Order Granting the Government's Motion for Summary Disposition and Recommendation

I find there is no genuine dispute regarding whether Respondent is a "practitioner" as that term is defined by 21 U.S.C. 802(21), and that based on the record the Government has established that Respondent is not a practitioner and is not authorized to dispense controlled substances in the state in which it seeks to operate under a DEA Certificate of Registration. I find no other material facts at issue, for the reasons set forth in the Government's Motion for Summary Disposition. Accordingly, I GRANT the Government's Motion for Summary Disposition.

Upon this finding, I ORDER that this case be forwarded to the Administrator for final disposition and I RECOMMEND the Administrator DENY Respondent's application for a DEA Certificate of Registration.

Dated: October 2, 2013.

Christopher B. McNeil,

Administrative Law Judge.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. 13–21]

Ralph J. Chambers, M.D.; Decision and Order

On February 11, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Ralph J. Chambers, M.D. (Applicant), of Sanford, Florida. GX 3. The Show Cause Order proposed the revocation of Applicant's DEA Certificate of Registration BC2172485, on the ground that his continued "registration would be inconsistent with the public interest." *Id.* at 1 (citing 21 U.S.C. 823(f)). The Order also sought the denial of Applicant's June 2, 2010 pending application for a DEA registration at an address in Orange City, Florida. 1 Id.

The Show Cause Order alleged that, from June 2006 through January 2009, Applicant "inappropriately prescribed excessive quantities and combinations of controlled substances" to eight confidential informants. *Id.* The Show Cause Order also alleged that a "medical

expert" reviewed patient files seized from Applicant's practice and determined that "for more than eighty patients, [he] inappropriately prescribed excessive quantities and combinations of controlled substances and failed to maintain proper medical documentation containing a legitimate medical purpose for [his] course of actions for those patients." *Id.* at 2.

On March 11, 2013, Applicant filed a request for a hearing, and the matter was assigned to an Administrative Law Judge (ALJ). GX 4. However, on June 13, 2013, Applicant submitted a letter to the ALJ, wherein Applicant "decided to waive [his] rights [sic] to a hearing regarding the revocation of my DEA Certificate." Id. at 2. The next day, the ALJ found that Applicant waived his request for a hearing and terminated the proceeding. Id. Subsequently, the Government forwarded the Investigative Record along with a Request for Final Agency Action to this Office, seeking the revocation of Applicant's DEA registration as well as the denial of any pending applications. Based on Applicant's letter of June 13, 2013, I find that he has waived his right to a hearing. 21 CFR 1301.43(d). I therefore issue this Decision and Final Order based on the record submitted by the Government and make the following findings of fact.

Applicant's Registration and Licensure Status

On August 25, 2010, Applicant was issued DEA Certificate of Registration BC2172485, pursuant to which he was authorized to dispense controlled substances as a practitioner in schedules II through V; this registration's expiration date was August 25, 2013. GX 1. On August 1, 2013, Applicant submitted a renewal application for this registration.²

Under an Agency regulation applicable to those applicants who are subject to an Order to Show Cause:

[i]n the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his/her

order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the Applicant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the Applicant, if the Administrator finds that such extension is not inconsistent with the public health and safety.

21 CFR 1301.36(i). Because Applicant had previously been served with an Order to Show Cause, and he did not apply to renew his registration until twenty-four days before it was due to expire, pursuant to the above regulation, I conclude that his registration expired on August 25, 2013. Having reviewed the record, I further conclude—for reasons explained below—that the extension of Applicant's registration during the pendency of this proceeding would be "inconsistent with the public health and safety." Id. I therefore hold that Applicant's registration expired on August 25, 2013. See Paul H. Volkman, 73 FR 30630, 30641 (2008). However, I further hold that Applicant's renewal application remains pending before the agency. See id.

Applicant is also the holder of a Florida state medical license, ME58544. However, he has been subjected to discipline by the Florida Board of Medicine on two occasions.

Applicant's first brush with the Board occurred in 2001. GX 2, at 1. That year, the Board filed an administrative complaint against Applicant, alleging, inter alia, that with respect to a patient, who had suffered a stroke, he "fail[ed] to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances," as well as that he "failed to keep written medical records justifying the course of treatment" for that patient. *Id.* at 9–10 (citing Fla. Stat. § 458.331(1)(m)). Applicant did not dispute the facts, and following a hearing, he agreed to: (1) Pay a \$5,000 fine, (2) pay \$1,728, this sum being the Board's costs in the case, (3) complete twenty hours of continuing medical education, (4) complete a medical records course, and (5) submit to a Quality Assurance Review. Id. at 2.

In 2010, the Board filed a new complaint, and in 2011, the Board filed two more complaints; these complaints culminated in a single final settlement order in 2012. *Id.* at 13. The 2010 complaint ³ alleged that, between December 16, 2009 and May 27, 2010, Applicant "dispensed medicinal drugs

¹ Notwithstanding this allegation, no evidence was put forward establishing that any such application is pending before the Agency.

²I have taken official notice of the Agency's registration records which show that Applicant filed a renewal application on August 1, 2013. See 5 U.S.C. 556(e); 21 CFR 1316.59(e); Attorney General's Manual on the Administrative Procedure Act § 7(d) (1947).

 $^{^3}$ State of Florida Department of Health Case number 2010–03851.

for human consumption for a fee or remuneration" when he "was not registered with the Board of Medicine to dispense medicinal drugs for human consumption," in violation of Fla. Stat. § 465.0276(2). *Id.* at 76. The complaint also alleged that, by dispensing medication without a proper registration, Applicant violated Florida law by "practice[ing] beyond the scope permitted by law" *Id.* at 78 (citing Fla. Stat. § 458.331(1)(v) (2013)).

The first 20114 complaint made numerous factual allegations regarding Applicant's treatment of Patient J.D.⁵ Id. at 28-54. Count I of the complaint then alleged, *inter alia*, that over various periods, Applicant committed malpractice by prescribing controlled substances including Xanax, Lortab (hydrocodone), oxycodone, and Dilaudid (hydromorphone), "in doses which were not medically justified." Id. at 55-56 (citing Fla. Stat. § 458.331(1)(t)). Count II of the complaint alleged that the aforesaid prescribing constituted "inappropriate[] or excessive[] prescrib[ing] [of] medications." *Id.* at 57 (citing Fla. Stat. § 458.331(1)(q)). Finally, Count III alleged that during the various periods, Applicant "fail[ed] to document a justification for the prescription[s]" of the four drugs, and that he also "fail[ed] to document a specific examination of Patient J.D. from December 23, 2006, to August 16, 2010." Id. at 59-60 (citing Fla. Stat. § 458.331(1)(m)).

The second 2011 complaint 6 made numerous factual allegations regarding Applicant's treatment of patient L.S. Id. at 63–68. Count I of the complaint then alleged that on three occasions, Applicant committed malpractice by: (1) Prescribing Xanax "in doses which were not medically justified," or 2) "[b]y authorizing . . . refills of the prescription of Xanax and Lortab," or 3) "[b]y failing to refer . . . L.S. for a psychiatric consultation." *Id.* at 69–70 (citing Fla. Stat. § 458.331(1)(t)). Count II alleged that the aforesaid prescribing of Xanax and Lortab constituted "inappropriate[] and/or excessive[] prescribing [of] medications." Id. at 71

(citing Fla. Stat. § 458.331(1)(q)). Finally, Count III alleged that Applicant "fail[ed] to document a justification for the prescription of the amount of Xanax" on three occasions, and that he "fail[ed] to document a physical examination or assessment of . . . L.S. on February 10, 2007." *Id.* at 72 (citing Fla. Stat. § 458.331(1)(m)).

On August 17, 2012, Applicant entered into a Settlement Agreement with the Board. Therein, "Applicant neither admit[ted] nor denie[d] the allegations of fact contained in the Administrative Complaint [sic] for purposes of these proceedings only." Id. at 18. However, he did "admit[] that the facts alleged in the Administrative Complaint [sic], if proven, would constitute violations of Chapter 458, Florida Statutes, as alleged in the Administrative Complaint [sic]." Id. Moreover, he further agreed that when the Agreement was presented to the Board, he would "offer no evidence, testimony or argument that disputes any stipulated fact or conclusion of law." Id. at 24.

Pursuant to the Agreement, Applicant was reprimanded and his medical license was suspended until he submitted to an evaluation by either a state program or Board-approved evaluation and appear before the Board's Probation Committee. Id. at 19. The Board also assessed an administrative fine of \$60,000 against his license and required that he pay \$15,910.65 to the Department of Health for its costs in investigating and prosecuting the matter. Id. at 19-20. Applicant also agreed to cease practicing if, within 105 days of the filing of the Board's final order, he did not receive written confirmation from the Board that it had received the full amount of both the fine and costs. Id. Finally, he agreed to take three courses: (1) A course in the "Legal and Ethical Implications in Medicine," (2) a course in prescribing controlled drugs, and (3) a course in quality medical recordkeeping. Id. at 21.

