tr. 484; GX 17, at 3. He also noted that J.N. was “overweight” and testified that being overweight commonly contributes to lumbar strain.³⁷ Tr. 488; GX 17, at 3. J.N.’s patient record contains no indication that Respondent obtained a substance abuse history. See GX 17. Respondent dispensed 60 Lorcet, with one tablet to be taken once every six hours, a fifteen-day supply if taken in accordance with the dosing instruction recorded in J.N.’s chart, but only a three-day supply if taken according to his oral instructions. GX 17, at 3.

Four days later on May 22, J.N. obtained a refill of 90 Lorcet, with one tablet to be taken once every four hours, and on both May 29 and June 5, he received refills of 120 Lorcet. *Id.* On the latter date, Respondent also dispensed 30 Xanax to him, with one tablet to be taken twice a day. *Id.* However, J.N.’s patient file has no indication as to why Respondent added the Xanax.

On September 12, Respondent dispensed 150 Lorcet to J.N., as well as 30 Valium, with one tablet to be taken twice a day. *Id.* at 15. Respondent did not document in the file why he had changed J.N. to Valium from Xanax. Thereafter, there was a gap of two months between refills. See *id.* at 9–15.

On November 2 and 7, J.N. obtained refills of 180 Lorcet; on November 13 and 17, he received refills of 150 Lorcet; and on November 27 and December 7, he received further refills for 180 Lorcet. *Id.* at 9. On the latter date, he also obtained 30 Valium, his first Valium refill since September but with no indication provided in the medical record as to why the drug was medically necessary.³⁸ *Id.* Moreover, although the December 7 Lorcet refill should have lasted at least nine days, just four days later on December 11, J.N. obtained another 180 Lorcet. *Id.*

On December 19, J.N. obtained another 180 Lorcet and 60 Valium, the

latter providing a thirty-day supply. *Id.* at 8. On January 4, 2007, J.N. obtained refills for 180 Lorcet and 30 Valium, the latter refill occurring two weeks early. *Id.* On both January 9 and 12, 2007, J.N. obtained additional refills for both 180 Lorcet and 30 Valium. *Id.*

On January 18, J.N. obtained refills for both 180 Lorcet and 30 Valium; on this date, he also obtained 60 Xanax (a thirty-day supply based on the dosing instruction). *Id.* at 10. Yet there is no indication in J.N.’s patient file as to why Respondent authorized the simultaneous dispensing of Xanax and Valium. *Id.*

Just four days later on January 22, J.N. obtained another 180 Lorcet and 30 Valium. *Id.* Thereafter, J.N. obtained refills for 180 Lorcet and 90 Valium (a forty-five day supply) on January 25 and 29, as well as on February 1. *Id.*

Only four days later on February 5, J.N. obtained a further 180 Lorcet and 120 Valium (a sixty-day supply). *Id.* On February 19, J.N. obtained refills of both 180 Lorcet and another 120 Valium. *Id.* at 11. J.N.’s record ends three days later with an entry of “cancel,” which is initialed by Respondent. *Id.*

On cross-examination, Government counsel asked Respondent about the numerous refills he dispensed to J.N. for Valium. Tr. 580–84. Noting Respondent’s testimony that the maximum daily dosage of Valium was two tablets per day and that where there was a refill of ninety tablets after just four days, J.N. must have been consuming twenty Valium tablets per day, Government counsel asked Respondent whether “a person can function on 20 Valium a day?” *Id.* at 581–82. Respondent answered, “[n]o,” and that taking this much would cause “[s]omnolence and disorientation.” *Id.*

Although Respondent testified that it was best to see pain patients at least every six months, in the nine-month period in which he dispensed controlled substances to J.N., Respondent examined him only at his initial visit. Tr. 434; cf. GX 17, 1–23. On redirect, Respondent testified that J.N. had developed a tolerance to Valium and that he never observed J.N. having side effects like somnolence. Tr. 616. However, this seems rather unlikely given that Respondent only examined J.N. once.

While J.N. called in refill requests forty-six times, on only thirteen occasions did Respondent note either the last time he had been seen or when he had last obtained a refill. GX 17, at 16–23. There is also no evidence that Respondent ever requested a urine or blood test to confirm whether Respondent was consuming the

medication and to check his liver function.

S.R.

S.R., who was twenty-four, first saw Respondent on June 1, 2006. GX 18, at 3. She reported that she had back pain as a result of a car accident one year earlier; she also indicated that she had tried Motrin for the pain but that it had not worked. Tr. 431, GX 18, at 3. Respondent diagnosed a “muscular ligament strain [of the] lumbar back muscles” and dispensed 60 Lorcet, to be taken once every six hours. Tr. 433; GX 18, at 3. The patient record, however, contains no indication that Respondent took a substance abuse history. See GX 18.

On June 8, S.R. obtained a refill for 90 Lorcet, as well as a prescription for 30 Xanax, the latter being a fifteen-day supply under the dosing instruction of one tablet every twelve hours. *Id.* at 3. S.R.’s record, however, contains no indication of Respondent’s medical reason for adding the Xanax. *Id.*

Only five days later on June 13, S.R. obtained refills for 120 Lorcet and another 30 Xanax. *Id.* at 5. Just six days later on June 19, S.R. obtained 150 Lorcet, 30 Xanax, as well as 30 Valium, with both the Xanax and Valium to be taken twice a day (and therefore a fifteen-day supply of each). *Id.* The file, however, bears no indication as to Respondent’s medical justification for prescribing the Valium.

Just four days later on June 23, S.R. obtained another 150 Lorcet and another 60 Valium, a thirty-day supply of the latter. *Id.* On June 27, after just another four days, S.R. obtained another 150 Lorcet and 30 Xanax. *Id.*

On July 13, S.R. received a refill of 150 Lorcet, and on July 17, 120 Lorcet. *Id.* at 6. This was followed by refills for 150 Lorcet on July 20, 25, and 28. *Id.*

On August 1, S.R. obtained refills of only 90 Lorcet and 30 Xanax. *Id.* On August 4, S.R. sought additional refills for Lorcet and Valium but was turned down as “too soon.” *Id.* at 20. However, a phone message slip states that the refills would be “Ok by 08/7/6.” *Id.* On August 7, she obtained another 90 Lorcet. *Id.*

An undated phone message indicates that S.R. sought refills of 120 Lorcet, 30 Xanax and 30 Valium. *Id.* at 19. While Respondent turned down the refills as “too soon,” he indicated that refills were “ok for 8/14/06.” *Id.*

On August 15, S.R. obtained 150 Lorcet, as well as 30 Valium. *Id.* at 8. She obtained additional refills of 150 Lorcet on August 21 and 25, as well as on September 1, 7, and 11. *Id.* Moreover, in September 7, she obtained an

³⁷ With respect to patient E.A., Respondent also testified that he always advises about weight loss when appropriate. Tr. 510.

