(emphasis added); *see also Armstrong* v. *La. State Bd. of Med. Examiners,* 868 So. 2d 830, 840 (La.App. 4 Cir. Feb. 18, 2004) (upholding two year suspension of physician's license; noting that when prescribing controlled substances for relief of non-malignant pain is ''unaccompanied by appropriate testing, diagnosis, oversight and monitoring * * * the physician falls below generally accepted standards of care''); *Pastorek* v. *La. State Bd. of Med. Examiners,* 4 So. 3d 833 (La.App. 4 Cir. Dec. 17, 2008). The Board's rules further require that a ''medical diagnosis * * * be established and fully documented in the patient's medical record.'' La. Admin. Code tit. 46:XLV.6921(A)(2) (2008).

Louisiana law also prohibits a physician from ''[a]ssist[ing] a patient or any other person in obtaining a controlled dangerous substance through misrepresentation, fraud, forgery, deception, or subterfuge.'' La. Rev. Stat. Ann. § 40:971.2 (2008) (effective Aug. 15, 2005). It is also unlawful for a physician to ''prescribe * * * legally controlled substances beyond his respective prescribing authority or for a purpose other than accepted medical treatment of disease, condition, or illness. *Id.,* at § 40:971(C)(1) (2008) (effective Sept. 9, 1988).

As found in my Decision and Order of July 27, 2011, on four occasions, Applicant prescribed drugs containing hydrocodone (including Lortab and/or Lorcet), which are schedule III narcotics; Xanax, a schedule IV controlled substance; and Phenergan with codeine, a schedule V narcotic cough syrup; to Louisiana State Troopers acting in undercover capacities. *See* 76 FR at 49508. Notably, Applicant issued these prescriptions without conducting a physical examination at any of the visits and the undercover agents received these prescriptions even though they did not demonstrate conditions or symptoms that would justify the prescriptions. *Id.*

Moreover, both undercover agents initially denied they were in pain, but Applicant assisted the agents in obtaining controlled substances by encouraging them to make false statements. *See id.* For example, while he denied being in pain, UC1 asked Applicant for ''[h]ydrocodone pain pills,'' and then ''negotiate[ed]'' with Applicant to ''falsely state'' he had a sexually transmitted disease. *Id.* Likewise, Applicant also ''coached'' the second undercover agent on what to say to ''justify issuing the prescriptions and wrote her coached statements in a medical file.'' *Id.* Therefore, Applicant failed to establish a physician-patient relationship, lacked a legitimate medical purpose, and acted outside of the usual course of professional practice in prescribing controlled substances to the undercover agents and thus violated Federal law. *See id.* (citing 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1); *see also Louisiana* v. *Moody,* 393 So. 2d 1212, 1215 (La. 1981) (holding that physician furnished prescriptions for ''other than a legitimate medical purpose'' based on evidence showing that prescriptions were issued in response to specific requests of patients and physician did not conduct physical examinations or take medical histories)).

I therefore hold again that granting Applicant's applications for a new registration ''would be inconsistent with the public interest.[8]'' 21 U.S.C. 823(f). Accordingly, I will order that Applicant's pending applications be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the applications (Control Numbers W10020882C and W10078290C) of Jose Gonzalo Zavaleta, M.D., for a DEA Certificate of Registration as a practitioner be, and they hereby are, denied. This order is effective November 19, 2012.

Dated: October 8, 2012.

Michele M. Leonhart,

Administrator.

[FR Doc. 2012–25576 Filed 10–17–12; 8:45 am]

BILLING CODE 4410–09–P

[8] As found above, Applicant stated in his second application that ''the DA made me an offer for a program called PTI and no DEA license for two years,'' and that because he has ''completed two years without [a] DEA license,'' he ''want[s] [his] unrestricted DEA license back.'' GX 6. Respondent has presented no evidence that any DEA official agreed to the deal he made with the district attorney, and in any event, a state official has no authority to bind this Agency. *See Edmund Chein,* 72 FR 6580, 6590 (2007) (Congress granted the authority to determine whether a registration ''is consistent with the public interest'' to ''the Attorney General of the United States, and that authority has been delegated solely to the officials of [DEA]. State officials therefore lack authority to resolve a matter pending before the Drug Enforcement Administration'' and cannot bind this Agency.) (citing 21 U.S.C. 824, 28 CFR 0.100(b), and *Fourth Street Pharmacy v. DEA,* 836 F.2d 1137, 1139 (8th Cir. 1988)); *see also* 21 U.S.C. 823(f)).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–34]

Zvi H. Perper, M.D., Decision and Order

On July 19, 2011, Administrative Law Judge (ALJ) Gail A. Randall issued the attached recommended decision. The Respondent did not file exceptions to the decision.

Having reviewed the entire record, I have decided to adopt the ALJ's recommended rulings, findings of fact, conclusions of law, and recommended Order except for her legal conclusions as to the initial visits of the two undercover officers (UCs) and her discussion in the first full paragraph at page 34 of her slip opinion.[1] However, I need not decide whether the prescriptions Respondent issued at the initial visits of the two UCs violated 21 CFR 1306.04(a), because there is substantial evidence to support the ALJ's legal conclusions that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing prescriptions at the UCs' subsequent visits.

More specifically, one week after the initial visit of David Hays (UC1), at which he was prescribed 150 Percocet, a drug which combines 10 mg of oxycodone with 325 mg of acetaminophen, Hays returned to Respondent complaining that the drug was causing digestive problems. Respondent then prescribed 150 Roxicodone (oxycodone) 30 mg, without any inquiry into Hays' pain level. Tr. 54, GX 3a, at 13. Respondent noted in the chart, however, that Hays ''had no relief [from] pain.'' GX 12, at 14.

With respect to this prescription, the Government's Expert testified that the ''[m]edication would not have been indicated given the complaints of the patient, [and] certainly not that particular agent and certainly not that dose or frequency.'' Tr. 54. Notably, this

[1] The ALJ noted that Respondent and his PA ''were given direct evidence of diversion and failed to act.'' Slip Op. at 34. More specifically, the ALJ noted that UC1 had told the PA that his girlfriend had used some of his controlled substances and that the PA did nothing in response and that UC2 had told both Respondent and his PA that he had bought controlled substances off the street and that neither Respondent nor his PA took any action. *Id.* The ALJ thus reasoned that ''[a] practitioner who takes no 'precautions against * * * misuse and diversion' exceeds the bound of professional practice when he prescribes controlled substances[,]'' and that ''[s]uch action violates the standard of diligence expected of a DEA registrant.'' *Id.* (quoting *United States* v. *Moore,* 423 U.S. 122, 142–43 (1975)).

While purchasing drugs off the street may well be evidence that a patient is a substance abuser, the record contains no evidence establishing the appropriate course of professional practice when a practitioner is confronted with such information. Likewise, while UC1's statement to the PA that his girlfriend had gotten into his medication supports a finding that diversion is occurring, here again, the record contains no evidence establishing what precautions were required to be taken under the standard of professional practice. Thus, while I find this conduct extremely disturbing, I do not rely on it.

testimony was unrefuted. I thus conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate purpose in issuing the prescription and thus violated federal law. 21 CFR 1306.04(a).

Hays returned three weeks later (May 19, 2010) and saw Respondent's Physician Assistant (PA). While during the visit, the PA initially confused Hays with a patient whose name was spelled Hayes, upon recognizing his error he nonetheless noted that Hays was ''too early.'' GX 4, at 14. During the visit, Hays asked the PA if he could increase the Roxicodone 30 mg prescription because he was probably going to be gone for three or four months working on a tugboat. *Id.* at 23. The PA instead offered to give Hays ''the fifteen milligrams * * * strength.'' *Id.* at 25. Hays asked the PA if he ''[c]ould * * * increase the thirties * * * just to whatever is reasonable and add some fifteens,'' to which the PA answered: ''I have to ask.'' *Id.* The PA then told Hays To ''have a seat in the waiting room'' and ''[l]et me find out for you.'' *Id.* Notably, during this visit, Hays did not tell the PA that he was experiencing breakthrough pain.

Approximately fifteen minutes later, the PA spoke with Hays and told him that Respondent ''was very generous'' but that the ''the deal'' was that Hays could not see the PA again until after the fourth of July. *Id.* at 31. The PA then told Hays that Respondent had given him 210 Roxicodone 30 mg and 90 Roxicodone 15 mg. *Id.* at 32; GX 12, at 23 (copies of prescriptions). On the prescription for the Roxicodone 15 mg, Respondent noted that it was for ''breakthrough'' pain, even though Hays never complained of having breakthrough pain.[2]

While the progress note for this visit stated ''Earliest pt. can be seen until 7/5/10,'' *id.* at 20; on June 16, Hays returned and saw Respondent. GX 5, at 16. While Hays was nearly three weeks early, Respondent did not raise this as an issue, *see id.* at 16–19, even though according to the Government's Expert, this is a ''red flag'' indicative of ''[d]rug-seeking behavior'' and either abuse or diversion. Tr. 65, 67. Moreover, Hays told Respondent that he still had not been on the tugboat assignment—the purported reason for why he needed an increase in his prescriptions—and once again asked for an increase. GX 5, at 16–19.

Respondent then noted that Hays' ''pain level is only a two over ten'' and that this was ''pretty good.'' *Id.* at 17. Respondent then asked Hays if he was ''having some breakthrough pain mostly at work.'' *Id.* Hays answered: ''Every now and then something feels * * * a little bit hey-wire back there,'' that it was ''mostly in the mornings,'' and that he would ''get all sore and stiff back there.'' *Id.* Respondent noted that at the last visit, Hays had been ''given a prescription for breakthrough pain'' and Hays was ''going kind of rapidly with [his] medicine.'' *Id.* Notwithstanding that Hays had reported his pain level as only a two and was nearly three weeks early, Respondent gave him a prescription for 210 tablets of Roxicodone 30 mg, a prescription for 90 Roxicodone 15 mg for breakthrough pain, and a prescription for a liver function test, which Hays never obtained. GX 12, at 26.

Hays returned on July 20 and saw the PA. Hays told the PA that he was doing ''pretty good'' and that his back had improved. GX 6, at 3–4. During the visit, Hays told the PA that his girlfriend had gotten into his medicine (which according to the Government's Expert was indicative of ''misuse and diversion,'' Tr. 65) and wanted to come to the clinic. GX 6, at 5. The PA told Hays that ''we could only see her with a valid reason * * * like an MRI report'' and ''not just because [the drugs] made her feel good.'' *Id.* at 6. The PA, however, then commented that ''she got that subtle euphoria and of course she liked it. But if she doesn't have a true pain area * * * it's not appropriate.'' *Id.* The PA then explained that the laws had changed and that the clinic would never fill prescriptions again and that Hays would have to go to a pharmacy to fill the prescriptions and that the clinic was going to discuss with local pharmacies where they could ''at least direct patients to.'' *Id.* at 7.