On October 12, 2012, the Settlement Agreement was submitted to the Florida Board, and on October 24, 2012, the Board issued a final order approving the Agreement. *Id.* at 13–14. Applicant's license is currently classified as "Obligations Active" by the Florida Department of Health, which means that "the licensed practitioner may practice his/her profession in the State of Florida under the conditions specified by the licensing board or department." ⁷

The Investigations of Applicant The 2005–2006 Investigation

In 2005, the Florida Department of Law Enforcement (FDLE) notified a Sergeant with the Daytona Beach Police Department, who was then assigned to a Drug and Money Laundering Task Force, that a female who had been arrested for trafficking in hydrocodone and alprazolam might have information related to Applicant. GX 17, at 1. Subsequently, the Sergeant oversaw four undercover buys from Applicant, which were done by two confidential sources (CS1 and CS2); CS1 did the June 24, 2005 visit, and CS2 did the May 30, 2006, June 27, 2006, and July 26, 2006 visits. Id.

During the operations, the police observed the CSs enter and exit Applicant's office; they also placed a recording device on the CSs. *Id.*However, during the last operation, the recording device did not work. *Id.*During each operation, the CSs obtained prescriptions for controlled substances, which they subsequently provided to the police. *Id.* Copies of these prescriptions were submitted in the record provided by the Government, as were the recordings and transcriptions for the three visits when the recording device functioned properly. *See* GX 9–12

Following the buys on June 24, 2005, June 27, 2006 and July 26, 2006, the confidential sources told the Sergeant that Applicant failed to perform any physical examination. *Id.* at 2. For the May 30, 2006 undercover buy (which was CS2's first visit), the CS told the Sergeant that Applicant had briefly touched his back. *Id.*

The recordings of the June 24, 2005 operation establish that the CS did not complain of any pain and that Applicant neither asked her any questions about her medical condition (indeed, nearly all of the interaction involved a discussion of the CS's family issues), nor performed a physical examination. GX 9. Applicant nonetheless gave CS1 prescriptions for 60 tablets of OxyContin 20mg (oxycodone, sch. II), 90 tablets of Lorcet 10/650 (hydrocodone/acetaminophen, sch. III), 90 Xanax 1mg (sch. IV), and 90 Soma (carisoprodol, then unscheduled under federal law). Id. CS1 paid \$65.00 in cash and then left. GX 9.

As for the May 30, 2006 operation, the transcript of the operation corroborates the CS's hearsay statement that the Applicant physically touched him. GX 10, at Tr. 1, at 11–12. Yet there is no

⁴ State of Florida Department of Health Case number 2009–05877.

⁵These included that Applicant failed to document a patient's vital signs, failed to record the quantities of the controlled substances prescribed, and continued to increase the dosage amounts for Lortab and alprazolam for one patient despite continuously noting "no change" in that patient's medical record. See id. at 28–52. In another instance, Applicant prescribed oxycodone, Lortab, and alprazolam to a patient who "reported to Applicant that he had been getting Lortab off the street while waiting for his appointment." Id. at 36.

 $^{^6}$ State of Florida Department of Health Case number 2009–20428.

⁷ I have taken official notice of the status of Applicant's medical license by accessing the online database of all licensed providers maintained by

Florida Department of Health. See http://ww2.doh.state.fl.us/IRM00PRAES/PRASLIST.ASP.

other evidence establishing that Applicant's physical examination of the CS was inadequate. See David Ruben, 78 FR 38363, 38384 (2013). Moreover, the CS complained of pain, stating that he had strained his back lifting a fire extinguisher (weighing 40–60 pounds) and that he had pain "all over," that his back was "tender," and that when he woke up, his back "cramps" on him. Id. at 10. Applicant gave the CS a prescription for 60 Naprosen (a noncontrolled drug) and 60 Lortab 10, a schedule III controlled substance containing hydrocodone.

As for the June 27, 2006 operation, the prescriptions establish that the same CS, who made the previous visit, made this visit. The recording and transcript show that Applicant did not perform a physical examination. However, there is no evidence that the Government's Expert reviewed this encounter or the CS's patient file, and there is no evidence that under the standards of accepted medical practice, the performance of a physical exam was required at this visit.

The recording and transcript do reflect that after Applicant and the CS greeted each other, a lengthy discussion ensued of such matters as Applicant's prior experience treating gunshot wounds as a trauma surgeon and critical care physician, his decision to move to Florida, and the skill required to perform cardiac and orthopedic surgery, the latter being "just carpentry," which requires knowledge of "some anatomy" and "patience." GX 11, Tr. Part 4, at 1–8. Applicant then asked the CS: "What's going on with you?" *Id.* at 8

To this, the CS replied: "Well . . . that . . . what you gave me last time. Made me feel really good. Ah . . . coming to see if I can get something a little stronger this time." Id. Applicant than asked the CS if he wanted something "[s]tronger or just more" of what he had previously gotten; the CS answered: "[m]aybe more stronger." Id. Applicant then stated: "Okay, no problem," and asked the CS if he was getting "any therapy?" Id. The CS replied that he was not. *Id.* Applicant then asked the CS, "not into it?" Id. The CS answered "[y]eah," and Applicant said "fair enough." Id. Applicant then left the exam room and subsequently provided the CS with prescriptions for 60 Ultram (tramadol, a non-controlled drug) and 120 oxycodone 15mg, a schedule II controlled substance.

CS2 returned to Applicant on July 27, 2006. GX 12, at 5. However, as explained above, the recording device malfunctioned. In his affidavit, the Sergeant stated that the CS told him that Applicant did not perform a physical exam. GX 17, at 2. The CS also told the Sergeant that Applicant did not recognize him and did not remember what he was being treated for. Id. Most significantly, the CS told Applicant that he had "previously pulled a muscle in his back, but was no longer in pain" and that "he just liked how the pain medication made him feel and wanted something stronger than the oxycodone 15mg tablets" he obtained at the "previous visit." Id. The CS also told the Sergeant that he received a prescription for 90 tablets of oxycodone 30mg. Id. Of note, the Sergeant's statement is corroborated by a copy of the prescription. GX 10, at 5.

The 2008-2009 Investigation

Several years later, a DEA Diversion Investigator (DI), in conjunction with the Volusia County Florida Bureau of Investigation (VBI) and the Department of Health and Human Services Medicaid Fraud Control Unit (DHHS), conducted four undercover visits of Applicant. GX 18, at 1. The visits were done on September 18, 2008, October 16, 2008, November 24, 2008, and January 15, 2009, and were performed by two different confidential sources (CS3 and CS4), who were equipped with a recording device, and after each visit the CSs were debriefed. *Id.*

According to the DI, after each of the visits, the confidential sources told her that Applicant did not perform a physical examination yet prescribed controlled substances to the CSs. *Id.* at 2. Subsequently, a search warrant was obtained from the Florida courts authorizing the search of Applicant's clinic, and was executed on October 1, 2009. *Id.* Pursuant to the warrant, Applicant's medical records were seized. *Id.* These records were turned over to Dr. Theodore Parran, an expert working for the Government, for review. ¹⁰ *Id.*

On September 18, 2008, CS3 visited Applicant at his place of business. GX 13. After stating that "I just can't move" and "I'm just so uncomfortable," Applicant asked "[s]o what do we need to do?" *Id.* at Tr. 1, at 7. CS3 then asked if she could "get something for the discomfort that I have." *Id.* Applicant said "okay" and asked if she was no

longer getting therapy. *Id.* at 8. CS3 said that she had not "been able to fin[d] anybody that does this deep tissue," but that she was getting massages. *Id.* After CS3 made a further vague comment about her condition, Applicant stated that "at one point I g[a]ve you some Percocets, at one point, I gave you some Lortab. I mean, do you want, did anything work for you?" *Id.* CS3 replied: "Well, first, the, um . . . I guess the last one was the Percocet. That didn't work, but that helped with anti-inflammatory, too. I think you gave me something." *Id.*

Applicant replied, "[w]ell, now you saw me one time. You saw that other guy, the other guy gets it cheaper than this place." *Id.* CS3 then denied that she had "see[n] anybody in that office," an apparent reference to Applicant's former practice location, and Applicant noted that it has been "like two (2) years ago." Id. CS3 again stated that she had not gone back to that office because it did not have a therapist and she "didn't really care for his . . . chiropractic procedure." Id. at 9. Applicant said "okay" and asked the CS if she was "tak[ing] something for pain, an antiinflammatory?" Id. The CS said "yeah," after which CS and Applicant discussed various other matters, none of which related to the CS's medical condition.

Consistent with the DI's statement that the CSs had informed her that Applicant did not perform a physical exam, there is no evidence that Applicant performed a physical exam of CS3. Applicant nonetheless wrote CS3 a prescription for 180 tablets of Percocet 10/325mg. GX 13. CS3 paid \$90.00 for the visit. *Id.* at 8.

On October 16, 2008, CS3 returned to Applicant and paid \$90.00 in cash. GX 14. After greeting each other and discussing how she could lose weight, CS3 asked Applicant if he could "give [her] a little extra this time?" *Id.* Tr. 1, at 10. Applicant answered, "uh-hum," but never asked CS3 why she wanted or needed more medication. *Id.*

CS3 then told Applicant that she had a friend who wanted to come in asked if he was seeing new patients. *Id.* at 11. Applicant said he was but he had rules and the CS's friend would have to bring documentation and that he would let the patient "know beforehand what the rules are gonna be as far as what you get . . . cause somebody walks in here and wants strong pain medication and they've never had anything before, I say, 'Let's start out with anti-inflammatories and muscle relaxers, first, and therapy, and let's see how things go.' So . . . I don't know." *Id*.