³⁸ Respondent conceded on cross-examination that he prescribed the Valium without doing a physical examination. Tr. 580.

additional 30 Valium (a fifteen-day supply), and on September 11, she also obtained 30 Xanax (a fifteen-day supply). *Id.*

On September 26, S.R. obtained another 150 Lorcet as well as 60 Xanax. *Id.* This was followed by refills for 150 Lorcet on October 2, 10, 16, 20, 24, and 30, as well as November 6, 10, 17, and 22. *Id.* at 7–9. In addition, on November 22, S.R. obtained 60 tablets of both Xanax and Valium, each refill being a thirty-day supply based on the dosing instructions. *Id.* at 9.

While on November 27, when S.R. received a further 180 Lorcet, she did not obtain a refill of either the Xanax or Valium, on both December 4 and 8, she received refills of both 180 Lorcet and 30 Valium (fifteen-day supply). *Id.* Thus, the December 8 refills were early as to both the Lorcet and Valium.

On December 14, S.R. obtained another refill of 180 Lorcet. *Id.* Only four days later on December 18, S.R. obtained another 180 Lorcet, as well as both 60 Xanax (a thirty-day supply) and 60 Valium (also a thirty-day supply), the latter refill being weeks early. *Id.* Only three days later on December 21, S.R. obtained another 180 Lorcet and 30 Valium. *Id.* at 12. S.R. obtained additional refills for both 180 Lorcet and 30 Valium on December 26, as well as on January 2, 12, 16, and 19, 2007. *Id.*

On January 22, S.R. obtained refills of 180 Lorcet, 60 Xanax, and 30 Valium. *Id.* at 11. Only three days later on January 25, she obtained a further 180 Lorcet and 60 Valium, and on January 29, 180 Lorcet and 90 Valium. *Id.* And just three days later on February 1, 2007, she obtained another 180 Lorcet. *Id.*

One week later, a note dated February 8, 2007 states: “[s]hould reduce Lorcet #90 q 2 wks. Needs visit.” *Id.* However, on February 15, S.R. obtained another 90 Lorcet and 30 Valium; there is, however, no documentation in her file that she was examined by Respondent prior to the dispensings. *Id.* Only five days later on February 20, 2007, S.R. obtained 120 Lorcet (again with no indication of a visit with Respondent) and 120 tablets of Valium, her largest refill of this drug. *Id.* at 13. The patient record concludes at this point.

Respondent treated S.R. for eight months but examined her only at the initial visit. Of fifty-one refill requests S.R. phoned in, only eleven phone messages contain any notation suggesting that the dates of her previous refills had been checked. *Id.* at 15–23. There is no indication that Respondent ever had S.R. complete a Pain Medication Agreement or that he performed blood or urine tests either to

determine whether she was taking the medication and/or to check her liver function.

B.W.

B.W., who was then thirty-four, first saw Respondent on February 21, 2006. GX 20, at 8. He complained of pain in his lower back from lifting heavy building materials while working on his home patio. *Id.*; Tr. 543. In the physical examination, Respondent observed “muscle spasms,” and he diagnosed the cause of Respondent’s pain as “acute musculo-lig[ament] strain lumbar back muscles.” GX 20, at 8; Tr. 547. Respondent dispensed 60 Vicodin ES, to be taken once every six hours. GX 20, at 8. The patient record bears no indication that Respondent took a substance abuse history. *See id.*

B.W. did not see Respondent again until August 25, 2006, and during this period, he did not obtain any refills. *Id.* On this date, B.W. told Respondent that he had hurt his back the day before while lifting a couch. *Id.*; Tr. 549. Respondent again noted that he had observed muscle spasms in B.W.’s lumbar region and he diagnosed the cause of B.W.’s pain as “[a]cute M/L strain lumbar back muscles.” GX 20, at 8. Respondent again dispensed 60 Vicodin ES, with one tablet to be taken every six hours. *Id.* On August 29, B.W. called requesting a refill “claim[ing] his housekeeper threw away his meds.” *Id.* at 9.

As noted above, the ALJ credited Respondent’s testimony that he told his patients they could safely take up to twelve Vicodin ES per day; each refill of 60 Vicodin ES would therefore have lasted a minimum of five days. On this assumption, B.W.’s patient chart thus does not record a pattern of early refills until November 2006. *See id.* at 9–10. However, on November 3, 6, and 9, B.W. obtained refills of 60 Vicodin ES. *Id.* at 10. On November 13, he obtained a refill of 120 Vicodin ES (a ten-day supply but with the dosing noted in the chart as one tablet every six hours), which he refilled only four days later on November 17.³⁹ *Id.* While B.W. did not obtain a refill until November 27, he then obtained additional refills of 120 Vicodin ES on December 1, 7, 11, and 15. *Id.* Although B.W. did not obtain another refill until December 26, he then obtained more refills of 120 Vicodin ES on December 29, as well as on January 2, 4, 8, 11, 15, 18, 22, and

³⁹ However, Respondent’s note on the phone message for this refill indicates that it should not be picked up until November 20. GX 20, at 22.

25; and February 5, 8, and 12, 2007. *Id.* at 11–12. *Id.* at 13.

The phone message for the latter refill request states that B.W. “[n]eed[ed] [a] visit.” *Id.* at 18. However, on February 15, 19, and 22, B.W. received more refills of 90 Vicodin ES without appearing for a visit. *Id.* at 13.

On March 6, B.W. was examined by Respondent, who dispensed 90 Vicodin ES with the dosing instruction of one tablet every four to six hours as needed. *Id.* at 15. B.W. obtained more refills for 90 Vicodin ES on March 12, 15, and 19, and for 120 Vicodin on March 22 and 30, as well as on April 3, 6, and 10, 2007, when the patient file ends. *Id.* at 14–15.

In his testimony, Respondent conceded that the refills between March 15 and April 10 were early.⁴⁰ Tr. 557. However, numerous other refills were also early.

B.W. called in requests for refills forty-nine times. Yet on only twelve of the forms documenting these requests was the date of B.W.’s last visit and/or refill noted. GX 20, at 16–26. Nor is there any evidence that Respondent ever did blood or urine tests on B.W. to confirm whether he was taking the medication and/or to check his liver function.⁴¹

J.W.

