

The Respondent presented numerous witnesses involved in Dr. Reitman's rehabilitation and medical practice. [FOF 48, 49, 57, 66, 72, 80, 85, 90]. Every witness on the topic of rehabilitation stated that he has excelled and is extremely committed to overcoming his addiction. [FOF 54–55, 62, 64, 70, 77, 87]. Furthermore, he is involved with his synagogue and has the full support of his wife and family. [FOF 67, 69, 70, 79]. Nine months have passed since the day he was confronted by the DEA, and he has not ingested or even ordered a controlled substance since. [FOF 28, 42].

Past DEA cases have involved practitioners whose registrations were either not revoked or their applications were not denied despite more reprehensible conduct than Dr. Reitman's self-prescribing. *See Judy L. Henderson, D.V.M., Grant of Restricted Registration*, 65 FR 5,672 (DEA 2000); *Jimmy H. Conway, Jr., M.D.*, 64 FR 32,271 (DEA 1999) (Respondent was addicted to Lorcet and Soma and used the names and DEA registration numbers of his partners to order the drug for his personal use. He candidly admitted the abuse and began a treatment program. The abuse occurred in 1996, the Order to Show Cause was issued in 1998, and the final order was submitted in 1999. Despite felony convictions, the Respondent was permitted to retain his registration with restrictions.); *Robert G. Hallermeier, M.D.*, 62 FR 26,818 (DEA 1997) (Respondent was an alcoholic with serious prescribing problems; granted a registration with restrictions.); *Thomson*, 65 FR at 75,971 (both DA and ALJ agreed that the physician "minimized her criminal actions and significant breaches of professional judgment," but the evidence of her "strong efforts to rehabilitate herself" ultimately warranted granting her a restricted registration); *John Porter Richards, D.O.*, 61 FR 13,878 (DEA 1996) (Applicant had been convicted of two felonies related to controlled substances and subsequently sentenced to thirty years in prison, twenty years of which were suspended. Thereafter, the respondent's license to practice osteopathic medicine was revoked before eventually being reinstated. However, at the application hearing in *Richards*, that applicant "continued to maintain that he had not committed the crimes for which he had been convicted." Nonetheless, in *Richards*, the DA approved the applicant's application without restrictions despite the fact that, at the hearing, the applicant accepted his conviction but

did not completely admit to the crimes for which he was convicted.). Here, Dr. Reitman has without a doubt, readily admitted fault and sought treatment, at which he has thrived. [FOF 44, 54–55, 70, 77, 84, 88]. The Respondent testified and was candid and truthful about his past abuse. [FOF 38–47]. Thus, the Deputy Administrator consistently decides each case on its own merits. This case warrants retaining a restricted registration.

I therefore find that Dr. Reitman has presented evidence sufficient to prove that he can be entrusted with a DEA Certificate of Registration.

V. Conclusion and Recommendation

I do not condone nor minimize the seriousness of the Respondent's prior misconduct; however, because the Respondent seems to be well on the road to rehabilitation, I recommend that Dr. Reitman be granted a registration that restricts his handling of controlled substances to merely prescribing and not storing or dispensing such drugs, and requiring that he not issue controlled substance prescriptions to himself or his family members. Further, I recommend the Respondent be subject to quarterly reporting to his local DEA office of his prescribing of controlled substances. I also recommend that Dr. Reitman be ordered to consent to unannounced inspections by DEA personnel without requiring an administrative inspection warrant. I recommend these restrictions apply for three years from the date of the final order so directing this result. In this way, the DEA can assure itself of the Respondent's compliance with DEA regulations and of the protection of the public interest.

Date: July 20, 2010.

Gail A. Randall,

Administrative Law Judge.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–14]

Jack A. Danton, D.O.; Decision and Order

On June 17, 2011, Administrative Law Judge (ALJ) Gail A. Randall issued the attached recommended decision.¹ Thereafter, the Government filed exceptions to the ALJ's decision.

¹ All citations to the ALJ's decision are to her slip opinion as originally issued.

Having considered the entire record and the Government's exceptions, I have decided to adopt the ALJ's decision except for her legal conclusions with respect to whether the Respondent issued prescriptions for controlled substances to several undercover officers and several of her findings under factor five. However, because I otherwise agree with the ALJ's findings as to the public interest factors, I adopt her ultimate conclusion that the Government has shown that "Respondent's continued registration would not be in the public's interest" and that the Respondent "has not accepted responsibility for all of her wrongdoing, nor has she adequately assured this tribunal of future compliance." ALJ at 64. I will therefore order that Respondent's registration be revoked and that any pending application be denied.

The Government's Exceptions

The ALJ concluded that the Government failed to establish that Respondent's prescriptions to three undercover officers (UC) lacked a legitimate medical purpose. ALJ at 42–51; see also 21 CFR 1306.04(a) ("A prescription for a controlled substance * * * must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."). In so concluding, the ALJ explained that the Government "provided no expert testimony to support this finding," and that while the Government "introduced the transcripts and recordings of the undercover transactions, and a summary of those transactions via officer testimony[,] * * * the Government ha[d] provided no meaningful lodestar by which this court can measure the legitimacy of the Respondent's medical practice under Florida statutory and regulatory requirements." *Id.* at 43. The ALJ noted that "while the [A]gency has considered over fifty cases concerning the legitimacy of a practitioner's prescriptions since [Gonzales v. Oregon, 546 U.S. 243 (2006)], the [A]gency has seldom found a violation of 21 CFR 1306.04(a) absent expert testimony[.]" and that "where the [A]gency has found such illegitimacy without an expert's testimony, that finding was based on patent violations, where diversion was either unrefuted or unquestionable." *Id.* at 43–44 (citing cases).

The ALJ also noted that "expert testimony may not be required" where the evidence shows that a registrant "has acted in a manner that clearly contravened state law governing what constitutes a legitimate medical practice," such as where a physician

issues a prescription where “no physical examination or face-to-face communication was conducted” as through Internet or telephone consultations. *Id.* at 44–45. However, the ALJ then explained that “when the Government seeks to use a state law violation as a means of establishing a violation of § 1306.04(a), the question remains to what extent that state law violation is so tethered to a finding of actual illegitimacy that, without expert testimony, it can be used as a predicate to a violation of the federal law.” *Id.*; see also *id.* at 45–46 (citing *Gonzales*, 546 U.S. at 70 (“the CSA ‘bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood’”); and *Laurence T. McKinney*, 73 FR 43260, 43266 (2008) (rejecting Government’s contention that physician’s failure to listen to undercover officer’s heart and lungs and take her blood pressure established a violation of 21 CFR 1306.04(a); while physician’s actions violated a state regulation, the officer had presented a medical complaint, identified a specific area of her body that was the cause of pain and complained of a relatively high pain level and at no point stated that she was not in pain, and physician had put her through several different range of motion tests”)).²

I agree with the ALJ that where the Government fails to provide expert testimony to support a finding that a practitioner acted outside of the usual course of professional practice and lacked a legitimate medical purpose, it can nonetheless prove a violation by: (1) Providing evidence that a practitioner committed a violation of a state medical practice standard which is sufficiently tied to a state law finding of illegitimacy to support a similar finding under Federal law, or (2) providing evidence showing that Respondent knowingly diverted drugs. However, I also conclude that a violation of a state medical practice standard which has a substantial relationship to the CSA’s purpose of preventing substance abuse and diversion is also sufficient to support a violation of 21 CFR 1306.04(a). Moreover, I disagree with the ALJ’s conclusion that the Government has not proved a violation of the CSA’s prescription requirement.

² As *McKinney* explained, establishing a violation of the prescription requirement “requires proof that the practitioner’s conduct went ‘beyond the bounds of any legitimate medical practice, including that which would constitute civil negligence.’” 73 FR at 43266 (quoting *United States v. McIver*, 470 F.3d 550, 559 (4th Cir. 2006)).

In its exceptions, the Government argues that it proved that Respondent did not perform a physical examination of either UC1 or UC2. Gov. Exc. at 3. The ALJ found otherwise, noting that Florida law does not define the term “physical examination,” and that at the time of the events at issue here, the meaning of the term under the State’s law was “nebulous.” ALJ at 47 & n.25. The ALJ further explained that Respondent’s “interpretation, in light of the Government’s failure to provide a contrary one, must be given considerable weight” and that Respondent had explained that “[a] physical examination does not necessarily entail touching the body” as “in the case of chronic injury ‘you can’t see—whether you’re putting your hands on the patient or not, you can’t see that evidence of chronic inflammation and disease by visual inspection or palpation.” *Id.* The ALJ also credited Respondent’s testimony that she performed a physical examination through “silent observation,” i.e., by watching how the patients walked from the waiting room to the exam room and how they sat. Tr. 413, 449; ALJ at 47–48. However, when questioned on cross-examination as to why Respondent had made no findings in the undercover officers’ charts as to her observations, Respondent testified that she only recorded observations if the patient had complained of pain and then “done an inappropriate action” such as “complain[ing] of severe low back pain” and then “bent over and jumped in the air.” Tr. 543.

It is far from clear why Respondent’s explanation should be entitled to “considerable weight” given the ALJ’s acknowledgment that it “has the potential for being self-serving,” ALJ at 43 n.23; and appears to be patently disingenuous.³ Moreover, just as jurors are not required in criminal cases to

³ Among the ALJ’s findings which she then proceeded to ignore in giving “considerable weight” to Respondent’s testimony as to the proper scope of a physical examination was Respondent’s discussion of UC2’s MRI. More specifically, the ALJ found that Respondent had “explained that she would have ‘to take the clinical symptoms and * * * the exam, [and the] neurological examination’ of the patient to determine if there was any significance to the bulging disc. She further explained that if ‘someone has a bulge but has no symptomatology, now, it’s there * * * [but] it’s not clinically significant.’” ALJ at 25 (quoting Tr. 454–55). Respondent did not, however, perform a neurological exam on UC2 at any time. Tr. 289, 297, 300. In addition, as Respondent’s testimony suggests, an MRI might well show that a person has a bulging disc but that the condition is asymptomatic. Yet as the evidence shows, Respondent prescribed oxycodone to UC1 and UC2, notwithstanding that neither complained of having pain at a level, which according to Respondent’s own statement to UC3, warrants oxycodone.

disregard “their own experiences in doctors’ care over their lives” in assessing evidence as to whether a physician performed a bona-fide physical exam and thus prescribed in the usual course of professional practice, *United States v. Armstrong*, 550 F.3d 382, 389 (5th Cir. 2008), so too, an Agency adjudicator can call on her experiences with physicians and conclude that merely watching a patient walk to an office and sit down does not constitute a physical exam, let alone one sufficient to support prescribing narcotics.

However, I need not decide whether Respondent performed a legitimate physical exam of any of the undercover officers, or whether, as the Government argues, “the plain meaning of the term ‘physical examination’ is that a physician [must do] something more than watch the patient walk into her office.” Gov. Exc. at 5. Here, the record contains sufficient other evidence to conclude that Respondent both: 1) knowingly diverted drugs, and 2) violated State medical practice standards that have a substantial relationship to the CSA’s purpose of preventing drug abuse and diversion so as to support a finding that she acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the prescriptions. 21 CFR 1306.04(a).

As the ALJ recognized, the Florida Board of Osteopathic Medicine has, by regulation, promulgated “Standards for the Use of Controlled Substances for Treatment of Pain.” ALJ at 47 (citing Fla. Admin. Code Ann. r.64B15–14.005). The Board has explained that the standards “communicate what the Board considers to be within the boundaries of professional practice.” Fla. Admin. Code Ann.r.64B15–14.005(1)(g).

The first of these standards is the Board’s standard for “Evaluation of the Patient.” This provision states:

A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Id. r.64B15–14.005(3)(a). In addition, the standards state that “[a]fter treatment begins, the osteopathic physician should adjust drug therapy to the individual medical needs of each patient.” *Id.* r.64B15–14.005(3)(b). As

the Board further explained in its discussion of pain management principles, “[p]ain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain.” *Id.* 64B15–1.005(1)(c).

Of note here, even if the Government has not proved that Respondent’s physical examination was medically inadequate to support her diagnoses of UCs 1 and 2, the evidence shows that Respondent’s evaluations of them failed to comply with the Board’s standards in several other ways. Moreover, because these violations have a substantial relationship to the CSA’s purpose of preventing drug abuse and diversion they support the conclusion that the prescriptions violated 21 CFR 1306.04(a).

At her first visit, UC1 (Tanya Hall), who indicated that she was from Illinois, obtained a prescription for 180 oxycodone 15 mg, as well as 30 Xanax 2mg.⁴ RX1, at 1, 5. Yet on her intake form, UC1 rated her pain as a 3 on a scale of 1 to 10, and gave as her reason for visiting Respondent, “soreness in neck and shoulder.” RX 1, at 2, 6. While during her first meeting with Respondent, UC1 reported that two months earlier, she had been working in a school cafeteria and had some boxes of chicken nuggets fall on her as she was getting one of them out of a freezer and that she also had a slip and fall incident,⁵ UC1 did not make any statement to Respondent that she was currently in pain and Respondent did not conduct any further inquiry into the nature and intensity of her pain and what effect, if any, it had on her physical and psychological functioning. GX 14B. Moreover, during her visit with Respondent, UC1 never claimed to suffer from “breakthrough pain.”

Notably, during an encounter with UC3 (which occurred the same day), Respondent explained that under her pain scale, pain between 1 and 3 was “mild pain,” that pain at level 4 was “comfortable pain,” and that at this level, “I can do whatever I want to do because the pain is just not that bad.” GX 13B, at 12 & 14. Respondent then asked rhetorically: “Is that the time to take a break with narcotic, an opiate, a dangerous heroin related drug? No, it’s not.” *Id.* at 14. Shortly thereafter, Respondent added: “So, if the worst

⁴ UC1 also obtained prescriptions for 30 Soma 350 mg (carisoprodol) and 90 Ibuprofen 800 mg.

⁵ UC1 also reported auto accidents in 1999 and 2003. However, this did not prompt Respondent to ask UC1 about the extent of her injuries from these accidents and what treatment had been provided for any injuries.

pain is being tolerable pain [or level 5 according to Respondent] and it’s never being as bad asitching pain [level 6 according to Respondent], maybe you don’t need a narcotic. Or may be some * * * Vicodin * * * You know, Hydrocodone, not an Oxycodone.” *Id.* As this makes clear, under Respondent’s own pain scale, the oxycodone prescriptions she issued to UC1 (and UC2) were not medically necessary to treated UC1’s (or UC2’s) reported pain level.

Moreover, when Respondent asked UC1 “what kind of medicine have you been on?,” UC1 reported that she had been taking Vicodin and Tylenol III (a drug with codeine). GX 14B, at 10. However, Respondent did not ask her whether she had previously been (or was currently being) treated by another physician, and if so, what treatments had been tried. *Id.* Finally, when Respondent offered to prescribe a drug combining oxycodone with acetaminophen, UC1 complained that drugs with acetaminophen hurt her stomach. However, when Respondent then asked: “Does it make[] you nauseous or bother your stomach? Tell the truth,” UC1 replied: “No, not really.” *Id.* at 12. UC1 persisted in not wanting a drug with acetaminophen, and asked Respondent if she could try oxycodone 15 mg. *Id.* at 13. Respondent then agreed, stating: “Alright, no big deal,” and added “Lucky, I love my patients.” *Id.* While at this point, Respondent had reason to know that UC1 was not a legitimate patient, but rather a drug seeker, she nevertheless prescribed 180 tablets of Oxycodone 15 mg to UC1, with the dosing instruction to take one tablet every 6 hours and ½; tablet for level 6 breakthrough pain.⁶ RX 1, at 5. Notably, at no point did Respondent—even though she had reason to know that UC1 was a drug abuser—question her about her past drug abuse.

At UC1’s second visit (Mar. 22, 2010), Respondent indicated on the progress note that UC1 had pain levels of 6–7/10 and 2–3/10. *Id.* at 15. While UC1 had circled her left shoulder on a pain assessment form, she indicated on the form that the worst her pain got was a 3. *Id.* at 16; Tr. 220. Moreover, during the visit, Respondent did not ask UC1 about her condition. Tr. 220–21. Respondent, however, issued UC1 a prescription for 360 Oxycodone 15 mg, double the amount of the original prescription, with the dosing instruction to take two tablets every six hours and one tablet for level six breakthrough

⁶ Respondent also prescribed 30 Xanax 2 mg.

pain,⁷ as well as 30 Xanax 2mg. RX1, at 19. Moreover, on this day, Respondent saw UC1 and UC2 (Pedro Castillo) together.

On April 20, 2010, UC1 and UC2 returned to Respondent. Once again, they saw Respondent together. While at this visit, UC1 indicated that 2 was her “acceptable level of pain,” she left blank the entries on the pain assessment form for indicating the “[p]resent” intensity, the “[w]orst pain gets,” and “[b]est pain gets.” RX1, at 21. Moreover, during the visit, Respondent did not ask her any questions regarding her pain levels and asked her only if she was getting in the pool and the frequency of her doing so, and whether the dosing of the Xanax was working well for her. GX 17C, at 7; 17D, at 6. Respondent, however, issued UC1 more prescriptions, including one for 180 Oxycodone 15 mg and 30 Xanax 2mg. RX1, at 22.

As for UC2, who also represented that he was from Illinois, at his first visit he listed “stiffness in neck” as the reason for his visit; however, he left the form for indicating his general health history entirely blank. RX 2, at 5, 12. Moreover, on his pain assessment form, UC2 rated his pain intensity as a 2 on a scale of 1 to 10 and left the rest of the form blank including the entries for describing the “quality,” “onset”, “manner of expressing,” “what relieves your pain,” and “what causes or increases your pain.” *Id.* at 15.

When Respondent asked UC2 what medicine he had been on, UC2 stated that he had not “gotten anything from a doctor” and he “was just getting some Oxys from a friend * * * because that was the only thing that was helping my neck.” GX 15B, at 34. Respondent noted that UC2 had “one * * * mild bulging disc * * * which is basically what Tanya has.” *Id.* Respondent added that he would “normally say, ‘You know what, I have four herniated discs, in fact bulging discs, and I get fine on Percocet’” 10/325. *Id.* Respondent then said he would prescribe oxycodone 15 mg, but not oxycodone 30s, which UC2 had stated were the ones he was getting from his friend. *Id.* at 35.