CS3 then stated that she had "shared a little bit [of her medications]" with her

⁸ As explained below, there is a lengthy report of an Expert regarding his review of numerous patient files. However, the Expert did not discuss these visits.

⁹ DI Stocum's declaration states the date as November 25, 2008. GX 18. The date on the issued prescriptions for that CS, however, is November 24, 2008. See GX 15.

friend and did not "know if that was the right thing to do." Id. Applicant replied that "it's neither right or wrong, as far as I'm concerned, but you must understand, and, although, I don't think you can get in trouble for it, you both broke the law by doing that." Id. After CS3 replied "I did?" Applicant explained that "[y]ou were dealing drugs and he was taking illegal medication; these are controlled substances." *Id.* at 12. After CS3 asked if it would "be better now if I just get him an appointment," Applicant stated that "he can call," but that he would have to meet with his colleague and "bring in his documentation." Id.

Applicant asked if the CS's friend "had surgery before," but the CS did not know. Id. Applicant then explained that if "he's had surgery before, then I just need to see some documentation . . . about the surgery." Id. After CS3 stated that she did not "think it was that" and that he may be "going to a chiropractor," Applicant added that "if he can show me that he's had therapy and things like that, that makes a difference." Id. at 12-13. Applicant then explained that "in other words, there are a lot of people who just want to walk in and say, 'Give me pain medicine.' And I say, 'You don't just get pain medicine without some documentation." *Id.* at 13. Applicant advised that if the CS's friend "gets his medical records together and gets it to us . . . we'll get back to him." Id. Applicant then authorized the dispensing of 210 tablets of Percocet (oxycodone/apap) 10/325mg, for which the CS paid \$200.11 Id.

On November 24, 2008, CS3 returned to Applicant's clinic and obtained 240 more tablets of Percocet 10/325mg. GX 15, at 2. However, as found above, the recording device malfunctioned. GX 18, at 2. In her affidavit, the DI stated that during the post-visit debriefing, the CS said that Applicant did not perform a physical exam and only took her weight and blood pressure. Id. While the DI's affidavit states that Applicant also required that CS3 sign a form in which she agreed not to share her medications and that she did not ask for an increase in her prescription, the affidavit offers no further information regarding the interaction between the CS and Applicant. Id.

According to the DI, on January 15, 2009, CS4 visited Applicant. ¹² GX 16. After exchanging greetings and discussing the holidays, CS4 stated that

he was "feeling better though." *Id.*, Tr. 1, at 5. After discussing whether CS4 needed his prescriptions "split up the same way again," Applicant asked the CS, "[h]ow's work?" *Id.* The CS replied, "[p]retty good, not too bad. Doing pretty good these days. My pain is getting better . . . that that makes it real good." *Id.* Applicant then asked the CS if he did "anything for New Year's Eve"; the CS replied that he had gone to his uncle's party. *Id.* at 6–7. Shortly after that, the CS's encounter with Applicant ended. *Id.*

CS4 filled his prescription at Applicant's clinic. As the evidence shows, Applicant dispensed 240 tablets of Oxycodone 15mg. *Id*.

The Government Expert's Analysis of the Seized Medical Records

As found above, after the execution of the search warrant, the DI provided over 115 medical records to Dr. Theodore Parran for his review, GX 18, at 2. Dr. Parran, who has practiced medicine for thirty years, is a board-certified specialist in addiction medicine and internal medicine. GX 6. Dr. Parran is a member of the faculty at the Case Western Reserve University School of Medicine and developed the school's Addiction Fellowship Programs. Id. at 1, 13; GX 7. He is also the Medical Director for the Detoxification Unit at Huron Hospital in East Cleveland, Ohio, and the Medical Director for the Cleveland Treatment Center Methadone Maintenance Clinic. GX 6, at 14. He has also served as a reviewer for several professional journals on issues related to substance abuse, presented numerous lectures on substance abuse and controlled substance prescribing, and authored (or co-authored) a large number of articles for professional journals and book chapters for treatises. Id. at 6-13.

Following his review, Dr. Parran offered the following findings. Most significantly, Dr. Parran opined "that there are many cases where the prescribing of controlled drugs appears to have been for other than [a] legitimate medical purpose and appears not to have taken place within the usual course of medical practice." GX 7, at 1.

Dr. Parran then identified several "general characteristics" of Applicant's "prescribing behaviors that are concerning and even alarming." *Id.* Specifically, he found that: (1) "There [was] virtually always a very scant initial history and typically no documented evidence of a sufficient physical exam done on patients" in the records; (2) there was a remarkable similarity in how Applicant treated each patient, suggesting a lack of

individualized treatment; (3) there was typically no note in the patient chart to explain why Applicant started, increased, or changed a drug regimen; (4) there were very few, if any, referrals to alternative treatments (i.e., physical therapy) and specialists (*i.e.*, psychiatry, rheumatology, neurology, orthopedics and neurosurgery); and (5) Applicant routinely "provide[d] on-going supplies of multiple controlled drugs in an escalating pattern, typically culminating in quite high doses, in potentially dangerous combinations." Id. at 1-2. Dr. Parran thus opined that Applicant's "pattern of relentlessly prescribing controlled drugs, with insufficient history and physical . . . and no clinical reasoning evident in progress notes what-so-ever, without initiating a clinical work-up or demonstrating evidence of an effort to obtain prior records, and in the face of noncompliance and often out of control behavior on the part of patients, is not consistent with the usual course of medical practice and constitutes prescribing of controlled drugs for other than [a] legitimate medical purpose." Id. at 2. A more detailed discussion of Dr. Parran's findings with respect to several of the patients follows.

K.B

At K.B.'s initial visit, she reported that she suffered from head and face trauma and seizures, and was taking undocumented dosages of Xanax, Dilantin and Naproxen. *Id.* at 4. The file included prior medical records from a neurology pain office several years earlier indicating that she had taken "Oxy 40 BID [twice a day] and Roxi 5 and Xanax 2 TID," three times a day. *Id.* Dr. Parran found that there was "no evidence of a [physical exam] and little evidence of any history taking." *Id.*

The next progress note in K.B.'s file is dated 6/6/06, sixteen months after K.B.'s initial visit, and states "Duragesic does not seem to be effective for pain . . . refills." *Id.* Apparently, no explanation was provided as to when Applicant prescribed Duragesic (fentanyl), a schedule II controlled substance to her. *Id.*

The next visit documented in K.B.'s record is dated 7/19/06; the progress notes states "former WS pt. with chronic back pain/Lmyalgias/HA/seizures and anxiety." *Id.* Dr. Parran again noted that there is "no evidence of a PE [physical exam] at all, or health history, or documentation of current RX or labs (to check Dilantin level, etc.) or studies, prior records, etc." *Id.* Yet Applicant prescribed 120 OC 30 mg (oxycodone), 120 Oxy (also oxycodone)

¹¹ The evidence shows that the drugs were dispensed by Applicant's clinic. GX 14.

 $^{^{12}}$ However, the transcript lists the date of the visit as January 5, 2009

40mg, 150 Xanax 2mg, Dilantin 300 mg/d, Naprosyn, and 90 Soma.

On 8/16/06, Applicant added 120 Fiorinol to K.B.'s existing medications, without noting why in her record. *Id.* Dr. Parran opined that "[a]dding a potent barbiturate or an existing barbiturate (soma) and a high dose very potent benzodiazepine and two CII opioids... is dangerous to health or even life of a patient and is clinically reckless." *Id.*

K.B. received the same prescriptions the following month, but the visit note documents only the prescriptions. *Id.* Thereafter, there were no progress notes until February 2007, when the note stated that K.B. was going to a neurosurgeon and needed a new MRI, and the same prescriptions were provided. *Id.* Yet K.B. did not provide an MRI at either her April or May office visits, and in August 2007, the progress note stated that K.B. had complained that the "pharmacist shorted me . . . so [she was] in bed almost all of last month." *Id.*

Dr. Parran then noted that there was no evidence of a physical examination at any time in the past year except for a note regarding "spasm/tenderness in L/SP," and yet Applicant added a prescription for 60 MS XR (morphine sulfate extended release)—"a third CII opioid with no mention in the record at all!" Id. Dr. Parran noted that K.B. received prescriptions that month for Soma 150, 150 OC 30 mg, 150 Xanax 2mg, Dilantin, 120 Oxy 40mg, and had refills that were still active for Naproxen and Fioricet. Id. However, her chart included a note stating that: "Medicaid refused Soma due to too high a dose and Oxy due to excessive quantity." Id.