J.W., who was then twenty-four, first saw Respondent on March 6, 2006, complaining of back pain. GX 21, at 12. According to Respondent, J.W. had neck and back spasms. *Id.*; Tr. 435–36. J.W.’s record contains medical records documenting his treatment for neck and back pain by two other physicians as well as a chiropractor, which included prescriptions for Norco (hydrocodone 10mg./apap 325 mg.) and Xanax.⁴² GX 21, at 4–10; Tr. 435. J.W. was still being treated by an orthopedist and a chiropractor. Tr. 436–37. J.W.’s patient record contains no indication that Respondent took a substance abuse history. *See* GX 21, at 12.

At that first visit, Respondent dispensed 90 Lortab (noting in J.W.’s record that one tablet was to be taken

⁴⁰ According to a Patient Activity Report obtained from CURES, from the time of B.W.’s August 2006 appointment with Respondent through the April 10, 2007 refill, B.W. was obtaining hydrocodone/apap 5 mg./500 mg. and 7.5 mg./750 mg. from ten other physicians. GX 46, at 7–8. Moreover, during the period prior to B.W.’s August 2005 visit, he obtained the same drugs from at least seven different physicians. *Id.* at 5–6.

⁴¹ On B.W.’s March 6, 2007 visit, Respondent obtained a signed Pain Management Agreement and B.W. completed a Patient Comfort Assessment Guide. GX 20, at 3–6.

⁴² Norco contains 10 mgs. hydrocodone and 325 mgs. acetaminophen. Tr. 68.

every four to six hours), as well as 90 Xanax, one tablet to be taken twice per day and thus a 45-day supply. *Id.* On March 16, J.W. obtained both 90 Lorcet and 60 Xanax, the latter being more than a month early. *Id.* at 17. Just five days later on March 21, J.W. received 90 more Lorcet and another 30 Xanax. *Id.*

Six days later on March 27, J.W. received 120 Lorcet and another 30 Xanax. *Id.* He received refills for 120 Lorcet on April 6, 21, and 27; May 11, 19, and 29; as well as June 8 and 23; he also received 30 Xanax on each of these dates except for on May 11 and 19, when he received 90 tablets on each date, and on June 23, when he obtained 60 tablets. *See id.* at 14–15, 17.

J.W. received 180 Lorcet and 90 Xanax from Respondent on July 5, 13, 24, and 31, and August 7. *Id.* at 14. Thereafter, J.W. obtained 180 Lorcet from Respondent on August 21 and 28; September 7, 12, 19, and 28; October 3, 10, 12, 16, 23, and 30; November 2, 6, 10,⁴³ 21, 27, and 30; and December 4, 7, 12, and 26 (but only 90 tablets this date) and 28. *Id.* at 14, 18–19.

As for the Xanax, on August 21, J.W. obtained only 30 tablets. *Id.* at 14. Thereafter, he obtained the Xanax in the following quantities by date: August 28 (120); September 7 (60), 12 (120), 19 (120), and 28 (120); October 3 (120), 10 (180), 12 (90), 16 (180), 23 (180), and 30 (180); November 2 (120), 6 (180), 10 (120), 21 (90), 27 (90), and 30 (90); and December 4 (90), 7 (60), 12 (60), 26 (180), and 28 (60). *Id.* at 18–21. In each entry, the Xanax dosing was noted as one tablet every twelve hours. *See id.*

During 2007, J.W. continued to receive early refills of both Lorcet and Xanax. With respect to Lorcet, he obtained 90 tablets on January 2 and 9; 180 tablets on January 15; another 90 tablets on January 18; followed by 180 tablets on January 22, 25, 29; as well as on February 1 and 5. *Id.* at 20 & 22. As for Xanax, J.W. obtained 60 tablets on January 2; 180 tablets on January 9; 30 tablets on January 15; 60 tablets on January 18, 22, and 25; 90 tablets on January 29; 120 tablets on February 1; and 30 tablets on February 5. *Id.*

The patient record ends with an entry dated February 8, 2007, which reads, “Pt. requests too much meds—Needs visit to discuss lowering amounts.” GX 21, at 22. When asked whether J.W.’s not coming in for the needed visit indicated that he had been abusing the drugs, Respondent answered, “Not necessarily.” Tr. 439. Respondent testified that “what [he] was thinking

* * * is that [J.W.] probably had gone back to the orthopedic consultant who is also trying to treat him for the same type of pain.” *Id.*

During the eleven-month period in which Respondent dispensed controlled substances to J.W., Respondent examined him only once. While J.W. called in refill requests fifty-one times, in only nine instances is there evidence that Respondent checked either the last time J.W. had been seen or the date of his last refill. *Id.* at 24–32. J.W. never entered a Pain Medication Agreement with Respondent. Nor did Respondent ever test J.W.’s urine or blood.

Summary

As Dr. Chavez noted, none of the patients files reviewed above documents that Respondent had discussed with the patient the risks and benefits of taking the controlled substances he dispensed to them. Similarly, none of the files contains a treatment plan with stated objectives for assessing the efficacy of the treatment. While some of the files contained signed Pain Medication Agreements, there is no evidence that Respondent ever enforced them by requiring his patients to undergo urine or blood testing. Moreover, while Respondent dispensed large quantities of opiate medications containing acetaminophen, he never performed tests to assess what effect the medication was having on his patients’ liver function.⁴⁴

Respondent regularly dispensed refills without regard to when he had last dispensed the drugs to a patient. While he also testified as to the importance of follow-up visits to monitor how his patients were doing and to adjust their medication regime, he dispensed numerous refills to the above patients and did so for months on end without conducting follow-up examinations. Indeed, he dispensed numerous refills to patients (J.N., S.R., and J.W.) for an extensive period of time (9 months, 8 months, and 11 months, respectively) even though they never returned for a second examination. *See* GXs 17, 18, 21.

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that the Attorney General “shall register practitioners * * * to dispense * * * controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense * * * controlled substances

under the laws of the State in which he practices.” 21 U.S.C. 823(f). However, the statute also provides that the Attorney General “may deny an application for such registration if he determines that the issuance of such a registration is inconsistent with the public interest.” *Id.* In determining consistency with the public interest, the statute requires that the following factors be considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant’s experience in dispensing * * * controlled substances.
- (3) The applicant’s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

Id.

“These factors are considered in the disjunctive.” *Robert A. Leslie*, 68 FR 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 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 proof. 21 CFR 1301.44(e). However, where the Government makes out a *prima facie* case to deny an application, the burden shifts to the Respondent to show why granting its application would be consistent with the public interest. *See Steven M. Abbadessa*, 74 FR 10077, 10081 (2009); *Arthur Sklar*, 54 FR 34623, 34627 (1989).