The PA then discussed giving Hays ''this new medicine called Dilaudid, which is a morphine derivative'' for his breakthrough pain. After discussing how Dilaudid (hydromorphone) was different from oxycodone, the PA and Hays resumed discussing where the latter could fill his prescriptions with the PA stating that because of the number of pills (210 Roxicodone), it was ''extremely hard to believe that [Hays would] be able to get'' the Oxycodone 30s from big chain drug stores such as CVS or Publix. *Id.* at 11. Hays then asked the PA to recommend a pharmacy which would fill the prescriptions; the PA told him he would give him a list and that the pills would cost four dollars each. *Id.* at 12. In response, Hays stated that he could not afford to fill 210 pills and asked if the PA could split his prescription; the PA agreed. *Id.* at 12–13. The PA stated that a lot of the small pharmacies were going to ''require a non-narcotic, non-controlled medicine to go with'' the narcotic prescriptions and that ''[t]hey wouldn't just take * * * the Roxicodone, Dilaudid script from'' him because there is ''a perception problem.'' *Id.* at 14–15. The PA then explained that he would give Hays a prescription for thirty Motrin to put in his ''back pocket'' which he could produce if the pharmacist questioned the prescriptions. *Id.* at 15. However, the PA told Hays to ''shred'' the script if the pharmacist did not question the prescriptions. *Id.*

Later, the PA asked Hays if he was ''satisfactory in the sleep department and in the anxiety department?'' *Id.* at 18. Hays answered: ''You know, I never have anxiety, really. And I sleep pretty good.'' *Id.* Following a discussion of a new state law prohibiting pain management clinics from dispensing and a proposal to establish a state prescription database, the PA left to have Respondent review and sign the prescriptions. *Id.* at 23. Respondent issued Hays two prescriptions totaling 210 tablets of Roxicodone 30 mg, as well as prescriptions for 60 Dilaudid 4 mg and 30 Motrin.

Hays returned on August 18 and again saw the PA. Notably, on the Patient Comfort Assessment form, Hays indicated that the worst his pain had been in the last month was a ''3'' on a ''0'' to ''10'' scale, that his pain had averaged a ''2'' during the last month, and that it was currently a ''1.'' GX 12, at 33. Hays also wrote that his pain ''was in my lower back but feels better now'' and circled that pain was ''occasional'' and not ''continuous.''

Hays told the PA that the Dilaudid made him ''kind of dizzy and nauseous'' and that he thought the oxycodone were ''good for'' him and asked if Respondent ever prescribed the 80s. GX 7, at 22–23. The PA stated that Respondent would ''start out a little slower[,] like the 40's * * * but yes, we do, do the 80s.'' *Id.* at 23. Hays told the PA that he did not have any problems getting the thirties and that his ''girlfriend knew [a] a place that has them * * * readily available.'' *Id.* The PA then asked Hays whether he had ''hand[ed] two split scripts in in one time''; Hays said ''No.'' *Id.* at 24. The PA then told Respondent that he had to get his liver function tested and told him where to get it and that it would cost $45. *Id.* at 24–25.

[2] Under Federal law, a practitioner may issue a patient ''multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substance'' provided, *inter alia,* that the prescriptions otherwise comply with 21 CFR 1306.04(a) (as well as other provisions of the CSA and state law), the prescriptions include the earliest date on which they can be filled, and that they ''do not create an undue risk of diversion or abuse.'' 21 CFR 1306.12(b)(1).

Next, the PA asked Hays if his ''lower back [was] okay this month?'' *Id.* at 25. Hays answered: ''You know, I think it really feels pretty good.'' *Id.* The PA then asked: ''Do you even need a breakthrough * * * I mean * * * [y]ou're taking seven * * * a day, why don't you just stick with them?'' *Id.* Hays answered: ''well, there might be that occasion when I did need it but * * * I don't know.'' *Id.* at 26. The PA replied: ''I'll throw you a few Percocets then just to get on the safe side but the 15s are very hard to come by and they're very expensive.'' *Id.*

Hays asked if the stuff Michael Jackson had taken would work; the PA stated that that drug was only indicated to ''put people out with and perform surgery.'' *Id.* at 27. Hays then asked ''if there is some other creative way that you could deal with me?'' *Id.* at 28. In response, the PA asked: ''Are you having trouble sleeping? Is [that] what you're getting at?'' *Id.* Hays answered ''I wonder * * * I do have trouble sleeping. I don't sleep much.'' *Id.* The PA then asked Hays if he had ''ever tried Valium?'' *Id.* After Hays answered that he had not, the PA asked if he would like to. *Id.* Hays replied ''You know I might, because there are times when I * * * and it could be because * * * I've got too much on my mind, with work and everything, and I wake up at night and then I just stay awake.'' *Id.* The PA then told Hays to ''try it one hour before you want it to work,'' but not to drive on it and not to take it every night.[3] *Id.* at 29.

Hays and the PA returned to discussing his use of Dilaudid, with the PA stating that he was going to discontinue it. *Id.* at 30. The PA then asked Hays to move each leg up to his hand, and whether doing so bothered his back; Hays indicated that it did not. *Id.* at 31; *see also* GX 20 (audio recording of visit). The PA asked Hays if he needed the prescriptions split again; Hays answered that he did not. GX 7, at 31. The PA then said he was going to give Hays ''a couple [of] Percocet for the day'' for ''breakthrough'' pain and advised him to ''eat with them.'' *Id.* at 31–32. The PA added that ''hopefully the seven thirties a day will be enough pain relief for you and you don't need anything else'' and advised Hays to fill the Percocet prescription only if he needed it. *Id.* Following a discussion of doctor shopping, the PA went to Respondent to obtain his approval for the prescriptions. *Id.* at 39. Thereafter, Hays was provided with prescriptions for 210 Roxicodone 30 mg, 60 Percocet 10/325mg, 30 Valium 10mg, and Motrin. GX 12, at 35.

With respect to the Dilaudid prescription Respondent issued to Hays, the Government's Expert testified that there was no evidence that Hays was experiencing break-through pain ''of any significant degree.'' Tr. 60. The Expert further explained that ''[t]here was no history consistent with severe break-through pain and it appeared that [Hays'] pain was adequately—more than adequately managed, even based on the subjective history.'' *Id.* The Expert thus concluded that Dilaudid prescription was ''not justified.'' *Id.* This testimony stands unrefuted.

I therefore conclude that substantial evidence supports the conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the Dilaudid prescription to Hays. 21 CFR 1306.04(a). Moreover, for the same reasons that the Expert concluded that the Dilaudid prescription was not medically justified, I also conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the May 15 and June 16 prescriptions for Roxicodone 15mg, as well as the August 18 prescription for Percocet 10, all of which were purportedly issued for breakthrough pain.

As for the Valium prescription, the Government's Expert observed that the progress note ''indicated that the patient had insomnia for the past month'' but that Respondent did not explain ''in his note why Valium [was] being added, although the prescription is to be taken one at bedtime only.'' *Id.* at 61. Continuing, the Expert testified that while he could ''hypothesize why [Valium] may have been chosen * * * there was nothing that would justify that dose * * * for this individual.'' *Id.*

The Government's Expert further explained that before prescribing Valium for insomnia, ''[t]he first reasonably standard thing to do would be to ensure that the patient wasn't doing anything that may be promoting insomnia'' such as having ''caffeine at night or excessive meals right before bedtime.'' *Id.* at 62. Once this was addressed, the Expert stated that if ''medications were indicated there are [other] agents that are appropriate for insomnia, rather than a benzodiazepine like Valium, [which is available in 2, 5 and 10 mg tablets], at its highest dose.'' *Id.* at 63. Finally, the Expert noted that Valium's ''primary purpose is not [to treat] insomnia.'' *Id.*

Here too, the testimony of the Government's Expert was unrefuted. I therefore conclude that substantial evidence supports the conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the Valium prescription to Hays. 21 CFR 1306.04(a).[4]

As for the prescriptions issued to Eddie Martinez, the evidence showed that Respondent increased his prescription from 120 Percocet 10/325 at the initial visit (for a total daily dose of 40 mg of oxycodone) to 90 Oxycodone 30 mg (for a total daily dose of 90 mg of oxycodone) at the second visit. GX 13, at 16, 20. The Government's Expert opined that Martinez's complained-of pain level did not justify a prescription for Roxicodone 30, which was more than double the dosing of the previous prescription, as ''[t]here wasn't any physical examination abnormality or focal neurological deficit * * * consistent with his MRI finding or even his complaints that * * * would have warranted those medications at that dose[].'' Tr. 85. This testimony was unrefuted.

At the third visit, Martinez told Respondent that he had run out a week early and bought drugs on the street even though in Respondent's words ''[y]ou changed from Percocet to Oxycodone, that's a much stronger medicine than what you were using'' and ''there's a significant increase in the total amount of medicine you're getting daily.'' GX 11, at 20; *see also id.* at 22. At the visit, Respondent wrote Martinez

[3] Under DEA precedent, a registrant is strictly liable for the misconduct of those employees that he has authorized to act on his behalf with respect to the registrant's handling of controlled substances. *See Anthony L. Capelli,* 59 FR 42288 (1994) (holding registrant strictly liable for unauthorized prescriptions issued under his registrant by unlicensed persons). *See also Scott C. Bickman,* 76 FR 17694, 17703 (2011); *Harrell Robinson,* 74 FR 61370, 61377–78 2009, *Paul Volkman,* 73 FR 30630, 30644 n.42 (2008). While in this case the PA did not have authority to issue controlled substance prescriptions under Florida law, it is clear that Respondent authorized the PA to act on his behalf in evaluating his patients and relied on the PA's evaluation to issue controlled substances prescriptions. Accordingly, Respondent is strictly liable for issuing the prescriptions.

[4] Noting that Hays had asked the PA ''if there is some other creative way that you could deal with me?'' and the PA's response that: ''Are you having trouble sleeping? Is [that] what you're getting at?,'' the ALJ reasoned that the circumstances surrounding the prescription ''nearly equate[] to outright drug dealing.'' ALJ at 31. I go one step further and conclude that it was an outright drug deal, noting not only unusual nature of Hays' statement, but also that Hays had denied a sleep problem just one month earlier, as well as the Expert's testimony that: (1) the PA's evaluation of Hays' sleep problem was inadequate, Tr. 62; (2) that there are other drugs which are indicated for insomnia and that Valium's ''primary purpose is not [to treat] insomnia''; and (3) that the prescribed dose was ''very high.'' *Id.* at 63.

prescriptions for 90 Roxicodone 30 mg, as well as 60 Percocet 10 mg, the latter being for ''breakthrough pain.'' GX 13, at 24. Notably, on the Patient Comfort Assessment Guide for this visit, Martinez noted that at its worst, his pain was a ''5'' on a scale of 0 to 10, a decrease from the level of 7–8 which he reported the previous month. GX 13, at 17, 21. Moreover, at no point did Martinez complain of having breakthrough pain. *See* GX 11, at 20–24.