Next, Dr. Parran found that the progress note for 11/7/07 listed K.B.'s pain as 8/10, and that she reported she "only got ½ of meds from pharmacy this month." *Id.* Dr. Parran noted there were "no studies, referrals, evidence of a PE, evidence of a neurological exam ever" and yet Applicant wrote prescriptions were for 120 Fiorinal; 150 Xanax 2mg; 120 MS XR 60mg QID (four times a day, notwithstanding that the drug is to be taken twice a day); 150 Soma; 150 OC 30mg; 60 Oxy 80mg. *Id.*

Dr. Parran further found that the February 2008 progress note stated that K.B. "self-increases medication in cold weather." *Id.* Moreover, while the note of 3/27/08 states that K.B. "will sched f/u with surgery;" and the note dated 4/08 states, "surgery next month"; the note of 5/22/08 states that she "ran out early," with "no mention of WD [withdrawal management]," abstinence symptoms, nor mention of surgery. *Id.*

Next, Dr. Parran observed that the 7/17/08 note stated: "Hold RX until mother comes in with cash payment." *Id.* Applicant noted that he was providing an additional prescription of "OC 15mg #300" to K.B.'s medications, but did not document a justification for doing so. *Id.*

The 8/14/08 progress note reported K.B.'s "Pain 7/10." *Id.* Moreover, the note stated that K.B. received the following prescriptions: 150 OC 30mg; 300 Oxydose 15 mg; 120 Fiorinal; 150 Xanax 2mg; 56 Oxycontin 80 mg. BID; 112 MS XR 60 mg QID; and 150 Soma. *Id.* Dr. Parran then explained that this provided K.B. with "four CII opioids all at quite high dose and three sedative hypnotics!" and was "[s]imply unbelievable." *Id.*

As for K.B.'s 9/11/08 visit, the note listed her pain as "7/10" and stated that "OC 15 mg's have helped smooth out pain well." *Id.* Dr. Parran then explained that this was "inconsistent data in the medical record." *Id.*

On 10/09/08 Applicant increased the prescription dosages to 180 OC 30 mg; 120 MS; 60 Oxycontin; 180 Soma; 180 Xanax. *Id.* Yet notwithstanding the increases, the progress notes for her next month's visit stated that her pain was a "7/10" but that the "meds [were] effective." *Id.*

On February 5, 2009, Applicant again increased K.B.'s prescriptions. *Id.* These prescriptions provided K.B. with 300 OC 30 mg, 180 OC 15 mg, 60 OxyContin 80 mg, Fiorinol 120 X3, 200 Xanax 2mg, and 200 Soma, as well as two prescriptions for MS XR 60 mg, one for 94 tablets and one for 56. *Id*

In April 2009 the progress notes include "pharmacy call re: Concern[s] about amounts of OC and too early refills." *Id.* In June 2009, Applicant prescribed 30 OxyContin 80mg in addition to the existing 60 OxyContin 80mg; Dr. Parran found, however, that there was "no indication in PN [progress notes] as to why." *Id.* Dr. Parran then opined that:

The prescribing of four and a half years of markedly escalating opioids and other controlled drugs to this patient with no evaluation, an insufficient H&P, non-existent work-up, lack of studies/consults/evaluation, up to exceedingly high doses of opioids, is inconsistent with the usual course of medical practice and was for other than a legitimate medical purpose.

Id.

D.B.

Regarding D.B., Dr. Parran found that "prior records recommend avoiding long-term narcotic medications." *Id.* at 5. D.B. reported "spinal and back pain" and yet "mark[ed] off in the patient self

report[,] pain in each and every part of the body listed." *Id.* She also reported being on methadone 40mg, oxycodone 30 mg, Xanax 2mg, and Soma, but another note "explicitly state[d] that the patient was not on any medications currently." *Id.* Applicant nonetheless prescribed 120 OC 30mg and 60 Valium10mg at the initial office visit. *Id.* Dr. Parran concluded that "this is clinically reckless and if taken as directed would result in patient harm and even an accidental potentially fatal OD." *Id.*

At her next appointment (four weeks later), Applicant changed the prescriptions to 120 Percocet 10mg; 120 methadone 40 mg; 90 Xanax 2mg. *Id.* According to Dr. Parran, this was a "massive increase," which was "even more clinically reckless, and in a patient who was not on any current medications just 4 weeks earlier, could and should have caused harm or even death if taken as directed." *Id.*

Next, Dr. Parran found that the progress notes showed that the following month, asthma medications were added. *Id.* Dr. Parran reported that there was "no discussion of asthma (a medical concern in the face of this huge amount of opioid and benzo prescribing), no evidence of a lung exam or evaluation of the severity of pulmonary function." *Id.*

Over the next three months, D.B.'s patient file documents multiple increases in her prescriptions, such that by December, she was receiving 240 methadone 40mg, 120 Xanax 2mg, 120 Oxycodone 30mg, and 90 Soma, "with no indication in the medical record." Id. Dr. Parran explained that "[t]his bears no resemblance to the usual course of medical practice." *Id.* Additional increases in Applicant's prescribing of oxycodone, as well as other drugs followed, notwithstanding that Applicant documented in D.B.'s file that the "meds are working good." Id. Regarding the prescriptions, Dr. Parran explained that "[t]he prescribing of three years of markedly escalating opioids and other controlled drugs to this patient with no evaluation, an insufficient [history and physical], nonexistent work-up, lack of studies/ consults/evaluation, up to exceedingly high doses of opioids, is inconsistent with the usual course of medical practice and was for other than a legitimate medical purpose." Id.

J.H.

Dr. Parran found that J.H.'s patient file indicated that during an initial office visit in January 2007, she complained of back pain from a motor vehicle accident in 1994, as well as anxiety from deaths

in the family. *Id.* at 16. J.H. also reported that she had not seen a doctor since 1994 and was not on any medications. *Id.* In the patient file, Applicant wrote that "we would treat her for anxiety and not to expect any pain meds." *Id.* However, an additional note stated that J.H. was getting "Percocets from her dad" for back pain. *Id.*

Dr. Parran found that there were "no prior records/studies/referrals/work-up" or significant history and physical documented in her patient file. *Id.* Yet, at the initial visit, Applicant prescribed to J.H. 180 Percocet 5 mg. and 30 Xanax 2mg. *Id.* Dr. Parran explained that "[t]his is completely unsupported by the medical record, [and] is inconsistent with the usual course of medical practice and lack [sic] legitimate medical purpose." *Id.*

Dr. Parran found that at J.H.'s next visit (one month later), Applicant nearly tripled the oxycodone to 120 Oxy 15 mg, but made no mention of this in the progress note. *Id.* Dr. Parran then explained that if J.H. "had not been on prior opioids . . . and she took it as prescribed . . . it could have resulted in [an] accidental OD [overdose] and even fatal accidental OD." *Id.*

Dr. Parran observed that at J.H.'s next visit, Applicant added 180 Percocet 5mg to her prescriptions for 120 Oxy 15mg and 30 Xanax 2mg and merely noted that these were refills. *Id.* Three months later, Applicant documented that the medications "were working fine," even though he noted that she was "doubling up on [her] meds" and had been "out of medications for one week." *Id.* Yet he did not document any withdrawal symptoms in J.H.'s record and did not change her prescriptions. *Id.*

Two months later, he again increased her Oxycodone 15mg prescription and doubled her Xanax to 60 tablets. Id. The following month, he noted that J.H. had "been doubling on Oxy 15s... would like increase"; Applicant increased the prescription to 120 Oxycodone 30mg. Id. Within no more than a few days, J.H. claimed that she had been "robbed at knife-point in [a] local store" and that her prescriptions were stolen and she "want[ed] more." Id. at 16-17. Applicant documented that he told her "no," and that J.H. later "called back and reported maybe only half the RX was stolen and [that] she could probably make it to the next" visit. Id. at 17. Yet at the next visit, J.H. reported being "better" and that "all is well." Id. Applicant provided new prescriptions and did not document any discussion about J.H.'s claim that half of her medicine had been stolen or whether she actually "only need[ed] half the medication." Id.

By June 2008, Applicant had increased J.H.'s oxycodone prescription to 200 oxycodone 30mg. *Id.* That month, she also asked Applicant to increase the Xanax, and Applicant increased the prescription to 90 tablets. *Id.* In November, he again increased her oxycodone prescription by 30 more tablets to 240,¹³ even though he noted that she was "fine" and there were "no new issues or complaints." *Id.*

Dr. Parran also noted that between February and May 2009, J.H.'s chart contained no indication of a visit or prescriptions. Id. Yet on May 15, 2009, Applicant "restart[ed] all meds at [the] prior dosages." Id. Dr. Parran explained that "[t]his is clinically reckless and demonstrated disregard for the health and safety of a patient." Id. He then opined that "the prescribing of controlled drugs to this patient was done in a manner that is inconsistent with the usual course of medical practice, and appears to have been done for other than legitimate medical purpose." Id.

A.C.

Reviewing the file for Patient A.C., who complained of back pain, Dr. Parran noted that the history forms were "basically blank" except for a notation of "back pain" and "Xanax/Lortab/ Oxy." Id. at 10. He further found that there was "no evidence of a significant PE or neuro exam," that there was "no imaging," and that there was "no verification of prior RX." Id. Yet Applicant prescribed to A.C. 120 oxycodone 30mg, 180 Lortab 10mg, and 30 Xanax 2mg. Id. Dr. Parran explained that "[t]his is simply unbelievable and demonstrates reckless disregard for the health and safety of a patient." Id.