Factor One—the Recommendation of the State Licensing Board

As the ALJ noted, the State Board has not made a recommendation in this matter. ALJ at 34. The ALJ further noted that in a proceeding involving Respondent’s treatment of three patients who are not at issue here, the Board concluded that cause did not exist to find that he prescribed without a good faith examination and medical indication for each of the three patients. *Id.* The Board found, however, that Respondent had failed to maintain adequate medical records with respect to one of the patients and issued a public reprimand.

Ultimately, I conclude that this factor neither supports nor refutes a finding

⁴³ There are actually two entries for November 10; both of which indicate that J.W. received 180 Lorcet and 120 Xanax.

⁴⁴ There is also no evidence that Respondent attempted to coordinate his prescribing activities with other physicians who were still treating his patients and might be prescribing controlled substances to them.

that issuing Respondent a new registration would be inconsistent with the public interest. While possessing a State license is a statutory prerequisite for holding a registration under the CSA, *see* 21 U.S.C. § 823(f), DEA has long held that a practitioner's possession of State authority to dispense controlled substances is not dispositive of the public interest inquiry. *See Mortimer B. Levin*, 55 FR 8209, 8210 (1990) ("DEA maintains a separate oversight responsibility with respect to the handling of controlled substances and has a statutory obligation to make its independent determination as to whether the granting of [an application] would be in the public interest."); *see also Jayam Krishna-Iyer*, 74 FR 459, 461 (2009).

Factors Two and Four—The Applicant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

Under a longstanding DEA regulation, a prescription for a controlled substance is not "effective" unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). This regulation further provides that "[a]n order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. § 829] and * * * the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.*

As the Supreme Court recently explained, "the prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006) (citing *United States v. Moore*, 423 U.S. 122, 135 (1975)).

While many cases under the public interest standard involve practitioners who intentionally or knowingly violated the CSA's prescription requirement, the Agency's authority to deny an application (or to revoke an existing registration) is not limited to those instances in which a practitioner intentionally diverts a controlled substance. *See Paul J. Caragine, Jr.*, 63 FR 51592, 51601 (1998). As my predecessor explained in *Caragine*: "[j]ust because misconduct is unintentional, innocent or devoid of

improper motivation, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify" the revocation of an existing registration or the denial of an application for a registration. 63 FR at 51601. Accordingly, a practitioner's failure to properly supervise his patients to prevent them from personally abusing controlled substances or selling them to others constitutes conduct "inconsistent with the public interest" and can support the denial of an application for registration, or the revocation of an existing registration. *Id.*; *see also Gonzales*, 546 U.S. at 274.

In her decision, the ALJ did not address whether the prescriptions Respondent wrote during the undercover visits of the Special Agent and informant were issued in the usual course of professional practice and for a legitimate medical purpose. *See* ALJ at 35. *Id.*

With respect to the Special Agent's visit, from the beginning of the encounter, Respondent knew that she was not seeking Vicodin to treat a legitimate medical condition as, after the Agent told him that she took the drug because "[it] just made me feel better," he replied: "I don't prescribe Vicodin for recreational purposes or to feel better * * * because Vicodin is a controlled drug and it is specifically for specific pains, you know?" Moreover, when the Agent asked him whether if her "back hurt" would justify a prescription, and he asked "what happened to your back," the Agent replied that nothing had really happened to it. When Respondent then asked her "where in your back are you having the pains," the Agent again replied: "I don't specifically have it, I was just asking you if that would be a reason someone would have it?" Even though at this point the Agent had made no representation that she had pain, Respondent stated that "if it is for that reason, for now * * * I can give you a prescription" and asked "which Vicodin are you using?"

It is true that Respondent then asked the Agent to show him which part of her back was hurting and the Agent pointed to her lower back; however, she then added that "it's not really sensitive." It is also true that Respondent then asked the Agent how long she had the back pain, to which she answered: "A couple of years I guess." Yet Respondent undertook no further inquiry as to the origin and cause of the pain, what activities made it worse, how intense it was, and if it was affecting her ability to function. He did not take a substance

abuse history even though the Agent had indicated that she had previously been on Vicodin and that she took the drugs because they made her feel better. As the Agent testified, she believed that Respondent was trying to provide her with what he needed to hear to justify prescribing the Vicodin.

The physical exam Respondent performed was superficial, lasting all of five seconds, and was limited to touching the SA's back a few times without even lifting up her clothing.⁴⁵ Respondent's subsequent statement—after indicating that he would give the Agent a prescription for 30 Vicodin ES—that "we have to have more documentation as to why these controlled drugs are being prescribed for you" further suggests that he knew full well that he did not have a legitimate medical purpose for issuing the prescription.

In addition, while in his testimony, Respondent maintained that he diagnosed the Agent as having back spasms and wrote this on the progress note he prepared, he never communicated this to the Agent. It is strange that a physician would not discuss his diagnosis with his patient. Likewise, he did not discuss the risks and benefits of taking Vicodin with the Agent. Finally, Dr. Chavez concluded that Respondent's treatment of each of the fifteen patients whose files he reviewed constituted "an EXTREME DEPARTURE from the standard of care expected of a licensed practicing physician in the U.S. today." GX 6, at 33.

Based on the above, I conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual

⁴⁵ The ALJ found credible Respondent's testimony that "he believed he saw muscle spasms, which would be consistent with back pain." ALJ at 7. I reject the ALJ's finding because she did not reconcile this testimony with the Agent's testimony that he did not even lift the garment that was covering her back.

The ALJ also found that Respondent "credibly testified that he believed [the Agent] was suffering from back pain for the past two years." *Id.* at 7. However, the Agent had previously stated several times that she did not have pain and Respondent agreed to give her a prescription immediately after she stated: "I don't specifically have it." Moreover, even after this, the Agent said her back was "not really sensitive" and her answer that she had pain "a couple of years I guess" was equivocal at best. This was then followed by Respondent's statement that "we" need to have more documentation to justify prescribing Vicodin. As the Agent testified, she believed that Respondent needed her to indicate that she had back pain to justify his prescribing of Vicodin. The nature of the conversation and Respondent's failure to comply with the accepted standards of medical practice for evaluating his patient establish that Respondent was not practicing medicine in good faith, but rather, that this was prescribing with a wink and a nod. I therefore reject the ALJ's finding.

course when he prescribed Vicodin to the Agent. He therefore violated the prescription requirement of Federal law. 21 CFR 1306.04(a).