According to the Government's Expert, that Martinez said he had run out early and complained of unrelieved pain was not a legitimate medical justification for increasing the dosing of oxycodone because it was ''[n]ot based on the history, physical, and objective information available in this patient's file.'' Tr. 87. The Expert further opined that while it would be within the course of professional practice to prescribe analgesic medications ''if the clinical justification existed,'' Martinez's ''history and physical'' did not meet the criteria for prescribing. *Id.* at 90.

Here again, this testimony was unrefuted. Accordingly, I hold that substantial evidence supports the conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing oxycodone prescriptions to Martinez at both his second and third visits. 21 CFR 1306.04(a). I thus conclude that Respondent violated Federal law in issuing numerous controlled substance prescriptions to both UCs.

This finding provides reason alone to conclude that Respondent has committed acts which render his registration inconsistent with the public interest. *See* 21 U.S.C. 824(a)(4). However, this conclusion is buttressed by the ALJ's additional findings and legal conclusions, including those regarding the shortages of controlled substances ordered under Respondent's registration (nearly 24,000 dosage units of oxycodone 30 and 2,565 dosage of Endocet 10/325), his failure to take initial inventories after moving his practice, 21 CFR 1304.11, and his failure ''to provide any explanation for his conduct or any assurances regarding his future conduct.'' ALJ at 37. *See also Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008).[5]

Accordingly, I adopt the ALJ's recommended order that Respondent's registrations be revoked and any pending applications be denied. For the same reasons which led me to order the Immediate Suspension of Respondent's registrations, I conclude that the public interest requires that this Order be made effective immediately. *See* 21 CFR 1316.67.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificates of Registration Nos. FP1312406, BP8477639, and BP3429835, issued to Zvi H. Perper, M.D., be, and they hereby are revoked. I further order that any pending applications of Zvi H. Perper, M.D., to renew or modify any of his registrations, be, and they hereby are denied. This Order is effective immediately.

Dated: October 8, 2012.

Michele M. Leonhart,

Administrator.

Frank Mann, Esq., for the Government
Richard G. Lubin, Esq. & *Anthony Vitale, 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 Administrator, Drug Enforcement Administration (''DEA'' or ''Government''), issued an Order to Show Cause and Immediate Suspension of Registration (''Order I'') dated February 18, 2011, proposing to revoke the DEA Certificate of Registration, Number FP1312406, of Zvi H. Perper, M.D., (''Respondent'' or ''Dr. Perper''), as a practitioner, pursuant to 21 U.S.C. § 824(a)(4) (2006), and deny any pending applications for renewal or modification of such 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). Order I 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 Administrator, Drug Enforcement Administration, issued a second Order to Show Cause and Immediate Suspension of Registration (''Order II'') dated March 4, 2011, proposing to revoke the DEA Certificates of Registration, Numbers BP7732349,[6] BP7622764,[7] BP7622752,[8] BP3429835, and BP8477639, of Dr. Perper, as a practitioner, pursuant to 21 U.S.C. § 824(a)(4) (2006), and deny any pending applications for renewal or modification of such registrations 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). Order II also immediately suspended these registrations pursuant to 21 U.S.C. § 824(d), because the Respondent's continued registration constituted an imminent danger to the public health or safety. [ALJ Exh. 3].

The Respondent was served with the Order II on March 7, 2011. [ALJ Exh. 2].

The Orders asserted that the Respondent dispensed controlled substances to undercover law enforcement officers for other than a legitimate medical purpose and/or outside the usual course of professional practice. [ALJ Exh. 1]. Further, the Orders also alleged that Respondent's Physician's Assistant coached an undercover law enforcement person on how to procure large amounts of narcotics from pharmacies without ''arousing suspicions that the prescriptions were being issued for other than legitimate medical purposes.'' [ALJ Exh. 1 at 2].

By letter dated March 15, 2011, the Respondent, through counsel, timely filed a request for a hearing in the above-captioned matter. [ALJ Exh. 4].

At the Respondent's request, the hearing was held in St. Lucie, Florida, on May 18–19, 2011. [ALJ Exh. 6; Transcript (''Tr.'') Volume I–II]. At the hearing, Counsel for the DEA called witnesses to testify and introduced documentary evidence. The Respondent, through Counsel, elected not to present any evidence. [Tr. 346]. After the hearing, both Counsel 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 evidence that the Drug Enforcement Administration should revoke the DEA Certificate of Registrations, Numbers FP1312406, BP7732349, BP7622764, BP7622752, BP3429835, BP8477639, of Zvi H. Perper, M.D., (''Respondent''), as a practitioner, pursuant to 21 U.S.C. § 824(a),

[5] As explained in *Medicine Shoppe-Jonesborough,* where, as here, ''the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must 'present[] sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.'" 73 FR at 387 (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988)). Moreover, because ''past performance is the best predictor of future performance, *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.'' *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Prince George Daniels,* 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination).

[6] This registration expired by its own terms on March 31, 2011, and the Respondent did not file an application to renew it. [Tr.293–94, 323; Govt. Exh. 1].

[7] This registration expired by its own terms on March 31, 2011, and the Respondent did not file an application to renew it. [Tr. 297, 323–324; Govt. Exh. 1].

[8] This registration expired by its own terms on March 31, 2011, and the Respondent did not file an application to renew it. [Tr. 297, 324; Govt. Exh. 1].

and deny any pending applications for renewal or modification of such registrations, pursuant to 21 U.S.C. § 823(f), because his continued registrations would be inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). [Tr. 8; ALJ Exh. 5].

III. FINDINGS OF FACT

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

A. Stipulated Facts

The parties have jointly agreed to the following stipulated facts:

1. Respondent is registered with DEA as a practitioner in Schedules II–V under DEA registration numbers FP1312406, BP7732349, BP7622764, BP7622752, BP3429835, and BP8477639 at the following locations, respectively: (1) Delray Pain Management, 102 N. Swinton Avenue, Delray Beach, Florida 33444; (2) Women's Center of Hyde Park, LLC, 502 S. Magnolia Avenue, Tampa, Florida 33606–2257; (3) 1103 Lucerne Terrace, Orlando, Florida 32806; (4) 609 Virginia Drive, Orlando, Florida 32803; (5) 3025 Andrews Place, Boca Raton, Florida 33234; and (6) Ocala Womens Center, 108 NW Pine Avenue, Ocala, Florida 34475. [ALJ Exh. 5].

2. DEA registration Nos. BP7732349, BP7622764, and BP7622752 expire by their terms on March 31, 2011; DEA registration Nos. FP1312406 and BP8477639 expire by their terms on March 31, 2012; and DEA registration No. BP3429835 expires by its terms on March 31, 2013. [*Id.*{.

3. Respondent is currently licensed in the State of Florida as a Medical Doctor (Dispensing Practitioner), Lic. No. ME 65525, expiration date: 1/31/2013. [*Id.*].

B. Background Facts

4. The Respondent works at Delray Pain Management (''clinic''). The clinic disqualified some patients because of the distance they had to travel to get to the clinic. [Tr.183].

5. In 2009, the Respondent ordered 321,600 dosage units of oxycodone. [Tr. 318; Government Exhibit (''Govt. Exh.'') 14 at 3]. From January 1 to June 30 of 2010, the Respondent ordered 387,248 dosage units of oxycodone. [Tr. 318–19; Govt. Exh. 14 at 4]. Based on these purchases, the Respondent ranked 22nd in the nation regarding practitioners purchasing oxycodone. [Tr. 319].

6. The Respondent accepted cash for office visits and prescriptions. [Tr. 320–323; Govt. Exh. 34].

7. The record does not contain any legal documents indicating the ownership of Delray Pain Management. Mr. Kent Murray appears to have been the owner of the pain clinic for some time, but the Respondent acted as either the general manager or also the owner of the clinic. [Tr. 326–329].

8. The clinic requires a valid Florida identification for the patients seen there. [Tr. 332].

9. The clinic also requires each patient to provide an MRI. [Tr. 332–33]. The MRIs of Mr. Hays and Mr. Martinez were verified by an individual named Lynette or Lynn. [Tr. 334–35; Govt. Exh. 12 at 16; Govt. Exh. 13 at 12].

10. Both undercover agents were required to take a urinalysis examination on their first visit. [Tr. 335].

11. Each new patient at the clinic was required to give a medical history with an emphasis on their pain complaint. [Tr. 336]. The undercover agents, on their first visits, had a face-to-face meeting with the Respondent. [Tr. 336].

C. Dr. Rubenstein's Testimony

12. Dr. Rubenstein, a medical doctor, is board certified in Physical Medicine in Rehabilitation, in Pain Medicine, and in Electrodiagnostic Medicine. [Tr. 20; Govt. Exh. 25 at 1]. Dr. Rubenstein has a private practice focused on his specialties, and he is licensed to practice medicine in Florida and Virginia. [Tr. 23]. Approximately 90 percent of his patients have some type of pain complaint. [Tr. 24].

13. He also has two certificates, one as a Diplomate of the American Academy of Pain Management, and Board Certification through the American Board of Medical Specialties, with a sub-specialty in Pain Medicine. [Tr. 21]. He has been practicing pain medicine since 1993. [*Id.*].

14. Dr. Rubenstein holds four academic appointments and teaches pain medicine at each one. [Tr. 22].

15. Dr. Rubenstein was qualified as an expert in pain management and pain medicine. [Tr. 24].

16. Prior to rendering his opinion concerning the Respondent's prescribing of controlled substances, Dr. Rubenstein reviewed the medical records reporting the treatment of two individuals, David Hays [9] and Eddie Martinez.[10] Dr. Rubenstein also reviewed the transcripts of their visits with the Respondent. [Tr. 29–30, 34; Govt. Exhs. 12 and 13, 2–11].

D. Treatment of David Hays

17. David Hays first visited the Respondent on April 21, 2010. [Govt. Exh. 12 at 5; Govt. Exh. 15]. On that date, Mr. Hays' chart [11] notes a drug screen was taken with negative results for all tested substances, to include opiates. [Tr. 123–24; Govt. Exh. 12 at 8]. At none of the other visits, after controlled substances were prescribed, did the Respondent require a urinalysis screen. [Govt. Exhs. 3–7, 9–11].

18. In his medical history forms, Mr. Hays reported taking over-the-counter anti-inflammatories such as Advil or Motrin. [Govt. Exh. 12 at 9–10]. From the medical history, Dr. Rubenstein concluded that he had not taken opiates in the past. [Tr. 40–41]. The urinalysis results corroborated this conclusion as to the immediate past. [Tr. 96].

19. The medical history form also indicated that Mr. Hays did not have a primary physician, and that his last physical examination was in August 1980. [Govt. Exh. 12 at 4].

Mr. Hays also wrote that he had never taken opiates before. [Govt. Exh. 12 at 11].