Dr. Parran further found that while A.C.'s file indicated that he had suffered a back injury at work and had seen an orthopedist, Applicant never had A.C. sign a release for the records maintained by the orthopedist. *Id.* Moreover, A.C. missed several visits, showing up several days later, and that during one such late visit, A.C. said that he had been out of medications "for two days." Id. Yet there was "no evidence" that A.C. went through withdrawal, although this "should have been severe." Id. Dr. Parran also noted that Applicant did not perform a urine drug screen on A.C. Id. Finally, A.C.'s medical record showed that he had been simultaneously seeing another physician for six months. *Id.* Here again, Dr. Parran opined that Applicant acted outside of the usual course of professional practice and

lacked a legitimate medical purpose in prescribing controlled substances to

S.H.

Dr. Parran found that S.H. complained "of coccyx/tail bone pain" which Applicant documented as being "sporadic." Id. at 17. Dr. Parran then found that there was "virtually no HX [history] and no PE [physical exam]' done at S.H.'s initial office visit and that "all patient health history and registration paperwork is blank." Id. Dr. Parran further observed that while S.H. had been a patient at Applicant's previous clinic and there were patient notes for the period of June through September (which immediately preceded) S.H.'s first visit to Applicant's new clinic, there was "basically no clinical information on them what so ever," again with "virtually no" history and "nearly no PE performed." Id.

Dr. Parran found that at the first visit (Oct. 2007), Applicant prescribed 200 oxycodone 30mg to S.H., who was driving from Tampa to Sanford, a distance of more than 100 miles. *Id.* at 18. Dr. Parran further found that over the following two years, the progress notes included notations that S.H. had run out of medications. *Id.*

For example, two months after the first visit, Applicant noted that S.H. "overtook medications—not strong enough—ran out," yet there was no indication that S.H. had withdrawal symptoms. *Id.* Moreover, even though this was "contrary to [S.H.'s] Pain Agreement," Applicant increased S.H.'s oxycodone prescription to 240 tablets. *Id.*

In April 2008, S.H. reported having undergone knee surgery and asked for more pain medication because the surgeon would not prescribe more to him. *Id.* Applicant did not obtain the records, nor was there a release in the file. *Id.* While it is unclear whether Applicant increased the medications at this visit, in May, he prescribed 300 oxycodone 30mg. *Id.*

In July 2008, S.H. claimed that he "ran out of medications" because he "lost 50 in the water while fishing." *Id.* Here again, there was no discussion of whether S.H. had undergone withdrawal symptoms. *Id.* Yet Applicant issued another prescription. *Id.*

In October 2008, S.H. reported that he had run "out of medication 10 days ago," but then changed his story "to 5 days ago." *Id.* S.H. then claimed that he did "not [have] enough medication" and that he was "stretch[ing] meds from prior visits." *Id.* Applicant than

 $^{^{\}rm 13}\,{\rm He}$ had previously increased the prescription to 210 tablets in late July.

increased the prescription to 360 oxycodone 30mg. *Id.*

In December 2008, S.H. reported that he had been out of medication for two days. *Id.* According to Dr. Parran, S.H. should have had "horrendous" withdrawal symptoms but there was no notation that he had undergone withdrawal. *Id.* Applicant then increased S.H.'s prescription to 390 oxycodone 30mg. *Id.* While at S.H.'s January 2009 visit, he told Applicant that "everything is okay" and that he had "left over meds," Applicant nonetheless increased the prescription to 400 oxycodone 30mg. *Id.*

Dr. Parran also found that S.H. was seven days late for his March visit (at which he was prescribed a different drug—Morphine Sulfate Immediate Release) and nineteen days late for his April visit (at which Applicant returned to prescribing 400 oxycodone 30mg), and yet there was no mention of why S.H. had been late at either visit. *Id.* Dr. Parran opined that "[t]his is dangerous and demonstrates clinically reckless disregard for the health and safety of the patient." *Id.*

Finally, Dr. Parran noted that at S.H.'s last visit, there was "no mention of anxiety/depression/sleep/muscle spasm issues and no mention of [benzodiazepines] at all, yet" Applicant added a prescription for 90 Xanax 2mg. to the prescription for 400 oxycodone 30mg. *Id.* Dr. Parran opined that this was also "dangerous, and demonstrates clinically reckless disregard for the health and safety of the patient." Id. Dr. Parran then concluded that "the prescribing of controlled drugs to this patient was done in a manner that is inconsistent with the usual course of medical practice, and appears to have been done for other than [a] legitimate medical purpose." *Id.*

D.F.

Applicant treated D.F. from May 2008 through September 2009. *Id.* at 14–15. During those sixteen months Applicant prescribed increasing amounts of oxycodone, Dilaudid, methadone and Soma.

The records of the initial office visit showed that D.F. complained of "fibromyalgia and chronic pain endorsing 31 symptoms in the patient self-report sheet and 12 of 15 pain descriptors—and pain everywhere in his body except hips." *Id.* at 14. The progress note then stated: "spoke with PT . . . he wants to get off methadone and use the Duragesic and other less expensive medications." *Id.* Regarding this, Dr. Parran opined that "methadone is the least expensive" of these drugs and that "this is inconsistent!" *Id.*

The file also contained a letter indicating that D.F. had been on a methadone maintenance program at 70 mg/d since 12/07. *Id.* at 15. Dr. Parran noted that the file included prior records from a pain management specialist dated April 2007, a normal MRI, and that D.F. had been "on Lyrica and Lidoderm (but no other controlled drugs)." *Id.*

Dr. Parran found that there was "[b]asically no H&P [History and Physical]" and yet Applicant started issuing prescriptions for 180 Oxycodone 30mg, Duragesic 75mics, and 50 methadone 10mg. *Id.* Dr. Parran then found that at D.F.'s last visit (9/28/09) before the search of his clinic, Applicant had increased D.F.'s prescriptions to: 240 Oxycodone 30mg; 150 Dilaudid 8mg; 240 Oxycodone 15mg; 300 Methadone 10mg; and 60 Soma. *Id.*

Dr. Parran found that throughout D.F.'s file, there were multiple notations that that she was running out early and yet Applicant increased the prescriptions. *Id.* More specifically, the note for D.F.'s second visit (June 2008) states "doing good and ran out early"; Applicant then increased the prescriptions to 200 Oxy 30 mg. and 90 methadone 10mg. *Id.* Moreover, when, in July 2008, D.F. "asked about Soma," Applicant added a prescription for 28 Soma. *Id.*

Next, Dr. Parran found that the 8/8/08 progress note again stated that D.F. "ran out early," and that Applicant increased her prescriptions to 220 Oxy and 120 methadone. *Id.* Two months later (on 10/8/08), Applicant noted that "Pt. ran out one week ago (no W/D)," and increased the "Soma up to 60 and Oxy to 270." *Id.*

Dr. Parran found that at D.F.'s November 2008 visit, Applicant noted that he was increasing the methadone prescription to 200 tablets and the Oxy 30mg to 300 tablets; he also noted that he was ceasing the Duragesic patches because they were "not working well." *Id.* Dr. Parran then observed that "this is totally contrary to the first OV notes and completely internally inconsistent." *Id.*

Next, according to the February 2009 note, D.F. "request[ed] more methadone" and Applicant increased the prescription to 270 tablets; he also prescribed 300 tablets of Oxy 30mg. *Id.* At the April 2009 visit, Applicant added 120 Dilaudid 4mg to D.F.'s medications, which also included 240 Oxycodone 15mg, 180 Oxycodone 30mg, and 60 Soma. *Id.*

The following month, Applicant changed D.F. from Dilaudid back to methadone, issuing prescriptions for 240 Methadone 10 mg, 240 Oxycodone 15 mg, 180 Oxycodone 30 mg, and 60 Soma. *Id.* And in June, Applicant resumed prescribing 120 tablets of Dilaudid 4mg and again increased the methadone to 270 tablets, which he further increased to 300 tablets the next month. *Id.* Dr. Parran found Applicant's methadone prescribing remarkable given that this was for "a patient who was supposedly being taken off a methadone program and [being given] other medications and patches!" *Id.*

Next, Dr. Parran found that the August 2009 progress note stated that D.F. had "request[ed] 8 mg of Dilaudid" and that Applicant "increase[d] [the] Dilaudid to 8mg #120." *Id.* Moreover, Dr. Parran found that the following month, Applicant increased the Dilaudid to 150 tablets (again of 8mg), and also prescribed 240 Oxycodone 30mg. *Id.* Finally, Dr. Parran found that at D.F.'s last visit before the 2009 search, Applicant issued prescriptions for 240 Oxycodone 30mg, 240 Oxycodone 15mg, 150 Dilaudid 8mg, 300 methadone 10mg, and 60 Soma. Id. According to Dr. Parran, "[t]his is just plain dangerous." Id. Dr. Parran thus concluded that Applicant's "prescribing of controlled drugs to this patient was done in a manner that is inconsistent with the usual course of medical practice, and appears to have been done for other than legitimate medical purpose." Id.