By contrast, at R.E.'s initial visit, he complained that he suffered neck pain and had for a couple of years; he also complained of difficulty sleeping. Respondent's questioning of R.E. regarding his condition was somewhat more detailed (although still lacking according to Dr. Chavez) than it was with the Agent and at no point in the encounter did R.E. suggest that he did not have pain. Moreover, while the record suggests that Respondent did only a superficial physical exam, and again, he did not discuss his diagnosis with R.E., he did recommend alternative treatments.

I need not decide whether the prescriptions Respondent gave R.E. at the initial visit violated 21 CFR 1306.04(a) because it is clear that the subsequent Lorcet refills which Respondent authorized far exceeded what he had determined was medically necessary to treat R.E.'s condition. More specifically, Respondent's initial dispensing of 60 Vicodin should have lasted twenty days if taken at the prescribed dosage of one tablet every eight hours.⁴⁶ Yet only one week later on October 20, R.E. obtained a refill for 120 tablets; this prescription should have lasted forty days (or until November 29) as Respondent did not change the dosing. However, on November 9, which was nearly three weeks early, Respondent dispensed to R.E. 120 Lorcet, which was a different drug.

Respondent changed the dosing of the Lorcet to one tablet every six hours; thus, this dispensing provided a thirty-day supply. However, on December 1, more than a week early, Respondent dispensed an even larger refill, increasing the amount to 150 tablets. And while this refill should have thirty-seven days (or until January 7), on December 7, Respondent dispensed another refill for 150 tablets.

None of these refills was supported by documentation of a plausible reason for it in the patient file. Given that R.E.'s requests were not merely days but weeks early, there was substantial reason to believe that he was either abusing the drugs or diverting them. Indeed, this should have been apparent by, if not the first, then R.E.'s second refill request. Yet Respondent did not recognize this problem until several

months later.⁴⁷ I therefore conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he dispensed the Vicodin and Lorcet refills to R.E. and therefore violated Federal law. 21 CFR 1306.04(a).

The record also supports the conclusion that Respondent's dispensings of controlled substances to the other patients lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. *Id.* As Dr. Chavez noted, none of the charts he reviewed contained sufficient documentation to "justify[] the use of opiate therapy to the level exhibited on the charts."

While Respondent testified that he had told his patients that they could take Lorcet and Vicodin ES in quantities amounting to nine to ten grams per day of acetaminophen, in his report, Dr. Chavez noted the potential toxicity of patients consuming in excess of four grams per day of acetaminophen and that blood chemistries must be regularly performed in order to monitor liver function. Yet in none of the files Dr. Chavez reviewed (and which are discussed above) is there evidence that Respondent performed blood tests to assess a patient's liver function and to determine whether the large quantities the patient was purportedly consuming were causing liver damage. Moreover, in none of the files is there evidence that the patients were referred for consultations with specialists and/or additional diagnostic testing. He did not take substance abuse histories. Nor did he ever require his patients to provide a urine sample.

With respect to many of the patients, Respondent authorized refills for them for months on end without requiring that they appear for a followup visit. As Dr. Chavez noted, many of the refills Respondent dispensed occurred at such rapid intervals that "[i]n many cases, it would have been impossible * * * to use this quantity of controlled medications within that short of period of time." GX 6, at 32.

Thus, even crediting Respondent's dubious testimony regarding his dosing instruction for Lorcet and Vicodin, there is still ample evidence that he dispensed refills for both of these drugs, as well as Xanax and Valium, that were

excessive and were not justified by a legitimate medical purpose. For example, on December 8, 2006, E.A. received 120 Valium tablets, which, according to the dosing noted in E.A.'s file, should have lasted sixty days. Yet Respondent proceeded to dispense an additional 120 Valium to E.A. on December 11, 15, 18, 19, 26, and 29; as well as on January 2, 8, 12, 15, 19, and 22, 2007. Moreover, on January 29 and February 2, Respondent dispensed additional refills of 80 Valium; he also dispensed an additional thirty tablets on both February 16 and 23. Thus, between December 8, 2006 and February 8, 2007, Respondent dispensed to E.A. more than thirteen times the amount of Valium which he had concluded was medically necessary. These amounts suggest that E.A. was selling the Valium.

During the same period, Respondent dispensed refills for 150 Lorcet to E.A. on December 8, 11, 15, 18, 19, 26, and 29; January 2, 8, 12, 15, 19, 22, 25, and 29; and February 2 and 5. Even crediting Respondent's testimony that he told his patients that they could safely take up to 20 tablets of Lorcet per day, during the 8.5-week period between December 8 and February 5, E.A. had a medical need for 1,200 tablets. Yet Respondent dispensed 2,550 tablets to him. Moreover, notwithstanding the extraordinary quantities of Lorcet Respondent was dispensing to E.A., he never did a blood test.

It is acknowledged that E.A.'s record contains two notes during the month of February indicating that Respondent had refused refills as too early. However, given the frequency and quantities of these refills, especially for the Valium which provided a 60-day supply, it should have been obvious well before this point that E.A. was either abusing and/or selling the drugs. And even after this, Respondent provided E.A. with additional refills, which even he conceded were early. Moreover, Respondent rarely, if ever, reviewed E.A.'s record to determine when he had last authorized a refill and/or seen him. In short, Respondent's dispensings to E.A. manifest an egregious failure to properly monitor his patient to ensure that he was not abusing the drugs or selling them.

M.D. repeatedly obtained early Lorcet refills from Respondent. For example, in the winter of 2006–2007, M.D. obtained refills for 120 Lorcet on December 1, 5, 8, 12, 15, 18, 21, and 28; January 5, 9, 12, 15, 18, 22, 23, 25, and 29; as well as February 5 and 8. Even assuming that Respondent told M.D. that he could take 20 tablets per day—a questionable assumption in light of the note Respondent made following M.D.'s

⁴⁶ As found above, the recording of the visit contains no indication that Respondent told R.E. he could take more than the prescribed amount.

⁴⁷ R.E. apparently did not seek a refill from Respondent between December 7, 2006, and February 27, 2007. Notwithstanding this nearly three-month hiatus, Respondent resumed dispensing to him on the latter date without examining him (providing another 150 Lorcet, also a thirty-seven day supply) and did so again only two weeks later, at which time he increased the dosing to one tablet every four hours without examining him.

arrest that a narcotics detective would be calling and that the 120 tablets that had been recently dispensed to him was a ten-day supply—these nineteen refills should have lasted 114 days rather than a little more than two months. Indeed, based on Respondent's note, the supply should have lasted 190 days or slightly more than six months.