Subsequently, Respondent noted that UC2 had one bulging disc, which was neither torn nor herniated, and was “not even pressing” on a nerve; Respondent advised that this condition did not warrant oxycodone 30 mg and required only 10/325. *Id.* at 39. Respondent further explained that oxycodone 10/325s cost only twenty-five cents more

⁷ The actual prescription was issued on a script bearing the name Daniel M. Jacobs, M.D., and apparently signed by Dr. Jacobs. See RX 1, at 19. However, UC1 did not see Dr. Jacobs that day, and received the prescription from Respondent. Tr. 222.

than oxycodone 15mg, and that when he had hurt his neck and had four herniated discs, he had used 10/325s with his pool program. *Id.* at 41–42.

Respondent noted that if UC2 used his pool program and stayed on the Ibuprofen, UC2 would not need to spend \$200 on oxycodone “which you don’t need.” *Id.* at 42. Continuing, Respondent asked: “So, now that I’ve given you all the options which do you want?* * * Which medicine you want?” *Id.* UC2 stated that he wanted the oxycodone 15s and not the oxycodone 10s, because he thought the 15s would be better and he knew his buddy had given him that. *Id.* Respondent then told UC2 that he was out of oxycodone 15mg and that he would have to come back like his “friend” UC1. *Id.* at 43. UC2 then asked if “I’ll get the same other stuff that [UC2] got?” *Id.* Respondent answered: “Yes, yes, exactly the same.”

Finally, Respondent got around to asking UC2 how he got hurt. *Id.* at 44. Initially, UC2 said that he “had a little accident at home,” but Respondent then asked if he had a “car accident or what?” *Id.* UC2 said he had been in a motorcycle accident “in the last year, some time” and that was how he hurt his neck. *Id.* UC2 stated, however, that he did not hurt his lower back, that he did not have numbness or tingling in his hands, that he did not have pain radiating into his arms or hands, and that his pain was not constant but “comes and goes sometimes.” *Id.* at 44–45. Respondent explained that he was going to prescribe 180 oxycodone 15mg and that UC2 should take a half of a 15mg tablet “[w]hen level five (5) tolerable pain become level six,” or “very uncomfortable, miserable, bitching pain.” *Id.* Respondent then asked UC2 whether he had difficulty sleeping, to which UC2 answered “sometimes.” *Id.* at 47. Respondent said he would give him Xanax, even though he had already stated that he would give UC2 the same drugs he gave UC1.⁸

Here again, notwithstanding that UC2 never represented at this visit that he had pain higher than level 2, Respondent issued him prescriptions for 180 oxycodone 15 mg and 30 Xanax 2mg (as well as Ibuprofen and Soma). Moreover, on the progress note documenting the visit, Respondent wrote that UC2 had a neck injury and that his “pain comes & goes,” but did

not document any pain level. RX 2, at 1.

As noted above, on March 22, UC2 and UC1 saw Respondent together. This time Respondent indicated in the progress note that UC2 had “Chronic left shoulder pain” and wrote pain levels of 6–7/10 and 2–3/10. RX 2, at 17. UC2 testified, however, that during the second visit, there was no discussion of whether he had pain. Tr. 297. UC2 further stated that he complained of having only stiffness in his neck, and not chronic pain in his left shoulder. *Id.* at 313–14. Respondent gave UC2 prescriptions (which, just as for UC1, were written on the script and DEA number of Dr. Jacobs⁹) for 360 Oxycodone 15mg (also double the previous dose), 30 Xanax 2mg, Ibuprofen and Soma. RX 2, at 19.

Likewise, at the third visit, UC2 noted a pain level of three on a form, but again complained only of a stiff neck. RX2, at 16; Tr. 300–01. On the progress note, however, Respondent noted that UC2 had pain levels of 6–7/10 and 2–3/10 and had “chronic left shoulder pain.” RX 2, at 20. While Respondent asked UC2 how he was doing on “the 180 program,” a reference to his oxycodone prescribing, to which UC2 answered “awesome,” at no point during the visit did Respondent ask UC2 what his pain levels were. *See GX 17C & 17D.* Respondent then gave UC2 a prescription for 180 oxycodone 15 mg, as well as 30 Xanax, and the other two drugs.¹⁰

UC2 testified that Respondent did not perform a physical examination of him at any of the three visits. Notwithstanding Respondent’s testimony that she silently observed UC2, unexplained is the basis for her diagnosis that UC2 had “chronic left shoulder pain” when he never complained of anything other than a stiff neck.

As the forgoing demonstrates, even assuming that Respondent’s silent observation of UC1 and UC2 constitutes a valid physical exam,¹¹ the evidence shows that in multiple other ways, Respondent did not comply with the State’s standard for evaluating his patient and determining whether prescribing controlled substances was warranted. She failed to inquire as to whether the UCs had been, or were currently being, treated by other doctors for their purported conditions and what

those treatments involved. Likewise, Respondent made no inquiry as to the effect of the UCs’ pain on their physical and psychological functioning. Moreover, she did not ask either UC about their history of substance abuse even though Respondent had reason to know that both UC1 and UC2 were drug seekers. Finally, at their second (joint) visit, Respondent doubled the amount and dosage of UC1’s and UC2’s oxycodone prescriptions even though she did not discuss with either of them their current pain levels and the efficacy of the prior prescriptions.

The ALJ did not address whether these requirements, which Respondent clearly violated, have a substantial relationship to the CSA’s core purpose of preventing drug abuse and diversion so as to support a finding that Respondent lacked a legitimate purpose and acted outside of the usual course of professional practice in prescribing controlled substances to UCs 1 & 2. I conclude that they do.

For example, inquiry into whether a patient is currently being treated, or has previously been treated for pain, might reveal that the patient is engaged in, or has a history of, doctor shopping or other non-compliant behaviors consistent with self-abuse or diversion; such inquiry might also show that controlled substances were previously tried and not effective. Fla. Admin. Code r.64B15–14.005(3)(d)(noting important of reevaluating “the appropriateness of continued treatment”). Inquiry into the effect of pain on a patient’s physical and psychological functioning would seem to be an essential step in determining whether the patient’s report of pain is consistent with his level of function, and whether prescribing controlled substances is even medically indicated to treat a patient’s pain, as well as the appropriate drug and dosage level, another critical step in preventing diversion and self-abuse. Likewise, inquiry into whether a patient has a history of substance abuse has an obvious relationship to the CSA’s purpose. Finally, the failure to adjust drug therapy based on a re-evaluation of the patient could lead to a patient’s becoming addicted or overdosing.¹²

Respondent’s failure to comply with these requirements with respect to UC1 and UC2 is fundamentally different than the situation at issue in *McKinney*, where the practitioner clearly violated a state regulation by not listening to an undercover officer’s heart and lungs and taking her blood pressure but otherwise

⁸ Respondent also asked UC2 if he got “muscle spasms at night?” GX 15B, at 48. UC2 answered, “yeah.” *Id.* Respondent then said he would prescribe Soma 350 mg as well, without any further inquiry as to how often UC2 has spasms and how debilitating they were. *See id.*

⁹ Here too, UC2 testified that he did not see Dr. Jacobs that day. Tr. 299.

¹⁰ Respondent also asked UC2 if he was “doing wonderful[ly] on” the Xanax dosing; UC2 answered that “[i]t’s working for me.” GX 17D, at 2–3.

¹¹ It is also noted that Respondent did not document the results of her silent observation.

¹² It could also result in the patient having extra drugs which could be sold on the street.

performed a physical exam. To make clear, this is not a case where a physician made some attempt to comply with various state medical practice standards and the adequacy of those efforts is at issue.¹³ Rather, it is a case where a physician has utterly failed to comply with multiple requirements of state law for evaluating her patients and determining whether controlled substances are medically indicated and thus has “completely betrayed any semblance of legitimate medical treatment.” *McKinney*, 73 FR at 43266 (quoting *United States v. Feingold*, 454 F.3d 1001, 1010 (9th Cir. 2006)). Indeed, the State Board’s statement that its standards “communicate what the Board considers to be within the boundaries of professional practice,” Fla. Admin. Code r.64B15–14.005(1)(g), provides further support for the conclusion that Respondent, by failing to comply with them, acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing oxycodone to UC1 and UC2¹⁴ and thus violated Federal law. 21

¹³ Such a case would likely require expert testimony to show that a physician did not merely commit malpractice, but rather, acted outside the boundaries of professional practice.

¹⁴ The Government takes exception to the ALJ’s finding of fact 116, in which she credited Respondent’s testimony that she “was willing to make a small salary so that people could afford to come and learn” and that “if I could dispense the pills at a reasonable price, it would be an incentive for them * * * to come and stay with the program. If they kept with the program and they got used to the program, eventually they would be able to get off of narcotics.” ALJ at 33–34 (FoF 33–34); Exceptions at 6–7.

That this testimony is patently self-serving and disingenuous is made clear by the undercover visits of UC1 and UC2, in which Respondent prescribed oxycodone to them notwithstanding that the UCs reported low pain levels (which were also well below the levels Respondent stated warranted oxycodone), and Respondent made no inquiry into how each of the UCs’ respective pain levels were affecting their physical and psychological function, made no inquiry into whether they had a history of substance abuse, and made no inquiry into whether the UCs had previously been or were currently being treated for pain. In any event, having concluded that Respondent violated 21 CFR 1306.04(a) with respect to UC1 and UC2 and thus unlawfully distributed controlled substances to them, whether Respondent charged the highest price she could or discounted the drugs does not make the distributions any less unlawful.

The Government also takes exception to the ALJ’s having given no weight to the testimony of a Diversion Investigator that Respondent had stated that she did not dispense controlled substances at a patient’s first visit. Exceptions at 8 (citing FoF 30 & n.5). It is acknowledged that the ALJ stated that she gave “this testimony no weight.” ALJ at 10 n.5. However, it is not clear whether the ALJ was referring to the DI’s testimony or the statement Respondent made to the DI as the ALJ also noted that Respondent’s statement to the DI “is inconsistent with her conduct regarding the undercover visits.” ALJ at 10 n.5. However, because it is clear that Respondent issued prescriptions to the UCs at their first visits, I conclude that it is not

CFR 1306.04(a); *see also* Fla. Stat. Ann. § 893.05(1) (“A practitioner, in good faith and in the course of his or her professional practice only, may prescribe * * * a controlled substance”).¹⁵

Moreover, Respondent’s testimony makes clear that she does not accept responsibility for her misconduct in prescribing to the UCs. When asked by her own counsel whether her oxycodone prescriptions were medically appropriate, she asserted that they were because “the PDR allows up to 30-milligrams, which is twice the 15 that I recommended for these patients,” Tr. 484, ignoring that UC1 and UC2 never complained of pain warranting prescriptions at this level of drug. Likewise, in addressing why she gave UC3 an extra twenty oxycodone pills after he requested them so that he could repay a friend, Respondent offered the disingenuous testimony that she did so so that UC3 would “have those twenty extra pills as a parachute” and she “didn’t want him to worry.” *Id.* at 512. While in her testimony Respondent maintained that this was “an error of judgment,” in fact, it was a criminal act. 21 U.S.C. 841(a)(1).

It is true that at UC3’s third visit, Respondent refused to give UC3 additional pills. However, here again Respondent gave false testimony, stating that she had told UC3 that “[i]f you know you’re going to be short, you break and take half pills so you won’t go into

necessary to resolve what the ALJ meant and whether she improperly gave no weight to the DI’s testimony.

¹⁵ In her discussion of factor five—such other conduct which may threaten public health and safety—the ALJ found that many characteristics of Respondent’s practice increased the risk of diversion. ALJ at 60–62. More specifically, the ALJ noted that Respondent did not conduct urine drugs screens on the undercover patients, operated a cash-only dispensary thus foreclosing third-party review, did not verify the MRIs that were presented by the UCs, and failed to obtain past treatment records. *Id.*

In contrast to the requirements imposed under the State’s standard for “Evaluation of the Patient,” the Florida standards then in effect did not explicitly require that a doctor perform urine drug screens or verify the authenticity of an MRI. Moreover, while the State’s standard required documenting a patient’s past treatments for pain, it says nothing about obtaining past treatment records. Given that these requirements were not explicitly imposed by the State’s rules, either expert testimony or perhaps medical treatises (or articles in peer-reviewed medical journals) was necessary to establish that each of these is required as part of the accepted standard of professional practice. Because there is no such evidence, the ALJ’s conclusions that each of these omissions constitutes conduct which may threaten public health and safety must be rejected.

As for Respondent’s operation of a cash-only clinic, while this may be probative evidence of illegal activity when considered with the other evidence in the case, by itself, operating a cash-only clinic does not constitute conduct which may threaten public health and safety.

withdrawal.” Tr. 513. However, as the transcript of the undercover visit makes clear, there was no discussion of withdrawal. Instead, she advised UC3 that if he owed people, he could break the pills and “take a fifteen instead of a thirty and that way” he could save the extras and “give the money back.” GX 16B, at 22.¹⁶

Respondent’s advice to UC3 is fundamentally inconsistent with a registrant’s obligation to prevent drug abuse; her giving of false testimony on this and other issues, as well as the numerous violations of the CSA which have been proved on this record make clear that she cannot be entrusted with a registration. Accordingly, I will adopt the ALJ’s ultimate conclusion that Respondent’s continued registration would be inconsistent with the public interest and her recommendation that I revoke her registration and deny any pending applications to renew or modify her registration.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration FD1749057, issued to Jack A. Danton, D.O., a/k/a/ Jacalyn A. Danton, D.O., be, and it hereby is, revoked. I further order that any pending application of Jack A. Danton, D.O., a/k/a Jacalyn A. Danton, D.O., to renew or modify her registration, be, and it hereby is denied. This Order is effective October 31, 2011.

Dated: September 19, 2011.

Michele M. Leonhart,

Administrator.

Carrie Bland, Esq., for the Government.

Brian Y. Silber, Esq., for the

Respondent.

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

I. Procedural Background

Gail A. Randall, Administrative Law Judge. The then Deputy Administrator, Drug Enforcement Administration (“DEA” or “Government”), issued an Order to Show Cause and Immediate Suspension of Registration (“Order”) dated November 19, 2010, proposing to revoke the DEA Certificate of Registration, Number FD1749057, of Jack A. Danton, D.O., (“Respondent” or “Dr. Danton”), as a practitioner, pursuant to 21 U.S.C. 824(a)(4) (2006), and deny any pending applications for renewal or modification of such

¹⁶ The evidence shows that UC3 was given a prescription for 180 Oxycodone 30 mg at his third visit by Dr. Jacobs. *See RX 3*, at 11–12.

registration pursuant to 21 U.S.C. 823(f), because the continued registration of the Respondent would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f) and 824(a)(4). The Order also immediately suspended the registration pursuant to 21 U.S.C. 824(d), because the Respondent's continued registration constituted an imminent danger to the public health or safety. [Administrative Law Judge Exhibit ("ALJ Exh.") 1]. The Respondent was served with the Order on November 23, 2010. [ALJ Exh. 2].

The Order asserted that the Respondent dispensed "inordinate amounts" of controlled substances, primarily oxycodone and alprazolam, under circumstances where the Respondent knew or should have known "that such prescribing and dispensing are for other than legitimate medical purposes and are outside the usual course of professional practice." [ALJ Exh. 1 at 2].

Next the Order asserted that many of the patients are from out of state, and that they have indicated that the Respondent failed to perform physical examinations and only accepted payment in cash. [Id.].

Next, the Order asserted that between February and April of 2010, the Respondent treated three law enforcement personnel, operating in an undercover capacity. At each of at least eight visits the Respondent issued prescriptions for other than legitimate medical purposes and outside the usual course of professional practice. The Respondent's prescribing of controlled substances to these individuals violated both State and Federal law, per the Order. [Id.].

By letter dated December 14, 2010, the Respondent, through counsel, timely filed a request for a hearing in the above-captioned matter. [ALJ Exh. 3].

At the Respondent's request, the hearing was held in Fort Lauderdale, Florida, on April 5–7, 2011. [ALJ Exh. 5–8; Transcript ("Tr.") Volume I–III]. At the hearing, Counsel for the DEA and Counsel for the Respondent called witnesses to testify and introduced documentary evidence. After the hearing, the Government¹⁷ submitted Proposed Findings of Fact, Conclusions of Law and Argument.

II. Issue

The issue in this proceeding is whether or not the record as a whole establishes by a preponderance of the

¹⁷ The Respondent attempted to submit her post-hearing brief late. Her request for permission to submit it late was denied. The Government timely submitted its brief.

evidence that the Drug Enforcement Administration should revoke the DEA Certificate of Registration Number FD1749057 of Jack A. Danton, D.O., as a practitioner pursuant to 21 U.S.C. 824(a), and deny any pending applications to renew or modify this registration under 21 U.S.C. 823(f), because to continue Respondent's registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f). [Transcript ("Tr.") at 6].

III. Findings of Fact

I find, by a preponderance of the evidence, the following facts:

A. Stipulated Facts

1. Respondent is registered with DEA as a practitioner in Schedules II–V under DEA registration number FD1749057.

2. Respondent's DEA registration expires by its terms on June 30, 2012.

B. Background Facts

3. The Respondent is a doctor of osteopathic medicine who practices in cosmetic dermatology, cosmetic surgery, and some family practice. [Tr. 378]. She has practiced in those areas for thirty-five years. [Tr. 379]. A greater percentage of her practice was "dealing with musculoskeletal injury." [Tr. 384]. In 2009, after the demand for cosmetic surgery declined, the Respondent added pain management to her area of practice. [Tr. 385–87].

4. Dr. Danton is a veteran of the United States Army and the Viet Nam war. [Tr. 379–80].

5. "Palliative care" means that "once the acute injury heals, that there's still something going on from either pinched nerves or some kind of pressure or spinal problems that cause the pain nerve to remain in active pain, even though the initial injury might heal." [Tr. 386]. Up to the time of the hearing, the Respondent treated from five to ten-thousand pain management patients seeking treatment for acute injuries all the way to chronic palliative care. [Tr. 390]. However, the Respondent is not Board certified in pain management. [Tr. 391].

6. At the hearing, Dr. Danton was recognized as an expert in the field of osteopathic medicine with extensive experience in pain management assessment and treatment. [Tr. 392].