T.T.

Reviewing T.T.'s file, Dr. Parran found that at the initial visit (2/8/06), she complained of chronic lower back pain, but reported taking "no medications." *Id.* at 36. Dr. Parran observed that T.T. reported no prior doctor and that her file contained no studies, labs, or records and that there was "virtually no" history and physical documented "with no neuro[logical] exam." *Id.* Applicant nonetheless diagnosed T.T. as having "thoracic and Lumbar Myalgias" and issued her a prescription for 90 tablets of Lortab (hydrocodone/apap) 5mg. *Id.*

Dr. Parran than observed that at T.T.'s next visit (3/06), Applicant increased her prescription to 120 Lorcet 10mg, and thus nearly tripled the daily dose. Id. Next, Dr. Parran found that in late April, T.T. was provided an "early [prescription] by 10 days." Id. Moreover, in late May, Applicant increased her Lortab prescription to 150 tablets and yet seven days later (June 7), he gave her a prescription for another 120 tablets. Id. Later the same month, Applicant gave T.T. prescriptions for additional drugs including 60 Valium 10mg, 30 Darvocet, and 60 Soma, and in October, he increased the Lorcet to 180

tablets. Id. Moreover, in November, Applicant added 90 oxycodone 30mg to her medications, and also prescribed 60 Valium 10mg, 180 Lortab 10mg, and 60 Soma. Id. Dr. Parran then observed that there was no discussion in T.T.'s progress notes regarding the prescriptions. Id. Moreover, in January, Applicant further increased T.T.'s oxycodone prescription to 120 tablets.

On February 7, 2007, T.T., who did not have an appointment, obtained new prescriptions for all of the drugs, claiming that her brother was addicted to methamphetamine and had beaten her and taken all of her drugs. Id. Applicant again increased T.T.'s oxycodone prescriptions to 180 tablets.

Next, Dr. Parran found that while the May 2007 note stated that T.T. got tired a lot and did not take either the Valium or Soma, Applicant again prescribed both drugs. *Id.* Dr. Parran then noted an early refill for Valium (10/20/07), which was followed in November by a change to 60 Xanax 2mg (which doubled the dose), as well an increase to 200 oxycodone 30mg which was further increased to 240 tablets in December, which was followed by an increase to 90 Xanax 2mg in January. Id.

While in February, T.T. reported having doubled up on her medications and sought an early refill, Applicant did not grant her request. Id. However, in March, T.T. reported she was "out of Xanax [and] asked for more," and Applicant obliged, increasing her prescription to 120 tablets. Id.

Over the next several months, Applicant changed T.T.'s Lortab prescription to 90 oxycodone 15mg, and increased her Xanax prescription to 150 tablets (and also prescribed to her, both oxycodone 30mg and 15mg, as well as Soma). Id. In October 2008, Applicant further increased her oxycodone 30mg prescription to 270 tablets, her oxycodone 15mg prescription to 120 tablets, her Xanax 2mg prescription to 180 tablets, and also prescribed 60 Soma. *Id.* Dr. Parran described this as "incredibly bizarre!" *Id.* Yet at T.T.'s next visit, which occurred later that month on October 30th, Applicant further increased her prescriptions for oxycodone 15mg and Xanax to 150 and 200 tablets respectively, prompting Dr. Parran to opine that "[t]here is no legitimate medical purpose for this prescribing." Id.

Only two days later, T.T. reported that medications were stolen and Applicant gave her a prescription for 30 Xanax, which was followed only four days later with a prescription for 180 Xanax. Id. Later that month, T.T.'s sister called and

asserted that T.T. was stealing her medications; the same day, T.T. called and claimed her medications had been stolen. *Id.* Moreover, in the middle of December, Applicant received a phone call from an apparent relative of T.T. stating that T.T. was getting addicted. Id. Yet at T.T.'s next visit, he again gave her a prescription for 180 Xanax, as well as increased her Soma prescription to 90

Dr. Parran found that in February 2009, Applicant received a report that T.T. was "seeing other doctors and selling her pills in the pharmacy parking lot." Id. He also found T.T.'s file included a March 2009 fax from an addiction treatment program with a release for her records. Id.

Dr. Parran further found that notwithstanding that T.T. had been undergoing treatment for addiction and had not seen Applicant for approximately three months, in June 2009, Applicant again saw her and prescribed both oxycodone 30mg and Xanax to her, prompting Dr. Parran to opine that "[t]his is simply unbelievable." Id. Subsequently, in August, T.T. requested an early refill of her Xanax prescription, claiming that she had spilled the pills in the toilet. *Id.* While Applicant did not give her a refill, at her next office visit, he "wrote all" of the prescriptions for her. *Id.* Dr. Parran thus concluded that "the prescribing of controlled drugs to this patient was done in a manner that is inconsistent with the usual course of medical practice, and appears to have been done for other than legitimate medical purpose." Id.

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner's registration may be denied "if the Attorney General determines that the issuance of such registration . . . would be inconsistent with the public interest." 21 U.S.C. 823(f). In making the public interest determination, Congress directed that the following factors be considered:

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

"These factors are . . . considered in the disjunctive." $Robert\ A.\ Leslie,\ 68\ FR$ 15227, 15230 (2003). I "may rely on any one or a combination of factors and may give each factor the weight . . . [I] deem[] appropriate in determining whether . . . an application for registration [should be] denied." Id.; see also Kevin Dennis, 78 FR 52787, 52794 (2013); MacKay v. DEA, 664 F.3d 808, 816 (10th Cir. 2011).

The Government has the burden of proving, by substantial evidence, that the requirements for a denial of an application, pursuant to 21 U.S.C. § 823(f), are met. 21 CFR 1301.44(e). This is so even in a non-contested case. Gabriel Sanchez, 78 FR 59060, 59063 (2013). Having considered all of the factors, I conclude that the Government's evidence with respect to factors two and four establishes, prima facie, that the issuance of a DEA certificate of registration to Applicant "would be inconsistent with the public interest." See 21 U.S.C. 823(f).14

Factor One: Recommendation of the Appropriate State Licensing Board

At the outset, it should be noted that the Board has not made a formal recommendation as to what action the Agency should take in this matter. However, "DEA precedents have typically taken a broader view as to the scope of this factor." Tony T. Bui, M.D., 75 FR 49979, 49986 (2010).

The Government argues that the Florida Board of Medicine has found that Applicant "prescribed controlled substances excessively and/or inappropriately" to two patients (J.D. and L.S.) and that his "license was suspended." Request for Final Agency Action, at 6. The Government further argues that the Board's findings "cannot be collaterally attacked in a DEA proceeding" and that while his license has since been reinstated, this is not dispositive of the public interest inquiry." Id. at 7.

It is well settled that while the possession of state authority to dispense controlled substance is a prerequisite for obtaining (and maintaining a registration), the possession of such authority is not dispositive of the public interest inquiry. See Jayam Krishna-Iyer, 74 FR 459, 461 (2009) (quoting Mortimer B. Levin, 55 FR 8209, 8210 (1990)). Thus, while Applicant currently holds an active medical license with the State, the Controlled Substances Act requires that the Agency make an independent determination from that made by the Florida Medical Board as to whether

¹⁴ The Attorney General has delegated this authority to the Administrator. See 28 CFR 0.100(b).

granting controlled substance privileges to him would be in the public interest. See id.

That being said, I do not rely on the findings of the Florida Medical Board regarding Applicant's prescribing of controlled substances to the two patients. While the state proceedings resulted in the assessment of substantial fines and costs, a suspension until he appeared before the Board's probation committee, and other conditions including that he take three courses, Applicant "neither admit[ted] nor denie[d] the allegations of fact contained in the Administrative Complaint[s]." GX 2, at 18. Moreover, there was no hearing in the matter, and while DEA has held that the findings of fact and legal conclusions that are made pursuant to a consent agreement or a stipulated settlement may be entitled to preclusive effect in an Agency proceeding, see David A. Ruben, 78 FR 38363, 38365 (2013),15 the settlement agreement between Applicant and the Board says nothing about whether Applicant would be estopped from challenging the findings in a subsequent proceeding brought by the Board (or other another state agency) against him. See id. at 38366-67 (giving preclusive effect to findings of state consent agreement which provided that physician could not "contest the validity of the Findings of Fact . . . contained in the [o]rder in any present or future administrative proceedings before the Board," in a proceeding before "any other state agency" of the same State, and physician agreed not to challenge any portion of the order in state or federal court). 16 Here, while Applicant agreed that he could not seek judicial review of the Agreement, the Government does not cite to any authority of the Florida courts holding that settlement agreements that contain similar wording as that in Applicant's, are entitled to preclusive effect. See also id. (noting that state courts gave preclusive effect to findings made in consent agreements).

Accordingly, I do not rely on the Board's findings of fact and legal conclusions. Nor is there any need to do so given the extensive evidence which supports the conclusion that Applicant

has repeatedly violated the CSA's prescription requirement.¹⁷

Factors Two and Four: Applicant's Experience in Dispensing Controlled Substances and Record of Compliance With Laws Relating to Controlled Substances

To effectuate the dual goals of conquering drug abuse and controlling both the legitimate and illegitimate traffic in controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." Gonzales v. Raich, 545 U.S. 1, 13 (2005). Consistent with the maintenance of the closed regulatory system, a controlled substance may only be dispensed upon a lawful prescription issued by a practitioner. Carlos Gonzalez, M.D., 76 FR 63118, 63141 (2011).