20. Mr. Hays also signed an agreement regarding his responsibilities in taking medications that may be prescribed (''Agreement''). The Agreement informed Mr. Hays of his agreement to random drug testing, to only receiving pain medications from the Respondent, to understanding that lost medications will not be refilled, and to keeping referral appointments should the Respondent make such a referral. The Agreement also defines actions Mr. Hays may take that would result in his being discharged from the practice. Such actions include selling or distributing prescribed medications, obtaining pain medication from a source other than ''my doctor,'' forging or altering a prescription, or failing to receive any therapeutic benefit from the pain medication. Mr. Hays and the Respondent signed this Agreement on April 21, 2010. [Tr. 41–42; Govt. Exh. 12 at 12].

21. At the initial visit there was no evidence that Mr. Hays was doctor shopping. [Tr. 97].

22. Mr. Hays' medical history also disclosed, in response to questions asked on the form, that his pain was sharp and had been with him for three years, and that his pain interfered with work, sleep, and daily activities. [Tr. 190–93; Govt. Exh. 12 at 10]. However, the form did not provide space for Mr. Hays to discuss the basis for his answers to these questions, and nowhere else in the medical record are these concerns addressed. [Tr. 42–43; Govt. Exh. 12 at 10–11].

23. When asked on the intake form if Mr. Hays had provided honest and valid medical records to the clinic, he answered ''Yes.'' [Tr. 193]. As for his treatment goals, Mr. Hays wrote that he wanted to ''work better''. [Tr. 193]. Mr. Hays also wrote and told the Respondent that the pain interfered with his self-esteem, his overall energy, and his ability to perform physical activities. [Tr. 193–94, 198; Govt. Exh. 12 at 11]. Mr. Hays also told the Respondent that his back ''hurt.'' [Tr. 200]. However, none of these complaints, other than pain, was discussed with Mr. Hays. [Govt. Exh. 2].

24. Mr. Hays' magnetic resonance imaging (''MRI'') report noted that there was ''L4/5 and L5/S1, small protrusions with annular bulge and no nerve effacement.'' [Tr. 44; Govt. Exh. 12 at 16]. Per Dr. Rubenstein, the MRI report, alone, does not justify prescribing of narcotics on April 21, 2010. [Tr. 46]. This MRI, ''in and of itself, (doesn't) define necessarily a pain generator, maybe a potential pain generator, that needs to be related to the patient's history and physical examination.'' [Tr. 46].

25. Mr. Hays' basic complaint was low back stiffness, having never said pain during the physical examination. [Tr. 129, 189]. Low back pain is a diagnosis, however. [Tr. 47]. Mr. Hays explained that he restored BMW motorcycles, and his back was ''stiff and jammed up and all.'' [Govt. Exh. 2 at 22]. He agreed, however, that his pain had worsened over the last three years. [Govt. Exh. 2 at 23]. He managed his pain with over-the-counter

[9] David Hays is the undercover name used by Special Agent Jack Lunsford. For consistency with the documentary exhibits, I will refer to this individual as Mr. Hayes. Since this investigation, SA Lunsford has retired from the DEA. [Tr. 118, 179, 308].

[10] Eddie Martinez is the undercover name used by Special Agent Eddie Brigantty. [Tr. 308].

[11] The Respondent maintained a medical record for Mr. Hays. [Govt. Exh. 12].

medications like Aleve. He denied currently taking any medications or having taken medications in the past year. [Govt. Exh. 2 at 23, 27]. The Respondent then instructed Mr. Hays that he only gives prescriptions for one month and that Mr. Hays must only be seen by him. [*Id.* at 25].

26. Next, the Respondent physically examined the patient. [*See id.* at 27]. The Respondent noted that Mr. Hays experienced ''no pain with straight leg raising bilaterally and normal motor and sensory.'' [Govt. Exh. 12 at 14]. Dr. Rubenstein opined that this would represent a limited neurologic exam for this patient. [Tr. 47]. But the results were ''normal,'' and Dr. Rubenstein opined that he did not see ''what the justification is, then, to even treat (him) if the exam is normal.'' [Tr. 98].

27. As part of the physical examination, the Respondent noted that there was a ''positive, moderate tenderness at L5/S1.'' [Tr. 48]. In response to the question of whether his pain was in his lower back, Mr. Hays responded ''yes.'' [Tr. 203]. However, Dr. Rubenstein noted that Mr. Hays did not complain of pain or tenderness during the physical examination, and such a complaint would need to be made for the Respondent to make such a legitimate observation. [Tr. 49].

28. The Respondent diagnosed Mr. Hays with ''chronic lumbar pain with bulge L4–5 and L5/S1 with protrusions. No radiculopathy.'' [Tr. 48; Govt. Exh. 12 at 14]. During the visit, the Respondent discussed a back brace that Mr. Hays could use, and he even showed Mr. Hays how to wear the belt. [Tr. 204; Govt. Exh. 2 at 32–40].

29. Mr. Hays paid $250.00 cash for an examination fee at this first visit. He was a ''walk-in patient'' without an appointment. [Tr. 121, 178].

30. On April 21, 2010, the Respondent prescribed Percocet 10/325 in a quantity of 150, to be taken every four to six hours. [Govt. Exh. 12 at 17]. Dr. Rubenstein opined that the ''doses and frequency of the medication were excessive. . . Percocet 10 milligrams would be excessive for an opioid naïve patient . . . and that quantity of medication would be excessive given the patient's pain complaints and lack of any objective pathology on physical examination.'' [Tr. 52]. Although muscle spasm may be expected given this diagnosis, opiates are not often given as a result of this observation. [Tr. 55–56].

31. Mr. Hays purchased 150 Percocet tablets and paid $195.00 cash for them. [Tr. 130, 178].

32. Mr. Hays next visited the Respondent, unscheduled, on April 28, 2010. On that date the Respondent wrote in Mr. Hays' medical records that the patient had complained of severe stomach upset and that the Percocet did not relieve his pain. The Respondent then prescribed Roxycodone, 30 milligrams, 150 dosage units to be taken as needed for pain. [Tr. 52, 150; Govt. Exh. 12 at 14, 18].

33. Yet Mr. Hays told the Respondent that the prior medication ''doesn't seem to be having the total effect I expected. And another side thing it does is it, it's giving me some kinda like-digestive-anxiety or something. I'm always feeling kinda unsettled.'' Later in the conversation, Mr. Hays stated that the medication ''[k]inda makes me not want to eat.'' [Govt. Exh. 3A at 11–12; *see also* Tr. 312; Govt. Exh. 16]. When asked about the Flexeril, Mr. Hays responded that ''I don't know that it does anything at all.'' [Govt. Exh. 3A at 13]. He was not asked if the Percocet relieved his pain, and he did not comment about the Percocet and pain. [Tr. 145; Govt. Exh. 3A]. Yet Mr. Hays medical chart contained the statement that the prior prescription had provided ''no relief (from) pain.'' [Govt. Exh. 12 at 14. Mr. Hays denied making such a statement, and no such statement appears on the recording or in the transcript. [Tr. 145; *see also* Govt. Exh. 3A and 16A]. Dr. Perper did not ask Mr. Hays whether he still had pills from the earlier script for Percocet, nor did he instruct him what to do with those remaining pills, if they existed. [Govt. Exh. 3A at 12, 16].

34. Dr. Rubenstein disagreed with this prescription, noting that the medication ''would have not been indicated given the complaints of the patient, certainly not that particular agent and certainly not that dose or frequency.'' [Tr. 54].

35. Mr. Hays did not pay anything for this visit. [Tr. 178].

36. On May 19, 2010, Mr. Hays visited with Mitchell Cohen, a physician's assistant at the Respondent's clinic. [Tr. 151, 312; Govt. Exh. 17 and 17A]. Mr. Hays reported that his pain was between zero to five on a ten point scale, and it was completely alleviated by taking the prescribed medication of six Roxycodone 30 milligram tablets per day. [Tr. 56; Govt. Exh. 12 at 21–22]. Mr. Hays rated his average pain as a ''2'' for the prior month, and rated his current pain level as ''no pain''. [Tr. 152; Govt. Exh. 12 at 22]. He also wrote ''was in lower back; gone now.'' [*Id.*]. Mr. Hays told Mr. Cohen that his lower back was ''no problem at all'' and denied having any side effects from the medication. [Govt. Exhs. 4 at 18, 17A]. He did state, however, that his symptoms ''might come back if (he) didn't have medication.'' [Govt. Exh. 4 at 19; Govt. Exh. 17A].

37. Mr. Cohen performed a cursory physical examination, asking him to raise and lower his legs, declaring that Mr. Hays' back felt ''a little tight'' but not ''horribly bad.'' [Govt. Exh. 4 at 21; Govt. Exh. 17A]. During this examination, Mr. Hays expressed no pain or discomfort. He also denied any anxiety or sleep problems. [Govt. Exh. 17A]. Here, Mr. Cohen asked about Mr. Hays'earlier prescription for Percocet, which Mr. Hays stated he still had. Mr. Cohen then instructed him to flush those pills and not to give them to anyone. [Govt. Exh. 4 at 22].

38. Mr. Hays requested a larger amount of pain medication, because he was joining a tugboat crew and would be gone for three months. [Tr. 156; Govt. Exh. 17A]. Mr. Cohen refused to approve this request and advised Mr. Hays to ''stretch out'' his medication by breaking it in half and ''tak(ing) some Advil in between.'' [Govt. Exhs. 4 at 24, 17A]. Mr. Cohen then offered to give Mr. Hays some 15 mg. strength oxycodone tablets instead of increasing the number of 30 mg. strength tablets prescribed to Mr. Hays. Mr. Hays again requested a greater quantity of Roxicodone (30 mg pills) as well as the 15 mg. oxycodone pills. [Govt. Exh. 4 at 24; Govt. Exh. 17A]. Mr. Cohen agreed to speak to the Respondent, whom Mr. Cohen later stated had been ''very generous'' in his prescribing to Mr. Hays. [Govt. Exh. 4 at 31–32; Govt. Exh. 12 at 23; Govt. Exh. 17A]. Ultimately, the Respondent added a prescription for 15 mg. strength oxycodone to Mr. Hays' 30 mg. prescription. [Govt. Exh. 12 at 20].

39. On this date, Mr. Hays received two prescriptions signed by the Respondent; one for Roxycodone 30 mg, 210 tablets, and one for Roxycodone 15 mg., 90 tablets. [Tr. 164; Govt. Exh. 12 at 23]. Mr. Cohen told Mr. Hays not to return to the clinic until after July 4. [Tr. 157; Govt. Exh. 4 at 31].

40. Mr. Hays paid $175.00 for this visit and $510.00 for the medication. [Tr. 178].

41. On June 16, 2010, Mr. Hays reported, and the Respondent acknowledged that Mr. Hays' lower back pain ranged from zero to four out of ten, with an average pain level of two, and a current pain level of one. [Tr. 58; Govt. Exh. 12 at 24, Govt. Exh. 5]. Mr. Hays circled on his intake form that his pain was ''gnawing'' and ''nagging.'' [Tr. 209; Govt. Exh. 12 at 24].