7. Dr. Danton described how the human body becomes dependent on pain medications and how the body grows to tolerate pain medication. [Tr. 395–399]. The Respondent testified that she restricted her patients to taking four

15 mg oxycodone tablets a day. [Tr. 400].

8. In diagnosing muscular-skeletal injuries, the more important part of the diagnostic tools would be the MRI, for it is objective evidence of such an injury. [Tr. 558].

9. Prior to opening her own practice, the Respondent worked at a pain clinic called the Pain Center of Broward. [Tr. 554]. She also supervised a physician assistant, signing all the controlled substance prescriptions herself. The role of the physician assistant is to examine patients and to either continue or follow the physician's treatment plan, or if the physician assistant sees any noted change in the patient's condition based on the examination, to inform the physician of the change. The physician would write the prescription appropriately. [Tr. 570].

10. The Respondent testified that, although over 400,000 dosage units of oxycodone were attributable to her per the ARCOS reports, she in fact did not see all of the patients represented by this dosage number. The physician assistant saw multiple patients per day as well. [Tr. 526, 554]. Another physician was hired, and the Respondent does not know whether controlled substances purchased using the Respondent's DEA registration were actually dispensed by this physician as well. [Tr. 555]. The Respondent left that practice when her "180 program" was not being followed. [Tr. 526]. She left her DEA Form 222s at the Pain Center of Broward when she left the practice. [Tr. 556].

11. When asked if "any time an order was placed using your DEA number, was that an order done appropriately and legitimately or for other purposes," the Respondent replied that she was not sure. Specifically, she stated that the DEA Form 222s she signed "were done appropriately and legitimately, but if my former employer went and ordered stuff and signed my name to it, I had no knowledge or concept that it was being done." [Tr. 574–75]. It's possible that some of the over 400,000 dosage units were ordered without the Respondent's knowledge. [Tr. 575].

12. The Respondent primarily wrote prescriptions using a computer. However, she did have prescription pads, and it was possible that such a pad was outside her control on the day the search and seizure warrant was executed, although she did not intentionally leave such a pad outside her control. [Tr. 557]. The Respondent was a dispensing physician. [Tr. 210, 237, 341, 346–47, 362].

13. A pain management clinic would dispense a large number of oxycodone

because the clinic's patients are being seen regularly for chronic pain problems and obtaining controlled substances every month. [Tr. 527]. The Respondent also believed this over 400,000 dosage units figure reported in ARCOS actually corresponds to the number of chronic pain patients she and Dr. Jacobs treated. [Tr. 528].

14. Dr. Danton developed a treatment program she described as the "180 program." [Tr. 402]. The essential point of the 180 program was to help patients control their pain without developing tolerance to the pain medication and to keep the patient safe from a drug overdose. [Tr. 402]. To her knowledge, Dr. Danton is the only physician who limits oxycodone prescriptions to 180 dosage units of 15 mg oxycodone. [Tr. 403]. However, depending on the patient's pain level and the diagnosis, the Respondent would sometimes prescribe 30 mg oxycodone. [Tr. 403].

15. Dr. Danton described a bulging disc as a disc between vertebrae in the back that acts as a gel-filled shock absorber. After a high velocity injury, the gel begins to thin out and form a bulge of the disc material outward, pressing on the nerve roots, causing pain. [Tr. 406–09].

16. Dr. Danton described a herniated disc as a disc where the gel actually cracked out of the disc and escapes into a very small space in the spine, causing more pressure on the nerve roots, thus causing more pain. [Tr. 410]. The added pressure can also cause inflammation, which causes swelling around the nerve roots, making the pain worse as well. [Tr. 410–11].

17. Scoliosis is an abnormal curvature of the spine and can cause pain. [Tr. 417–19]. The nerve roots in the back become impinged and inflammation around the nerve roots results which causes the pain. [Tr. 419]. Scoliosis comes in degrees, and the severity of the scoliosis impacts upon the severity of the pain. [Tr. 419–20]. If a patient elects not to have surgery, then the appropriate treatment is pain management with analgesics. [Tr. 420].

18. To diagnose and treat scoliosis, Dr. Danton would ask about the patient's history, to determine whether the scoliosis was developmental and to find out what kind of past treatment the patient has experienced. [Tr. 421]. A prior physician would have prescribed an MRI, and the patient would bring that MRI report for Dr. Danton to review. [Tr. 421–23]. Unlike an X-ray, an MRI shows soft tissue changes such as impingement of nerves caused by a herniation of a disc. [Tr. 423–24].

19. To determine if a patient has either a bulging disc or a herniated disc,

the Respondent listens to the level of the patient's complaint, looks at the medical history forms, and evaluates how the patient moves into the treatment room, watching how the patient walks and sits as part of the physical examination. [Tr. 412–13]. Next, Dr. Danton would look at a purely objective evaluation, such as an MRI. [Tr. 414]. She is also evaluating the consistencies of the MRI with the patient's complaint, and looking to see if the patient is honest and truthful. [Tr. 414]. Patients who are not honest and truthful tend to exaggerate their pain levels, so that their complaints do not match up with their MRI results. [Tr. 415–16]. The Respondent also testified that when patients subjectively rated their pain level, she interpreted that rating to mean their pain level with medication. Therefore, if a patient rated his pain at 2, then she interpreted the patient's pain to be at a level 7 without pain medication. [Tr. 469–70].

20. According to Dr. Danton, a physical examination does not necessarily "entail touching the body." [Tr. 425]. For example, in the chronic injury "you can't see—whether you're putting your hands on the patient or not, you can't see that evidence of chronic inflammation and disease by visual inspection or palpation." [Tr. 428]. But the physician can inspect the painful area, can get an idea of the pain by watching the patient move the body, which is also a part of the physical examination. [Tr. 428–29]. Although different now, in early 2010, the physician also needed to get a urinalysis test within the first four to six months of treatment with oxycodone. [Tr. 429].

21. The Respondent prescribed 2 mg tablets of Xanax or alprazolam. She described this as a moderate dose, and she instructed her patients to take .5 mg during the day, .5 mg in the evening, and 1 mg at night. If the patient stops taking Xanax in these quantities, there would be no adverse side effects. [Tr. 535].

22. The Respondent was aware that a complete medical history and physical examination must be conducted and noted in a patient's medical file. [Tr. 557].

23. The Respondent has been convicted of four counts of mail fraud, but the record contains no information that this conviction entailed the handling of controlled substances. [Tr. 560].

C. Respondent's Practice

24. The Respondent is neither a DATA-waived physician nor registered as a Narcotics Treatment Program. [Tr. at 533]. The Respondent denied

providing her patients with detoxification services. [Tr. 533]. However, she did see her role as "to educate patients how to take medicine safely and how to safely get off, away from the narcotics. That was my goal." [Tr. 581]. She also stated her goal was to have patients functioning at "100%." [Tr. 500]. The Respondent is also not registered as a pain management clinic with the Florida Department of Health. [Tr. 185].

25. Mr. Gordon Berman worked with the Respondent as the primary administrator of her practice. He owned the building. [Tr. 163].¹⁸ He ordered the medications, maintained the records, and ensured the practice's procedures were consistent with the legal requirements. [Tr. 505]. He was also responsible for dispensing the medications and for conducting the inventories. [Tr. 163]. As of November of 2010, no inventories had been conducted. [Tr. 178, 183]. Mr. Berman is not a licensed pharmacist, and has had no previous experience dispensing drugs or controlled substances. [Tr. 190].

26. Mr. Berman told DEA personnel that he was aware of the State law which had come into effect on October 1, 2010, providing that only a 72 hour supply of medication could be dispensed. [Tr. 185]. However, in November of 2010, he had dispensed 180 oxycodone 30 mg., a one-month supply. [Govt. Exh. 2 at 4–6; Tr. 185]. He stated that he knew of the limitations, but that he had just dispensed the entire amount. [Tr. 185].

27. Mr. Berman had told DEA personnel that every patient basically received the same thing; 180 oxycodone 30 mg., Xanax, Ibuprofen, and Soma. [Tr. 185–86; *see also* Govt. Exh. 2–5]. The medication was purchased in pre-measured volumes of 90 oxycodone, and the physician would issue an order sheet showing the amount to be dispensed. Mr. Berman would receive the order sheet, he would hand an employee the requisite amount of medication, and the employee would take the medication to the physician for review, the physician would sign the order sheet and either hand the medication to the patient or instruct the employee to do so. [Tr. 190]. The Respondent did not have access to the computers, and when questioned about them, she referred DI McRae to Mr. Berman. [Tr. 170].

¹⁸ Mr. Berman did not testify at the evidentiary hearing. Therefore, to the extent that the conversation he had with DI McRae constitutes hearsay, I will analyze the weight to give such evidence accordingly.

28. The Respondent accepted cash as a form of payment. It is unclear whether this was the sole form of payment accepted. The Respondent stated to DI McRae that to accept insurance would require a billing department, and that would cost a lot. [Tr. 165–66]. Further, a Diversion Investigator overheard the receptionist tell a patient that the clinic only accepted cash. [Tr. 226–7]. However, Mr. Berman stated that the practice also accepted Medicaid and Medicare. [Tr. 184]. The office visit cost \$200.00,¹⁹ and the medication cost \$600.00 per patient. [Tr. 170].

29. Mr. Berman had a nine-year-old daughter who would sometimes come to the office after school. When Ms. Hall saw Mr. Berman and his daughter walking in the hallway, Mr. Berman said that his daughter was a good little helper, and that he had her counting pills.²⁰ [Tr. 215; Govt. Exh. 14B at 27]. However, Ms. Hall did not observe the child handling pills and the Respondent credibly testified that she never saw the daughter touch any pills. [Tr. 259, 589].

30. The Respondent's job was patient care, making sure the patients were appropriately treated. The Respondent also managed the front office. [Tr. 505]. The Respondent told DI McRae that she saw between 25 and 50 patients a day. [Tr. 166]. She had told DI McRae that she did not dispense controlled substances on the first visit of a patient. [Tr. 167].²¹

31. Another physician in the practice, Dr. Jacobs, is also practicing the Respondent's "180 program." [Tr. 592].

32. The Respondent acknowledged that the medications were ordered under her DEA registration number and that she took full responsibility for them. [Tr. 506, 516]. Yet she acknowledged that she gave people authority to take certain actions using her registration. [Tr. 507]. She stated that to the best of her knowledge "we were doing everything that we thought" was within the law. [Tr. 507]. There was no power of attorney on file affording Mr. Berman with the authority to sign the order forms for the controlled substances. [Tr. 163].

33. When the Respondent became aware of discrepancies, she made corrections. She learned that her pain patients could be manipulative, and she "became a little harder and a little more

¹⁹ However, I note that the undercover officers paid \$150.00 for their office visits. [Tr. 288, 337].

²⁰ As Mr. Berman did not testify at this proceeding, I am unable to determine the credibility or sincerity of this comment. Therefore, I give this exchange no weight.

²¹ This is inconsistent with her conduct regarding the undercover visits. Therefore, I give this testimony no weight.

careful in how" she responded to her pain patients. [Tr. 508–09].

34. The Respondent's office was burglarized four times, and her computer systems with all the backups were stolen. [Tr. 515]. The computers the Respondent had on November 23, "were basically only a month old, and the information on them was basically information from a month or two." [Tr. 515]. Three of the four break-ins occurred when the Respondent had no oxycodone on the premises. But in the instances that drugs were stolen, the Respondent did not handle informing the DEA. The thefts were reported to the Sheriff's Department but not to the DEA. [Tr. 122–23, 125, 549]. The Sheriff's Department made no mention of the Respondent's obligation to inform the DEA. [Tr. 514]. The Respondent credibly testified that she believed the Sheriff's Department would handle that responsibility. [Tr. 550]. No DEA theft and loss reports were found. [Tr. 125].

35. For security measures, the Respondent had an alarm system, video camera system, and security doors as required between the treatment area and the medication room. [Tr. 518]. The oxycodone was stored in the medication room. [Tr. 518]. Mr. Berman told the Respondent that the facility had been inspected and found to be in compliance. However, the Respondent did not know who had inspected the facility, and the record does not contain any inspection reports indicating such compliance. [Tr. 550].

36. Ms. Danielle Demers, an employee of the Respondent's, would bring her Rottweiler to the office wearing a police service dog vest. The dog was a deterrent and stayed in the administrative area of the office. [Tr. 516–17]. Ms. Demers wore a police belt with a tazer and a baton, but she did not carry a firearm in the clinic. [Tr. 517–18]. Ms. Demers was subsequently terminated from her employment. She worked for the Respondent approximately five months. [Tr. 520].

37. Ms. Demers had access to all the records in the practice, to include inventory records, DEA Form 222s, and invoices. She also had access to the computer systems. [Tr. 520–21]. She knew what security measures were in place. [Tr. 521].

38. The Respondent used two large safes behind the secured medicine room doors. One safe was for the Respondent's medications, and the other safe held the medications of Dr. Jacob.²² [Tr. 521–522, 592]. A pharmacy

²² It is unclear when these safes were added to the premises. The Government did not see any safes when personnel conducted a search of the offices

tech, Ms. Teresa Way, had access to the medication, Mr. Berman had access, and Ms. Demers had access. Ms. Terry Friedman, an employee who worked with the Respondent since she started this practice, may also have had access to the medications. [Tr. 522].

39. The physician would prepare a charge sheet, noting the prescriptions authorized for the patient. The charge sheet would go to the pharmacy technician for filling. [Tr. 590]. [See Resp. Exh. 1–3]. For her patients, the Respondent would then sign the prescriptions. [Tr. 590].

40. The Respondent has interpreted approximately four or five thousand MRI written reports in the course of her medical practice. [Tr. 561]. In reviewing the MRI reports pertaining to the undercover individuals, the Respondent saw nothing that led her to believe the reports were fraudulent, modified or illegitimate. [Tr. 561].

41. The Respondent tried to "correspond the patient's history and their presentation with the MRI report, and in those three (undercover) cases they seem to match." [Tr. 561]. Later in her practice, the Respondent instructed her front office personnel to call and verify the MRI report. If the office staff was unable to do so, they were instructed to require the patient to take another MRI locally. [Tr. 586]. "We didn't do that in the first three months because at that point in time I was, and I accept responsibility for it, I was naïve. And I believed if somebody brought in an MRI that had their name on it and the doctor's signature, that it was a real MRI. I found information to the contrary. I changed." [Tr. 586].

D. DEA's Investigation

42. On November 23, 2010, the DEA served a Federal search warrant at the Respondent's office, as well as the Immediate Suspension Order. [Tr. 19]. The clinic had the name posted as J.A. Danton. [Tr. 47]. During the search, Group Supervisor Susan Langston discovered a closet containing video equipment and several bottles of oxycodone 30 mg, 100 count each. [Tr. 21, 112–13; *see also* Tr. 111; Govt. Exh. 9]. This closet was located in Mr. Berman's office on the second floor of the clinic. [Tr. 22]. GS Langston testified that the closet was not a securely locked, substantially constructed cabinet suitable for the storage of controlled substances, however could not testify as to why it did not meet this requirement. [Tr. 22]. The pill bottles

in November of 2010. [Tr. 63, 115] In addition, it is similarly unclear whether a safe is depicted in Government Exhibit 9.

were all sealed. [Tr. 112]. GS Langston did not know whether the closet was locked, and did not inspect the closet. [Tr. 48, 55]. In addition, DI Milan, who also saw the closet, stated she did not know whether the closet was locked or could be locked, she was not the first to see the closet, it was already open when she saw it, and that she did not otherwise investigate whether the Respondent had security on the premises. [Tr. 109–111].

43. Also during the search, GS Langston located an empty prescription bottle with a label showing that the bottle had contained 360 Oxycodone 30 mg tablets. The bottle was found in the Respondent's office on the first floor of the facility, and the label indicated that the medication was prescribed by Dr. Jack Danton to patient Jacqueline Danton, a name the Respondent also used. [Tr. 23, 377].

44. During an interview with a local reporter, the Respondent asserted that she was not providing her patients with large quantities of oxycodone, she was weaning them off the drug. [Govt. Exh. 19].

45. GS Langston identified "red flags" from the Respondent's practice. First,

she received telephone calls from pharmacists inquiring as to whether prescriptions written by the Respondent were legitimate. [Tr. 36–37, 45]. GS Langston also thought it significant that the Respondent saw a large number of people from out of state. [Tr. 45–46; *see also* Tr. 93–95; Govt. Exh. 4].

1. The Audit

46. DI Marjorie Milan also participated in the serving of the Immediate Suspension Order. [Tr. 68]. Her assignment was to collect any controlled substances that were on the premises. [Tr. 69]. DI Milan found bottles of oxycodone 30 mg. She found a total of 4,000 pills. [Tr. 69–70].

47. DI Milan ran an ARCos²³ report, searching for the oxycodone purchases made using the Respondent's DEA registration number from January 1, 2009, through March 31, 2011. [Tr. 70–71]. The first transaction date was December 28, 2009, and the last transaction date was November 15, 2010. [Tr. 72; Govt. Exh. 18]. To order oxycodone, the purchaser would need to use a DEA Form 222. [Tr. 72]. The Respondent was ranked in the top 100

practitioners purchasing oxycodone throughout the United States. [Tr. 151].

48. DI Milan used the ARCos information to identify the suppliers of oxycodone to the Respondent. [Tr. 73]. She then contacted the suppliers and received copies of the DEA Form 222 and invoices for the purchases made to the Respondent from Paragon Enterprises, Inc., Dispensing Solutions, Sunrise Wholesale, Inc., and Anda, Inc. [Tr. 74–80; Govt. Exh. 6]. The DEA Form 222 indicates the drug shipped, the date shipped, and the quantities shipped. [Tr. 77]. The DEA Form 222s were those issued to the Respondent. [Tr. 108].

49. DI Milan also reviewed the purchase orders that were seized from the Respondent during the execution of the search warrant. [Tr. 81–82; Govt. Exh. 7].