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

As the Supreme Court has 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)); *United States* v. *Alerre*, 430 F.3d 681, 691 (4th Cir. 2005), cert.

denied, 574 U.S. 1113 (2006) (stating that the prescription requirement likewise stands as a proscription against doctors acting not "as a healer[,] but as a seller of wares.").

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act "in the usual course of . . . professional practice" and to issue a prescription for a "legitimate medical purpose." Paul H. Volkman, 73 FR 30629, 30642 (2008), pet. for rev. denied, 567 F.3d 215, 223-24 (6th Cir. 2009); see also Moore, 423 U.S. at 142-43 (noting that evidence established that the physician exceeded the bounds of professional practice, when "he gave inadequate physical examinations or none at all," "ignored the results of the tests he did make," and "took no precautions against . . . misuse and diversion"). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a legitimate doctorpatient relationship. Volkman, 73 FR 30642.

In Florida, a physician is barred from "prescribing, dispensing, administering, mixing, or otherwise preparing . . . any controlled substance, other than in the course of the physician's professional practice." Fla. Stat. § 458.331(q). The statute further explains that "prescribing, dispensing . . . or otherwise preparing . . . controlled 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." Id.; see also Fla. Stat. § 893.05(1) ("A practitioner, in good faith and in the course of his or her professional practice only, may prescribe . . . a controlled substance[.]"). As such, when a physician acts outside the course of professional practice, he is shirking his "responsibility to dispense . controlled substances only in the course of [his] professional practice." Florida v. Toth, Case No. 80-2309, 1981 WL 180354, at *8 (Fla. Div. of Admin. Hearings Mar. 31, 1981).

Moreover, prior to the conduct at issue here, the Florida Board of Medicine promulgated Standards for the Use of Controlled Substances for the Treatment of Pain, which were codified in the Florida Administrative Code. *See* Fla. Admin. Code R.64B8–9.013 (2003).¹⁸ Therein, the Board explained

¹⁵ See University of Tenn. v. Elliot, 478 U.S. 788, 797–98 (1986) ("When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata[.]") (internal quotations and citations omitted); Robert L. Dougherty, M.D., 76 FR 16823, 16830 (2011).

¹⁶ Of these clauses, only the latter is contained in Applicant's settlement agreement.

¹⁷I also place no weight on the findings of fact and legal conclusions of the 2001 Board Order. Those findings do not establish that Applicant committed any violations of controlled substance laws and regulations but only that he committed malpractice. As the Administrator has explained, "the CSA and its case law 'amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally,' an authority which remains vested in the States." *Bui*, 75 FR 49988 (quoting *Gonzales* v. *Oregon*, 546 U.S. 243, 270 (2006)).

¹⁸ The standards were first adopted on December 21, 1999, and subsequently amended on November 10, 2002 and October 19, 2003. New standards were promulgated on October 17, 2010; these standards substituted the word "shall" and thus made mandatory various provisions which had formerly

that the "standards are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice." *Id.* R.64B8–9.013(1)(g).

Of particular significance here are the Board's standards pertaining to the "Evaluation of the Patient" and "Medical Records." With respect to the former, the Board's standard provided that:

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

Id. R.64B8–9.013(3)(a). And with respect to Medical Records, the Board's standard provided that:

The physician is required to keep accurate and complete records to include, but not be limited to:

- 1. The medical history and physical examination, including history of drug abuse or dependence, as appropriate;
- 2. Diagnostic, therapeutic, and laboratory results;
 - 3. Evaluations and consultations;
 - 4. Treatment objectives;
 - 5. [D]iscussion of risks and benefits;
 - 6. Treatments;
- 7. Medications (including date, type, dosage, and quantity prescribed);
- 8. Instructions and agreements; and
- 9. Periodic reviews. Records must remain current and be maintained in an accessible manner and readily available for review.

Id. R.64B8-9.013(3)(f).

Here, there is substantial evidence to support the conclusion that on multiple occasions, Applicant acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances. 21 CFR 1306.04(a). The evidence shows that notwithstanding that the Florida Board's standards clearly required that he perform a patient history and physical examination before prescribing to CS1, he did not ask the CS any questions about her medical condition nor performed a physical examination. Yet, he issued her prescriptions for 60 tablets of OxyContin (sch. II), 90 tablets of Lorcet 10/650 (sch. III) and 90 tablets of Xanax (alprazolam, sch. IV), as well as carisoprodol. 19 I thus conclude that

Applicant violated 21 CFR 1306.04(a) in prescribing OxyContin, Lorcet and Xanax to CS1.

With respect to CS2, it is acknowledged that the evidence showed that he complained of pain and that Applicant performed a brief physical exam at his first visit. Moreover, there is no evidence establishing that under the standards of professional practice, the examination was inadequate. Nor is there any evidence that under the standards of professional practice, Applicant was required to perform a physical exam at CS2's subsequent visits

That being said, at CS2's second visit, Applicant made no inquiry into CS2's purported pain condition and CS2 made no mention of being in pain. To the contrary, CS2 made clear that he was seeking the controlled substances to abuse them as he told Applicant that the drug that was prescribed at the previous visit "[m]ade [him] feel really good" and that he had "com[e] to see if [he] could get something a little stronger this time." After Applicant asked the CS if he wanted something "stronger or just more" of what he had gotten at the previous visit, the CS stated that he wanted something "more stronger"; Applicant stated: "Okay, no problem," after which the CS told Applicant that he was not doing "any therapy" and admitted that he was "not into it." Applicant then gave the CS a prescription for 120 oxycodone 15mg. As this conversation demonstrates, this was not a legitimate medical encounter between a doctor and his patient, but rather the negotiation of a drug deal, and thus, I hold that Applicant violated 21 CFR 1306.04(a) when he issued the prescription.

As for CS2's final visit during which the recording device malfunctioned, according to the Sergeant, the CS related in the post-operation debriefing that he told Applicant that he "was no longer in pain," that "he just liked how the pain medication made him feel," and that he wanted something stronger than oxycodone 15mg, which was what he had received at the previous visit. The CS also told the Sergeant that he received a prescription for oxycodone 30mg, which is corroborated by a copy of the prescription.

Notwithstanding that the CS's statements are hearsay and unsworn, I

carisoprodol was placed in schedule IV, based, in part, on its abuse as part of cocktail of other controlled substances which included narcotics such as oxycodone or hydrocodone, and benzodiazepines, such as Valium (diazepam) and Xanax (alprazolam). See Schedules of Controlled Substances, Placement of Carisoprodol Into Schedule IV, 76 FR 77330 (2011).

find that they are reliable and entitled to weight given that several other of the CS's hearsay statements were corroborated by other evidence. More specifically, the CS's statement to the Sergeant regarding the scope of the physical exam which was performed by Applicant at the May 30, 2006 visit and the absence of any such exam at the June 27, 2006 visit were corroborated by the recordings. So too, the CS's statement that he received a prescription for oxycodone 30mg was corroborated by the prescription itself. In addition, the recordings of the other visits portray a physician who showed no real interest in determining whether his patients actually had medical conditions which warranted treatment. I therefore find that Applicant acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed 90 tablets of oxycodone 30mg to the CS. See 21 CFR 1306.04(a).

As for the September 18, 2008 visit, the recording establishes that Applicant had previously seen CS3 at least two years earlier and that he did not perform a physical exam of her. That being said, CS3 did complain of pain ("I just can't move" and "I'm just so uncomfortable") and, while Florida's regulation requires a physical exam as part of the initial evaluation of a patient, the Government adduced no expert testimony as to whether it was within the usual course of professional practice to prescribe a controlled substance without performing a new physical exam.²⁰ I therefore find that the Government has not proved that Applicant violated the prescription requirement when he prescribed 180 tablets of Percocet 10/ 325mg to CS3 at this visit.

As for CS3's visit of October 16, 2008, the evidence shows that she asked Applicant if he could "give [her] a little extra this time." Applicant, however, never asked CS3 why she wanted or needed more medication. Moreover, later in the encounter, CS3 told Applicant that she had a friend who wanted to see him and that she had "shared a little bit [of] her medications" with him, and that she did not "know if this was the right thing to do." While Applicant told CS3 that she had broken the law and she was "dealing drugs and he [her friend] was taking illegal medication" because these "are controlled substances," Applicant nonetheless gave her a new prescription, and increased the quantity

used the word "should" in setting forth the scope of a physician's obligations.

¹⁹ At the time, carisoprodol was not a controlled substance under federal law. However, in 2011,

²⁰ Nor do we know if Applicant performed at physical exam at the previous visit. That being said, it was the Government's burden to produce evidence that Applicant had not performed a physical exam at that visit.

to 210 tablets of Percocet 10/325. Notably, at no time during this visit did Applicant ask CS3 any questions about her pain condition, how it affected her ability to function, and whether the medication was effective. Accordingly, I conclude that Applicant acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he issued this prescription to CS3. 21 CFR 1306.04(a).