42. There was no discussion about Mr. Hays returning to the clinic before July 4. [Tr. 165].

43. During this visit, the Respondent again remarked that he was due to set out on a three month tug boat excursion, and asked for additional pills to tide him over. The Respondent noted that Mr. Hays was going through his medication rather quickly. [Govt. Exh. 5 at 17]. The Respondent asked Mr. Hays whether his break-through pain was mostly with work. Mr. Hays had not complained of break-through pain, however. [Tr. 166; Govt. Exh. 5 at 17]. Yet, at this visit he received a prescription for 210 Roxycodone 30 mg and 90 Roxycodone 15 mg., with ''break through pain'' written on the bottom. [Govt. Exh. 12 at 26].

44. Mr. Hays was prescribed a liver function test. [Tr. 210; Govt. Exh. 12 at 26]. However, Mr. Hays did not get such a test. [Tr. 210].

45. Mr. Hays paid $175.00 for this visit and $638.00 for his medication. [Tr. 178].

46. On July 20, 2010, Mr. Hays returned to the clinic. [Tr. 169; Govt. Exh. 6]. He met with Mitchell Cohen on that date. [Tr. 170]. Mr. Hays reported that his lower back pain ranged from zero to three out of ten, with complete relief after taking seven oxycodone [12] 30 milligram tablets and three oxycodone 15 milligram tablets per day. [Tr. 57; Govt. Exh. 12 at 29–30]. When asked if his lower back had improved with the medicine, Mr. Hays said that he thought it had improved. [Govt. Exh. 6 at 4].

47. On this date, the Respondent [13] prescribed Dilaudid four milligrams, 60 tablets to be taken one, twice daily, as needed for breakthrough pain. [Tr. 59; Govt. Exh. 12

[12] Roxycodone is a medication containing oxycodone. [Tr. 83].

[13] Although Mr. Cohen saw Mr. Hays, the prescriptions bore the Respondent's signature. [Govt. Exh. 12 at 3].

at 31]. He also signed two prescriptions [14] for Roxycodone 30 mg., one for 120 tablets and one for 90 tablets. [Govt. Exh. 12 at 31]. However, after reviewing the medical records for this date, there was no evidence that Mr. Hays was experiencing any breakthrough pain. [Tr. 60].

48. This shift of medication to Dilaudid was not justified according to Dr. Rubenstein. [Tr. 60]. Further, Dr. Rubenstein noted that no neurological musculoskeletal exam had been performed, and that Mr. Hays had violated his pain contract by allowing his girlfriend to share his medications. [Tr. 39–41; Govt. Exh. 12 at 12]. Dr. Rubenstein agreed that sharing medication with a girlfriend would be a violation of the Agreement. [Tr. 42]. In reviewing Mr. Hays' medical chart, Dr. Rubenstein found that ''drug-seeking behavior is suspected.'' [Tr. 95].

49. On this date, Mr. Hays told Mr. Cohen that his girlfriend ''got into [his] medication'' and ''liked it.'' [Tr. 170–71; Govt. Exh. 6 at 5; Govt. Exh. 19 and 19A]. Next, Mr. Hays said that his girlfriend wanted to come to the Respondent's clinic, but he was unsure whether she had a ''valid reason'' for requesting medication. [Govt. Exh. 6 at 5–6]. Mr. Hays also admitted that his own medication made him euphoric. [Govt. Exh. 6 at 6]. Mr. Cohen took no action in response to these comments except to tell Mr. Hays that the Respondent would not see his girlfriend unless she had a ''valid reason.'' [Govt. Exh. 6 at 6]. Mr. Cohen further stated that if Mr. Hays' girlfriend ''has a legitimate area of pain'' that is ''proven with an objective test . . . like an MRI, then no problem.'' [Govt. Exh. 6 at 6–7]. Mr. Cohen made no response to the news that Mr. Hays' girlfriend had gotten into his medication or that Mr. Hays experienced euphoria from his controlled substances. [*Id.*]. During this visit, Mr. Cohen also had a long conversation with Mr. Hays about the price of medication and where to have his prescriptions filled. Mr. Cohen advised Mr. Hays that ''at this level,'' he should not go to large chain pharmacies and that the clinic would provide him with a list of places to go. [Govt. Exh. 6 at 7–14]. Mr. Cohen then indicated that he would give him a script for Motrin, even though he already had two refills, because otherwise the script for controlled substances would not be filled by the pharmacy. [Govt. Exh. 6 at 14–15]. Then Mr. Cohen asked Mr. Hays how he would like his ''pills split.'' [Govt. Exh. 6 at 16].

50. Mr. Hays spent $200.00 cash for this visit. [Tr. 178].

51. On August 18, 2010, Mr. Hays returned to the clinic and met with Mitchell Cohen. [Tr. 174–75; Govt. Exh. 7; *see also* Tr. 314; Govt. Exh. 20]. Mr. Hays spent $200.00 for this visit. [Tr. 178].

52. Mr. Hays reported that his back pain ''feels better now,'' with a pain level from zero to three out of ten, averaging two, and a present rating of one. [Tr. 59; Govt. Exh. 12 at 33–34]. Further, during a physical exam where Mr. Cohen told Mr. Hays to move his legs up against Mr. Cohen's hand, Mr. Hays indicated that neither action caused him any discomfort or pain. [Govt. Exh. 7 at 30–31; Govt. Exh. 20]. He told Mr. Cohen that his girlfriend knew of a place for him to get prescriptions filled.

53. On this date, Mr. Hays asked Mr. Cohen whether there was some other ''creative way that he could deal with him.'' [Govt. Exh. 7 at 28]. To this Mr. Cohen responded, ''Are you having trouble sleeping? Is that what you're getting at?'' [*Id.*]. Mr. Hays replied, ''ummm….you know. I wonder . . . I do have trouble sleeping. I don't sleep much . . .'' [*Id.*]. Mr Cohen then asked if Mr. Hays had ever tried Valium and if he'd like to this month. [*Id.*]. The Respondent prescribed Roxycodone 30 mg, 210 tablets, Percocet 10 mg., 60 tablets for break-through pain, and Valium 10 mg., 30 tablets. [Tr. 177; Govt. Exh. 12 at 35]. Although the treatment note documented Mr. Hays' insomnia and noted that he was to take one Valium at bedtime only, Dr. Rubenstein opined that ''there was nothing that would justify that dose . . . for this individual.'' [Tr. 61–62; *see also* Govt. Exh. 7 at 28]. Rather, Dr. Rubenstein stated that the ''first reasonably standard thing to do would be to ensure that the patient wasn't doing anything or taking anything that may be promoting insomnia . . .'' [Tr. 62]. Dr. Rubenstein objected to the fact that the Respondent prescribed Valium at the highest available dose, which would be a very high dose, and ''its primary purpose is not for insomnia.'' [Tr. 63].

54. The Respondent had told Mr. Hays to obtain a liver function test, yet the medical records fail to indicate that such a test was taken. [Tr. 68]. Mr. Cohen also emphasized at this visit that the Respondent should get the test, and he told the Respondent where he could go and the cost of the test. [Govt. Exh. 7 at 24–25]. Dr. Rubenstein opined that he would be concerned about Mr. Hays' lack of compliance with the test recommendation, as well as being concerned about the possible liver toxicity that results from the medications being prescribed to Mr. Hays. [Tr. 68, 102–03].

55. Mr. Hays also told Mr. Cohen that he was not experiencing any side effects from the medication and that he felt ''real good'' now and was able to work better. [Tr. 212].

56. Dr. Rubenstein ultimately opined that, after reviewing the transcripts of the visits, the medical records, and the recording of the first visit, he did not believe the prescribing of controlled substances was within the acceptable standard of care, given the quantities and frequency of such prescriptions. [Tr. 68–69]. There was also a problem with patient safety because of the large dose of controlled substances prescribed at the initial visit. [Tr. 52, 69]. He also opined that the prescribing of controlled substances to Mr. Hays was not based on sound clinical grounds. [Tr. 69]. Dr. Rubenstein would not consider the prescribing appropriate, given ''the history and physical examination and objective information.'' [Tr. 69–70]. Thus, this prescribing of these controlled substances was outside the usual course of professional practice and without a legitimate medical purpose. [Tr. 70].

57. Further, Dr. Rubenstein did not find any evidence that the Respondent discussed the risk and benefits of the use of controlled substances with Mr. Hays. [Tr. 70].

58. Lastly, Dr. Rubenstein identified numerous ''red flags'' indicating potential diversion and/or abuse of controlled substances. [Tr. 65]. The Respondent seemed to ignore these red flags, for there was no reaction to Mr. Hays' constant requests for more narcotic medication or his sharing of medication with a girlfriend. [Tr. 65; *see also* Govt. Exhs. 3A at 7]. Also, no mention was made of Mr. Hays' visit before July 5, 2010. [Tr. 68].

E. Treatment of Eddie Martinez [15]

59. Mr. Martinez was first treated by the Respondent on June 10, 2010. He did not have an appointment. [Tr. 73, 226; Govt. Exh. 13; *see also* Tr. 314; Govt. Exh. 21 and 21A]. Digital audio and video recordings were made of the visit. [Govt. Exh. 21 and 21A]. A transcript of the audio recording was also made. [Govt. Exh. 8].

60. On the intake documentation,[16] Mr. Martinez answered ''yes'' to several of the questions asked in reference to his pain information. [Govt. Exh. 13 at 4]. However, the form did not provide space for Mr. Martinez to discuss his ''yes'' answers, and nothing in the medical record indicates that the Respondent discussed these questions with Mr. Martinez. [Tr. 73; Govt. Exh. 13]. The Respondent did not discuss the lack of information in Mr. Martinez documentation, for he did not list an emergency contact or a previous doctor. [Govt. Exh. 13 at 1]. When asked to note how long he had been on opiates, Mr. Martinez left that question blank. He also left blank the questions asking if he had taken a list of controlled substances. [Govt. Exh. 13 at 4]. He never described the duration of his pain or whether it was constant. [Govt. Exh. 13 at 2]. On the intake documents, Mr. Martinez denied taking Motrin, Advil, Aleve, or Naproxyn [Govt. Exh. 13 at 4], but then told the Respondent that he had tried taking at least some of those drugs. [Govt. Exh. 8 at 13–14]. Mr. Martinez even admitted that over-the-counter medications provided ''temporary'' relief. [Tr. 228; Govt. Exh. 13 at 14].

61. Yet the Respondent did enter into a physician-patient relationship with Mr. Martinez. [Tr. 92]. He had a face-to-face meeting with Mr. Martinez, and he kept medical records and evidence of the prescriptions he wrote to Mr. Martinez. [Tr. 92; Govt. Exh. 13].

[14] Instead of writing one prescription for 210 Roxicodone tablets, the prescriptions were divided into two separate prescriptions, one for 120 tablets and one for 90 tablets. Mr. Cohen advised Mr. Hays to hand in one of the prescriptions, then ''wait a couple of days or a week and go hand in the other one.'' [Govt. Exh. 6 at 13; Govt. Exh. 19 and 19A]. In this way Mr. Cohen advised Mr. Hays in how to avoid arousing suspicion when presenting his prescriptions to a pharmacy. Further, Mr. Cohen gave Mr. Hays a prescription for ibuprofen, saying that by providing a prescription for a non-controlled substance, he could waylay such suspicion, if needed. If the ibuprofen prescription was not needed in this way, Mr. Hays was to shred the prescription. [Govt. Exh. 6 at 15].