M.D. also obtained unwarranted refills of Xanax from Respondent. On February 15, 2007, Respondent dispensed 60 Xanax to him.⁴⁸ Four days later, Respondent dispensed another 60 Xanax, a thirty-day supply based on the dosing noted in the record of one tablet every twelve hours. This was followed by additional dispensings of 90 tablets on March 1 and 9, with the same dosing instruction of one tablet every twelve hours.

Here again, Respondent dispensed controlled substances in quantities which far exceeded the amount he had determined was medically necessary to treat a patient's condition. And once again, it is clear that Respondent failed to properly monitor his patient to ensure that the patient was not abusing or selling the drugs.⁴⁹

While S.M. did not seek early refills of Lorcet (at least if it is assumed that he took twenty tablets per day) during the initial seven months of his seeing Respondent, beginning in March of 2007, he did. More specifically, Respondent dispensed 120 Lorcet to him on March 1, 5, 9, 12, 16, 19, 23, 26, and 30; as well as on April 2, 6, and 9, 2007. These dispensings totaled 1,440 tablets in a forty-day period, and were enough to provide 72 days worth of medication if they were taken at a rate of 20 tablets per day.

At the hearing, Respondent admitted that some of these refills were too early. Again, Respondent failed to properly monitor his patient to ensure that he was not abusing drugs and/or selling them.

D.M. received numerous refills for both Xanax and Valium that were typically weeks early. Respondent dispensed 30 Xanax, which provided a fifteen-day supply based on the dosing instruction, to D.M. on July 7, 11, 15, 22, and 29; August 4, 11, 16, 22, and 26; and September 1. Then, with no change in the dosing, he dispensed 60 tablets (a thirty-day supply) to D.M. on September 6, 12, 19, and 26; as well as on October 10, 17, and 24; and 90 tablets on October 3. In just this period, which was

not even four months long, Respondent dispensed 840 tablets to D.M., a quantity which was enough to treat him for nearly fourteen months.

Respondent then switched to Valium, dispensing 60 tablets, with a dosing of one tablet to be taken every twelve 12 hours (a thirty-day supply), to D.M. on November 7, 17, 23, and 29; December 6, 13, 22, and 27 (all in 2005); January 10, 16, 23, and 30; February 6, 13, 20, and 27; March 7, 13, 20, 27, and 31; April 4, 7, 14, 20, and 27; May 5, 11, 18, 19, and 23; June 9, 15, 23, and 27; and July 5, 7, 11, 14, 18, 21, 25, 28, and 31 (on both July 7 and 28, the refills were for 90 tablets). Most of Respondent's dispensings of a thirty-day day supply were more than three weeks early; the dispensings of 90 tablets were even earlier. Moreover, the dispensings totaled 2,640 tablets and provided 1,320 days worth of medication in a nine-month (approximately 270-day) period.

In September 2006, D.M. also began obtaining clearly excessive refills for Lorcet. Specifically, he obtained refills for 120 or 150 Lorcet on September 5 (120), 7 (120), 11 (120), 14 (120), 18 (150 tablets), 22 (120), and 25 (150); October 2 (120), 5 (120), 9 (120), 12 (150), date undecipherable (120), date undecipherable (150), 23 (120), 26 (150), and 30 (120); November 2 (150), 6 (120), 9 (150), 13 (120), 20 (120), 22 (120), and 30 (150); December 3 (120), 7 (150), 11 (120), 14 (150), 18 (150), 21 (150), and 28 (150). In each of these months, Respondent dispensed between 300 and nearly 600 more tablets than the amount which Respondent claimed he told his patients they could safely take (600 to 620 a month).

As the evidence shows, even in the initial months of Respondent's relationship with D.M., there was ample reason to believe that D.M. was either abusing the Xanax or selling it to others. Indeed, although D.M.'s refill requests became even more brazen in their frequency, Respondent rarely rejected any of his 146 refill requests and continued to dispense controlled substances to him until he surrendered his registration. Respondent's dispensings to D.M. manifest a complete abdication of his obligation to properly supervise his patient "to prevent addiction and recreational abuse." *Gonzalez*, 546 U.S. at 274. It is clear that these prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice and thus violated Federal law. 21 CFR 1306.04(a).

J.N. also received excessive refills of both Lorcet and Valium. Between November 2, 2006 and February 19, 2007, Respondent dispensed sixteen

refills for 180 Lorcet and 2 refills for 150 Lorcet for a total of 3,180 tablets, with most of the refills being dispensed within three to five days of the previous refill. Even if Respondent told J.N. that he could take up to twenty tablets of Lorcet per day, the quantity he dispensed in this period would have provided enough medication for 159 days and was thus well in excess of what Respondent's dosage recommendation required.

Moreover, on twelve occasions beginning on December 7, 2006 and ending on February 19, 2007, Respondent dispensed a total of 750 Valium tablets to J.N. According to the dosing instruction of one tablet every twelve hours, the dispensings would have provided 375 days of medication and thus provided nearly five times the amount of Valium which Respondent had determined was medically necessary. Moreover, on January 18, Respondent dispensed not only 30 Valium but also 60 Xanax to J.N.; J.N.'s record, however, contains no explanation as to why both drugs, which are benzodiazepines and schedule IV depressants, were medically necessary. *See* 21 CFR 1308.14(c).

Here again, it is clear that Respondent failed to properly monitor the amount of controlled substances his patient was seeking. It also clear that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in dispensing controlled substances to J.N. 21 CFR 1306.04(a).

From the beginning of his relationship with S.R., Respondent dispensed Lorcet, Xanax, and Valium in amounts that substantially exceeded what his dosing regime called for. For example, in the first two months Respondent dispensed 720 tablets of Lorcet, 120 tablets more than was necessary based on the twenty tablets per day maximum dose. He dispensed 30 Xanax to S.R. at her second visit, a fifteen-day supply based on his dosing instruction, only to do so again four days later and a third time, six days after the second dispensing. On the same day as the third Xanax dispensing, he also dispensed 30 Valium (also a fifteen-day supply), and only four days later, he dispensed another 60 Valium. Notably, Respondent did not note in the patient record a medical reason for prescribing either the Xanax or the Valium.

While S.R.'s file indicates that during August, Respondent turned down two

⁴⁸ It is not clear what the dosing was for this prescription.

⁴⁹ Only twelve of some fifty-five telephone requests for refills indicated that Respondent had checked the date of M.D.'s previous refill or last office visit.

refill requests,⁵⁰ beginning in October, S.R. successfully escalated her requests. In this month, S.R. obtained Lorcet refills totaling 900 tablets, nearly 300 tablets more than was required if she was taking 20 tablets per day; in November, she obtained 780 Lorcet, 180 tablets more than was necessary to provide the maximum dose. More striking, in December, she obtained 1,080 tablets (480 more than needed), and in January, she obtained 1,260, more than double what was needed.