50. DI Milan conducted an audit of oxycodone products from the beginning of business on December 1, 2009, through the close of business on November 23, 2010. [Tr. 87–88; Govt. Exh. 1]. DI Milan did not find an initial inventory in the records that were seized, so the beginning inventory amounts were recorded as "0". The computation chart is as follows:

CONTROLLED SUBSTANCES COMPUTATION CHART

Drug name, strength, form	Initial inventory	Received ^{*1}	Total accounted	Closing Inventory	Distributed ^{*2}	Total accounted	Deviation	Percent deviation
	A	B	A + B = C	D	E	D + E = F	F – C = G	G/C = %
Oxycodone 30 mg Tablets	0	260,700	260,700	4,224	156,753	160,977	–99,723	–38.25
Oxycodone 15 mg Tablets	0	18,340	18,340	0	8,880	8,880	–9,460	–51.58
Oxycodone 10 mg Tablets	0	500	500	0	200	200	–300	–60.00
Oxycodone 5 mg Tablets	0	1,600	1,600	0	100	100	–1,500	–93.75
Oxycodone 10 mg/325 mg Tablets	0	3,700	3,700	0	2,580	2,580	–1,120	–30.27
Oxycodone 5 mg/325mg Tablets	0	3,600	3,600	0	300	300	–3,300	–91.67

¹ Suppliers: Paragon Enterprises, Dispensing Solutions, Sunrise Wholesale, ANDA Inc. (December 2009–November 2010).

² Daily Dispensed Prescriptions.

* Includes Returns from Customers.

** Includes Returns to Suppliers, Thefts and Surrenders.

[Tr. 87–90; Govt. Exh. 1]. The Respondent was unable to account for a shortage of 99,723 dosage units of oxycodone 30 mg, and a shortage of 9,460 dosage units of oxycodone 15 mg tablets. [Govt. Exh. 1]. Only the Respondent's DEA registration was used to compute the audit figures. It is unclear in the record whether Dr. Jacobs' DEA number was ever used to

order controlled substances. [Tr. 190–91].

51. In looking at the prescriptions, DI Milan discovered that a number of the prescriptions did not have the required dispensing labels on the back of the prescriptions. [Tr. 97]. Further, a number of the paper copies of DEA Form 222s failed to have the received column and the date column properly

completed. [Tr. 121–23; Govt. Exh. 7]. A power of attorney from the Respondent authorizing another to act on her behalf in filling out the DEA Form 222 was not found during the search of the Respondent's premises. [Tr. 122].

2. Patient Interviews²⁴

52. DI McRae interviewed a patient from Kentucky. He had heard about the

²³ARCos stands for automation of reports and consolidated ordering system. [Tr. 70; *see also* 99–101].

²⁴To the extent that this evidence constitutes hearsay, I will afford it less weight in forming my opinion below.

Respondent from someone in Kentucky, and he had been to the clinic several times. [Tr. 174]. He said he had been buying Loracet or Lortab off the street, and "he realized that it was cheaper for him to come drive to South Florida to get oxycodone at the pain clinic." [Tr. 174].

53. GS Langston interviewed some of the Respondent's patients. She interviewed a lady, D. L., who admitted that day to having taken 5 oxycodone 30 mg tablets. GS Langston observed that this woman was "highly under the influence" of the medication. [Tr. 25, 44]. The woman was one of three people from Kentucky, and she had seen the Respondent the day before. The lady had received 180 oxycodone 30 mg. tablets. GS Langston saw the pill bottle, and credibly testified that there were at least twenty pills missing. [Tr. 26]. The lady's husband was to see the Respondent that day, and the third person, the lady could not remember her name, was waiting to join them for the return trip to Kentucky. [Tr. 25].

54. Also during the March 2010 visit, Ms. Hall talked with two individuals from Kentucky. One of the individuals explained that the doctor would not give him 180 30 mg. pills, but he would give the man 360 15 milligram pills. [Tr. 218].

55. Task Force Officer ("TFO") Thomas interviewed patients of the Respondent in August of 2010. [Tr. 128]. The patients were from Ohio, and they stated that they could not get the quantity of oxycodone in Ohio that they could get in Florida. They had heard of the Respondent's practice through word of mouth in Ohio. [Tr. 128-29]. They first started seeing the Respondent in June of 2010, when they received 180 dosage units of 30 mg oxycodone, some Soma, Xanax, and Ibuprofen. [Tr. 129]. The doctor and the patients talked about pain levels and locations of pain, but no physical examination or range of motion testing was conducted. [Tr. 129]. The encounter lasted probably less than ten minutes. [Tr. 129]. The same procedures were used on the second and third visits. During the first two visits, the patients were dispensed medication from the clinic, but on the third visit, the patients received prescriptions because the clinic had just moved to a new location, and the dispensary had not been set up yet. [Tr. 129-30].

E. Undercover Transactions

56. At the time Dr. Danton treated the undercover personnel, it was not a requirement to conduct a urinalysis or a blood test prior to treating a pain patient. [Tr. 429-30]. Effective November 8, 2010, the law changed and

required the physician to order a urinalysis before being allowed to prescribe controlled substances. [Tr. 430-31, 577-79; Fla. Admin. Code r. 64B15-14.0051(2)(f) (2010)]. The urinalysis will determine whether or not the patient is taking the prescribed controlled substances, and whether or not the patient ingested illicit drugs. [Tr. 596]. If a patient is found to have taken illicit drugs, the physician is to discharge that patient from the doctor's practice. [Tr. 431]. On the day of the search warrant, November 23, 2010, DI McRae noted that she was told that the Respondent had run out of urinalysis kits, and no such tests had been taken for the past three days. [Tr. 168].

57. Sometimes the Respondent saw patients in a group. She would explain her "180 program," and if the patients did not object, she would review each person's MRI and fill out the drug order form for that patient in the group setting. Sometimes she would have as many as a dozen people sitting through this process. [Tr. 168-69]. If a patient wanted to be seen one-on-one, the Respondent would accommodate that request. [Tr. 186, 169].

58. The Respondent did not refer any of her patients out to other doctors. [Tr. 169].

59. During follow-up visits, the Respondent did not ask any of the undercover individuals how many oxycodone, Xanax, or Soma they had left from their previous prescriptions. [Tr. 537]. However, if the patient did not have to take any medication for breakthrough pain, the Respondent would lower the quantity of medication prescribed to that patient. [Tr. 579]. However, none of the medical charts in this record demonstrate such action. [Resp. Exh. 1-3].

60. If the Respondent's medical files had no notations regarding her observations of a patient's movements, that indicated to the Respondent that she had not observed anything inappropriate or inconsistent with the patient's complaint and diagnosis. [Tr. 543]. If the Respondent did witness suspicious conduct, *i.e.* "complained of pain * * * bent over and jumped up in the air" that would have been noted. [Tr. 543].

61. Per the Respondent, the majority of the patients received a prescription for oxycodone. [Tr. 548]. Previous doctors may have prescribed hydrocodone, felt uncomfortable prescribing oxycodone, and would refer the patients to a pain management clinic for further treatment. [Tr. 548-49].

62. The patient files in this record contain no medical reports or documents from prior physicians as

related to the three undercover personnel. When asked if she had ordered such information, the Respondent stated that she could not recall. [Tr. 576-77; Resp. Exh. 1-3].

1. Tanya Hall²⁵ (Special Agent Hayes)

63. On February 15, 2010, Ms. Hall visited with the Respondent, and the visit was audio-recorded. [Tr. 203; Govt. Exh. 14A²⁶]. The audio recording was subsequently transcribed. [Tr. 205; Govt. Exh. 14B]. Ms. Hall signed in and placed her reason for the visit as "for meds." [Tr. 206]. Ms. Hall was asked for a copy of her identification and for her MRI report. [Tr. 207]. Ms. Hall was informed that she had to watch a video before seeing the doctor. The video was of Dr. Danton describing her prescribing of medications and her "180 program." [Tr. 207].

64. Ms. Hall was given paperwork to fill out, including a pain assessment form. Pain was to be rated from one to ten, and Ms. Hall rated her pain at a level 3. [Tr. 207; Resp. Exh. 1]. Ms. Hall signed a document stating "there will be no exception to [the rule that the maximum amount of 2.0 mg Xanax should be no more than 60 tablets in a 28 day cycle], so please do not ask the doctor to make an exception for you." [Resp. Exh. 1 at 8]. In addition, Ms. Hall signed documents consenting to be drug screened and acknowledging that a positive test result "disclosing the presence of an illegal substances no prescribed my [sic] any physician associated with Boca Pain and Wellness, will result in immediate termination as a patient * * *." [Respt. Exh. 1 at 9, 10]. Further, Ms. Hall signed a document stating that "lost, stolen or misplaced narcotics will not be replaced" and another form documenting that it is a third degree felony under Florida law to possess or attempt to possess a controlled substance by fraud." [Respt. Exh. 1 at 11, 12].

65. Ms. Hall was directed to sit in a chair across the desk from the Respondent. [Tr. 208]. She was not required to provide a urine sample during the visit. [Tr. 208]. Ms. Hall stated that she did not receive a physical examination. [Tr. 208]. Ms. Hall told the Respondent that she had used Vicodin before. However, she did not tell the Respondent that she was currently using Vicodin or any other controlled substances. [Tr. 209]. The

²⁵I will refer to the undercover operatives by their undercover names to coincide with the documentary evidence in this case. [Tr. 208; Resp. Exh. 1].

²⁶The actual visit begins at the 1 hour and 45 minute point of the audio recording. [Tr. 204].

Respondent told Ms. Hall that she had probably built up a tolerance to the Vicodin, and then offered to provide Ms. Hall with Percocet. Ms. Hall declined the Percocet, saying that the acetaminophen in the Percocet upset her stomach. [Tr. 274]. Although the Respondent clearly doubted the upset stomach, and Ms. Hall subsequently stated it didn't upset her stomach, the Respondent offered the oxycodone 15 mg rather than Percocet, pursuant to the patient's request. [Tr. 274; Govt. Exh. 14B at 11–13]. The Respondent later reiterated that she would have preferred to have given the patient Percocet. [Govt. Exh. 14B at 19].

66. Ms. Hall complained of neck and shoulder pain. [Resp. Exh. 1 at 6]. Her MRI report stated that the bottom of her spine had evidence of thinning of the disc. [Tr. 444; Resp. Exh. 1]. Under impressions, the MRI reported mild spondylosis, which means that there was some slippage of one vertebra onto another, which can cause pressure on the spine. [Tr. 444; Resp. Exh. 1]. Such spondylosis may cause "a chronic impingement of that nerve" which would cause chronic pain. [Tr. 445]. Such an MRI impression was "more significant than the patient's description of their pain levels because * * * patients tend to under-exaggerate or over-exaggerate their symptoms." [Tr. 445].

67. Ms. Hall told the Respondent that she had had an automobile accident in 1999 and in 2003, and she had slipped and fallen on the ice in December of 2009, [Govt. Exh. 14B at 9], which could have aggravated her spinal condition. [Tr. 446–47; 245; 612]. She also had an accident where a box of chicken tenders had fallen on her while she worked in a cafeteria. [Tr. 245; Govt. Exh. 14B]. The Respondent noted that the injury in 1999 could have resulted in osteophytes and slippage, and the slip and fall on the ice could have aggravated the situation, as well as the accident resulting in the box of chicken tenders falling on the patient. [Tr. 246, 447].

68. The MRI also noted disc osteophytes, which are bony protrusions on the discs that develop over time. [Tr. 446, 452]. The osteophytes were consistent with Ms. Hall's history of having been in accidents in 1999 and 2003. [Tr. at 446–447]. Osteophytes indicate that the injuries were chronic. [Tr. 451]. Ms. Hall's MRI showed more damage to her spine than the MRIs for Mr. Castillo and Mr. Swanson. [Tr. 542–43]. The Respondent further found that "[i]t had more extensive damage, but the extent of the extensive damage I didn't consider warranted increasing the

medication beyond the starting dose of 15 milligrams." [Tr. 563].

69. The Respondent did not find that the MRI was suspicious, in that it did not look fraudulent, modified or illegitimate. [Tr. 561]. Specifically, the Respondent was able to correspond the patient's history and her presentation with her MRI report. [Tr. 561]. The MRI report stated that it was conducted at Ingalls Memorial Hospital in Harvey, Illinois. [Respt. Exh. 4 at 5]. The Respondent asked Ms. Hall whether she always "drove this way" from Harvey Illinois, to which the patient responded, "Well, I'm kind of back and forth; I'm thinking about moving here 'cause I recently lost my jobs and I got some friends" down here. [Govt. Exh. 14B at 7].

70. The Respondent did not notice anything specifically when observing Ms. Hall walking and standing. [Tr. 449]. Such an observation would be consistent with the MRI results, however, since the initial accident which would have caused the initial injury happened seven to eleven years earlier. [Tr. 448–49]. The Respondent credibly testified that Ms. Hall may have "compensated * * * for that injury." [Tr. 449].

71. The Respondent diagnosed Ms. Hall as having a bulging disc with mild spondylosis, a disc slippage, and disc osteophytes. [Tr. 464]. Ms. Hall had been given Vicodin and Tylenol No. 3 by another provider. [Tr. 464; Resp. Exh. 1 at 1]. The Respondent relied upon the history of two motor vehicle accidents, her slip and fall, and the accident with the boxes. [Tr. 464]. The Respondent also relied upon Ms. Hall's description of her pain as a level three. [Tr. 465].

72. Ms. Hall presented no red flags, per the Respondent, for she was not "over-exaggerating" her pain. [Tr. 466].

73. The Respondent's treatment plan was to enter Ms. Hall into her "180 program." ²⁷ [Resp. Exh. 1 at 1]. Ms. Hall's patient chart indicates under "plan" the controlled substances prescribed by the Respondent on each visit, yet does not document anything else. [Respt. Exh. 1 at 1, 15, 20].

74. The first visit lasted about 15 to 20 minutes. [Tr. 209]. Ms. Hall refused the offered Percocet, and the Respondent then offered oxycodone. [Tr. 210]. The Respondent prescribed her 180 oxycodone 15 mg. [Tr. 211, Resp. Exh. 1 at 1]. When asked if she had anxieties, Ms. Hall responded "sometimes." [Tr. 210]. Ms. Hall credibly testified that the Respondent said she would prescribe the Xanax but

"didn't care if I took it." [Tr. 210; Govt. Exh. 14B at 16]. The Respondent prescribed her 30 Xanax 2 mg. [Resp. Exh. 1 at 1].

75. When asked if she had trouble sleeping, Ms. Hall again responded "sometimes." [Tr. 210]. The Respondent then agreed to prescribe the Soma, and she told Ms. Hall to take the Xanax and Soma together to help her sleep. [Tr. 210].

76. Ms. Hall partially filled the prescriptions in house with the Respondent. Ms. Hall received 30 Xanax 2 mg, 30 Soma 350 mg, and 90 Ibuprofen, 800 mg. [Tr. 212–13; Govt. Exh. 10; Resp. Exh. 1 at 5]. The Respondent told her that the clinic had run out of oxycodone 15 mg., and Ms. Hall returned on the 17th of February to get the oxycodone prescription filled. [Tr. 211–12; Govt. Exh. 10]. Although the receipt indicates that Ms. Hall received 90 oxycodone, she actually received 180 oxycodone. [Tr. 212].

77. Ms. Hall next visited the Respondent on March 22, 2010. The receptionist took Ms. Hall's blood pressure and weighed her. Ms. Hall asked Ms. Demers, the receptionist, if she and Mr. Castillo could get in to see the Respondent faster, and Mr. Castillo offered Ms. Demers \$100.00. Ms. Demers took the money and said she'd see what she could do. [Tr. 216–17, 254].

78. During this visit, Ms. Hall observed a male patient yelling at a female patient, saying "What are you doing with 15 milligrams?" He pointed to the examining room and told the female patient to "Get back in there and get 30." ²⁸ [Tr. 217]. The male patient then asked for the price of prescriptions for four individuals, and he paid cash for their prescriptions. [Tr. 217].

79. During this visit, Ms. Hall was with Mr. Castillo.²⁹ The Respondent saw Ms. Hall and Mr. Castillo together. They were directed to sit in front of the Respondent's desk. The Respondent gave Ms. Hall a pain assessment sheet, and Ms. Hall circled her left shoulder. Ms. Hall did not participate in a urinalysis test on this visit. [Tr. 219–22]. Ms. Hall told the Respondent that she did kickboxing. [Tr. 276]. The Respondent gave Ms. Hall the same prescription as on February 15, 2010. [Tr. 220]. Again, Ms. Hall testified that she was not physically examined. [Tr. 220]. Ms. Hall asked if the Respondent would up the dosage of the Xanax, and

²⁷ This record contains no evidence, however, that the Respondent actually prescribed or otherwise provided 30 mg. oxycodone for this patient. In addition, the Respondent testified that this patient was later discharged. [Tr. 545].

²⁸ Mr. Castillo is Mr. Cesar Flores. [Tr. 219].

²⁹ This program will be discussed in greater detail infra.

the Respondent refused to do that. [Tr. 221]. The Respondent did not note in Ms. Hall's medical file the number of pills she had left over from the first prescription. [Tr. 537; Respt. Exh. 1].

80. Ms. Hall received a receipt for 360 oxycodone 15 mg, and the receipt reflected Dr. Jacobs' name, even though Ms. Hall had seen Dr. Danton that day. [Tr. 222]. Further, Dr. Danton only prescribed 180, 15 mg. oxycodone, but Ms. Hall actually received 360 oxycodone 15 mg., 30 Xanax, 30 Soma and 90 Ibuprofen. [Tr. 222–23; Govt. Exh. 10].

81. Next, Ms. Hall visited the clinic on April 20, 2010. Again, she was accompanied by Mr. Castillo. A video was taken of the visit, and a transcription was also made of the visit. [Tr. 223–25; Govt. Exh. 17A, B]. Again, Ms. Hall and Mr. Castillo saw the Respondent together. [Tr. 228]. The Respondent asked Ms. Hall if the medication was working for her, and Ms. Hall responded yes. [Tr. 229]. Ms. Hall received prescriptions from Dr. Danton, and the receptionist explained that the clinic had run out of medication. [Tr. 236; Govt. Exh. 10]. The Respondent provided prescriptions for the same quantity, strength, and type of medications as the last visit. [Tr. 237; Govt. Exh. 10]. At no time did the Respondent ever try to lower the dose of oxycodone. [Tr. 275]. The Respondent again did not ask how many pills Ms. Hall had left over from the prior prescription. [Tr. 537].