[15] Eddie Martinez is the undercover name of Special Agent Ed Brigantty. [Tr. 218, 221 308].

[16] The Respondent maintained a medical record for Mr. Martinez. [Govt. Exh. 13].

62. Mr. Martinez told the Respondent that he had pain in his leg and his back, and that the pain is worse in the morning. [Tr. 259]. On the pain assessment form, Mr. Martinez had circled his neck and upper spine as the locations for his pain. [Tr. 229–30, 259; Govt. Exh. 13 at 4]. Mr. Martinez told the Respondent that when he would lay down flat on a hard surface, that helped his pain. [Tr. 259].

63. Mr. Martinez signed a pain management agreement. [Govt. Exh. 13 at 5]. Mr. Martinez agreed not to obtain pain medications from any other sources other than the Respondent. [Tr. 74]. Dr. Rubenstein agreed that, if a patient stated that he had purchased illegally pain medications on the street, the patient would have violated this provision of the pain agreement. [*Id.*].

64. Mr. Martinez's urinalysis report was negative for all substances tested, to include opiates. [Tr. 96; Govt. Exh. 13 at 6]. After controlled substances were prescribed, at follow-up visits, the Respondent did not require any other urinalysis tests. [Tr. 112, 231, 249].

65. Mr. Martinez told the Respondent that his pain started ten years ago and ''slowly and surely got worse.'' [Govt. Exh. 8 at 11]. The Respondent asked him about his work, his other medications, and symptoms, and whether he saw any other physicians. [*Id.* at 12–14]. The Respondent conducted a physical examination of Mr. Martinez, which consisted of his raising his arm and leg and the Respondent asking if it hurt in various places on his body. [Tr. 227]. At no time did Mr. Martinez indicate he was experiencing any significant pain. [Govt. Exh. 8 at 16–17; *see also* Govt. Exhs. 21 and 21A]. Yet, compared to his MRI, Mr. Martinez's statements were contradictory. Though he circled areas on a diagram that corresponded to his center back and neck, he told the Respondent he was feeling pain ''[m]ore on my left.'' [Govt. Exh. 8 at 15; Govt. Exh. 13 at 4]. In the written documentation, Mr. Martinez had denied any ''lower back problems.'' [Govt. Exh. 13 at 2]. The Respondent did not address these inconsistencies.

66. The radiologist, interpreting an MRI of Mr. Martinez dated May 27, 2010, found a disc bulge at L3–4 which approached the canal where the nerve leaves at that level, but there was no evidence that the spinal cord was encroached. [Tr. 75; Govt. Exh. 13 at 12]. The radiologist also noted that at L4–5, there was a disc bulge that touched the front of the region where the spinal cord sat. The disc bulge ''was narrowing the canals where the nerves would leave on either side between the fourth and fifth vertebrae of the lumbar spine.'' [Tr. 75–76]. Also, at L5/S1 there were similar findings of enchroachment on both sides. [Tr. 76]. Dr. Rubenstein credibly opined that an MRI, alone, does not justify the prescribing of controlled substances. [Tr. 76]. However, these MRI results could lead a doctor to believe that ''there were some significant changes in the lower back that could be a pain generator.'' [Tr. 104]. Dr. Rubenstein also found a significant disconnect between Mr. Martinez's complaints and the actual diagnosis. Dr. Rubenstein found that Mr. Martinez's complaints of pain in his middle back and neck were not consistent with the MRI. [Tr. 77].

67. The Respondent made a diagnosis of Mr. Martinez, finding ''chronic lumbar pain with stenosis, and in parentheses, spasm, multiple bulges with spondylosis with neural foraminal enchroachment, which is the NFE, canal stenosis and lumbosacral stenosis, which is the LSS. No radicular pain.'' [Tr. 77; Govt. Exh. 13 at 15]. Yet Dr. Rubenstein opined that this is a radiologic diagnosis based on the MRI, not on the complaint of Mr. Martinez, for he complained of pain in his cervical and thoracic region, not the lumbar region. [Tr. 77–78, 106; Govt. Exh. 13 at 4]. Such an inconsistency raised a ''pink'' flag for Dr. Rubenstein. [Tr. 79]. Neither the medical record nor the transcript of the patient visit contain evidence that the Respondent explored this inconsistency with Mr. Martinez. [Tr. 79; Govt. Exhs. 13, 8]. Dr. Rubenstein pointed out that the Respondent seemed only to treat the pathology included in the MRI, while ignoring the fact that Mr. Martinez had identified pain in his middle back and neck. [Tr. 106–07; Govt. Exh. 13 at 4].

68. Mr. Martinez had indicated on his intake forms that he had only taken over-the-counter medications and that they provided temporary relief. [Tr. 79, 228; Govt. Exhs. 8 at 13–14, 13 at 4]. He also told the Respondent that he had taken some ''blues'' [17] and that he had purchased them from someone that he knew had them. [Tr. 228; Govt. Exh. 8 at 12–13; Govt. Exh. 21 and 21A].

69. However, the Respondent prescribed controlled substances to Mr. Martinez on his first visit, Percocet 10mg, 120 tablets, totaling 1200 mg of oxycodone. [Tr. 81; Govt. Exh. 13 at 15–16]. Dr. Rubenstein thought such prescribing would not be appropriate. [Tr. 80]. Specifically, he credibly testified that ''I think the prescription was excessive and not warranted based on the history and physical examination presented.'' [Tr. 81].

70. Mr. Martinez paid $250.00 in cash for this visit and $156.00 for his medication. [Tr. 226, 232–33]. There was no explanation of his diagnosis and no discussion about physical therapy or any other modalities. [Govt. Exh. 8].

71. Next, Mr. Martinez saw Mr. Cohen on June 17, 2010. [Tr. 314; Govt. Exhs. 9, 22, 22A]. Mr. Martinez told Mr. Cohen that the medication did not agree with him and that he wanted a different prescription. [Tr. 233–34]. Mr. Cohen refused to prescribe another medication. He offered to give Mr. Martinez a shot of pain medication, but he refused the offer. [Tr. 234–35]. In answer to a question concerning how he had managed his pain prior to coming to the clinic, Mr. Martinez told Mr. Cohen that he bought ''stuff'' off the street. [Tr. 235–36]. Mr. Cohen advised Mr. Martinez that he would have to ''go back to'' purchasing controlled substances on the street. [Tr. 236; Govt. Exh. 9 at 4–5]. He insisted that Dr. Perper would not change a prescsription for a patient who came back a week later. [Govt. Exh. 9 at 3].[18]

72. Next, the Respondent treated Mr. Martinez on July 28, 2010. [Tr. 82, 238, 314; Govt. Exh. 13 at 19, Govt. Exhs. 10, 23]. Again, Mr. Martinez told the Respondent that he had gotten meds off of the street. [Govt. Exh. 10 at 13]. The Respondent prescribed Roxicodone 30 mg, 90 tablets, a total of 2700 mg of oxycodone. [Tr. 82; Govt. Exh. 13 at 19–20]. This prescription was an increase in the dosage strength of the oxycodone prescribed at the initial visit. [Tr. 83–84]. Again, Dr. Rubenstein found that such prescribing was not warranted, given the lack of any physical examination noting an abnormality ''or focal neurologic deficit to be consistent with his MRI finding or even his complaints.'' [Tr. 85]. Dr. Rubenstein would have expected the Respondent to 're-examine strengths, sensation and reflexes; or at a minimum strength and reflexes at subsequent visits with those types of complaints. And gait would be something I would expect him to assess, too, at least to a degree.'' [Tr. 114]. Yet the medical record fails to indicate that any of these tests were performed at subsequent visits. [Govt. Exh. 13].

73. Lastly, the Respondent saw Mr. Martinez on August 25, 2010. [Tr. 85, 314; Govt. Exhs. 13 at 23–24, Govt. Exhs. 11, 24, 24A]. Again, the Respondent increased the amount of oxycodone given to Mr. Martinez by prescribing Percocet 10mg, 60 tablets for break-through pain, Roxycodone, also an oxycodone containing medication, 30mg, 90 tablets, with a total of 3300 mg of oxycodone. [Tr. 85–86; Govt. Exh. 13 at 24]. The only justification given for increasing the dosage was that Mr. Martinez ran out of his medication early, had purchased controlled substances illegally,[19] and was still complaining of unrelieved pain. [Tr. 86; Govt. Exh. 11 at 20–21; Govt. Exh. 13 at 23]. The Respondent was clearly suspicious of Mr. Martinez, for when Mr. Martinez attempted to argue that the Respondent had decreased his medications, the Respondent urged him to ''do the math.'' [Govt. Exh. 11 at 21]. Yet, in response to Mr. Martinez's statement that he had to get more, the Respondent issued him another prescription for Percocet, the same medication that Mr. Martinez had told Mr. Cohen had made him ill. [Govt. Exh. 11 at 22; Govt. Exhs. 24 and 24A; Govt. Exh. 9 at 3–4].

74. Dr. Rubenstein opined that ''[j]ust simply his complaint of pain without a physical exam that would correlate with the need for same, wouldn't be a reason to titrate the medications.'' [Tr. 86]. Dr. Rubenstein concluded that, based on the history, physical, and objective information available in Mr. Martinez's file, the increase in medication was not a legitimate medical justification. [Tr. 86–87].

75. Dr. Rubenstein did not believe that the Respondent's prescribing of controlled substances to Mr. Martinez was within the acceptable standard of care. [Tr. 87]. The

[17] ''Blues'' are street slang for Roxicodone which contains oxycodone. [*See* Tr. 75].

[18] Although this is inconsistent with Dr. Perper's treatment of David Hays. [*See* FOF 30–33].

[19] The Respondent made no comment regarding this break of the pain management agreement. [Tr. 245–46].

Respondent's prescribing demonstrated a lack of reasonable safety given Mr. Martinez's complaints. [Tr. 87–88].

76. Further, Mr. Martinez had also told the Respondent that he had purchased controlled substances on the street. [Tr. 88–89, 245–46; Govt. Exh. 11 at 20]. Per Dr. Rubenstein, the Respondent's prescribing of controlled substances did not evidence the diligence needed to prevent the risk of diversion or to monitor for such risk. [Tr. 88–89].

77. The Respondent told Mr. Martinez to get a liver function test, but Mr. Martinez did not do that. [Tr. 249–50]. Dr. Rubenstein was concerned that the Respondent failed to consider any treatment options other than prescribing controlled substances. For instance, Mr. Martinez had stated that over-the-counter medications provided ''temporary'' relief, yet no such approach was attempted. [Tr. 79–80].

78. In total, Dr. Rubenstein concluded that ''I don't believe that this patient's history and physical met that criteria for those prescriptions.'' [Tr. 90].