Moreover, between November 22 and January 29, Respondent dispensed fourteen refills of Valium to S.R. for a total of 570 tablets, a quantity sufficient for 285 days. On three separate dates during this period, Respondent also dispensed refills of 60 Xanax for a total of 180 tablets (a 90-day supply). Notably, many of these Lorcet and Xanax refills occurred only three to four days after a previous refill.

As noted above, S.R.'s file indicates that he twice rejected refill requests. However, in each instance, he subsequently approved refills only a few days later and apparently never asked why his patient was seeking refills so early. During the eight months in which he dispensed drugs to her, he saw her only at the initial visit. Once again, the evidence is clear that Respondent failed to properly monitor his patient to ensure that she was not abusing the drugs or selling them. Again, I hold that Respondent repeatedly acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he dispensed Lorcet, Xanax, and Valium to S.R. 21 CFR 1306.04(a).

B.W. sought an early refill four days after obtaining a Vicodin prescription, claiming that his housekeeper had thrown away his medication. B.W. did not otherwise begin to demonstrate a pattern of seeking early refills until several months later when, in November 2006, Respondent dispensed to him six refills totaling 540 tablets of Vicodin ES, an amount which based on the testimony that twelve tablets was the maximum safe daily dose, was 200 tablets more than was medically necessary to treat him for that month.⁵¹ In December, Respondent dispensed to B.W. six more refills, each for 120 tablets, for a total of 720 tablets, an amount which was nearly double the

monthly number of tablets (372) that Respondent testified could be safely taken.

In January 2007, Respondent dispensed eight more 120 tablet refills for a total of 960 tablets, an amount which was nearly 600 tablets more than could be safely taken (372). This was followed by six dispensings for a total of 510 tablets in February, providing approximately 170 tablets beyond what could be safely taken (336), and six dispensings in March for a total of 600 tablets, approximately 230 tablets more than necessary (372). Finally, in the first ten days of April 2007, Respondent dispensed three refills for a total of 360 tablets, the last refill occurring two days before Respondent surrendered his registration.

At no time did Respondent perform blood tests to determine how the medication was affecting B.W.'s liver function. Moreover, beginning in November 2006, B.W. had clearly escalated his refill requests and yet Respondent authorized doubling the quantity of the refills to 120 tablets. Respondent did so without doing a follow-up evaluation and continued to dispense to B.W. for several months thereafter before concluding in February 2007 that B.W. needed to be seen. Even then, he dispensed additional refills until early March, when he finally saw B.W.

In his testimony, Respondent conceded that the refills that occurred between March 15 and April 10, 2007 were early. However, in fact, nearly all of the refills between November 2006 and April 10, 2007 were early. Notably, during this period, B.W. was obtaining hydrocodone drugs from ten other physicians.

Here again, the quantities of Vicodin ES which B.W. sought and obtained from Respondent were indicative of self-abuse and/or selling to others. Once again, I conclude that Respondent failed to properly supervise his patient and that he lacked a legitimate medical purpose and acted outside of the usual course of professional practice in dispensing the refills. 21 CFR 1306.04(a).

Respondent examined J.W. only at his initial visit of March 6, 2006, yet dispensed refills to him for eleven months before finally concluding that he was requesting "too much meds" and that a second visit was needed "to discuss lowering [the] amounts." While J.W.'s Lorcet refills were not initially problematic (based on the twenty tablet per day max), from the outset the Xanax refills were excessive.

At the first visit, Respondent dispensed to J.W. 90 Xanax, a forty five-

day supply based on the dosing instruction of one tablet every twelve hours. Yet only ten days later, Respondent dispensed another 60 tablets to him (a thirty-day supply); this was followed by two more refills, each for 30 tablets during the month. In March 2006 alone, Respondent dispensed 210 Xanax to J.W., an amount which provided 105 days' worth of the drug.

During the course of Respondent's dispensing, his dosing instruction remained unchanged. Yet each month Respondent dispensed to J.W. quantities of Xanax far in excess of what his dosing instructions established was medically necessary (assuming he actually had a condition warranting the drug). In April, he dispensed 180 tablets; in May and June, 150 (each month); in July, 360; in August, 150; in September, 420; in October, 810; in November, 690; in December, 450; in January 2007, 540; and in February, 150 (although J.W. made only two refills requests in this month). Thus, from the outset, J.W. sought and obtained 2.5 to 3 times the monthly amount of Xanax which was medically necessary. And even after J.W. had become increasingly brazen and sought first seven, and then fourteen times the monthly amount of drug that Respondent's dosing regime required, Respondent continued to dispense grossly excessive quantities to him and did so for months.

Likewise, by October, J.W.'s requests for Lorcet refills had become increasingly brazen, with some requests occurring within two to four days of a previous refill. In October, Respondent dispensed 1,080 Lorcet tablets to J.W., an amount which was 460 tablets more than necessary if J.W. actually needed the maximum 20 tablets per day to treat a legitimate medical condition. In November, Respondent dispensed to J.W. another 1,080 tablets; in December, 810; in January, 990; and in the first five days of February, 360. Again, Respondent approved multiple refills within only a few days after approving a previous refill. And again, at no time during the course of his dispensing Lorcet to J.W., did Respondent do blood tests.

Given the frequency of the refills and quantities that he dispensed, it is incredible that it took Respondent eleven months to finally recognize that something was amiss and require that J.W. appear for a second visit. Once again, Respondent failed to properly monitor his patient. Moreover, even assuming that Respondent's evaluation of J.W. was adequate to support the initial prescriptions of Xanax and Lorcet, it is clear that most of the refills

⁵⁰ One of these was only three days after a prior refill, thus begging the question of what use S.R. was making of the drugs she was seeking.

⁵¹ The first November refill occurred on November 3; B.W. had obtained a refill for 60 tablets on October 31. The first three November refills were for 60 tablets each; beginning on November 13, Respondent doubled the quantity to 120 tablets.

he dispensed were not medically necessary and therefore lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. 21 CFR 1306.04(a).