As for CS3's final visit, while there is evidence that Applicant further increased her prescription to 240 tablets, the recording device failed. While in her affidavit, the DI stated that during the debriefing, the CS said that Applicant did not perform a physical exam and only took her weight and blood pressure, here again, there is no evidence as to whether, under the standards of medical practice, Applicant was require to perform a physical exam and the scope of an appropriate exam. Nor is there any other evidence as to whether Applicant asked the CS whether she had pain, how the pain affected her ability to function, and how the medication was working. Notwithstanding my conclusion that the prescription issued at CS3's previous visit violated federal law, because the Government has the burden of proof, I conclude that it has not produced substantial evidence to support a finding that Applicant acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he issued this prescription.

As for CS4's January 2009 visit, the recording of the visit suggests that the CS had previously seen Applicant. The Government, however, produced no evidence as to when this previous visit occurred (or that there had been no such visit) and whether Applicant had performed a physical exam at this visit.

To be sure, the recording establishes that Applicant did not perform a physical exam at the CS's January 2009 visit. However, here again, there is no evidence as to whether, under the standards of medical practice, a physical exam was required at this visit. Nor is there substantial evidence that, under the standards of medical practice, Applicant's evaluation was inadequate. Finally, the CS's statement that "[m]y pain is getting better . . . and that [i.e., the oxycodone] makes it real good" does not conclusively establish that the CS was seeking controlled substances for the purpose of abusing them or diverting them to others. Accordingly, I conclude that the Government has failed to prove that Applicant acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed oxycodone to CS4.

By contrast, the Government did produce substantial evidence—in the form of the Expert's report—that Applicant acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to numerous patients. As found above, the Government's Expert reviewed the medical records of over one hundred and fifteen of Applicant's patients and found numerous instances in which Applicant acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing controlled substances. GX

As support for his conclusion, Dr. Parran identified several "general" and "alarming" characteristics of Applicant's "prescribing behaviors." More specifically, he found that: (1) "there [was] virtually always a very scant initial history and typically no documented evidence of a sufficient physical exam done on patients" in the records; (2) there was a remarkable similarity in how Applicant treated each patient, suggesting a lack of individualized treatment; (3) there was typically no note in the patient chart to explain why Applicant started, increased, or changed a drug regimen; (4) there were very few, if any, referrals to alternative treatments (i.e., physical therapy) and specialists (i.e., psychiatry, rheumatology, neurology, orthopedics and neurosurgery); and (5) Applicant routinely "provide[d] on-going supplies of multiple controlled substances in an escalating pattern, typically culminating in quite high doses, in potentially dangerous combinations." GX 7, at 1-2. Dr. Parran thus opined that:

[Applicant's] pattern of relentlessly prescribing controlled drugs, with insufficient history and physical . . . and no clinical reasoning evident in progress notes . . . what-so-ever, without initiating a clinical work-up or demonstrating evidence of an effort to obtain prior records, and in the face of noncompliance and often out of control behavior on the part of patients, is not consistent with the usual course of medical practice and constitutes prescribing of controlled drugs for other than [a] legitimate medical purpose.

Id. at 2

Dr. Parran's conclusions are fully supported by the more detailed discussion he provided of Applicant's prescribing to various patients including K.B., D.B., J.H., A.C., S.H., D.F., and T.T., as well as others. As these findings show, Applicant repeatedly prescribed highly abused (and multiple) controlled substances including schedule II and III narcotics, as well as benzodiazepines to the patients, without doing a physical

exam or doing an inadequate exam and having obtained little to no history; failed to obtain prior records; failed to refer patients to specialists; repeatedly increased both the quantity and strengths of medications or prescribed additional medications without any justification and frequently did so while noting that previous prescriptions were "working good" or the patient was doing "better" or "fine"; prescribed large doses of controlled substances to patients even when presented with evidence that the patients were not currently on medications or had recently been in detoxification programs; prescribed controlled substances even in the face of evidence that the patients were doctor shopping, selling pills, or engaged in various scams (such as claiming that their medications were stolen or had been dropped into the toilet); and ignored evidence that patients did not go through withdrawal even when they reported having been out of drugs for several days.

As these findings (as well as the recordings of several of the undercover visits) demonstrate, Applicant was not engaged in the legitimate practice of medicine with respect to many of his patients, but was engaged in outright drug dealing. See Jack A, Danton, 76 FR 60900, 60917 (2011). I therefore find that the Government's evidence with respect to factors two and four establishes that the issuance of a new registration to Applicant "would be inconsistent with the public interest." ²¹ 21 U.S.C. 823(f). See also Eugene H.

That being said, such findings are not necessary to support the sanction I have decided to impose, given the unrefuted evidence that Applicant diverted controlled substances and the lack of any evidence that he acknowledges his misconduct. There being no evidence in the record that Applicant has accepted responsibility for his actions, Applicant has failed to rebut the Government's prima facie showing that his registration would be "inconsistent with the public interest." Medicine Shoppe, 73 FR 387 (citing 21 U.S.C. 823(f)).

 $^{^{21}\}mbox{In}$ its request for Final Agency Action, the Government alleges that Applicant lacked candor during the 2009 interview and that this conduct should be considered under factor five. While the Government cites to three pages of the interview transcript as support for its contention, it does not identify the specific questions posed by the Investigators to which it contends Applicant provided answers that lacked candor. Req. for Final Agency Action, at 9 (citing GX 5, at 38-39, 50). Indeed, many of the remarks of the various law enforcement personnel on these pages are not even properly characterized as questions. Thus, while '[c]andor during DEA investigations properly is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest," Hoxie v. DEA, 419 F.3d 477, 483 (6th Cir. 2005), because the Government does not identify the specific questions and false answers, I decline to make any findings on the issue.

Tapia, M.D., 52 FR 30458, 30459 (1987) (considering evidence that a physician did not perform physical exams and issued medically unnecessary prescriptions under factor two); Thomas Parker Elliott, D.O., 52 FR 36312, 36313 (1987) (adopting ALJ's conclusion that physician's "experience in the handling of controlled substances clearly warrants finding that his continued registration is inconsistent with the public interest," based on the physician's having "prescribed enormous quantities of highly addictive drugs to [ten] individuals" without adequate medical justification).

Under agency precedent, "where a registrant [or applicant] has committed acts inconsistent with the public interest, [he] must accept responsibility for his . . . actions and demonstrate that he . . . will not engage in future misconduct." Jayam Krishna-Iyer, 74 FR 459, 463 (2009); see also Medicine Shoppe-Jonesborough, 73 FR 364, 387 (2008). Here, because Applicant waived his right to a hearing (as well as his right to submit a written statement in lieu of a hearing), GX 4, at 2, the only evidence in the record to refute the conclusion that his continued registration is "inconsistent with the public interest" is that he apparently completed the courses required by the Florida Board of Medicine as evidenced by the fact that his medical license remains current and

There is, however, no evidence that Applicant acknowledges his misconduct, which is egregious, and accepts responsibility for it. Indeed, the Expert's report identifies dozens of patients (beyond the seven specifically discussed above) to whom Applicant diverted controlled substances. Accordingly, Applicant's application will be denied.²² See Krishna-Iyer, 74 FR 464 ("[E]ven where the Agency's proof establishes that a practitioner has committed only a few acts of diversion, this Agency will not grant [an application for] registration unless he accepts responsibility for his misconduct."); see also MacKay v. DEA, 664 F.3d 808, 822 (10th Cir. 2011) (sustaining agency order revoking practitioner's registration based on proof physician knowingly diverted drugs to two patients).

Order

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

Dated: January 17, 2014.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2014-01797 Filed 1-29-14; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration; United States Pharmacopeial Convention

By Notice dated September 27, 2013, and published in the **Federal Register** on October 25, 2013, 78 FR 64014, United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of Noroxymorphone (9668), a basic class of controlled substance listed in schedule II.

The company plans to import reference standards for sale to researchers and analytical labs.

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 United States Pharmacopeial Convention 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 United States Pharmacopeial Convention 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: January 15, 2014.

Joseph T. Rannazzisi,

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

[FR Doc. 2014–01784 Filed 1–29–14; 8:45 am] BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration; Cambrex Charles City, Inc.

By Notice dated September 27, 2013, and published in the **Federal Register** on October 25, 2013, 78 FR 64013, Cambrex Charles City, Inc., 1205 11th Street, Charles City, Iowa 50616–3466, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
4-Anilino-N-phenethyl-4-piperidine (8333). Phenylacetone (8501)	

The company plans to import the listed controlled substances for internal use, and to manufacture bulk intermediates for sale to its customers.

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

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 Cambrex Charles City, Inc., to import the basic classes of controlled substances 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 Cambrex Charles City, Inc., 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

²² As found above, because Applicant did not submit his renewal application at least 45 days before the expiration of his registration, and had been served previously with the Order to Show Cause, pursuant to 21 CFR 1301.36(i), his registration expired on August 25, 2013. Had his registration not expired per the Agency's rule, I would have revoked it.