F. The Respondent

79. The Government called the Respondent as a witness, and he asserted his Fifth Amendment rights against self-incrimination and refused to answer any questions beyond stating his name and business address. [Tr. 116–117].

G. Audit

80. Diversion Investigator Janice Barnes (''DI Barnes'') conducted an accountability audit based on the Respondent's records. [Tr. 280–81]. Specifically, she reviewed the Respondent's inventory records of controlled substances on hand, receiving records to include DEA Form 222 for Schedule II controlled substances, and dispensing records, to include prescriptions. [Tr. 281–82].

81. The audit covered the timeframe of March 2, 2010, to February 23, 2011. The beginning inventory came from the Respondent's computerized inventory. The beginning inventory and the amount of controlled substances received during the audit period are added together to reflect the total number of controlled substances for which the Respondent would be accountable. [Tr. 283]. For oxycodone 30 mg. that total number accountable was 199,752. [Tr. 283; Govt. Exh. 32]. On the date of the closing inventory, February 23, 2011, the Respondent had no controlled substances on hand. [Tr. 284; Govt. Exh. 32]. The Respondent was able to account for, using his prescriptions, 180,559 tablets of oxycodone 30 mg. [Tr. 284; Govt. Exh. 32]. Thus, he did not have records showing the dispensing of 19,193 tablets of oxycodone 30 mg. [Tr. 284; Govt. Exh. 32]. However, after verifying the receiving documents with the Respondent's suppliers, in fact the Respondent should have received an additional 4800 tablets of oxycodone 30 mg. [Tr. 285; Govt. Exh. 32 at 2]. Thus, the Respondent was actually responsible for 202,980, and the total accountable is now 204,552 tablets. The Respondent's records still only showed his dispensing of 180,559 tablets, resulting in his being unable to account for 23,993 tablets of oxycodone 30 mg. [Tr. 286–87; Govt. Exh. 32 at 2].

82. Using the same computation method and the Respondent's records, the DEA's audit disclosed that the Respondent had an overage, and therefore, was unable to account for 4808 tablets of oxycodone 15 mg. [Tr. 288; Govt. Exh. 32 at 1]. However, using the suppliers' records, the Respondent was only unable to account for 8 tablets of oxycodone 15 mg. [Tr. 288; Govt. Exh. 32 at 2].

83. Using the same computation method and the Respondent's records, the DEA's audit disclosed that the Respondent was unable to account for 38 tablets of oxycodone 40 mg., 71 tablets of oxycodone 80 mg., 2,565 Endocet 10/325 mg. and 365 tablets of Endocet 10/650 mg. [Tr. 289–293; Govt. Exh. 32 at 1]. Although DEA personnel searched for records disclosing controlled substances returned from customers, returns to suppliers, thefts, or surrenders of controlled substances, no such records were found. [Tr. 291; Govt. Exh. 32 at 1].

84. Lastly, the DEA personnel were unable to find an initial inventory which should have been taken on the date the Respondent moved to the North Swinton Avenue address. [Tr. 294]. Even if the Respondent had no controlled substances on hand, he needed to take an initial, written inventory reflecting this zero balance. [Tr. 294].

IV. STATEMENT OF LAW AND DISCUSSION

A. Position of the Parties

1. Position of the Government

The Government asserts that the Respondent's DEA Certificates of Registration should be revoked. As a basis for that assertion, the Government argues that the Respondent prescribed controlled substances to patients without a legitimate medical purpose and outside the course of professional practice, in violation of DEA regulations and precedent. Further, the Respondent violated Florida law when he prescribed controlled substances after an inadequate physical examination and history which failed to justify such prescribing. [Government's Proposed Findings of Fact, Conclusions of Law and Argument (''Government's Brief'') at 26–28]. The medical records actually contained inaccuracies and possibly false statements, the Government argues. [*Id.*]. Further, the Respondent failed to discuss the risks and benefits of using controlled substances, and he failed to refer Mr. Hays and Mr. Martinez for ''additional evaluation and treatment.'' [Government's Brief at 26–27].

Next the Government asserts that the Respondent issued controlled substance prescriptions knowing that his patients could be drug abusers or diverters. [Government's Brief at 27]. Prescribing under such circumstances ''constitutes prescribing outside the usual course of professional practice'' and is contrary to DEA regulations. [Government's Brief at 27]. Further, the Respondent increased the amount of controlled substances without a legitimate medical reason. The Respondent also prescribed additional types of controlled substances without medical justification. The Respondent ''demonstrated no skill when issuing prescriptions to the obviously opiate naïve DEA officers and issued those prescriptions without regard for their safety.'' [Government's Brief at 27–28].

The Government further asserts that the Respondent failed to follow the steps outlined in the Florida Administrative Code prior to prescribing pain medication. [Government's Brief at 28].

The Government also asserts that the Respondent violated DEA regulations when he failed to guard against diversion of controlled substances. The Respondent overlooked numerous instances of drug seeking behavior and prescribed controlled substances to such patients anyway. [Government's Brief at 28]. The Respondent's decision to keep providing those patients with controlled substance prescriptions increased the risk of illegal diversion. [Government's Brief at 29].

As for the actions taken by the physician assistant, Mr. Cohen, under both Florida law and DEA precedent, the Respondent is liable for Mr. Cohen's conduct. Mr. Cohen issued prescriptions for controlled substances signed by the Respondent, instructed Mr. Hays in ways to ensure pharmacists would fill controlled substances prescriptions, and he advised Mr. Martinez to go back to purchasing controlled substances on the street. The fact that Mr. Cohen performed these actions does not absolve the Respondent from his responsibilities in supervising Mr. Cohen. [Government's Brief at 29].

The Government argues that the Respondent's failure to maintain accurate medical records threatens the public health and safety. ''Moreover, Respondent's employment of a physician assistant who provides advice to patients to assist them in obtaining drugs for abuse and/or diversion is both troubling and inconsistent with the public interest.'' [Government's Brief at 30].

Lastly, the Respondent's failure to admit fault or to accept responsibility for his misconduct also weighs heavily in the public interest determination under DEA precedent. The fact that the Respondent neither testified nor presented any evidence to rebut the Government's *prima facie* case weighs in favor of revocation. The Government argues that an adverse inference should be taken from the Respondent's refusal to testify, and the record clearly lacks any evidence of mitigating circumstances to consider on the Respondent's behalf. In conclusion, the Government requests revocation of the Respondent's DEA Certificates of Registration. [Government's Brief at 30–32].

2. *Position of the Respondent*

The Respondent requests that his DEA Certificate of Registration be reinstated. He argues that the Government has failed to meet its burden of proof regarding his prescribing of pain medication; for he prescribed controlled substances for a legitimate medical purpose and in compliance with the standards set forth by the Florida Medical Board Guidelines. [Respondent Zvi H. Perper, M.D.'s Post-Hearing Brief (Resp. Brief) at 2,4,6]. Further, the Government has not met its burden of proof that the Respondent's registration is inconsistent with the public interest. [Resp. Brief at 6].

The Respondent next argues that the Court lacked subject matter jurisdiction of Certificate of Registration numbers BP7732349, BP7622752, BP7622764, BP3429835, and BP8477639 because the Order to Show Cause only addressed Certificate of Registration number FP1312406. He asserts that the DEA did not issue an Order to Show Cause for the remaining DEA registration numbers. [Resp. Brief at 2–3, 5].[20]

B. Statement of Law

Pursuant to 21 U.S.C. § 824(a)(4), the Deputy Administrator[21] 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.

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. Marvin L. Gibbs, Jr., M.D., 69 Fed. Reg. 18299, 18302 (DEA 2004) (citing Henry J. Schwarz, Jr., M.D., 54 Fed. Reg. 16,422 (DEA 1989)).

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 C.F.R. § 1301.44(e)]. The burden of proof shifts to the Respondent once the Government has made its prima facie case. [Medicine Shoppe, 73 Fed. Reg. 364, 387 (DEA 2008); Thomas Johnston, 45 Fed. Reg. 72,311 (DEA 1980)].

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)].

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 his actions and demonstrate that he will not engage in future misconduct.'' [*Medicine Shoppe,* 73 Fed. Reg. at 387; *see also* Samuel S. Jackson, 72 Fed. Reg. 23,848, 23,853 (DEA 2007)].

In this matter, factors two, four and five are relevant in determining the appropriate resolution.

C. Discussion

1. Factors 2 and 4: The applicant's experience in dispensing, or conducting research with respect to controlled substances; Compliance with applicable State, Federal, or local laws relating to controlled substances

a. Patient Care

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 C.F.R. § 1306.04(a); George C. Aycock, M.D., 74 Fed. Reg. 17529, 17541 (DEA 2009)]. 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'')].

Likewise, under Florida law, grounds for disciplinary action or denial of state licensure include ''prescribing . . . any controlled substance, other than in the course of the physician's professional practice,'' and prescribing such substances ''inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent.'' [Fla. Stat. § 458.331(q)(2009)].

Rulemaking authority regarding the practice of medicine within the state of Florida has been delegated to the Florida Board of Medicine (Florida Board). [Fla. Stat. § 458.326 (2009)]. Florida has promulgated a regulation, ''Standards for the Use of Controlled Substances for Treatment of Pain,'' Fla. Admin. Code r 64B8–9.013 (2009) (''Florida Standards''), which recognize that ''inappropriate prescribing of controlled substances . . . may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use.'' [*Id.* at § 9.013(d)]. The language employed by the regulation under the preamble section entitled ''Pain Management Principles'' makes clear that the standards ''are not intended to define complete or best practice, but rather to communicate what the [Florida Board] considers to be within the boundaries of professional practice.'' *Id.* at 9.013(1)(g). Thus, the plain text supports an inference that the standards provide the minimum requirements for establishing conduct that meets the professional practice of controlled substance-based pain management within the state. Likewise, the range of acceptable practice that is built into the regulation underscores the importance of seeking an expert opinion in reaching a correct adjudication of whether a registrant has met the applicable Florida standard.

Here, Dr. Rubenstein found that the Respondent issued prescriptions that were not for a legitimate medical purpose or in the course of usual medical practice. Specifically, he found that the prescriptions issued to Mr. Hays were not within the acceptable standard of care, given the quantities and frequency of such prescriptions. [FOF 56]. Also, given the medical history, the physical examination, and other objective information, Dr. Rubenstein opined that the prescriptions were not based on sound clinical grounds. Thus, he concluded that the prescriptions issued to Mr. Hays were issued outside the usual course of professional practice and were not issued for a legitimate medical purpose. [FOF 56].

Likewise, Dr. Rubenstein found that the Respondent issued prescriptions to Mr. Martinez outside the acceptable standard of care. [FOF 74–75]. Specifically, he found that the Respondent demonstrated a lack of reasonable safety in his prescribing, given Mr. Martinez's complaints. As he credibly concluded, ''I don't believe that this patient's history and physical met the criteria for those prescriptions.'' [FOF 78].