2. Pedro Castillo (Special Agent Flores)

82. Mr. Castillo visited with the Respondent in February, March, and April of 2010. [Tr. 285; Govt. Exh. 15A³⁰ and B]. His first visit was on February 15, 2010. [Tr. 287]. He paid \$150.00 for the office visit. [Tr. 288]. Mr. Castillo told the Respondent that he had stiffness in his neck. He stated that he did not receive a physical examination, and he did not participate in a urinalysis test. [Tr. 289]. The Respondent described to the patient her "180 Program" including the exercise component. [Govt. Exh. 15B at 23–42]. The Respondent described the medications that she offered, acknowledged that the Respondent had a mild disc bulge and stated that 30 mgs would be "overkilling" and that the Respondent does not need more than 15 mgs of oxycodone. [Govt. Exh. 15B at 34–35]. The Respondent then asked the patient "which medicine do you want?" The patient responded "I want oxys."

³⁰ The actual visit with the Respondent begins at 2 hours and 23 minutes on the audio recording. [Govt. Exh. 15A].

The Respondent confirmed that the patient wanted 15 mgs and not 10 mgs. [Govt. Exh. 15 at 42]. Then, the Respondent discussed with the patient how he acquired his injuries. The patient told the Respondent that he had been in a motorcycle accident. [Govt. Exh. 15B at 44]. On the pain assessment form, Mr. Castillo noted that his pain was at level 2. [Tr. 290; Resp. Exh. 2 at 15]. Mr. Castillo told the Respondent that he was getting oxycodone from a friend. [Tr. 290]. Mr. Castillo did not complain of problems sleeping or of anxiety. [Tr. 290].

83. Mr. Castillo's MRI³¹ noted mild scoliosis, with the "vertebral body heights and disc spaces * * * maintained despite the scoliosis, according to his interpretation." [Tr. 453]. Yet, when a specific analysis was written, the radiologist noted that there was mild bulging of the disc in the cervical spine. [Tr. 454]. The radiologist recommended that the physician interpret these results in conjunction with the clinical symptoms. [Tr. 454]. Dr. Danton explained that she would have "to take the clinical symptoms and * * * the exam, [and the] neurological examination" of the patient to determine if there was any significance to the bulging disc. [Tr. 454]. She further explained that if "someone has a bulge but has no symptomatology, now, it's there * * * [but] it's not clinically significant." [Tr. 455]. The Respondent did not find that the MRI was suspicious, in that it did not look fraudulent, modified or illegitimate. [Tr. 561]. Specifically, she was able to correspond the patient's history and his presentation with his MRI report. [Tr. 561].

84. Dr. Danton's diagnosis for Mr. Castillo was a bulging disc in the cervical spine area. [Tr. 455, 463; Resp. Exh. 2 at 1]. The proper treatment for this chronic condition would be analgesics, for "nobody would do surgery on a * * * bulge." [Tr. 456]. Mr. Castillo's patient chart indicates under "plan" the controlled substances prescribed by the Respondent on each visit, yet does not document anything else. [Resp. Exh. 2 at 1, 17, 20].

85. Mr. Castillo presented no red flags in Dr. Danton's observations, which meant that he was probably legitimate, for he also was not over-emphasizing his injury. [Tr. 456]. Dr. Danton also noted that Spanish men, like her assessment of Mr. Castillo, "in general tend to minimize * * * any

descriptions that they have." Further, they tend to under-describe their levels of pain. Someone who is faking pain will generally go overboard in their descriptions of their pain. [Tr. 457–58].

86. The appropriate treatment was to use a moderate analgesic. [Tr. 463]. The Respondent prescribed 180 oxycodone 15 mg., 30 alprazolam (Xanax) 2 mg, 30 tablets of carisoprodol (Soma) 350 mg., 90 Ibuprofen, 800 mg. [Tr. 291–93; Govt. Exh. 12]. Mr. Castillo signed forms identical to those signed by Ms. Hall regarding Xanax, urinalysis, lost medication, and fraud. [Resp. Exh. 2 at 8–11, 13].

87. Mr. Castillo next visited the Respondent on March 22, 2010.³² [Tr. 293, 315]. He stated that he did not receive a physical examination. [Tr. 297]. Again, Mr. Castillo did not do a urinalysis. [Tr. 297]. Mr. Castillo received a receipt for the medication he received, indicating that he received 360 oxycodone 15 mg from Dr. Jacobs, whom he had not seen that day. [Tr. 298–99; Govt. Exh. 12]. The Respondent actually ordered 180 oxycodone 15 mg. [Tr. 299; Resp. Exh. 2 at 17–18]. Yet Mr. Castillo actually received 360 oxycodone 15 mg. [Tr. 299]. Mr. Berman dispensed the controlled substances. [Tr. 328]. The Respondent did not note in Mr. Castillo's medical file how many pills he had left over from the first prescription. [Tr. 537].

88. Mr. Castillo's last visit was in April of 2010. [Tr. 285]. He stated he was not physically examined by the Respondent or asked to provide a urine sample. [Tr. 300, 328–29]. He was asked to assess his pain level, and he wrote a 3 for his level of pain, on a scale of one to ten. [Tr. 301].

89. Mr. Castillo received the same prescriptions, and he did not fill them at the clinic that day. [Tr. 301; Govt. Exh. 12]. Again, the Respondent did not ask how many pills remained from the last prescription. [Tr. 537].

3. Ron Swanson³³ (TFO Kevin Doyle)

90. Mr. Swanson visited the Respondent's clinic in February, March, and April of 2010. [Tr. 334]. The February visit was recorded, and the recording was transcribed. [Govt. Exh. 13A and B]. Mr. Swanson paid \$150.00 for the first visit. [Tr. 337]. Mr. Swanson signed forms identical to those signed by Ms. Hall and Mr. Castillo regarding Xanax, urinalysis, lost medication, and fraud. [Respt. Exh. 3 at 17–21]. Mr. Swanson explained that he had been in

³¹ The MRI did not have the name of the radiology facility written on it, but a physician's name was written on it [Resp. Exh. 4 at 1; Tr. 532]. The Respondent did not verify this MRI. [Tr. 532].

³² This visit was not audio or video recorded. [Tr. 315].

³³ Mr. Swanson is actually Task Force Officer Kevin Doyle. [Tr. 333].

a car accident, a friend had given him oxycodone, and that he had come to the Respondent to obtain oxycodone. [Tr. 337]. He did not indicate that he was currently taking oxycodone, however. [Tr. 338]. Mr. Swanson was not required to provide a urine sample. [Tr. 337–38]. The Respondent did ask Mr. Swanson to raise and lower his arms, and that was the extent of the physical examination. [Tr. 338]. Mr. Swanson had rated his pain at a level 2. [Tr. 338].

91. At the first visit, when asked, Mr. Swanson stated that he had problems sleeping and that he had anxiety. [Tr. 339]. Mr. Swanson was given a receipt for 90 oxycodone 15 mg., but that was not what had been prescribed that day. He actually was prescribed and received 180 oxycodone 15 mg. [Tr. 340, 374; Govt. Exh. 11]. He also received 30 alprazolam 2 mg. (Xanax), 30 carisoprodol 350 mg. (Soma) and 90 ibuprofen 800 mg. [Tr. 340–41; Govt. Exh. 11]. All of the prescriptions were dispensed on-site from a back room, out of sight of the patients. [Tr. 341, 362].

92. When looking at Ron Swanson's MRI,³⁴ Dr. Danton noted that if Mr. Swanson and Mr. Castillo had come into her office at the same time, she would have noticed that their MRIs were almost exactly the same. [Tr. 459]. However, at that time, the Respondent did not find that the MRI was suspicious, in that it did not look fraudulent, modified or illegitimate. [Tr. 561].

93. Dr. Danton noted that the MRI identified a bulging disc. She explained that "there was no pressure on the spinal cord as such from this bulge, but if there's a bulge, it means there's a narrowing of the disc, and if there's a narrowing of the disc, then there is going to be some impingement or some kind of abnormal pressure on that disc space which is going to effect those lateral nerves that are coming out and are going to effect things like the shoulder or parts of the neck." [Tr. 459].

94. The MRI also described a mild scoliosis, which means that "there was an abnormal curvature to the spine, and that abnormal curvature can put abnormal pressures on nerve roots, as well." [Tr. 459–60]. Dr. Danton acknowledged that the MRI showed very small changes, "but if you multiply those small changes, it can build into something." [Tr. 460].

95. Mr. Swanson complained of pain in his right shoulder. [Tr. 354, 460; Resp. Exh. 3]. Although he had minimal

³⁴The MRI did not have the name of the radiology facility written on it, but a physician's name was written on it [Resp. Exh. 4; Tr. 532]. The Respondent did not verify this MRI. [Tr. 532].

complaints, Dr. Danton noted that if he had taken medication, that would have lowered his pain levels. [Tr. 460]. Mr. Swanson had also told the Respondent that on December 23, 2009, he had had a motor vehicle accident. [Tr. 461]. Dr. Danton had also observed that there were no red flags concerning her observations of his behavior. [Tr. 461]. Specifically, she was able to correspond the patient's history, complaints, and his presentation with his MRI report. [Tr. 460, 561].

96. Mr. Swanson had reported to Dr. Danton that he had taken roxicodone, a form of oxycodone, for his pain. [Tr. 468; Resp. Exh. 3 at 2]. However, the documentation is unclear as to whether he had taken the medication recently. [Tr. 338; Resp. Exh. 3 at 2].

97. Putting all the information the Respondent had available, she determined that Mr. Swanson had chronic pain that was "not that bad" when he took pain medicine. [Tr. 461, 469]. The Respondent credibly testified that a mild to moderate pain killer would be appropriate. [Tr. 462]. Given his condition, absent medication, Dr. Danton would expect his pain level to be a five to a seven. [Tr. 469]. At a level seven, a person would be dysfunctional. [Tr. 470].

98. The Respondent confirmed that she did not need to do any further physical examination to reach her diagnosis in Mr. Swanson's case. [Tr. 470]. Under plan, the Respondent documented in the patient's chart her prescription of controlled substances. [Resp. Exh. 3 at 1].

99. During the March 22, 2010 visit, Mr. Swanson informed the Respondent that he owed a friend some oxycodone, and he asked for 20 extra oxycodone in his prescription. [Tr. 345, 512]. The Respondent gave Mr. Swanson prescriptions for 200 oxycodone 15 mg., and the same amount of the previous prescriptions for³⁵ Xanax, Soma, and ibuprofen. [Tr. 345–46; Govt. Exh. 11]. He had the prescriptions filled at the Respondent's clinic. [Tr. 346–47]. Mr. Berman brought the bag containing the medicine bottles to the receptionist, who handed it to Mr. Swanson. [Tr. 374]. Mr. Swanson did not see who

³⁵I do not find credible the Respondent's testimony that she gave the Respondent 20 extra oxycodone to save in case he did not make it back to her office in 30 days, since he was traveling from the Chicago area. Further, I do not find it credible that she gave him the extra 20 mills so he would not fear "the concept of withdrawal." [Tr. 510–11]. Rather, given her subsequent testimony concerning the wrongfulness of her conduct, I find it more credible that she prescribed the extra 20 mills at the patient's request for repaying his friend.

actually placed the tablets in the medicine bottles. [Tr. 374].

100. The Respondent told Mr. Swanson not to borrow pills, and she gave him an extra twenty pills. Later, she realized this conduct was wrong, and she "decided that I would never do it again." [Tr. 511]. She credibly testified that she knows not to give more than a thirty-day supply, that her giving of the twenty extra pills was "an error of judgment," but that she corrected it, and she has "never done it since." [Tr. 513]. In fact, when Mr. Swanson asked for additional pills on his next visit, the Respondent refused to give them to him. [Tr. 350, 513].

101. Mr. Swanson's second visit in March was not recorded due to malfunctioning equipment. [Tr. 342]. The waiting area was quite crowded, Mr. Swanson provided the receptionist with \$50.00 to be seen earlier, and the receptionist kept the money. [Tr. 344].

102. During the second visit, Mr. Swanson testified that the Respondent did not perform a physical examination on him. [Tr. 373]. The Respondent did not ask Mr. Swanson for a urine sample or how many pills he had left over from the first prescription. [Tr. 373, 537].

103. During the third visit, Mr. Swanson again paid the receptionist \$50.00 to be seen ahead of other waiting patients. [Tr. 347]. On this April visit, Mr. Swanson was seen by Dr. Jacobs. [Tr. 347–48]. This visit was also recorded and a transcription was made of the recording. [Tr. 348; Govt. Exh. 16A and B]. Dr. Jacobs asked Mr. Swanson whether he had any oxycodone remaining from his earlier prescription which he answered "no." Dr. Jacobs noted that in the patient's chart as well as that the patient was to continue the 180 program. [Govt. Exh. 16B at 15; Respt. Exh. 3 at 9]. Mr. Swanson received prescriptions for the controlled substances, and this time his prescription was for 180 oxycodone 30 mg. The remaining prescriptions for Xanax, Soma, and ibuprofen remained the same. [Tr. 352; Govt. Exh. 11].

104. Subsequently in the hallway, he saw the Respondent and again asked for 20 additional pills. The Respondent refused that request. [Tr. 350, 513; Govt. Exh. 16B at 21–23]. The Respondent did however instruct Mr. Swanson that if he had to repay anyone, to break down the 15's. [Tr. at 350].

F. The "180 Treatment Program"

105. The Respondent began her "180 Treatment Program" in January of 2010, and the program was discontinued by the DEA's action in November of 2010. [Tr. 495].

106. Dr. Danton explained to DI McRae that the “180 program” involved prescribing patients 180 oxycodone 30 mg, 30 Xanax 2 mgs, 90 Ibuprofen 800 mg, and either Soma or Flexoril. [Tr. 157–58]. The Ibuprofen helped with swelling and inflammation, and the patient was to take this medication three times a day with meals. [Tr. 158]. The Xanax tablet was to be broken into four parts, and the patient was to take one part in the morning, one part in the afternoon, and two parts at bedtime. The morning and afternoon portions were to control anxiety, and the bedtime portion was to assist with sleep. [Tr. 158].

107. After six hours, a pain medicine becomes ineffective. However, depending on what a patient is doing, the patient may need additional medication before the six hours is over to handle breakthrough pain. When the pain medication metabolizes down, pain starts to increase, and the patient’s ability to function can be compromised. [Tr. 479–80]. “And so the object of the program is to make people able to function at a hundred percent level all the time.” [Tr. 480].

108. Yet for breakthrough pain, Dr. Danton credibly testifies that the patient may not be given a dose equal to the original dose. A half of the original dose would control the breakthrough pain. [Tr. 480]. Dr. Danton would teach her patients to take this one-half tablet when their functioning was compromised. [Tr. 480]. Thus, a patient would be able to take 4 full-strength tablets and 4 half-strength tablets in a twenty-four hour time period, or six doses. That equals to 180 tablets in a month. [Tr. 481]. If the patient did not need the one-half tablet, the patient was to save these extra pills in a bottle the Respondent called an “emergency parachute.” [Tr. 159]. These pills were to be used in the event the patient could not get back to see Dr. Danton in exactly thirty days. [Tr. 482]. If the patient saved up 180 tablets in the “emergency parachute,” the patient would have a visit which was free, and the patient would not be prescribed any oxycodone on that visit. [Tr. 159]. Yet the patient medical files in this record do not demonstrate that the Respondent annotated the whereabouts of the extra pills or the exact quantity of pills consumed or retained by the patients. [Resp. Exh. 1–3].

109. The Respondent testified that it would still be medically appropriate for the patient to take the full 180 oxycodone pills during the course of a month. One hundred and eighty 30 mg dose tablets is the maximum safe dose for oxycodone. Such action by the patient, however, would not be

consistent with the Respondent’s treatment plan, and she would discharge the patient on that basis. [Tr. 488–89].

110. Dr. Danton credibly testified that prescribing 180, 15 mg oxycodone, was medically appropriate for the three undercover transactions. [Tr. 483–84].

111. Sometimes a patient will report anxiety and the lack of ability to sleep as well as pain. The Respondent instructed her patients to take .25 milligrams or .5 milligrams of Xanax for this problem. That dosage would “take care of anxiety, but it will still enable (the patient) to function at the hundred percent full level.” [Tr. 500; Govt. Exh. 15B at 47]. The Respondent instructed the patients not to take the Xanax if they did not need it. [Tr. 500; Govt. Exh. 14B and 15B]. The Respondent also prescribed a muscle relaxer to take at night to help a patient with sleep, while still allowing the patient to wake up after a full-night’s sleep and to be able to function at a hundred percent. [Tr. 500].

112. The Respondent asked the three undercover patients if they were having anxiety problems or muscle spasm problems, the patients answered “Yes,” and the Respondent wrote prescriptions for Xanax and Soma. The patients were told to take these medications only when needed. [Tr. 501; Govt. Exh. 14B and 15B].

113. Lastly, the Respondent prescribed ibuprofen, an anti-inflammatory medication that will treat the inflammation around the nerve roots. [Tr. 502]. For para-spinal inflammation, the Respondent credibly testified that a patient would need 2400 milligrams of ibuprofen per the twenty-four hour day. [Tr. 502]. Dr. Danton credibly concluded that “someone who’s got a chronic permanent injury is going to have to take an anti-inflammatory for most of their life.” [Tr. 503].

114. Also part of the “180 program” was an exercise component involving a swimming pool. The exercise was to assist the patient in pain management. [Tr. 160, 490–492]. Such exercising would produce endorphins, which create potent analgesic-like effects in the brain. [Tr. 492].

115. After four months, if the patient was saving a large quantity of medication, the Respondent would begin the weaning portion of the program.³⁶ [Tr. 485–86]. The weaning process consisted of weaning safely and

slowly to 90 oxycodone tablets within a month. [Tr. 486–87, 497]. This process avoided placing the patient into withdrawal. [Tr. 498]. “No one had a problem with withdrawal on the 180 program * * *.” [Tr. 498]. Yet when asked if anyone had successfully completed the program, “she said that there were a couple of patients who had called her and said that they no longer needed the medication.” [Tr. 161]. Yet the patient files of these individuals did not contain any annotations concerning these calls. [Tr. 161].

116. The Respondent credibly testified that she “was willing to make a small salary so that people could afford to come and learn.” [Tr. 494]. Dr. Danton also stated that “if I could dispense the pills at a reasonable price, it would be an incentive for them (the patients) to come and stay with the program. If they kept with the program and they got used to the program, eventually they would be able to get off of narcotics.” [Tr. 495].