The record here thus manifests an egregious failure by Respondent to properly supervise his patients to ensure that they were not abusing the drugs and/or selling them to others. *See Gonzales*, 546 U.S. at 274. In short, Respondent completely abdicated his role as a physician. I further hold that the Government has clearly met its *prima facie* burden of showing that Respondent's registration would be inconsistent with the public interest.⁵²

Sanction

Under longstanding Agency precedent, where, as here, "the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must 'present sufficient mitigating evidence to assure the Administrator that [he] can

be entrusted with the responsibility carried by such a registration.'" *Medicine Shoppe-Jonesborough*, 73 FR 363, 387 (2008), *aff'd*, 3000 Fed. Appx. 409 (6th Cir. 2008) (quoting *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), [DEA] 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*, 73 FR at 387; *see also Jackson*, 72 FR at 23853; *John H. Kennedy*, 71 FR 35705, 35709 (2006); *Prince George Daniels*, 60 FR 62884, 62887 (1995). *See also Hoxie v. DEA*, 419 F.3d at 483 ("admitting fault" is "properly consider[ed]" by DEA to be an "important factor[]" in the public interest determination).⁵³

Finally, an applicant/registrant is required not only to accept responsibility for his misconduct, but also to demonstrate what corrective measures he has undertaken to prevent the re-occurrence of similar acts. *Jayam Krishna-Iyer*, 74 FR 459, 464 (2009). Both conditions are essential requirements for rebutting the Government's *prima facie* showing that granting an application or continuing an existing registration would be "inconsistent with the public interest." 21 U.S.C. 823(f).

In her decision, the ALJ noted various facts which she deemed favorable to Respondent even though she ultimately concluded that he had not rebutted the Government's *prima facie* case. Several of these facts are not even supported by the record; others are insubstantial and do little to minimize the egregious nature of Respondent's misconduct.

First, the ALJ asserted that "Respondent was not dispensing controlled substances for monetary gain." ALJ at 48. As support for this finding, the ALJ cited the testimony of the DI that he did not find significant

amounts of money in Respondent's home or office and found no indication of abnormally large cash transfers or other evidence of trafficking. *Id.* Respondent did, however, charge for the pills he dispensed even if he did not charge the street price for drugs;⁵⁴ in any event, the price he charged is of little relevance in determining whether the refills were issued in the usual course of professional practice and lacked a legitimate medical purpose. Even if Respondent had charged nothing for a prescription (or given a patient a free manufacturer's sample), if he acted outside of the usual course of professional practice and lacked a legitimate medical purpose in doing so, the dispensing would still be unlawful.

Next, the ALJ found that Respondent had refused to prescribe OxyContin because of its addictive properties. ALJ at 43. However, given the extensive scope of the early and unwarranted refills he authorized for such highly abused drugs as Lorcet, Vicodin, Xanax, and Valium, the ALJ's finding does not mitigate the egregiousness of his misconduct.

Based on the initial conversation between the Special Agent and Respondent, the ALJ found that he "refused to prescribe controlled substances for recreational purposes." ALJ at 43. Yet, within a minute or so of his claiming that he did not prescribe for recreational purposes, he agreed to write a prescription to the Special Agent for Vicodin even though the Agent had yet to make any representation that she had pain. Thus, he was willing to prescribe for recreational purposes provided the Agent eventually said the magic words.

The ALJ also found that Respondent "stopped dispensing refills when a patient failed to keep a scheduled appointment" and that he "often times refused to dispense early refills." *Id.* As to the first assertion, the evidence showed, however, that Respondent rarely required his patients to appear for follow-up visits and that he authorized refills for months on end (frequently on a weekly or shorter basis) without requiring a visit. And contrary to the ALJ's second assertion, Respondent rarely refused a refill request, and even when he initially did so, he frequently approved it within a few days.

The ALJ noted that "in multiple cases * * * Respondent actually dispensed controlled substances at the rate he directed his patients to consume them." *Id.* Beyond the fact that one would

⁵² The Government also proved that Respondent violated California law by allowing unlicensed employees to dispense the controlled substances to his patients. *See Cal. Bus. & Prof. Code § 4170(a)*. Respondent admitted to the DI that one of his employees repackaged the controlled substances into vials which she labeled and that his receptionist would then deliver the controlled substances to his patients. He also admitted that he did not personally supervise his receptionist deliver the drugs to the patients. Tr. 593.

Section 4170 of the California Business and Profession Code provides in relevant part that "[n]o prescriber shall dispense drugs * * * to patients in his or her office or place of practice unless * * * [t]he dangerous drugs * * * are dispensed to the prescriber's own patient, and the drugs * * * are not furnished by a nurse or physician attendant." *Id.* § (a)(1); *see also id.* § (a)(5) (requiring prescriber to "personally dispense[] the dangerous drugs * * * to the patient"). While the statute allows a certified nurse-midwife, a nurse practitioner, a physician assistant or a naturopathic doctor to "hand to a patient of the supervising physician * * * a properly labeled prescription drug prepackaged by a physician," *id.* § (a)(8), neither H.C. nor the receptionist hold any of these licenses.

While Respondent contended that the Medical Board had inspected his pharmacy twice and found no violations, Respondent was not present during one of the inspections, and the record does not establish, whether at either inspection, the inspectors observed the actual manner in which Respondent dispensed the drugs. Moreover, the Government cited two Medical Board decisions holding physicians in violation of section 4170 because they allowed either unlicensed office staff (or employees who did not fall within the exceptions of subsection (a)(8)) to dispense drugs to their patients. *See Tan Shin Lee, M.D.*, Stipulated Surrender of License and Order, Ex. A, at 4, 17-18; *adopted by Tan Shin Lee, M.D.*, Decision (Med. Bd. Cal. 2008) (Gov. Br., at app. H); *Albert Peter Giannini, Jr., M.D.*, Stipulation in Settlement and Order, at 3 (Med. Bd. Cal. 2001); *adopted by Albert Peter Giannini, Jr., M.D.*, Decision (Med. Bd. Cal. 2001) (Gov. Br., at app. G). I thus conclude that Respondent violated California law when he allowed unlicensed personnel to dispense controlled substances to his patients.

⁵³ Relatedly, an applicant's/registrant's lack of candor is an important and typically dispositive consideration in determining whether he has accepted responsibility for her misconduct. *See Hoxie*, 419 F.3d at 483 ("Candor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a physician's registration is consistent with the public interest" and noting that physician's "lack of candor and failure to take responsibility for his past legal troubles * * * provide substantial evidence that his registration is inconsistent with the public interest."). *See also Craig H. Bammer*, 73 FR 34327, 34328 (2008); *Prince George Daniels*, 60 FR 62884, 62887 (1995).

⁵⁴ There was testimony that in the Los Angeles area, Vicodin sold on the street for up to \$5 per tablet. Tr. 141.

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

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

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.

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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

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.

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.