For both Mr. Hays and Mr. Martinez, the Respondent shifted medications, either increasing the dosages or adding Dilaudid and Valium without medical justification. [FOF 48, 53, 72, 73, 74]. In addition, the circumstances surrounding the Respondent's prescription of Valium nearly equates to outright drug dealing. [*See* FOF 53 (suggesting patient had trouble sleeping in response to his request that Mr. Cohen find a ''creative way to deal with him.'')].

Dr. Rubenstein found that the Respondent's physical examinations failed to provide an adequate basis for his prescribing of controlled substances. [*See* FOF 26, 27, 52]. Likewise, relying upon the MRI interpretation as a sole basis for prescribing controlled substances is not appropriate. [FOF 24]. However, it appears that the Respondent did so rely. For example, while Mr. Hays experienced no pain during the neurological examination, the Respondent prescribed controlled substances for him. [FOF 24, 26, 28, 52]. In addition, when treating Mr. Martinez, the Respondent, per Dr. Rubenstein, seemed only to treat the pathology included in the MRI, while ignoring the fact that Mr. Martinez had identified pain in his middle back and neck. [FOF 67]. [*See* Laurence T. McKinney, 73 Fed. Reg. 43260, 43265 n. 22 (DEA 2008)]. Further, the Respondent prescribed controlled substances to Mr. Hays too often, and in one instance prescribed controlled

[20] *But see* ALJ Exhibit 2 which shows that Order II had been served on the Respondent.

[21] The Deputy Administrator has the authority to make such determinations pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2011).

substances prior to the date he had told Mr. Hays to return without even discussing the early dispensing of controlled substances. [FOF 39, 41, 42]. This occurred despite the Respondent's assertion that he only gives out pills for one month, and Mr. Cohen's statement that Dr. Perper would not change a prescription for a patient that came back a week later. [FOF 25, 71]. Thus, based on the foregoing, it is clear that the Respondent issued prescriptions for excessive amounts without an adequate basis. Therefore, his prescriptions were for an illegitimate medical purpose in violation of both Federal and Florida law.

Subsequent to the initiation of treatment, ''the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.'' Fla. Admin. Code r 64B8–9.013(3)(b). Here, the Respondent failed to meet this standard. The Respondent failed to discuss other treatment modalities or physical therapy with Mr. Martinez, despite an indication in his case, that non-controlled substances had been utilized to control his pain in the past. [FOF 70, 77]. Although he ordered liver function tests, the Respondent failed to take action when the patients refused to comply other than to discuss their non-compliance. Both this failure to comply and decision not to discuss other treatment options concerned Dr. Rubenstein. [FOF 44, 54, 58, 77].

Further, the Respondent failed to adjust his drug therapy to the individual medical needs of each patient. Dr. Rubenstein found that the doses and frequency of prescribing to Mr. Hays were excessive given the medical indications. [FOF 30, 34, 53]. Subsequently, the Respondent [22] prescribed controlled substances at the patient's request, without medical justification for the increase in controlled substances. [FOF 38, 39].

Likewise, Dr. Rubenstein found that the Respondent's prescribing to Mr. Martinez on the first visit ''was excessive and not warranted based on the history and physical examination presented.'' [FOF 69].

Another standard adopted by the Medical Board, under the subheading ''Informed Consent and Agreement for Treatment,'' is the directive that ''[t]he physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent.'' [Fla. Admin. Code r 64B8–9.003(3)(c)]. Here the Respondent failed to discuss the risks associated with the use of controlled substances. [FOF 57].

The Florida Standards also state that, ''if the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician should employ the use of a written agreement between the physician and patient outlining patient responsibilities, including, but not limited to: ''1. Urine/serum medication levels screening when requested; 2. Number and frequency of all prescription refills; and 3. Reasons for which drug therapy may be discontinued (i.e. violation of agreement.)'' Yet the Respondent was provided with information from the patients that clearly showed a violation of the agreement, and the Respondent failed to take any action in response. [FOF 48, 73]. [Fla. Admin. Code r 64B8–9.003(3)(c)]. In addition, despite these red flags of diversion, the Respondent failed to follow up with urine screens beyond the first visit, to ensure the prescribed controlled substances were being consumed by the patient and not diverted. [FOF 64]. Yet, the Respondent utilized pain management agreements. [FOF 20, 63].

The Florida Standards direct that ''[p]hysicians should be diligent in preventing the diversion of drugs for illegitimate purposes.'' [*Id.* at 9.013(1)(d). Here, the Respondent and Mr. Cohen were given direct evidence of diversion and failed to act. Mr. Martinez clearly told the Respondent and Mr. Cohen that he had purchased controlled substances off the street. [FOF 68, 71, 76]. Yet neither one took any action in response to this information. Mr. Hays told Mr. Cohen that he had shared his controlled substances with his girlfriend, and again, Mr. Cohen failed to take any action. [FOF 49]. A practitioner who takes no ''precautions against . . . misuse and diversion'' exceeds the bounds of professional practice when he prescribes controlled substances. [United States v. Moore, 423 U.S. 122, 142–43 (1975)]. Such inaction violates the standard of diligence expected of a DEA registrant.

Florida law further provides that grounds for such disciplinary action also include:

> Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician . . . and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

[Id. § 458.331(m)].

Inherent in this law is the requirement that the medical records accurately report the required data. [*See* Fla. Admin. Code r. 64B8–9.013(3)]. Here, Mr. Martinez failed to complete his intake documentation, leaving critical portions, such as his level of pain, blank. [FOF 60]. The Respondent did not discuss the missing data with Mr. Martinez and made no effort to complete the medical history. [*Id.*].

Further, the Respondent charted inaccurately. For example, despite no discussion about the relief of pain Mr. Hays experienced from the Percocet, the Respondent wrote that Mr. Hays had experienced ''no relief (from) pain.'' [FOF 33]. Likewise, the Respondent charted ''break-through pain'' and utilized this information to justify increasing the amount of controlled substances dispensed to Mr. Hays. Yet Mr. Hays had not complained of break-through pain. [FOF 43, 47].

b. Inventory and Audit

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 C.F.R. § 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 C.F.R § 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 registrant 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 the required initial inventory after moving to a new practice location. [FOF 84]. Next, when conducting an accountability audit, the DEA found that the Respondent was unable to account for, among other discrepancies, 23,993 dosage units of oxycodone 30 mg tablets, [FOF 81], and 2,565 dosage units of Endocet 10/325, [FOF 83].

Factor Five: Such other conduct which may threaten the public health and safety.

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 Fed. Reg. 49,979, 49,988 (DEA 2010)].

Here, I find that Mr. Cohen advised Mr. Hays on ways to present prescriptions so that the pharmacy would not be ''suspicious.'' Specifically, Mr. Hays was to hand in one of the controlled substances prescriptions and then wait to hand in the other one. [FOF 49]. Further, Mr. Cohen gave Mr. Hays a prescription for ibuprofen, to be used to waylay the pharmacist's suspicion. If the pharmacist was not suspicious, Mr. Hays was to destroy the ibuprofen prescription. [FOF 49]. Such deception in handling

[22] The Respondent remains liable for Mr. Cohen's actions. Florida law states that ''[e]ach physician . . . supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and shall be individually . . . responsible and liable for the performance and the acts and omissions of [the] physician assistant.'' Fla. Stat. Ann. § 458.347(3) (2009).

prescriptions for controlled substances threatens the public health and safety, for it circumvents the checks and balances available in the pharmacist's corresponding liability for the dispensing of controlled substances. [*See* 21 C.F.R. 1306.04].

Next Mr. Cohen advised Mr. Martinez to go back to buying controlled substances on the street if he needed more drugs than the ones already prescribed. [FOF 71]. Advising Mr. Martinez to engage in illegal activity in purchasing controlled substances in this manner promotes diversion and therefore, directly threatens the public health and safety.

Lastly, Dr. Rubenstein found that the Respondent lacked concern for patient safety. He prescribed large amounts of controlled substances to opioid naïve patients. [FOF 30, 53, 56]. He also increased the amounts of controlled substances he prescribed, and such increases were unjustified and reflect a lack of concern for patient safety. [FOF 69, 72–74]. Dr. Rubenstein concluded that the increase in medication was not medically justified. [FOF 74].

The Respondent did not testify in this proceeding.[23] Therefore, he neither took responsibility for his misconduct nor provided any assurances that he has implemented remedial measures to ensure such conduct is not repeated. Such silence weighs against the Respondent's continued registration. [Medicine Shoppe, 73 Fed. Reg. at 387; *see also* Samuel S. Jackson, 72 Fed. Reg. 23,848, 23,853 (DEA 2007)].

V. CONCLUSION AND RECOMMENDATION

Consistent with the analysis in this matter, I conclude that the Government has met its burden and established its *prima facie* case for revocation. The Respondent has failed to provide any explanation for his conduct or any assurances regarding his future conduct. Therefore, I recommend that the Respondent's viable DEA registrations FP1312406, BP3429835, and BP8477639, be revoked and any pending applications for renewal or modification of such registrations be denied.

Dated: July 19, 2011

Gail A. Randall, Administrative Law Judge

[FR Doc. 2012–25618 Filed 10–17–12; 8:45 am]

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[23] The Government asks me to take an adverse inference from the Respondent's failure to testify. However, the Government does not assert what adverse inference it believes such silence establishes. Although I agree that the Government is entitled to such an inference as established by the cited case law, without a requested inference, I am at a loss in granting the Government's request.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances, Notice of Application, Noramco, Inc.

Pursuant to Title 21, Code of Federal Regulations (CFR), 1301.34(a), this is notice that on August 6, 2012, Noramco, Inc., 500 Swedes Landing Road, Wilmington, Delaware 19801–4417, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Phenylacetone (8501)	II
Opium, raw (9600)	II
Poppy Straw Concentrate (9670)	II
Tapentadol (9780)	II

The company plans to import raw Opium (9600) and Poppy Straw Concentrate (9670) to manufacture other controlled substances. The company plans to import Tapentadol (9780) in intermediate form for the bulk manufacture of Tapentadol (9780) for distribution to its customers. The company plans to import Phenylacetone (8501) in bulk for the manufacture of a controlled substance.

Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (2007).

In regard to the non-narcotic raw material, any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedules I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than November 19, 2012.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic class of any controlled substance in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: October 9, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–25644 Filed 10–17–12; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances, Notice of Registration, ISP Freetown Fine Chemicals

By Notice dated July 2, 2012, and published in the **Federal Register** on July 11, 2012, 77 FR 40910, ISP Freetown Fine Chemicals, 238 South Main Street, Assonet, Massachusetts 02702, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Phenylacetone (8501), a basic class of controlled substance listed in schedule II.

The company plans to import the controlled substance to manufacture amphetamine.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that the registration of ISP Freetown Fine Chemicals to import the basic class of controlled substance is consistent with the public interest, and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. DEA has investigated ISP Freetown Fine Chemicals to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic class of controlled substance listed.

Dated: October 9, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–25640 Filed 10–17–12; 8:45 am]

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