117. To determine if a patient was following the “180 Treatment Program,” the Respondent would ask the patient three distinct questions and the answers would tell the Respondent if the patient was actually following the program. [Tr. 496]. The patient was asked:

1. How many whole pills were they allowed to take in a 24-hour time period?

2. How many one-half pills were they allowed to take in a 24-hour period?

3. When could they take the one-half pills?

If the patient failed two quizzes, the patient would be discharged from the practice. [Tr. 496]. However, the record fails to demonstrate that on the subsequent visits of the undercover officers, these questions were asked. [Resp. Exh. 1–3].

IV. Statement of Law and Discussion

A. Position of the Parties

1. Government’s Position

The Government asserts that the Respondent failed to properly dispense and maintain readily retrievable records as required by Florida statutes for a dispensing physician. [Government’s Proposed Findings of Fact and Conclusions of Law “(Govt. Brief) at 11]. The Respondent also violated Florida law when she dispensed more than a 72-hour supply of controlled substances after October 1, 2010. [Govt. Brief at 11].

The Government notes that the Respondent was unable to account for more than 100,000 dosage units of oxycodone, failed to have an initial inventory, failed to properly execute DEA Form 222s, and had multiple DEA

³⁶ The Respondent credibly testified that the three undercover personnel did not stay in the program long enough to begin the weaning portion of the program.

Form 222s missing, in violation of DEA regulations. [Govt. Brief at 11]. The Government concludes on this point that the “Respondent’s inability to maintain effective controls against diversion and lack of compliance with State and Federal Laws regarding controlled substances is clear and weighs heavily in favor of revocation of her DEA Certificate of Registration.” [Govt. Brief at 11].

The Government next argues that prescriptions were issued not for a legitimate medical purpose nor in the usual course of professional practice, as required by law. Specifically, the Government asserts that undercover patients Hayes and Castillo asserted that they did not receive a physical examination. [Govt. Brief at 12]. The Government asserts that Florida law requires that a physician perform a physical examination and document that exam in the patients’ files, institute a treatment plan and document that plan in the patients’ files. [Govt. Brief at 8 (citing Fla. Admin. Code R. 64B8–9.013), 12]. The Government notes that what the Respondent did with Hayes and Castillo was not a physical examination, and even if it was, the exam results were not documented in the patient files. The only treatment plan was to continue prescribing controlled substances. [Govt. Brief at 12]. In conclusion on this point, the Government argued that the Respondent “did little that would indicate that she established a bona fide physician-patient relationship or that the controlled substances she distributed were for a legitimate medical purpose in the usual course of professional practice.” [Govt. Brief at 13].

Next, the Government argues that the Respondent knowingly engaged in diversion when she provided Mr. Swanson with extra oxycodone to repay a friend 20 tablets. [Govt. Brief at 13]. The Government further argues that instructing Mr. Swanson on how to break down pills to repay his friends constituted intentional diversion. *[Id.]*

Lastly, the Government argues that the Respondent did not truly accept responsibility for her misconduct, for her acceptance of responsibility “was often followed by an excuse, or a shift of blame.” [Govt. Brief at 14]. Although the medical files clearly established that Ms. Hall and Mr. Castillo were dispensed 360 oxycodone tablets when only 180 tablets had been authorized by the Respondent, the Respondent failed to address that error to the patients on their subsequent visit. Rather, at the hearing, the Respondent justified the error by stating that even 360 tablets would be within the standard of care for

a chronic pain patient. [Govt. Brief at 15].

Next, the Respondent failed to note that two patients, seen on the same day, actually gave the Respondent the same MRI. The Respondent ignored such red flags, and she presented “no evidence demonstrating that the Respondent could be trusted with a DEA registration and would not engage in similar misconduct should Respondent retain a DEA registration.” [Govt. Brief at 15]. In conclusion, the Government asserts that revocation of the Respondent’s DEA registration is needed to protect the public health and safety. [Govt. Brief at 16].

2. Respondent’s Position ³⁷

In reviewing the public interest factors from 21 U.S.C. 823(f), the Respondent first asserts that there were no recommendations from a state licensing board concerning these matters. [Tr. 605]. The Respondent’s experience in dispensing controlled substances was limited to her practice within the last two years. She asserts a large learning curve, and she states that the undercover officers came into the clinic during the first three months of operation. [Tr. 605]. The Respondent asserted that, as time progressed, she ascertained the rules and changed and modified her conduct to be consistent with those rules. [Tr. 605–06]. As she found errors or omissions in conduct, she took corrective action. [Tr. 606]. Also, as new requirements came into effect, such as urinalysis testing, she took action to adhere to that requirement. [Tr. 606].

Further, with experience, the Respondent realized that some of her patients were drug seeking individuals, and she instituted a policy of checking out all the MRI’s that were submitted, and if she had doubts, she would send her patients out to obtain a local MRI. [Tr. 606].

Next, the Respondent notes that she has had no convictions that relate to the manufacture, distribution or dispensing of controlled substances. [Tr. 606].

As for complying with state, federal or local laws in handling controlled substances, the Respondent admits she has made errors, especially in the accounting and inventory of controlled substances. [Tr. 607]. Yet, as she learned that her pharmacy technician was failing to handle controlled substances correctly, she terminated that technician. [Tr. 607]. She also

terminated Ms. Demers when the Respondent suspected, but could not prove, that Ms. Demers was involved in the theft of oxycodone. [Tr. 607]. Also, whenever there was a break-in, it was reported to the police. [Tr. 608]. Computers were stolen, which resulted in missing records. The Respondent believes that those missing records “would correlate to the missing oxycodone that the Government is saying is not accounted for.” [Tr. 608].

Next, the Respondent suggests that, in considering any other conduct that may threaten the public health and safety, I see the two main issues as the inventory and record-keeping problems, and the legitimacy of the Respondent’s prescriptions. [Tr. 610]. As for the legitimacy of the prescriptions, the Respondent notes that the Government failed to produce an expert witness to address that topic in the context of this case. [Tr. 610]. The Government has put on no evidence to explain to this Court what the appropriate standard in diagnosing a patient and when prescribing a treatment regimen. [Tr. 618]. Although the Government relies upon a Florida statute that requires a physical examination, there is no expert testimony that defines what an appropriate physical examination entails. “The only evidence before this Court is the evidence provided by Dr. Danton as testified in her expert capacity in the field of osteopathic medicine with experience in pain management, and her testimony is not refuted.” [Tr. 610]. The Respondent asserts that, rather than rely on my own personal knowledge of what a physical exam consists of, I should rely upon the Respondent’s testimony in light of her training and experience. [Tr. 611].

The Respondent argues that I should look closely at the evidence as it was before the Respondent when she made her diagnosis and treatment plan for the three undercover officers. [Tr. 611–12]. I should hear the patients’ complaints in light of their previous automobile or motorcycle accidents and the corresponding MRI reports. [Tr. 612]. Even though the patients complained of mild pain, the record contains no evidence that only severe or moderate pain should be treated. [Tr. 612]. “The field of palliative medicine addresses all chronic pain.” [Tr. 612–13].

The Respondent asks me to consider the Respondent’s “180 program,” and her true intent in implementing this program. [Tr. 613]. The Respondent argues that this program “is a legitimate and well thought out” program, with the results of treating her patients’ pain and to eventually wean them off narcotics. [Tr. 614].

³⁷ The Respondent failed to timely file her post-hearing brief. However, Counsel for the Respondent made a closing argument at the hearing. From this argument, I find the Respondent’s position regarding this case. [Tr. 603–619].

As for the regulatory violations, the Respondent acknowledged that she takes full responsibility for all discrepancies. [Tr. 614]. Given the learning curve and the complicated nature of the regulatory scheme, the Respondent asserts that revocation of her registration is too extreme of a sanction. [Tr. 615]. Rather, the Respondent proposes that her registration should be suspended and she be placed on probation, that she be required to take additional medical education on how to operate a pain management practice consistent with all the “legal requirements of the [C]ontrolled [S]ubstances [A]ct.” [Tr. 615].

The Respondent concludes that the public interest is best served by ‘‘having doctors who care like Dr. Danton,’’ who make changes when they learn that their practice is not in compliance, and who train their patients in how to properly consume controlled substances and to wean themselves off narcotics. [Tr. 616]. The Respondent argues that I should formulate an appropriate remedy, given the Respondent’s acknowledged failings in this matter. [Tr. 618–19].

B. Statement of Law

Pursuant to 21 U.S.C. 824(a)(4) (2006), the Deputy Administrator³⁸ may revoke a DEA Certificate of Registration if she determines that the continuance of such registration would be “inconsistent with the public interest” as determined pursuant to 21 U.S.C. 823(f). Section 823(f) 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, or conducting research with respect to controlled substances.
- (3) The applicant’s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

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

These factors may be considered in the disjunctive: The Deputy Administrator may properly rely on any one or a combination of these factors, and may give each factor the weight she deems appropriate, in determining whether a registration should be revoked or an application for registration denied. [David H. Gillis,

M.D., 58 FR 37,507, 37,508 (DEA 1993); *see also* D & S Sales, 71 FR 37,607, 37,610 (DEA 2006); Joy’s Ideas, 70 FR 33,195, 33,197 (DEA 2005); Henry J. Schwarz, Jr., M.D., 54 FR 16,422, 16,424 (DEA 1989)].

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, 143 (1975))]. When an administrative tribunal elects to disregard the uncontradicted opinion of an expert, it runs the risk of improperly declaring itself as an interpreter of medical knowledge. [Ross v. Gardner, 365 F.2d 554 (6th Cir. 1966)]. Whether expert testimony is needed in any case necessarily depends on the nature of the allegations and the other evidence in the case. Where, for example, the Government produces evidence of undercover visits showing that a physician knowingly engaged in outright drug deals, expert testimony adds little to the proof necessary to establish a violation of Federal law. [Michael J. Aruta, M.D., 76 FR 19,420, n. 3 (DEA 2011)].

Also, in an action to revoke a registrant’s certificate, the DEA has the burden of proving that the requirements for revocation are satisfied. [21 CFR 1301.44(e) (2010)]. Once the Government has met its burden of proof, the burden of proof shifts to the Respondent to show why her continued registration would be consistent with the public’s interest. [Medicine Shoppe, 73 FR 364, 381 (DEA 2008); *see also* Thomas Johnston, 45 FR 72,311, 72,312 (DEA 1980)]. Specifically, the Respondent must present “sufficient mitigating evidence to assure the Administrator that [she] can be entrusted with the responsibility carried by such a registration.” [Medicine Shoppe, 73 FR at 387].

DEA precedent has also held that “past performance is the best predictor of future performance.” [ALRA Labs, Inc. v. DEA, 54 F.3d 450, 452 (7th Cir. 1995)]. Further, DEA has repeatedly held that “where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [her] actions and demonstrate that [she] will not engage in future misconduct.” [Medicine Shoppe, 73 FR at 387; *see also* Samuel S. Jackson, 72 FR 23,848, 23,853 (DEA 2007)].

C. Analysis

1. Factor I. Recommendation of the Appropriate State Licensing Board

In this case, it is undisputed that the Respondent holds a valid and current State license to practice medicine. [Finding of Fact (“FOF”) 3]. The record contains no evidence of a recommendation regarding the Respondent’s medical privileges by any State licensing board or professional disciplinary authority.

However, that a State has not acted against a registrant’s medical license is not dispositive as to whether continuation of her registration is consistent with the public interest. [Patrick W. Stodola, M.D., 74 FR 20,727, 20,730 (DEA 2009); Jayam Krishna-Iyer, 74 FR 459, 461 (DEA 2009)]. It is well-established Agency precedent that a “state license is a necessary, but not a sufficient condition for registration.” [Robert A. Leslie, M.D., 68 FR 15,227, 15,230 (DEA 2003); John H. Kennedy, M.D., 71 FR 35,705, 35,708 (DEA 2006)]. Therefore, I find this factor neither weighs in favor of nor against a finding that the Respondent’s continued registration is consistent with the public interest.

2. Factors II and IV. Respondent’s Experience in Dispensing Controlled Substances and Compliance with Applicable Laws.

a. Legitimate Medical Purpose

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 “an 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 related to controlled substances.” [Id. *See also* 21 U.S.C. 802(10) (defining the term “dispense” as meaning “to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance”)].

Under the Controlled Substances Act (“CSA”), it is fundamental that a practitioner must establish and maintain a bonafide doctor-patient relationship in order to act “in the usual course of * * * professional practice” and to

³⁸The Deputy Administrator has the authority to make such determinations pursuant to 28 CFR § 0.100(b) and 0.104 (2010).

issue a prescription for a “legitimate medical purpose.” [Laurence T. McKinney, 73 FR 43,260, 43,265 n.22 (DEA 2008); see also *Moore*, 423 U.S. 122, 142–43 (1975) (noting that evidence established that physician “exceeded the bounds of ‘professional practice,’” when “he gave inadequate physical examinations or none at all,” “ignored the results of the tests he did make,” and “took no precautions against * * * misuse and diversion”)]. The CSA, however, generally looks to state law to determine whether a doctor and patient have established a bona fide doctor-patient relationship. [See *Kamir Garces-Mejias*, 72 FR 54,931, 54,935 (DEA 2007); United Prescription Services, Inc., 72 FR 50,397, 50,407–08 (DEA 2007)].

Here the Government asks this tribunal to conclude that the Respondent’s prescriptions to the three undercover officers, who presented fraudulent MRI’s to the Respondent, were for an illegitimate medical purpose. The Government, however, provided no expert testimony to support this finding. Rather, the Government introduced the transcripts and recordings of the undercover transactions, and a summary of those transactions via officer testimony. In that regard, the Government has provided no meaningful lodestar by which this court can measure the legitimacy of the Respondent’s medical practice under Florida statutory and regulatory requirements.

The Respondent, however, did present expert testimony. The Respondent was qualified as an expert in the field of osteopathic medicine with extensive experience in pain management, assessment and treatment.³⁹ [FOF 6]. She asserted that her issuance of prescriptions for controlled substances to the undercover agents, based on the objective evidence of their medical conditions as presented in the MRI reports and as corroborated by their subjective reporting, was well-within the standard of care for appropriate pain management. [FOF 68–71, 84–85, 93–96, 98–99].

The importance of expert testimony to support a finding of illegitimacy has been underscored by this agency in its post-*Gonzales* decisions. Specifically, while the agency has considered over fifty cases concerning the legitimacy of a practitioner’s prescriptions since *Gonzales*, the agency has seldom found a violation of 21 CFR § 306.04(a) absent

expert testimony. [See e.g. *Cynthia M. Cadet*, M.D., 76 FR 19,450 (DEA 2011) (expert); *Roni Dreszner*, M.D., 76 FR 19,434 (DEA 2011) (expert); *Aruta*, 76 FR at 19,420 (expert); *George C. Mathew*, M.D., 75 FR 66,138 (DEA 2010) (expert)].

In those instances where the agency has found such illegitimacy without an expert’s testimony, that finding was based on patent violations, where diversion was either unrefuted or unquestionable. For example, in *Robert F. Hunt*, 75 FR 49,995 (2010), the Deputy Administrator concluded that expert testimony was not required to make a finding of illegitimacy where the Respondent told the patient he was documenting a diagnosis of osteoporosis “just to cover [his] ass.” [Id. at 50,003]. Similarly, in *Peter W.S. Grigg*, 75 FR 49,992, 49,993 (DEA 2010), the agency found a violation where the Respondent met with an undercover police officer in a parking lot and sold the officer 60 tablets of oxycodone in exchange for \$100. [See also *Armando B. Figueroa*, M.D., 73 FR 40,380, 40,382 (DEA 2008) (where Respondent’s issuance of prescriptions to patients without seeing them and as many as twenty prescriptions at a time was tantamount to drug pushing); *Kennedy*, 71 FR 35,705 (where Respondent wrote prescriptions for a patient and instructed the patient to sell the drugs and return a portion of the profits to the Respondent)]. Such patent violations of § 1306.04(a) can best be described as “outright drug deals” as that phrase was used by the Deputy Administrator in her most recent decision on this point. [*Aruta*, 76 FR at 19,420, n. 3; See also *Dispensing Controlled Substances for the Treatment of Pain*, 71 FR 52,715, 52,717 (DEA 2006) (stating “that the types of cases in which physicians have been found to have dispensed controlled substances improperly under Federal law generally involve facts where the physician’s conduct is not merely of questionable legality, but instead is a glaring example of illegal activity.”)]

Similarly, where the Respondent has acted in a manner that clearly contravened state law governing what constitutes a legitimate medical practice, expert testimony may not be required. Violations in those instances are most obvious in Internet prescribing practices were no physical examination or face-to-face communication was conducted. [*Garces-Mejias*, 72 FR at 54,931 (where Respondent’s involvement in Internet scheme constituted drug dealing); *Dale E. Taylor*, 72 FR 30,855 (DEA 2007) (similar conclusion)]. However, when

the Government seeks to use a state law violation as a means of establishing a violation of § 1306.04(a), the question remains to what extent that state law violation is so tethered to a finding of actual illegitimacy that, without expert testimony, it can be used as a predicate to a violation of the federal law.

DEA precedent indicates that when a state law violation would compel a finding of illegitimacy under state law, the agency should reach a similar conclusion. For example, in *Kamir Garces-Mejias*, 72 FR 54,931 (DEA 2007), the Respondent’s failure to conduct an in person physical exam violated certain state laws including (1) a California law making it a crime to issue prescriptions via the Internet to its residents; (2) an Ohio law stating that a failure to conduct a physical examination would constitute the issuance of a prescription for an “illegitimate medical purpose;” and (3) a Virginia statute establishing no bona fide physician-patient relationship exists without a medical examination. [Id. at 54,935]. There, a clear nexus existed between the violation and a finding of illegitimacy under state law, and therefore, easily facilitated a similar conclusion under federal law.

However, absent such a nexus, a finding of per se illegitimacy under federal law under the circumstances of this case cannot be made. Indeed, to hold otherwise may result in the unfortunate corollary of a Respondent’s violation of *any* state law predicated on a violation of § 1306.04(a), a holding that would be inconsistent with the Supreme Court’s decision on this point and DEA precedent. [See *Gonzales*, 546 U.S. at 270 (stating the CSA “bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood”) (emphasis added); See also *McKinney*, 73 FR at 43,266 (finding that the Respondent’s failure to listen to the undercover officer’s heart and lungs and take her blood pressure may have violated Pennsylvania regulations, however, it does not support a finding that the Respondent engaged in illicit drug dealing, and noting the Government’s failure to create a connection between that regulatory violation and a violation of the Pennsylvania Controlled Substances Act)].

Therefore, it is clear that to establish a violation of § 1306.04, absent expert testimony, the Government must provide either (1) evidence that the Respondent committed a violation that is sufficiently tied to a state law finding of illegitimacy so as to make a similar finding under the federal law or (2)

³⁹I acknowledge that the Respondent’s testimony has the potential for being self-serving, however, and I take that factor into account when determining the weight to give her expert conclusion.

other evidence of “outright drug dealing.”

i. Violations of § 1306.04 Based on State Law Violations

The Government argues that *all* of the Respondent’s prescriptions to the undercover officers were issued for an illegitimate medical purpose, as they violated certain professional standards.⁴⁰ However, I find that the Government has either (1) not sufficiently proven a violation of those standards or (2) proven a violation yet not established a nexus between that violation and a finding of illegitimacy under state law to justify a *per se* violation under federal law.

First, it should be noted that although the Government, in its brief, cites to the regulatory provisions that govern a medical doctor’s practice in Florida, those regulations are inapplicable to the Respondent. [Govt. Brief at 8 (citing Fla. Admin. Code r. 64B8–9.013(g))]. The Respondent is a Doctor of Osteopathy, and the State of Florida treats the practice of medicine as an osteopathic physician distinct from the practice of medicine as a medical doctor. Indeed, each profession has separate boards, licensure requirements, and statutory and regulatory schemes. [See Fla. Stat. Ann § 458.001, *et seq.* (statutory scheme governing medical doctors); Fla. Stat. Ann. § 459.001, *et seq.* (statutory scheme governing osteopathic physicians); Fla. Admin. Code r. 64B8–9 (regulations governing practice of medicine set forth by Board of Medicine); Fla. Admin. Code r. 64B15 (regulations promulgated by the Board of Osteopathy (“Board”))]. In that regard, the standards that govern medical doctors cannot be used to ascertain the scope of professional practice for osteopathic physicians. Conveniently, however, the regulation governing appropriate pain management for osteopathic physicians is identical to that governing appropriate pain management for medical doctors. [Compare Fla. Admin. Code r. 64B15–14.005 (2009) with Fla. Admin. Code r. 64B8–9.013 (2009)].

⁴⁰ The Government also argues that the Respondent “did little that would indicate a bona fide patient relationship.” However, I find this argument unpersuasive as the Government has the burden of proof with regard to § 1306.04(a) violations. Further, I am not persuaded by the argument that the agency should find a violation in this case based on its similarity to another DEA matter where the Government met its burden of proof by providing expert testimony. [See Govt. Brief at 13 citing *Jacobo Dreszer, M.D.*, 76 FR 19386 (DEA 2011) (where the ALJ relied on expert testimony, that was unchallenged, to find the recordkeeping and documentation in patient files were substandard and that Respondent’s practice didn’t resemble a legitimate one)].

The Government alleges that the Respondent failed to conduct a physical examination on the patient. [Govt. Brief at 12]. However, I find that the Government has not met its burden of proof regarding this violation. First, the meaning of physical examination, as that term was used in Florida state law during the time of the Respondent’s actions here,⁴¹ is nebulous, and the Respondent’s expert interpretation, in light of the Government’s failure to provide a contrary one, must be given considerable weight. The Respondent testified that “[a] physical examination does not necessarily entail touching the body.” [FOF 20]. For example, in the case of chronic injury “you can’t see—whether you’re putting your hands on the patient or not, you can’t see that evidence of chronic inflammation and disease by visual inspection or palpation.” [Id.]. Further, she stated that her clinical observations of how the patients moved, coupled with the MRI reports and medical histories, provided an adequate and consistent basis for her diagnoses and treatment. [FOF 110, 41, 60, 69, 70, 83, 95, 98]. Therefore, without expert testimony to the contrary, I cannot find that the Respondent failed to conduct a physical examination of the three undercover patients as that term is used under Florida law. [See *McKinney*, 73 FR at 43,266 (“[n]otwithstanding that Respondent failed to perform several steps required by Pennsylvania law, the physical exam he conducted cannot be characterized as deficient or cursory in the absence of expert testimony establishing as much.”)].⁴² Accordingly, I find the Government has failed to sufficiently prove a violation of state law on this basis.

Next, the Government asserts that the Respondent failed to document a physical examination in the patient’s chart, as required by the Florida law.⁴³ [Govt. Brief at 12]. Similarly, however, I find that the Government has failed to prove that the Respondent’s documentation regarding the patient’s symptoms/physical examination in the chart fell below the state’s standard. To the extent that the review of an MRI report, coupled with a physical

⁴¹ See Fla. Admin. Code r. 64B15–14.005(2) (2009) (failing to define “physical examination”).

⁴² This interpretation is also supported by the Board’s new regulation, effective November 8, 2010, which states that “the exact components of a physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies the treatment.” Fla. Admin. Code r. 64B15–14.0051(2)(a) (2010).

⁴³ See Fla. Admin. Code. r.B15–14.005(e) and (f) (requiring a physical examination and documentation of such but not further defining it).

observation of the patient constitutes a “physical examination,” the Respondent included the MRI reports in her charts and would record those physical observations that she deemed suspicious. [FOF 60; Resp. Exhs. 1,2,3]. In addition, while I do find her decision not to write down her observations suspicious,⁴⁴ absent expert testimony to the contrary, I cannot find, however, that the Respondent’s lack of documentation failed to satisfy the Florida physical examination recordation requirement. [See *Jacobo Dreszer, M.D.*, 76 FR 19,386, 19,400 (DEA 2011) (basing a finding of a violation of Florida’s patient recordkeeping violations on unrefuted expert testimony)].

Last, the Government asserts that the Respondent failed to record a treatment plan in the patients chart and hence issued prescriptions for an illegitimate medical purpose. [Govt. Brief at 12–13]. While I find that the Respondent did violate this professional standard, I do not find that based on this violation, the Respondent issued prescriptions for an illegitimate medical purpose. Florida law states “the written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the osteopathic physician should adjust drug therapy to the individual medical needs of each patient.” [Fla. Admin. Code. r. 64B15–14.005(3)(b) (2007)].

Here, the Respondent’s recordkeeping clearly violates Florida law. While the Respondent’s charts indicate a continued plan of treating the patient with narcotics, there is no statement of objectives that she would use to ascertain treatment success, nor is there any indication of other potential treatment or diagnostic evaluation. [See FOF 73, 84, 98]. Further, the Respondent did not tailor her treatment to meet the individual needs of her patients. All of the undercover patients, for example, were prescribed the exact same combination of controlled and non-controlled substances at each visit despite the varying MRI reported results. [FOF 27, 61, 86, 91; see also FOF 53, 55]. Also, the Respondent’s treatment records failed to document any justification for this continued prescribing. Although the Respondent testified that she questioned her patients

⁴⁴ Although Mr. Swanson was asked to raise and lower his arms, even in Mr. Swanson’s case, the Respondent did not record her observations concerning this “physical examination.” [FOF 60, 65, 83, 88, 90, 91, 103].

to ensure compliance with her “180 program,” she did not engage the three undercover patients in such a dialogue. [FOF 77–81, 87–88, 103, *but see* FOF 103 (where Dr. Jacobs engaged Mr. Swanson in such a dialogue on his third visit and recorded such)].

Therefore, I find that the Respondent violated the Board of Osteopathy’s regulations in not properly documenting a treatment plan. However, I do not find that based on this failure, the Respondent issued prescriptions to the undercover officers for an illegitimate medical purpose. Specifically, I find that the Government has not sufficiently created a nexus between that violation and a finding of illegitimacy under state law so as to reach a similar conclusion under federal law.

The Florida Board of Osteopathic Medicine (“Board”) defined the bounds of prescription legitimacy when it stated that it “will consider prescribing, ordering, administering, or dispensing controlled substance for pain to be for a *legitimate medical purpose* if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds.” [Fla. Admin. Code r. 64B15–14.005(e) (2007) (emphasis added)]. In the preamble to its regulation, the Board states “[t]he following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.” *Id.* at (g). Recently, the DEA concluded that that language “supports an inference that the standards provide the *minimum* requirements for establishing conduct that comports with the professional practice of controlled substance-based pain management in the state.” *Dreszer*, 76 FR at 19,398 (emphasis in original). However, as the Deputy Administrator indicated in *McKinney*, a physician who falls below such minimum standards commits malpractice, yet he does not necessarily engage in illicit drug dealing. *See McKinney*, 73 FR at 43,266 (finding a violation of Pennsylvania’s “minimum standards” for pain management yet no violation of federal law).

Here, I find that the Respondent’s failure to document a treatment plan, as that term is defined in Florida law, does not lead to the conclusion that all of the Respondent’s prescriptions to the undercover officers were for an illegitimate medical purpose. The Board states, “Osteopathic physicians should not fear disciplinary action from the Board * * * for prescribing * * * controlled substances for a legitimate medical purpose and that is supported by appropriate documentation

establishing a valid medical need and treatment plan.” [Fla. Admin. Code r. 64B15–14.005(b) (2009)]. Thus, it is possible under Florida law that a practitioner could issue prescriptions for a legitimate medical purpose, *i.e.* based on sound clinical grounds, yet fail to provide sufficient documentation of a treatment plan. While that failure may subject the physician to professional discipline, it does not predicate a conclusion that the physician engaged in illicit drug dealing.

Based on this interpretation, I find that the Government has not proven that the Respondent issued prescriptions for an illegitimate medical purpose when she failed to record a proper treatment plan in her patient’s charts.

ii. Out-right Drug Dealing

However, I do find that there is evidence of outright drug dealing by the Respondent, and, therefore the Government has proved a violation of § 1306.04(a) on that basis. Specifically, when the Respondent prescribed an additional twenty pills to Ron Swanson on his second visit to her practice, that conduct constituted actual diversion. The Respondent admitted that she provided twenty extra pills to Ron Swanson upon his request for those pills and on the basis that he had borrowed twenty pills from his friend. In this circumstance, the Respondent knew or should have known that the patient was planning to re-pay his friend with those pills and that he would not use them for his own pain management.⁴⁵ [FOF 100]. Obviously, since the Respondent’s friend was not a patient of the Respondent, the Respondent’s issuance of those extra pills was outside the scope of her medical practice and therefore a violation of § 1306.04(a). [See *Garces-Mejias*, 72 FR at 54,935; *United Prescription Services*, 72 FR at 50,407 (requiring a bona-fide patient/physician relationship)]. Certainly no bona fide patient-physician relationship can exist,

⁴⁵ I do not find credible the Respondent’s explanation that she gave the patient extra pills to help him avoid possible withdrawal symptoms. [FOF 100, n.19]. Such an explanation is inconsistent with the Respondent’s later testimony that providing him with those pills was “wrong.” [FOF 100]. If the Respondent believed that such pills were necessary to treat him for his medical condition and prevent the onset of withdrawal, then the Respondent would not have testified that the prescription was “wrong.” Furthermore, if the Respondent believed that that quantity of medication, 200 dosage units, was necessary to manage the patient’s condition, such belief does not explain her decision to later issue a lesser quantity, 180 dosage units, to the patient. [see FOF 103]. Therefore, I find it more likely that the Respondent knew the twenty pills would not be used by the patient but were intended to be given to his friend.

where absolutely no patient-physician contact has occurred.

I do not find, however, that the Respondent violated § 1306.04(a), when she instructed Mr. Swanson on how to break-down his pills, [FOF 104], although I do believe such evidence weighs in favor of revocation under Factor V, as discussed *infra*. Although Mr. Swanson certainly presented red flags of diversion when he indicated that he needed additional pills, the Respondent did not supply him with additional pills on the subsequent visit. [FOF 104]. Thus, to the extent that she believed the prescription she issued him was necessary to manage his pain, I do not find the Respondent’s actions tantamount to actual diversion on this occasion.

Last, while I find suspicious the Respondent’s conversation with Pedro Castillo, I do not find that, without expert testimony, that conversation is sufficient evidence that the Respondent issued prescriptions to him for an illegitimate medical purpose. During her patient interview with Mr. Castillo, the Respondent explained her 180 program, including the exercise component. The Respondent then explained the controlled substances that she issued as part of that program. She then asked the patient “which medicine do you want?” The patient chose oxycodone, and the Respondent confirmed that he wanted 15 mgs and not 10 mgs. [FOF 82]. While I find that giving the patient the decision to choose his/her prescription could lead to the conclusion that those prescriptions were issued “on demand,”⁴⁶ I find that here, given the context of that question, these circumstances do not rise to the level of outright drug dealing. The Respondent was presented with an MRI report documenting objective injury, explained her program and the drugs she typically prescribed as part of that program, and confirmed with the patient the nature of his injuries. [FOF 82]. Therefore, without expert testimony to the contrary, I do not find that such conduct rises to the level of outright drug dealing and thus justifies a conclusion that the Respondent issued prescriptions to Pedro Castillo for an illegitimate medical purpose.

b. Dispensing Violations

As of October 1, 2010, a dispensing practitioner in Florida “may not dispense more than a 72-hour supply of a controlled substance listed in Schedule II, Schedule III, Schedule IV,

⁴⁶ See Robert L. Dougherty, 60 FR 55,047, 55,049 (DEA 1995); Harold Footerman, M.D., 56 FR 58,400 (DEA 1991).

or Schedule V * * * for any patient who pays for the medication by cash, check or credit card in a clinic registered under [section] 459.0137." [Fla. Stat. Ann § 465.0276]. Section 459.0137 requires "[a]ll privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain-management services, or employ an osteopathic physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the department unless" certain exceptions which do not apply here. [§ 459.0137].

As of the date of this hearing, the Respondent's clinic was not registered as a pain management clinic. [FOF 24]. Under a strict reading of the statute, the 72 hour requirement would apply to only those clinics actually registered with the state. However, I find it more likely that the Florida legislature intended this requirement to apply more broadly to clinics who are *required to* register and not just those who actually are. In line with that reading, I find that this requirement applies to the Respondent, and that the Government has proved by a preponderance of the evidence that the Respondent failed to abide by this limitation. [FOF 26].

d. Recordkeeping Violations

The Respondent credibly testified that on one occasion her office was broken into and controlled substances were stolen. However, she failed to report the theft and loss of the controlled substances to the DEA, in violation of federal law.⁴⁷ [FOF 34].

Under Florida law, a dispensing physician is required to abide by the statutory and regulatory recordkeeping provisions identical to those levied against a pharmacy. [Fla. Stat. Ann. § 465.0276(2)(b) (2009)]. That includes compliance with 21 CFR 1304.04, which requires dispensed prescriptions to be maintained in a readily retrievable manner for two years after dispensing. [See Fla. Admin. Code r. 64B16–28.140 (2009) (stating a pharmacy must comply with § 1304.04)].

In addition, under federal law, a dispensing physician is required to keep certain records similar to those kept by retail pharmacies. For example, 21 CFR

§ 1304.03(d) requires a registered practitioner who regularly dispenses to keep records of Schedule II–V controlled substances that he dispenses. Specifically, the registrant is required to keep inventories of schedules I and II controlled substances. In addition, the registrant is required to keep inventories of schedules III through V controlled substances either separate from all other records of the respondent or in a manner that is readily retrievable. [§ 1304.04 (f)(1) and (2); *See also* § 1304.04(g) (imposing this requirement on registered practitioners required to maintain records)].

Federal regulations also set out in detail the requirements of those inventories. [See § 1304.11(e)(3) (specifying that a dispensing practitioner's inventory of Schedules I and II must be conducted by hand count but that Schedules III through V can be estimated provided the container holds less than 1000 tablets and requiring the practitioner to maintain records identical to those maintained by manufacturers under § 1304.11(e)(1)(iii) and (iv)].

Here, the Respondent failed to meet such requirements. Specifically, the Respondent failed to conduct required inventories of controlled substances. [FOF 25, 50]. Next, when conducting an accountability audit, the DEA found that the Respondent was unable to account for 99,723 dosage units of oxycodone 30 mg tablets, 9,460 dosage units of oxycodone 15 mg tablets, 300 dosage units of oxycodone 10 mg tablets, 1,500 dosage units of oxycodone 5 mg tablets, 1,120 dosage units of oxycodone 10 mg/325 mg tablets, and 3,300 dosage units of oxycodone 5 mg/325 mg tablets. [FOF 50]. Here, there is evidence that those shortages resulted from actual diversion in the cases of Ms. Hall and Mr. Castillo. [FOF 76, 80, 87]. Further, this agency has made clear that it "need not find that diversion was the cause of the shortages to conclude that Respondent does not maintain effective controls against diversion." [McBride Marketing, 71 FR 35, 710 (DEA 2006). *See also* Sunny Wholesale, Inc., 73 FR 57,655 (DEA 2008), Alexander Drug Company, Inc., 66 FR 18,299 (DEA 2001)].

Further, the receipts given to the Respondent's undercover patients fail to correctly record what was actually dispensed, and in two instances, the correct name of the dispensing physician was missing. [FOF 76, 80, 87, 91]. Such recordkeeping errors contribute to the inability of the Respondent and subsequently the DEA to conduct an accountability audit with accurate results. In addition, it violates federal law. [See 21 CFR 1304.22(c)

(requiring dispensing practitioners to record "name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser")].

Next, the Respondent failed to safeguard her DEA Form 222s. Specifically, when she left the Pain Center of Broward, the Respondent left her DEA Form 222s there. [FOF 9, 10]. Also, Mr. Berman was given unsupervised access to the Respondent's DEA Form 222s to order controlled substances for the Respondent's practice. [FOF 25, 32]. The Respondent did not know, at any given time, whether the ordering was done in compliance with DEA statutory and regulatory provisions. Next, when asked if at "any time an order was placed using your DEA number, was that an order done appropriately and legitimately or for other purposes," the Respondent replied that she was not sure. [FOF 11]. Indeed, ARCOS data reflects that the Respondent was one of the top 100 purchasers of oxycodone from January 1, 2009, through March 31, 2011, however, she believed that all of the dosage units purchased under her registration during that time frame, over 400,000, were not necessarily dispensed to patients that she personally saw. [FOF 47, 10]

Although the Respondent intimated that copies of her 222's were stolen during the thefts and break-ins, the Respondent failed to report the lost or stolen 222's to DEA in violation of federal law. [§ 1305.16(b)–(e); FOF 34]. Therefore, the Respondent failed to handle the DEA 222's, a critical form used to account for Schedule II controlled substances, in a responsible manner.

Even though the Respondent credibly testified that she relied upon Mr. Berman to properly handle inventories, ordering and dispensing,⁴⁸ such reliance does not absolve the registrant from her responsibilities to ensure compliance with DEA regulations. Indeed, wrongful conduct by the registrant's agent is imputed to the registrant. [Edmund Chein, M.D., 72 FR 6580 (2007) (stating "under DEA precedents, a registrant is responsible for violations of the CSA committed by his employees and his practice's failure to comply with the Act") (citing Merkow, 60 FR at 22,076)].

⁴⁷ See 21 CFR 1301.76(b) (2010) (stating "the registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day upon discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office DEA Form 106 regarding the loss or theft").

⁴⁸ FOF 25.

e. Failure To Conduct Urinalysis Screening as Required by State Law

At the time the Respondent treated the undercover personnel, it was not a requirement to conduct a urinalysis prior to treating a chronic pain patient. However, effective November 8, 2010, the law changed, requiring a physician to order a urinalysis and review the results before the initial prescribing of controlled substances.⁴⁹ On the day the search warrant was executed, November 23, 2010, DI McRae noted that the Respondent had run out of urinalysis kits, and that no such tests had been taken for the past three days. [FOF 56]. However, the Government provided no evidence that the Respondent actually saw new patients and actually issued initial controlled substances prescriptions during that three-day window. Therefore, the Government has failed to meet its burden of proof regarding this violation.

f. Prescribing Controlled Substances for Her Own Use

Under Florida statutory law, the grounds for professional discipline of an osteopathic physician include “[p]rescribing or dispensing any medicinal drug appearing on any schedule set forth in chapter 893 by the osteopathic physician for himself or herself or administering any such drug by the osteopathic physician to himself or herself unless such drug is prescribed for the osteopathic physician by another practitioner authorized to prescribe medicinal drugs.” Fla. Stat. § 459.015(u) (2009). During the search of the Respondent’s clinic, the DEA found evidence that the Respondent was prescribing oxycodone for her own use. [FOF 43]. Therefore, the Respondent violated Florida law by self-prescribing this controlled substance.

g. Lack of Physical Security

Federal law requires that a registrant store controlled substances in a “securely locked, substantially constructed cabinet.” 21 CFR 1301.75. During the search of the Respondent’s clinic, the DEA found evidence of the Respondent’s failure to store controlled substances in a secured location. Oxycodone was found in a closet containing security monitoring equipment. [FOF 35, 42]. GS Langston testified that this closet failed to comply with 21 CFR 1301.75(b) as “it was not

a securely locked, substantially constructed cabinet suitable for the storage of controlled substances.” [FOF 42]. However, GS Langston testified that she did not know whether the cabinet was or could be locked and DI Milan was similarly unaware. [FOF 42]. Therefore, I find that GS Langston had an inadequate basis upon which to draw her conclusion concerning the adequacy of the storage cabinet. Likewise the photograph is unclear concerning the nature of this cabinet. The record does contain evidence that the cabinet was in the dispensing area of the clinic. [FOF 42].

Further, although the Government failed to locate the safes that the Respondent purportedly maintained on the premises, [FOF 38], the Government bears the burden of proof, and absent GS Langston’s conclusory statements, its evidence fails to establish that the Respondent violated this regulation. [See FOF 42]. Therefore, I find the Government has failed to prove the Respondent violate § 1301.75(b).

In sum, I find that the Government has proved by a preponderance of the evidence that the Respondent violated federal law when she prescribed an additional twenty pills to Ron Swanson and failed to maintain adequate dispensing records. In addition, I find that the Respondent violated state law when she failed to record a treatment plan, self-prescribed controlled substances, and dispensed controlled substances for more than a 72 hour period. Further, her failure to adequately account for over 100,000 dosage units of controlled substances is an egregious failure. To the extent that these violations represent her experience in handling controlled substances, they certainly do not merit a finding that her continued registration would be in the public’s interest. In total, Factors 2 and 4 weigh in favor of revocation of the Respondent’s registration.

3. Factor III. Respondent’s Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

It is uncontested that the Respondent has not been convicted of a federal or state crime relating to the manufacture, distribution, or dispensing of controlled substances. While a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction

is of considerably less consequence in the public interest inquiry. [Krishna-Iyer, 74 Fed Reg. at 461; Chein, 72 FR at 6,593 n.22]. Accordingly, that Respondent has not been convicted of an offense related to the distribution or dispensing of controlled substances is not dispositive of whether the continuation of her registration is consistent with the public interest.

4. Factor V. Such Other Conduct Which May Threaten The Public Health and Safety

a. Diversion Risks

Although factor five is quite broad, the Deputy Administrator has qualified its breadth by limiting the considerations made under that factor to those where there is “a substantial relationship between the conduct and the CSA’s purpose of preventing drug abuse and diversion.” [Tony T. Bui, 75 FR 49,979, 49, 988 (DEA 2010)].

Here, I find that many characteristics of the Respondent’s practice significantly increased the risk of diversion. I also find that the Respondent did little to otherwise mitigate that risk, to the peril of her practice and the public.

First, the Respondent testified that her “180 Program,” if successful, would result in patients having extra pain medication remaining at the end of the month. [FOF 108, 112]. However, on nearly all follow up visits, the Respondent did not account for those extra pills. [FOF 79–81; 87–88; 103; *see Resp. Exh. 1,2,3; but see Respt. Exh. 3 at 9* (where Respondent indicated in Ron Swanson’s chart that he had no remaining pills at the end of the month)]. Also, while Respondent instructed her patients not to take the Xanax if they didn’t need it, she provided her patients with a Xanax prescription at each visit and did not inquire whether or not the patient had taken the prior prescribed Xanax. She also did not conduct urine screens of the undercover officers to ensure they were actually taking the medication. [FOF 59, 74, 115]. Therefore, by conducting her practice in this manner, the Respondent created the opportunity for her patients to divert their medication, yet failed to otherwise screen whether such diversion was occurring.

Second, I find disturbing the Respondent’s choice to operate a cash-only dispensary concerning, in light of her refusal to adopt other effective controls against diversion. [FOF 28]. By eliminating pharmacies and third party payors, the Respondent removed necessary checks on patient doctor

⁴⁹ Fla. Admin. Code r. 64B15–14.0051(2)(f) (2010) (stating “patient drug testing * * * shall be conducted and the results reviewed prior to the initial issuance or dispensing of a controlled substance prescription, and thereafter, on a random basis at least twice a year and when requested by the treating physician).

shopping as well as her own prescribing.

In addition, while the Respondent attempted to mitigate the risk of doctor-shopping and diversion by other means, such as doctor-patient contracts, consent for urinalysis, warnings about lost medication, [FOF 64, 86, 90], she did so ineffectually. While she instructed patients to acknowledge their criminal liability for perpetuating fraud, she did not verify the source of a patient's diagnostic report despite the fact that those reports either (1) purported to be conducted at out-of-state facilities or (2) had no contact information for the facility. [FOF 64, 86, 90, 69, 83, 92]. For example, when the Respondent was presented with fraudulent MRI reports, she was unable to detect such as she failed to verify their authenticity. [FOF 40].

Further, despite physical conditions that were years' old, the Respondent did not obtain prior treatment records. [FOF 62]. Such treatment records would also provide a prescribing history so the Respondent could confirm prior drug use.

Third, I find it significant that, when risks of actual diversion were present, the Respondent failed to take action. For example, Mr. Castillo and Mr. Swanson told Respondent that, prior to their visits, they had received oxycodone from a friend. [FOF 82, 90]. However, the Respondent continued to prescribe them controlled substances. [FOF 86, 91]. Further, in the March 2010 visit, both Mr. Castillo and Ms. Hall were given twice what the Respondent had prescribed for them, 360 oxycodone 15 mg rather than 180 oxycodone, thus affording the patients with the opportunity to divert 180 dosage units of oxycodone each. [FOF 81, 89]. This prescribing was not discussed and subsequent prescribing altered accordingly in the April visit. [FOF 81, 88, 89].

The Respondent also instructed Mr. Swanson to "break down" his 15 mg pills if he needed to repay his friend, which is an inappropriate response to the patient's indication that he may be illegally obtaining controlled substances. [FOF 104]. It also interferes with the DEA's responsibility to prevent diversion.

In addition, the Respondent was often presented with large groups of out of state patients. [FOF 45, 57]. Her decision not to verify MRIs and to obtain past treatment records in those situations, if not culpable, may equate to turning a blind eye.

Fourth, I am not persuaded that the Respondent's choice to delegate dispensing authority to a non-

pharmacist was a wise one. [FOF 25]. Indeed, the Respondent exacerbated the risk that her delegate would irresponsibly handle the controlled substances by not conducting her own audits. Hence, the Respondent had no way of detecting whether controlled substances were being diverted under her registration, which they clearly were. [See FOF 76, 80, 87 (where Ms. Hall and Mr. Castillo received twice the number of oxycodone as actually prescribed)].

In sum, while a registrant may operate her practice in any manner she chooses provided she does so lawfully, when the means chosen increase diversionary risks and fail to otherwise mitigate those risks, her registration threatens the public interest. Here, I find that despite the increased risks the Respondent created through her practice's design, she failed to implement other adequate controls against diversion, thus weighing against her continued registration.

b. Subsequent Remedial Measures and Contrition

In general, the Respondent argues that she naively entered the practice of pain management, and has since become more aware of diversion risks as well as the specific legal requirements that govern her practice. However, naivety regarding the handling of controlled substances can weigh as heavily against continued registration as culpability. [See Paul J. Caragine, Jr., 63 FR 51562, 51601 (DEA 1998) (stating "just 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 revocation")]. Thus, if the Registrant is unable to adequately assure the agency of future compliance, a lack of intentional violation will do little to save her. [Jon Karl Dively, M.D., 72 FR 74332 (2007) (a proceeding under 303 "is a remedial measure based upon the public interest and the necessity to protect the public * * * Respondent must prove by a preponderance of the evidence that she can be entrusted with the authority that a registration provides by demonstrating that she accepts responsibility for her misconduct and that the misconduct will not reoccur.")].

Here, I find the Respondent credibly acknowledged some of her wrongdoing. Specifically, I find it highly persuasive that the Respondent did not prescribe additional pills to the undercover officer on his third visit, and admitted her earlier decision to do so was "wrong."

[FOF 100]. I find this admission, in light of its occurrence prior to her becoming aware of the DEA's investigation of her registration, highly probative of a finding that the misconduct will not reoccur. [FOF 100].

Yet, I also find that while the Respondent recognized her ultimate responsibility for the dispensing and accounting errors found at her practice, I did not find her remorseful for improperly managing that responsibility. Throughout the hearing she justified dispensing errors on the fact that those responsibilities were delegated to her business partner and justified that delegation. [FOF 32]. In addition, she alluded that some of her recordkeeping errors and, the corresponding shortages, may have been attributed to thefts. However, the record makes clear that at least some of those shortages were attributable to actual diversion, and, despite that clarity the Respondent failed to acknowledge her wrongfulness in irresponsibly managing her registration and creating the opportunity for that diversion.

As for future assurance of compliance, the Respondent presented evidence that she has, or would, implement some changes in her practice to address the DEA's concerns regarding her practice. Specifically, the Respondent testified that she instructed her staff to verify patients' MRI reports. [FOF 41]. Next, she has installed two safes for the storage of controlled substances. [FOF 38]. The Respondent also augments her prescribing of controlled substances with the requirement of exercise to help alleviate chronic pain. [FOF 114]. As for the myriad of other issues the Respondent was silent. The Respondent failed to provide any assurance that she would better account for controlled substances, better prevent the reoccurring thefts and break-ins at her practice, and address the diversion that occurred through her dispensary. Thus, I am not convinced that if the Respondent were allowed to continue operating under her DEA registration, that she would be able to adequately manage that responsibility.

V. Conclusion and Recommendation

In Conclusion, I find that Factors II, IV, and V weigh in favor of discontinuing the Respondent's registration. The Government proved by a preponderance of the evidence that the Respondent violated Florida law in failing to adequately document a treatment plan and by self-prescribing controlled substances. Also, the Government proved that the Respondent violated federal law in failing to adequately account for her controlled

substances and maintain her DEA 222 forms. More importantly, however, the record clearly reflects that the Respondent created serious risks of diversion through her practice and failed to otherwise mitigate those risks. Thus, I find the Government has met its burden of proof that the Respondent's continued registration would not be in the public's interest.

The Respondent, however, has not accepted responsibility for all of her wrongdoing, nor has she adequately assured this tribunal of future compliance.

In balancing the statutory public interest factors and the Respondent's remedial efforts, I conclude that revocation of the Respondent's DEA Certificate of Registration, and denial of any pending renewal applications, would be consistent with the public interest in this case.

Accordingly, I recommend that the Respondent's Certificate of Registration be revoked and any pending applications for renewal be denied.

June 17, 2011.

Gail A. Randall,
Administrative Law Judge.

[FR Doc. 2011-25231 Filed 9-29-11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10-77]

Kimberly Maloney, N.P.; Decision and Order

On February 4, 2011, Administrative Law Judge Timothy D. Wing issued the attached recommended decision. Neither party filed exceptions to the decision.

Having reviewed the entire record, I have decided to adopt the ALJ's ruling, findings of fact, conclusions of law (except as explained below), and recommended order. Accordingly, Respondent's application for a registration will be granted subject to a condition.

In his discussion of factor three—Respondent's "conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances," 21 U.S.C. 823(f)—the ALJ found that she had pled guilty to a felony count of obtaining a narcotic drug by means of a forged prescription in violation of Cal. Health & Safety Code § 11368. ALJ at 15–16.¹ However, pursuant to Cal. Penal Code

§ 1000.1, Respondent was allowed to participate in the deferred entry of judgment program, GX 10, and upon her successful completion of treatment, her guilty plea was set aside and the charge was dismissed. GX 11.

Noting that California law provides that "[a] defendant's plea of guilty pursuant to this chapter shall not constitute a conviction for any purpose unless a judgment of guilty is entered pursuant to" Cal Penal Code § 1000.3, and that Agency precedent holds that a deferred adjudication is nonetheless a conviction for purposes of the CSA, the ALJ explained that "the fact that a finding of guilt was specifically not entered as to Respondent and the charges dismissed, leaves open the question as to whether Respondent's plea constitutes a conviction under 21 U.S.C. 823(f)." ALJ at 17. The ALJ deemed it unnecessary to reach the issue, however, reasoning that the offense committed by Respondent "does not 'relate[] to the manufacture, distribution, or dispensing of controlled substances,' the standard embraced in" 21 U.S.C. 823(f)(3). *Id.* (citing *Super-Rite Drugs*, 56 FR 46014 (1995)).

Contrary to the ALJ's understanding, the Agency has long since resolved both issues. In *Edson W. Redard*, 65 FR 30616 (2000), a practitioner, who was charged with three felony counts of obtaining and attempting to obtain hydrocodone by fraud under California law, pled *nolo contendere* to a single count and was allowed to participate in the State's deferred entry of judgment program (the same statutory scheme at issue here), which he successfully completed. *Id.* at 30617–18. Thereupon, the state court granted deferred entry of judgment and the charges were dismissed. *Id.* at 30618.

Thereafter, the Agency proposed the revocation of the practitioner's registration on the ground that he had been convicted of a felony offense relating to controlled substances under state or Federal law. *Id.* (citing 21 U.S.C. 824(a)(2)). In opposition, the practitioner argued that he had not been "convicted of a felony offense [because] no judgment was entered against him and the criminal proceedings were dismissed." *Id.*

The Agency rejected the practitioner's argument, explaining that "there is still a 'conviction' within the meaning of the Controlled Substances Act even if the proceedings are later dismissed. * * * [A]ny other interpretation would mean that the conviction could only be considered between its date and the date of its subsequent dismissal." *Id.* (int. quotations omitted). The Agency thus held that the practitioner had

"been convicted of a felony relating to controlled substances" and that this was ground to revoke his registration under 21 U.S.C. 824(a)(2). *Id.*

In *Harlan J. Borchering*, 60 FR 28796 (1995), a practitioner who had been indicted under Texas law on three counts of prescribing a controlled substance "without a valid medical purpose," was allowed to plead guilty to a single misdemeanor count and was placed on probation; following the practitioner's completion of his probation, the proceeding was dismissed without an adjudication of guilt. *Id.* at 28797. While the practitioner argued "that he had not been 'convicted' of any offense within the meaning of 21 U.S.C. 823(f)(3)," the Agency rejected the argument, holding that "[t]he law is well settled that a DEA registrant may be found to have been 'convicted' within the meaning of the Controlled Substances Act, despite a deferred adjudication of guilt." *Id.* (citations omitted).

More recently, in *Pamela Monterosso*, 73 FR 11146, 11148 (2008), a case in which an applicant pled guilty to a state law controlled substance offense but was granted probation before judgment and the charge was dismissed, I explained that "DEA has long taken the view that even when a court withholds adjudication and ultimately dismisses the charge after the completion of probation, the proceeding is still a conviction within the meaning of the Controlled Substances Act." *See also Thomas G. Easter II*, 69 FR 5579, 5580–81 (2004) ("DEA has consistently held that a deferred adjudication of guilt following a guilty plea, is a conviction within the meaning of the Controlled Substances Act."); *Clinton D. Nutt*, 55 FR 30992 (1990); *Eric A. Baum*, 53 FR 47272 (1988); *Stanley Granet Rosen*, 50 FR 46844 (1985).

Moreover, the Superior Court form evidencing Respondent's guilty plea includes the "Court's Finding And Order." GX 9, at 3. This section of the form concludes by stating: "The Court accepts the defendant's plea and admissions, and the defendant is convicted thereby." *Id.* For purposes of the CSA, including whether this action must be disclosed on an application for registration and whether it provides ground to deny an application or revoke a registration, *see* 21 U.S.C. 824(a)(1) & (2), Respondent's plea and the Superior Court's finding constitutes a conviction notwithstanding that her plea was eventually set aside and the charge dismissed.

As discussed above, the ALJ also concluded that Respondent's offense of obtaining a prescription for a controlled

¹ All citations to the ALJ's decision are to the slip opinion as issued by him.